

Triumph And Tragedy

by Scott Barrett

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

by Paul A. Offit

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This book contains a story and an essay, connected by a singular event. The story is an American one, complete with a happy ending, of how polio was defeated in the United States. The essay is on the incentives that shape vaccine research and manufacturing today. The essential message of the essay is that were a disease like polio to emerge today, it might prove harder for the United States to defeat the disease, despite decades of advancement in science and medicine. The story of triumph that opens the book becomes, in the end, a tragedy—and one of our own making.

And what about the event that connects the story and essay? That, as you might have guessed, was a lawsuit. I told you this was an American story.

The narrative begins in 1955, with a mother taking her daughter and son to the pediatrician. They were lucky, she believed. Her children were to be among the first to receive the Salk vaccine. They were to be protected from the scourge that had killed and crippled thousands of children. Sadly, days later, the daughter contracted polio from the vaccine itself. She, like her brother, had been given vaccine produced by Cutter Laboratories. Her brother was lucky, but she became a victim of what later became known as the “Cutter Incident.”

At this point, the book draws back to de-

scribe the important events that led up to that dreadful incident, including the heightened concern, if not panic, that gripped the country during the polio epidemics, and the rivalry between the great polio researchers, Jonas Salk and Albert Sabin. These and other elements of this story are familiar, but they are told well, and the book contains many facts of which I was previously unaware. The author, Paul Offit, not only knows his subject but has researched it. Much of this research is original.

If there is a single hero in this book, it is Salk, although Offit explains that Salk’s achievement depended on a great many people making a variety of contributions—some small, some large, and not all of them helpful. A few of these people proved to be as essential to the overall enterprise as Salk himself. But Salk’s discovery of “immunologic memory,” Offit believes, was reason enough to award him the Nobel Prize he was denied.

It is a human tendency to celebrate the mythic hero—a person such as Salk. But in addition to the dozens of other scientists who contributed to the development of the polio vaccines, literally millions of people, mostly mothers, contributed their time and resources to raise the dimes needed to pay for the research. This, I believe, is another aspect of this story that is almost uniquely American. Alexis de Tocqueville, writing in the early nineteenth century, noted the peculiar tendency of Americans to volunteer, to associate, and to organize for a common cause, and that is just what the March of Dimes did in the mid-twentieth century—and to superb effect.

The public’s involvement in financing the National Foundation for Infantile Paralysis helped raise expectations for a successful out-

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come, and there was great pressure to develop and distribute a vaccine as quickly as possible. Satisfying these expectations was no easy task. The nature of this disease meant that the field trial had to be “the largest, most comprehensive test of a medical product ever performed” (p. 52). And this had to be done at a time when scientific protocols and a regulatory apparatus for vaccine testing were just being developed. Indeed, the procedures relied upon today to discover, develop, test, manufacture, and distribute vaccines were largely shaped by the polio effort.

Moving quickly required bold decisions. To encourage pharmaceutical companies to make Salk’s revolutionary vaccine, for example, the foundation offered to buy twenty-seven million doses for \$9 million. Surprisingly, this offer was made before the vaccine had passed its field trial, and payment did not depend on the trial’s success. Contrast this approach with the kinds of incentives being contemplated today. For example, a “vaccine purchase commitment” would pay a single winner for developing, say, a malaria vaccine only if it were demonstrated to work. The foundation paid for Salk’s research directly and guaranteed a market for manufacturers of his vaccine even if it did not work. The approach succeeded.

One of the five firms that competed to make the vaccine was Cutter Laboratories. Like the other companies, Cutter had been given imprecise directions for how to manufacture Salk’s vaccine; unlike the others, Cutter “showed a greater disregard for Salk and his theories” (p. 112), particularly the rules for inactivation. The consequence was horrible: In the end, 220,000 people were infected with live poliovirus in the Cutter vaccine, 164 were severely paralyzed, and 10 died.

Of the people paralyzed by the Cutter vaccine, one was the girl who opened the story, and her parents sued the company. The judge presiding over the case instructed the jury that “if Cutter’s vaccine had paralyzed [the girl],

then the jury had no choice but to find Cutter guilty” (p. 149). The jury found the company guilty, but it did not believe that Cutter was negligent. The jury simply could not deny that the girl was infected by Cutter’s vaccine.

This event—this ruling about liability—connects the story with the essay, which is about the incentives for vaccine development and manufacture today. As Offit explains, the “verdict means that if pharmaceutical companies made a product according to industry standards, using the best science that was available, and found months or years after its sale that it caused harm—a harm not predictable—they were liable for damage” (p. 154).

Here is why this matters: Infectious diseases pose risks to public health, but so do efforts to protect the public against these diseases. Society plainly needs to balance these risks. The problem with this decision about liability is that it places the costs of a vaccine failure squarely on the shoulders of the company, whereas the benefits of a vaccine success are shared by the company and the public. This upsets the balance that is needed; it makes companies overly cautious from the perspective of the public good. It overprotects society from vaccines and underprotects society from infectious diseases.

In writing this wonderful book, Offit had a plain purpose: to show how we got into this situation and the price we are paying for it, and to contrast the risk taking that led to the development of the Salk vaccine in the 1950s with the timidity that forces even effective vaccines to be withdrawn from the market today. The message is equally plain: The existing situation is both costly and avoidable; the rules need to be changed.

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