



# Reviews and Resources

## BOOKS

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

Paul A. Offit. Yale University Press, New Haven, Conn, 2005, 256 p., \$27.50.

This is an extraordinary book. I didn't expect it to be, as I had simply assumed little remained to be written about the first polio vaccine and the devastating incident that nearly led to its withdrawal. What makes this book extraordinary is the author's ability to weave the well-known and less-well-known historical events into a compelling and thought-provoking essay on the challenging vaccine issues of today. The author skillfully takes the reader from the 1950s "age of innocence" in science, public health, and public policy to the present complex and disturbing environment where almost everybody's motives are questioned by somebody else.

The motivation for developing the vaccine was never in doubt. The determined efforts of the National Foundation for Infantile Paralysis, families contributing to the March of Dimes, the scientific community, and the government were all about reducing fear, saving children's lives, and preventing the devastating, crippling effects of poliomyelitis. The clashing personalities, deep convictions, and strong egos of the main players, particularly Jonas Salk and Albert Sabin, and the running debates over killed (Salk) and live (Sabin) vaccine, well captured in the book, were unfortunate distractions (or fascinations), but all shared the same basic humanitarian goals. Personal glory, maybe, but monetary gains were never an issue. The same aura of innocence applies to the science behind polio vaccine development, federal approval procedures, and vaccine production standards, which made it difficult to fix blame for the 200 paralyzed children

and 10 deaths caused by residual live virus in the Cutter vaccine. As for most scientifically sound concepts, variables compromising inactivated vaccine (IPV) safety were shortly identified and resolved. No further incidents of residual live virus have occurred. The Cutter incident was tragic, but we learned from it and moved on. Only the legal fallout remains.

In January 1958, the jury found that Cutter Laboratories was not negligent in the production of polio vaccine, but was still financially responsible for harm caused by its product. Thus, "liability without negligence (fault) was born." The author does a fine job in teasing out the legal arguments and courtroom events that led to the verdict and makes a strong case that the Cutter liability trial was the pivotal point in the age of innocence in disease prevention through vaccines. The concept that the pharmaceutical industry should pay for harm caused by their products because they could defray the cost by increasing the price for the product did not take into consideration the future litigious nature of our society or the small size of the vaccine market.

The shock waves of the mid-1980s, when one award equaled more than one half of the total gross pertussis vaccine sales of all manufacturers and when the price of the vaccine increased nearly 60fold virtually overnight, led to the creation of the National Vaccine Injury Compensation Program. The Program provides fair compensation for legitimate claims and some relief from the excess awards by juries that establish their own scientific "facts," but it does not cover all vaccines. Individual and organized personal injury suites against vaccine manufacturers continue. Manufacturers have left the field; annual vaccine shortages have become the norm. Seven of the twelve childhood vaccines are produced by only one manufacturer.

The U.S. system for vaccine development, production, and supply is badly

flawed. The question is, when and how will we fix it? The author suggests that one possible solution is the extension of the National Vaccine Injury Compensation Program to preclude all tort litigation. We would do well as a nation to reflect on the author's question of "who [represents) the interests of 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?" I recommend this thoughtful book to everyone.

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