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VACCINE CRISIS

By STANLEY GOLDFARB

WHAT irony. As the nation tries to prepare for the possibility of an influenza pandemic, vaccine makers will be hard pressed to successfully implement the government's preparation plans.

And the reason those preparation plans may be hampered stems from the legendary Jonas Salk's miraculous polio vaccine, the 50th anniversary of whose discovery we celebrated earlier this year.

The word "polio" used to provoke a sense of dread in parents that is unimaginable today. It crippled the president of the United States, children were kept away from crowds, iron lungs filled hospital rooms, and the nation raised millions of dollars to support the March of Dimes to help find a cure.

But on April 12, 1955, a vaccine became the hope of the nation when the one developed by Dr. Salk was announced as highly effective in a large-scale trial. And as Dr. Paul Offit writes in his new book, "The Cutter Incident," the reverberations of those events — both good and bad — are felt to this day.

In that study, the vaccine virtually eliminated the occurrence of polio in a large group of at-risk children. Soon, though, it became apparent that some children who received the vaccine produced by Cutter Laboratories, a small pharmaceutical firm in California, had in fact developed polio and the attendant horrible paralysis from the vaccine. In some cases, the children died.

The virus was supposed to have been killed prior to injection, but the process for assuring that all the injected virus had been killed was defective. The series of errors that led to this horrible outcome is complex and difficult to understand. Suffice it to say, extensive investigations showed that Cutter Laboratories made mistakes but was not negligent. The problems that led to the catastrophe could only be identified in retrospect and were later completely eliminated.

The real issue here is not the process that led to the error, but the present-day legal consequences that emerged from the "Cutter incident." The ruling in the lawsuit involving Cutter's polio vaccine, *Gottsdanker v. Cutter Laboratories*, established the legal precedent for "liability without negligence." And ever since then, vaccine production in the United States has declined because of the growing legal concerns of pharmaceutical companies, namely, that producing vaccines might lead to patient injury and expose the company to substantial lawsuits, even if no negligence can be attributed to the company's actions.

Vaccines have also been demonized from several quarters, and the hysteria surrounding their alleged dangers has chilled development and production because no company can afford to risk inadvertently injuring patients and losing costly lawsuits under the liability theories that the *Gottsdanker* case introduced.

This chilling effect has come at a time when the oversight of vaccine production is far superior and vaccine safety is assessed much more rigorously than in 1955.

Offit, the chief of infectious diseases at Children's Hospital in Philadelphia (and a member of the same medical-school faculty as this reviewer), has written a fascinating and highly readable account of the development of the polio vaccine.

He also offers a compelling plea for a strengthened law to provide relief to companies that produce vaccines so that our nation may be afforded the most cost-effective and long-lasting form of prevention against many infectious diseases — an effective vaccine.

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