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Benefits, Risks, Vaccines, and the Courts

The hero of the 1500's was an explorer who blazed trails through hostile terrain to discover new worlds and wealth. The "hero" of the 1900's is a victim who blazes trails through hostile lower courts to establish a new precedent for lawsuits and wealth.

The high cost of such thinking is that few manufacturers want to make vaccines any more (see *Science*, 1 March, p. 1012). The profits are small; the risk of lawsuits very great. The country may soon be in the ludicrous position of developing a vaccine for AIDS and of not being able to find a manufacturer to produce it.

How have we strayed so far from the days of the 1700's when Zabdiel Boylston inoculated his son and friends to protect them against smallpox? Boylston inoculated 247 people with live pox, of whom 6 died—that is, 1 in 41. He was reviled by the medical profession and others. Then an epidemic occurred in which the remaining 241 survived while 1 in 7 of the general population died. Today Boylston is considered a pioneer, and the risk in vaccination is 1 in 100,000. Yet a lawsuit settlement in the millions of dollars for the one victim removes the incentive to protect the 99,999.

Boylston's heroic experiment had a risk ratio that would not be acceptable under today's regulatory codes. Those codes—considered too lenient by some, too strict by others—are at least based on some rational and statistical design. The lawsuit, however, is usually decided on highly emotional grounds, the poor victim against the infinitely wealthy government or corporation. Who would be so cruel as to deny a few millions here or there to a crippled victim or a bereaved family? Yet the result of such compassion is to deny protection to the many.

The dilemmas are large, and real. A probability of 50 children getting permanent brain damage after receiving vaccine against diphtheria, pertussis, and tetanus (DPT) is heartbreaking, even weighed against 3.5 million children inoculated. The control experiment has been done, however. When the DPT vaccine fell into disuse in England and Japan during the 1970's the death rate shot up (for example, during one 2-year period in England 36 children died per 100,000 who were infected with whooping cough). Various forms of legislation are being considered, but the approach of having the government subsidize whatever the courts allow, either to companies or to victims, seems unworkable. If a federal judge can order a drug company to pay \$10 million to a single victim, \$8 million punitive damages, what will the judgments be when the federal government is the ultimate underwriter?

It is not appropriate to shield companies or the federal government from punishment for lax or incompetent procedures. It is appropriate, however, to face the reality that a conscientiously executed procedure for making vaccines will still produce some tragic side effects. Do we continue to act out a play in which any bad result must have a villain, or do we face the reality that modern vaccines have great benefits and some built-in risks?

At some point the judicial system will have to face the most inexorable of all laws, the law of probability. Risks of diseases and harmful side effects from vaccines are steadily being reduced, but they will never be absolutely zero. Damage from industrial accidents involved lengthy court battles until the Workmen's Compensation Act was passed. With drugs and vaccines, some national compensation system in which medical costs, lost pay, and so on are calculated on an appropriate statistical basis will need to be enacted. The law would of necessity exclude extra compensation for emotional trauma and the life-style to which the lawyer has become accustomed. Such a law could allow moderately priced vaccines to be produced with appropriate compensation calculated into the price on an actuarial basis. Then we may be able to introduce into government the concept of a statistical morality as the foundation of a more rational approach toward all compensation situations. The next hero may be the statistics advocate who has the courage to say, "The healthy can afford to help the sick, but we do not live in a risk-free world."—DANIEL E. KOSHLAND, JR.