

The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis

Paul Offit



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When I lecture medical students on immunisation, I explain that the antivaccine lobby contains few elderly people because most of them have lived through epidemics of vaccine preventable diseases such as polio or diphtheria. They have seen the devastation that these diseases can cause, and also seen them controlled by immunisation. After reading *The Cutter Incident*, I marvelled that most older people have maintained their confidence in immunisation despite also living through a massive and highly publicised disaster that left many crippled, and some dead, as a result of vaccine-induced polio.

Author Paul Offit, a prominent US infectious diseases physician and vaccinologist, has traced the origins of today's "vaccine crisis" to an incident during the 1950s in which thousands of people received polio vaccine containing live polio virus. Offit describes the development of polio vaccine, from trials of early vaccines through to the appearance on the scene of Jonas Salk.

In 1951 Salk was the beneficiary of \$200 000 a year for his research (a massive amount at that time), thanks to the largest public fundraising activity ever held—The March of Dimes. By this time, there were 59 000 cases of polio each year in the United States. Salk undertook research on a scale never seen before. By 1954 his vaccine was ready for a clinical trial that was to include 1.8 million children: 420 000 receiving the vaccine, 200 000 receiving placebo, and 1.2 million receiving nothing.

The vaccine was highly effective and safe. It was licensed the next day thanks to political

pressure, and during the next two weeks, five companies distributed about five million doses. Thirteen days after the first doses were administered, there were reports of cases of polio in immunised children. All of these initial cases had received vaccine manufactured by one company—Cutter Laboratories (although vaccine made by Wyeth also caused some cases of polio). In the end, at least 220 000 people were infected with live polio virus in Cutter's vaccine (including 100 000 contacts of immunised children), 70 000 developed muscle weakness, 164 were severely paralysed, and 10 died.

Offit outlines a series of events that contributed to vaccine containing live virus being released from Cutter Laboratories. These included the use of a highly virulent strain (Mahoney), deficiencies in the inactivation of vaccine virus, inadequate safety tests, and poor communication with other scientists and the government. However, Cutter Laboratories was doing all that the licensing authority required of it.

Sixty lawsuits were subsequently filed. The first resulted in a verdict that "affected all pharmaceutical companies for the next fifty years." The jury found that Cutter was not negligent in producing the vaccine, but had breached an implied warranty that their product was safe. The concept of liability without fault was born. In other words, companies were responsible for the effects of their products even when they were not negligent in their design or manufacture.

Offit goes on to record the litany of successful lawsuits that arose from this precedent. These led to the 1986 National Vaccine Injury Compensation Program, designed to protect companies from lawsuits not supported by scientific evidence. Despite this, pharmaceutical companies are gradually abandoning vaccines. In 1957, 26 companies made five vaccines in the United States. By 2004 four companies made 12 vaccines. Offit points out that the cost of litigation is eventually paid by the consumer and is an important contributor to the high cost of vaccines. It also prevents the development of important new vaccines.

The Cutter Incident is an enjoyable read, at times like a detective thriller, at others like a courtroom drama. Offit portrays many of the heroes—Jonas Salk and Albert Sabin, among others—as egotistical and flawed. There are some slightly irritating stylistic features—individuals and themes are repeated and re-introduced too often, the science is "dumbed down" too much on



Jonas Salk

occasion, and the frequent launching into tangential stories interrupts the flow of the main plot.

Some readers may be annoyed at the particularly American perspective from which this book is written. For example, Offit portrays Sabin's oral polio vaccine as vastly inferior and downright dangerous, despite being cheap and used far more throughout the world than Salk's, and he describes the move to a two dose schedule of conjugate pneumococcal vaccine brought about by vaccine shortages in the United States as harmful (including a single example of a child who died after failure of a two dose schedule), when the evidence then and now supports the efficacy of a two dose primary schedule. But these are minor quibbles.

Like my parents and grandparents, I have been lucky enough to experience the virtual elimination of a dread disease by immunisation in my community—in my case *Haemophilus influenzae* type B. I tell my students that I hope they, too, will see similar things in their lifetime. *The Cutter Incident* reminds us how close we have been—and indeed still are—to losing immunisation as our most effective public health tool.

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(4=excellent)