

and vaccines), resulting in legal possession of agents that might be converted to weapons. In this context, Guillemin offers a particularly interesting analysis of the economic concerns that have been a barrier to verification efforts: given the highly secretive and competitive pharmaceutical marketplace, pharmaceutical companies have significant concerns about allowing international inspection of their research facilities.

Guillemin's analysis of the political, social, and, especially, economic factors that have inhibited verification measures might be particularly useful for efforts to overcome these obstacles. Transparency among state actors, however, may be insufficient to achieve nonproliferation, as the most significant contemporary threat to use biological weapons consists of non-state actors. Unfortunately, even rigorous international state efforts are unlikely to keep scientific experts inaccessible to these groups.⁴ Nonetheless, Guillemin's book is an extremely valuable and insightful work on a topic of significant national and international concern.

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History, Polio

The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis, by Paul Offit, 238 pp, with illus, \$27.50, ISBN 0-300-10864-8, New Haven, Conn, Yale University Press, 2005.

THE CREATION OF THE POLIO VACCINE remains a major triumph of 20th-century medicine, but its development did not come without heavy costs. In *The Cutter Incident*, Paul A. Offit, MD, not only explores the steps leading to

the poliovirus vaccine disaster of the 1950s but also illustrates the legacy of public mistrust and rampant litigation that endures to this day. While giving the reader a "behind the scenes" look at the development of an effective polio vaccine, Offit puts a face on the tragedy through detailed descriptions and histories of the polio victims, providing the strong sense of humanity that this story deserves.

The story begins with a glimpse of the early 20th-century United States dealing with a disease it did not understand and could not control. The 1916 polio epidemic in New York City instilled fear and panic. In the years following that and other major outbreaks, US researchers sought an effective vaccine. Offit reminds us that the first attempts at a polio vaccine, initiated in the 1930s, met with the same fate as the Cutter incident; live poliovirus escaped inactivation and left many children paralyzed. These incidents left an indelible mark on polio researchers, and although polio research continued at an impressive rate (funded primarily by the March of Dimes Foundation), few researchers were willing to pursue a vaccine.

In contrast to many of his peers, Dr Jonas Salk took a bold step forward by developing an inactivated polio vaccine, which was highly successful in a 1954 field trial of 1.8 million participants. Salk prepared the vaccine using one of the most virulent strains of polio known at that time, the Mahoney strain, which left no room for error in the steps toward total virus inactivation. During the switch from field trials to mass public vaccination, several pharmaceutical companies were licensed to prepare 5 million doses of inactivated polio vaccine. Cutter Laboratories produced vaccine in which some of the virus was still alive. The result was the worst man-made polio epidemic in America: hundreds of thousands of children were injected with live poliovirus, leading to 164 cases of paralysis and 10 deaths.

Cutter Laboratories was soon brought to court. In the landmark case involv-

ing Anne Gottsdanker of California, aged 7 years, who was severely and permanently paralyzed by the Cutter polio vaccine in 1955, the jury did not find Cutter negligent (after all, they had followed the governmental guidelines for virus inactivation) but did find Cutter liable for the harm that their vaccine had caused. As Offit writes, "Liability without negligence (fault) was born." This finding has had profound impact on vaccine manufacturers, with few companies willing to risk being sued for damages that may or may not be directly related to the use of their product, albeit prepared according to strict US Food and Drug Administration regulations. The result, Offit argues, is that vaccine shortages are becoming more common, as indicated by the influenza vaccine shortage of 2004. Moreover, owing to fears of continued litigation in a society with near-zero risk tolerance, companies have little incentive to invest in further vaccine research. This reluctance may lead to children dying of potentially preventable diseases. Offit ends by noting that injury lawyers will gladly represent those potentially hurt by vaccines but asks, "[W]ho will represent the interests of the thousands of children hospitalized, permanently harmed, and killed by viruses and bacteria for which existing vaccines are in short supply or for which new vaccines may never be developed?"

The Cutter Incident is well written and easily understood by nonspecialists, who will understand the challenges of infectious disease and vaccine development, yet balanced with enough technical detail for a medical professional to read informatively cover to cover. Readers who enjoy books such as *Viruses, Plagues, and History* by Dr Michael Oldstone that relate medical history to current events will also enjoy *The Cutter Incident*.

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