

## PUBLIC HEALTH

### A Vaccine Disaster and Its Fateful Shadow

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Five decades ago in Ann Arbor, Michigan, Thomas Francis made a momentous announcement: the polio vaccine developed by Jonas Salk and his team worked. The news was hailed as one of the greatest triumphs of science, medicine, and public health. Development of a safe and effective polio vaccine, through the leadership of the National Foundation for Infantile Paralysis and its March of Dimes campaigns, reaffirmed the spirit of volunteerism in the United States and restored public confidence in vaccines following two decades of disaster. Church bells rang throughout the land in celebration, and Jonas Salk enjoyed celebrity unprecedented for a medical scientist. As Paul Offit vividly describes in *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis*, the announcement came at a time of devastating polio epidemics that paralyzed tens of thousands of children each year, a time when Americans' fear of polio was surpassed only by their fear of nuclear war. The new vaccine was promptly licensed, and communities were mobilized to deliver millions of doses to children throughout the country.

Within three weeks, triumph turned to tragedy as reports streamed in of polio cases among recently immunized infants and children, principally from the western states. The clinical and epidemiologic findings clearly implicated the polio vaccine and narrowed the risk to specific lots produced by Cutter Laboratories of Berkeley, California, one of the five American producers of the vaccine. In his gripping narrative, Offit (an immunologist and pediatrician at the Children's Hospital of Philadelphia and the University of Pennsylvania School of Medicine) recounts the terrible dilemma faced by public health officials as they urgently sought a way to prevent further cases while not undermining public confidence in the polio vaccine just as the peak transmission season for circulating polioviruses was beginning. Because the regulations governing vaccine

production were at the time quite limited, the officials had essentially no knowledge of the problems that Cutter and other manufacturers had encountered in producing polio vaccine lots free of infectious virus. Crucial decisions were made on the basis of very limited information. A consequential backdrop to these events was widespread skepticism about Salk's polio vaccine among leaders in the scientific community—skepticism fueled by a mixture of intense personal rivalry and the view that the attenuated polio vaccine then under development offered a more technically elegant, and potentially more broadly applicable, solution. In the wake of the Cutter tragedy, some leading scientists even asserted that Salk's theories and methods were fundamentally flawed and that production of an inactivated polio vaccine free of infectious virus was theoretically impossible.

**The Cutter Incident**  
How America's  
First Polio Vaccine  
Led to the Growing  
Vaccine Crisis  
by Paul A. Offit

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**Ready for the rollout.** Drawing on stockpiles of bottles (such as these photographed in New Jersey in January 1955), the five manufacturers distributed more than 4.8 million doses of polio vaccine in the first three weeks after the April 1955 licensing of the vaccine.

Subsequent events have vindicated the Salk vaccine, because many millions of doses were produced and administered after 1955 without incident. The availability of an effective polio vaccine in 1955 saved tens of thousands of children in the United States, Canada, and Europe from lifelong paralysis and demonstrated the feasibility of widespread immunization to control polio. Immunization with the live, attenuated oral polio vaccine of Sabin, licensed in 1961, completed the task already well advanced by use of Salk's vaccine, and the last pockets of indigenous poliovirus transmission were eliminated in the United States by the 1970s. Building upon the successful elimination of polio from developed countries, the World Health Organization established the Global Polio Eradication Initiative in 1988 to fulfill the promise of a polio-free world first envisioned in 1955. In this global effort, the more easily administered Sabin vaccine has been the primary weapon against polio, but many countries, including the United States, have returned to the Salk vaccine to maintain a polio-free status.

Offit's book is a comprehensive and readily comprehensible account that seamlessly moves from historical narrative through technical exposition, mystery thriller, courtroom drama, and legal review to social commentary. In this last aspect, Offit presents his most compelling message: that the Cutter incident lies at the root of our current vaccine crisis. He recounts how thoughtful jurors, following a judge's strict instructions, reluctantly found Cutter liable for financial damages even though they believed that Cutter was not negligent in the production of polio vaccine. He then traces how the principle of liability without negligence was aggressively expanded in subsequent court decisions to liability even for the manufacture of safe products. Echoes of the Cutter decision still reverberate today in the diminishing number of vaccine manufacturers, the high prices for vaccines in the United States and other developed countries, and the insufficient current supply of influenza vaccine as we face a possible pandemic.

*The Cutter Incident* offers a concise and thoroughly documented account (well illustrated with rare period photos) of a medical tragedy and its continuing consequences. Offit presents a powerful case for a far more enlightened approach to the development and use of lifesaving vaccines.

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