Theodore Dalrymple
Why New Vaccines Are Scarce
Blame the tort lawyers, argues Paul Offit’s important new book.
8 March 2006

While mass immunization against infectious disease is one of western medicine’s great triumphs, it has always given rise to considerable anxiety and opposition. In Britain, for example, opponents of vaccination against smallpox managed for 70 years to sustain a vigorous and popular political movement, as well as a journal with a wide circulation. Supporting them were such ignorant luminaries as George Bernard Shaw and a number of doctors who claimed, among other things, that vaccination caused leprosy, quite apart from outbreaks of the very disease it supposedly prevented.

Immunization fears have swept through the western world ever since. The dangers of immunization have sometimes appeared more real to the parents of young children than the dangers of traditional killers such as diphtheria, measles, and whooping cough. Even the best scientific evidence never seems completely to refute the scare stories in the public mind: it is as if something had programmed most people to believe that there could be no smoke without fire.

In his enthralling The Cutter Incident: How America’s First Polio Vaccine Led to the Growing Vaccine Crisis (Yale University Press), Paul Offit, professor of pediatrics at the University of Pennsylvania, tells the story of a genuine disaster caused by mass immunization—a disaster that was, however, embedded in an overall medical and scientific triumph: the elimination of polio from much of the world.

The incident was historically important not only because of the children damaged, but because it led to a legal ruling that subsequently inhibited pharmaceutical companies from developing and manufacturing vaccines. If America now routinely has a shortage of vaccines, it is in part the long-term consequence of the Cutter Incident.

The basic research to produce a polio vaccine took place under the auspices of a voluntary association, the National Foundation for Infantile Paralysis, which organized the
famous March of Dimes. The foundation oversaw and funded more research on polio than did the rest of the world put together.

It was the foundation that carried out the first field trial of Jonas Salk’s vaccine and established that the vaccine (which contained polio virus killed by formaldehyde) was safe and effective. It was the largest medical trial ever conducted, involving more than 400,000 participants. It seemed that polio, which at the time terrorized parents (my best friend was one of the last children in Britain to contract it, and my parents spent several weeks in dire fear that I had suffered infection also) was about to go down to defeat.

At this point, the foundation withdrew and handed over its project to the government. Five companies received licenses to produce the vaccine, including the Cutter Company of California. The licensing authority, the Laboratory of Biologics Control, also issued instructions about how to produce the vaccine, but unfortunately those instructions proved in two respects less stringent than those that the foundation had issued prior to the first trial of the vaccine. The foundation had stipulated that the manufacturers should report any difficulties in eliminating live virus from their vaccine, and also that they should be able to produce 11 successive lots of vaccine without live virus in it. The Laboratory of Biologics Control made no such stipulation.

The Cutter Company, the smallest of the five producers, followed the instructions to the letter, which proved insufficient to guarantee the vaccine’s safety. The company also made a couple of unfortunate technical mistakes, for which in the then current state of knowledge one could not blame it, with the result that live virus survived in some of its vaccine. Seventy thousand of the immunized experienced the transient flu-like symptoms of mild polio, 200 wound up paralyzed by polio, and 10 died because of it.

In the modern world, when tragedy strikes, can tort be far behind? The plaintiffs’ lawyer was Melvin Belli, then the most famous and flamboyant tort lawyer in America. The trial outcome was in a sense a draw, rather than an outright victory for the plaintiffs, but it established a principle that would be nearly fatal to the production of vaccines.

The trial established beyond reasonable doubt that Cutter had not been negligent. But the judge stated—as a matter of law, so that the jury was powerless to disagree—that the company was liable for damages, even if it had done nothing wrong, simply because its product had harmed its recipients.
This principle of absolute liability soon found itself defended in legal journals on the grounds that a large company was best able, via its insurance, to distribute the costs of risks among all the relevant parties, and society as a whole would benefit from the arrangement.

Quite apart from its repugnance to natural justice, this principle has been disastrous to the manufacture of vaccines. It opened the way for huge claims against the manufacturers. Since the courts are often cavalier in their complete disregard of scientific evidence, awarding huge damages against companies not only innocent of any negligence but whose products have done no objectively demonstrable harm, it is not surprising that pharmaceutical companies have largely withdrawn from the vaccine market. For them, the potential profits are small, and the risks great. SmithKlineGlaxo, for example, one of the world’s largest vaccine producers, withdrew its safe and effective vaccine against Lyme disease because of the expense of defending it against speculative tort actions of no merit. One almost wishes that an epidemic of Lyme disease would strike the whole tribe of tort lawyers.

Offit suggests a sensible remedy: an extension of the powers of the National Vaccine Injury Compensation Program, to the exclusion of all tort litigation surrounding vaccines. Unless a remedy of this sort applies, he says, the sectional interest of a small group of people, the tort lawyers, will continue to inflict damage upon public health.

The Cutter Incident is an absolute model of its genre. It is so tautly written that it reads like a good thriller, such that one is eager to find out what happened next. Offit conveys the science with admirable clarity, and he presents the philosophical and legal issues simply but without simplification. It is the best kind of medical history.