

March 31, 2008

OP-ED CONTRIBUTOR

Inoculated Against Facts

By PAUL A. OFFIT

Correction Appended

Philadelphia

ON March 6, Terry and Jon Poling stood outside a federal courthouse in Atlanta, Ga., with their 9-year-old daughter Hannah and announced that the federal government had admitted that vaccines had contributed to her autism. The news was shocking. Health officials at the Centers for Disease Control and Prevention and at the American Academy of Pediatrics have steadfastly assured the public that vaccines do not cause autism. Now, in a special vaccine claims court, the federal government appeared to have said exactly the opposite. What happened?

The answer is wrapped up in the nature of the unusual court where the Poling case was heard. In 1986, after a flood of lawsuits against vaccine makers threatened the manufacture of vaccines for children, Congress created the National Vaccine Injury Compensation Program, financed by a tax on every dose of vaccine.

As part of the program, a group of scientists, doctors and lawyers listed all the health problems that might be linked to vaccines. The oral polio vaccine could in rare cases cause paralysis, for example, and an early version of the rotavirus vaccine might cause intestinal blockage. (In the interest of full disclosure: I am a co-inventor and co-patent holder of a newer rotavirus vaccine.)

If, at a trial in a special court, a preponderance of scientific evidence suggested that a vaccine caused one of these problems, a family would be compensated quickly, generously and fairly. Because no one could sue vaccine makers without going through this special court, the number of lawsuits against vaccine makers fell drastically.

The system worked fine until a few years ago, when vaccine court judges turned their back on science by dropping preponderance of evidence as a standard. Now, petitioners need merely propose a biologically plausible mechanism by which a vaccine might cause harm — even if their explanation contradicts published studies. In 2006, for example, Dorothy Werderitsh claimed in the vaccine court that a hepatitis B vaccine had triggered an autoimmune response in her brain that led to multiple sclerosis. Two large studies had clearly shown that hepatitis B vaccine could neither cause nor exacerbate multiple sclerosis, but the court ruled in favor of Ms. Werderitsh, elevating a hypothesis above epidemiological evidence.

The Hannah Poling case is similar. In 2000, when Hannah was 19 months old, she received five shots against nine infectious diseases. Over the next several months, she developed symptoms of autism. Subsequent tests showed that Hannah has a mitochondrial disorder — her cells are unable to adequately process nutrients —

and this contributed to her autism. An expert who testified in court on the Polings' behalf claimed that the five vaccines had stressed Hannah's already weakened cells, worsening her disorder. Without holding a hearing on the matter, the court conceded that the claim was biologically plausible.

On its face, the expert's opinion makes no sense. Even five vaccines at once would not place an unusually high burden on a child's immune system. The Institute of Medicine has found that multiple vaccines do not overwhelm or weaken the immune system. And although natural infections can worsen symptoms of chronic neurological illnesses in children, vaccines are not known to.

"There is no evidence that children with mitochondrial enzyme deficiencies are worsened by vaccines," Salvatore DiMauro, a professor of neurology at Columbia who is the nation's leading expert on the disorder, told me. Indeed, children like Hannah Poling who are especially susceptible to infections are most likely to benefit from vaccines.

Supporters of the Vaccine Injury Compensation Program argue reasonably that the program should err on the side of overcompensation — a relief valve that is needed in a society that mandates vaccines. But there is a price for this largesse. In the past few years, parents of 4,800 autistic children have filed claims to the vaccine court which have yet to be heard. And average awards in other recent vaccine cases have been more than \$800,000. Furthermore, because uncompensated claims in vaccine court can spill into state courts, the Poling decision will likely draw more personal-injury lawyers to the fray. "It's a beginning," said Kevin Conway, a Boston-based lawyer who represents more than 1,200 families with vaccine injury claims.

The vaccine court should return to the preponderance-of-evidence standard. But much damage has already been done by the Poling decision. Parents may now worry about vaccinating their children, more autism research money may be steered toward vaccines and away from more promising leads and, if similar awards are made in state courts, pharmaceutical companies may abandon vaccines for American children. In the name of trying to help children with autism, the Poling decision has only hurt them.

Paul A. Offit, chief of the infectious diseases division of the Children's Hospital of Philadelphia, is the author of "Vaccinated: One Man's Quest to Defeat the World's Deadliest Diseases."

Correction: April 2, 2008

An article on the Op-Ed page on Monday about the federal vaccine court inaccurately described the legal proceedings in the case of a girl who developed autism symptoms after receiving childhood vaccines. An expert who provided an opinion on behalf of the girl's family did not testify in court; he submitted a written affidavit.

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