NO LONGER IMMUNE?

Court Opens Door to Cases Claiming Link Between Autism and Vaccine Preservative

WENDY N. DAVIS

Jay Kilpatrick's suit against thimerosal makers is the first to skip "vaccine court."

LIKE ALMOST ALL U.S. CHILDREN born in the 1990s, Robert Edgar Holder and his brother, Matthew Clayton Holder, of Newton County, Miss., received a series of vaccinations to immunize them against childhood diseases.

And, like almost all such vaccinations back then, the injections contained thimerosal, a mercury-based preservative that makes it possible to package vaccines in containers that may be used for more than one dose.

Both Holder children, now 15 and 13, were diagnosed with autism, a complex developmental disability that affects an individual's social interaction and communication.

Recently, however, many scientists have come to believe that thimerosal may cause autism. According to published accounts, a study by an epidemiologist for the federal Centers for Disease Control and Prevention reported in 2001 that thimerosal is linked to the dramatic rise in the number of reported cases of autism.

Since then, more than 4,000 suits have been filed by parents of affected children. This March, plaintiffs may have won the first major victory in a thimerosal case when the New Orleans-based 5th U.S. Circuit Court of Appeals ruled that their lawsuit against three companies that manufactured thimerosal could proceed in federal court. *Holder v. Abbott Laboratories Inc.*, 444 F.3d 383.

The ruling is significant because a federal appeals court apparently for the first time said a suit may bypass a special court set up to resolve liability claims against vaccine manufacturers. Under the 1986 National Childhood Vaccine Injury Act, which created a no-fault system to compensate plaintiffs for injuries caused by vaccines, cases must be routed to the U.S. Court of Federal Claims.

The "vaccine court," as it is called, tries cases without juries and issues damages that are usually far lower than those assessed in regular courts—and are often insufficient to compensate severely injured children, plaintiffs attorneys say.

However, the 5th Circuit agreed with the Holders' attorney, Jay Kilpatrick of Jackson, Miss., that thimerosal is merely a preservative and not itself a vaccine. "The vaccine act does not bar the Holders' claims against the thimerosal defendants," the 5th Circuit wrote.

"Thimerosal defendants are not vaccine manufacturers, as that is contemplated by the vaccine act statute," Kilpatrick says.

As many as 1.5 million Americans—children and adults—are thought to have autism, according to the Autism Society of America.

While autism is considered a spectrum disorder that affects each individual differently and with varying degrees of severity, the Holders' condition is especially acute, Kilpatrick says.

"They have a very severe case of autism," he says. "Allergies are heightened. They can't go to school." Without intensive help, they won't be able to stay in their parents' home, he adds. Many autistics can function at a high level, Kilpatrick says. "Mine can't."

'AN UNNECESSARY PRODUCT'

THE HOLDERS BROUGHT SUIT IN 2002 IN MISSISSIPPI AGAINST a host of defendants—including the doctor who administered the vaccines, the medical centers where they were given, and the pharmaceutical companies that manufactured them.

Along with other plaintiffs, the Holders argue that thimerosal isn't even necessary.

While upholding the lower court's dismissal of several of the Holders' claims, the 5th Circuit ruled that their lawsuit against three companies that manufactured thimerosal—Eli Lilly and Co., Sigma-Aldrich Inc., and Spectrum Chemical Manufacturing Corp.—could proceed in federal court. (Although Abbott was the lead defendant, the company was not included in the remand.)

The court cited its 2004 decision that thimerosal's "sta-

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tus as a vaccine component no more makes thimerosal a 'vaccine' than does the inclusion of a piston under the hood of an automobile make that object an 'engine.' " *Moss v. Merck & Co.*, 381 F.3d 501. The result, the court said, is that claims against thimerosal manufacturers are not governed by the vaccine act.

That argument has been endorsed by Robert F. Kennedy Jr., an environmental lawyer and co-director at Pace University School of Law's Environmental Litigation Clinic.

In a June 2005 article for *Rolling Stone* magazine, Kennedy condemned the pharmaceutical industry for adding thimerosal to vaccines—a move he decries as a completely unnecessary risk undertaken for no reason other than to save a paltry sum on packaging inoculations.

"The injury was not caused by the vaccine. The injury was caused by the inclusion of an unnecessary product by the pharmaceutical industry," Kennedy says.

While mercury has long been considered a neurotoxin, the potential link between thimerosal in vaccines and autism wasn't widely publicized until the early part of this decade.

In recent years, the possible connection has received a great deal of publicity, including Kennedy's much-noticed article in *Rolling Stone*. "The story of how government health agencies colluded with Big Pharma to hide the risks of thimerosal from the public is a chilling case study of institutional arrogance, power and greed," Kennedy wrote in the article, "Deadly Immunity."

One lawyer-writer alleges that "government health agencies colluded with Big Pharma to hide the risks of thimerosal."

"If, as the evidence suggests, our public-health authorities knowingly allowed the pharmaceutical industry to poison an entire generation of American children, their actions arguably constitute one of the biggest scandals in the annals of American medicine."

Kennedy says he has filed freedom of information requests seeking records that show the possible link between thimerosal and autism. He has not filed any of the personal injury lawsuits stemming from thimerosal.

Kennedy and other lawyers say the vaccine act was passed in recognition that inoculations, which contain a small dose of live viruses, are inherently dangerous to a small proportion of the population with a very low tolerance to such viruses.

But the defense bar says the cases belong in vaccine court. Attorney Gary J. Spahn, co-chair of the ABA Litigation Section's Products Liability Committee, says that making the distinction between live viruses and other materials used to manufacture a vaccine is "slicing the bologna pretty thin."

The vaccine act was intended "to protect the folks that get into the business of manufacturing the vaccines," which includes the pharmaceutical companies that put thimerosal in the product, says Spahn, who practices in Richmond, Va. He adds that the policy behind the vaccine act was to encourage pharmaceutical companies to produce vaccines—a policy he says will be defeated if they can be sued for having included a preservative in the vaccines.

Marjorie Powell, senior assistant general counsel of the Pharmaceutical Research and Manufacturers of America, the industry's advocacy group, adds that plaintiffs should prefer vaccine court.

The court is "intended to provide prompt and inexpensive decision-making," similar to workers' compensation hearings. She says plaintiffs don't have to prove causation, plus the process is streamlined and intended to provide consistency.

GETTING THEIR CHANCE

PLAINTIFFS LAWYER KILPATRICK, however, says the 5th Circuit decision is the only hope his clients have of getting real relief for their injuries. He says the Holders might have missed the three-year statute of limitations in vaccine court because they didn't file suit until 2002, shortly after they learned of the possible link between thimerosal and autism. This date was more than three years after the autism symptoms appeared, which is when the clock starts running, Kilpatrick says. "It's a violation of due process for these children not to have any remedy whatsoever."

With thousands of cases filed against thimerosal makers wending their way through the courts, most trial courts have so far agreed with the pharmaceutical industry and held that cases stemming from thimerosal in vaccines belong in vaccine court. (In 2002, Congress passed a rider that stated claims against thimerosal manufacturers must be brought in vaccine court, but that provision was repealed in 2003.)

As for the Holders, they still have an uphill battle in court. Kilpatrick says that, under Mississippi law, they will have to prove which of the three potential manufacturers was responsible for the thimerosal that the Holder children received.

Then, he will have to prove that the thimerosal actually caused the autism—a potentially challenging battle because scientists are divided on that issue. "It's going to be hard," he says. "It's going to be a difficult case." ■

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321 North Clark Street
Chicago, IL 60610
312.988.5000

American Bar Association
Service Center
321 North Clark Street
Chicago, IL 60610
312.988.5522
800.285.2221

American Bar Association
740 15th Street, N.W.
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