



VACCINES ARE SCARCE. WHY?

IN THE STANDARD TELLING, THE DEVELOPMENT OF THE polio vaccine was a triumph of public initiative. Within a generation polio had disappeared from the U.S. But most vaccine manufacturers disappeared with it. Their slow suffocation began on the day the authorities took charge of competition. Dr. Paul A. Offit tells the story in *The Cutter Incident*, the best account you will ever read about the interplay between big drug companies and bigger government.

President Roosevelt, a polio victim himself, helped launch the foundation behind the March of Dimes, which attracted thousands of volunteers and millions of donors. The dimes funded breakthrough research by Jonas Salk, followed by a trial involving 420,000 children, by far the largest such trial ever conducted.

By early 1953 Salk had pushed the lab science to the point where he would vaccinate his own three children. But, as Salk acknowledged, scaling up the process was a separate challenge. Mass production required a protocol that would inactivate every last particle of the virus in millions of doses but still leave the virus sufficiently intact to trigger an immune response.

Basil O'Connor, the Wall Street lawyer who was running the foundation, made the right call: He used his checkbook to spur private competition and mobilize corporate capital. O'Connor first approached Parke-Davis, a company that already manufactured other vaccines and had been working on polio, too. The company signed on, but it had patented a different method for inactivating the virus, and that created a conflict. Salk urged the foundation to add some competitors. So O'Connor simply committed to buy 27 million doses of the vaccine after the trial had been completed, however it ended, and whether or not the vaccine ever made it to market.

Five companies were soon vying to supply vaccine for the trial. The foundation demanded that suppliers first deliver 11 consecutive lots that had passed safety tests with

monkeys. Only Parke-Davis and Eli Lilly made the cut. The field trial was a resounding success. The foundation then handed control over to the small federal agency that was in charge of regulating vaccines at that time. That was the beginning of the end.

The agency just summarized the protocol that had been used successfully to inactivate the virus and licensed five manufacturers. One was the Cutter Co., which had failed to meet O'Connor's requirements earlier. Cutter followed the government's instructions, such as they were, but failed to kill all the virus. Seventy thousand people suffered mild forms of polio as a result. Two hundred were paralyzed. Ten died.

The authorities had moved too quickly and carelessly. They would atone by slowing everything to a lawyer-clogged crawl. The ensuing lawsuits established new standards that made it much easier to sue vaccinemakers. Case by case, liability claims came to dominate the industry's economics. Junk claims overtook legitimate ones and then eclipsed them completely. When liability problems threatened to cut off the supply of some vaccines, Congress imposed a broad-based tax on vaccines to fund an alternative compensation system.

The government's role in buying and distributing vaccines expanded in parallel. Federal agencies began funding childhood

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vaccination programs soon after the polio vaccine was commercialized. The government now buys over half of all vaccines used in the U.S., at prices it effectively dictates.

As the government's role advanced, the private sector retreated, to the point where this segment of the industry now looks and operates much like a public utility. In 1957, 26 companies were supplying 5 vaccines.

By 2004, 4 companies were supplying 12. Mergers accounted for some of the attrition, but most was caused by companies simply abandoning the business. Eli Lilly and Parke-Davis (now part of Pfizer) were among the dropouts. Seven of the 12 vaccines routinely given to young children in 2005 were being provided by just one manufacturer; another 4 had only 2 suppliers.

Every week rotavirus kills one child in America and 12,000 children in the developing world. A vaccine against it was developed by Dr. Offit and his colleagues, working at the Children's Hospital of Philadelphia and the Wistar Institute. Their work took 10 years. Merck needed another 16 to deliver a vaccine that the FDA approved in February. Nobody wants another Cutter. But what a pity it is that the 16 years could not have been, say, 8. That could have saved 5 million lives.

Developing vaccines is much easier today than it was half a century ago—Dr. Offit says half a dozen important ones could readily be designed and assembled by laboratories like his. It doesn't happen because no drug company wants to market them. **F**



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