The Vexing Problems of Vaccine Compensation

The recent dropout of two vaccine companies has rekindled the debate about how to compensate children injured by vaccines

Spurred by the recent decision of two major drug companies to stop distributing whooping cough vaccine, lawmakers and public health policy-makers are making fresh attempts to safeguard the nation's vaccine supply. Caught between the conflicting demands of parents and drug manufacturers, Congress has finally begun to grapple with manufacturers' appeals for immunity from lawsuits generated by adverse drug reactions, while at the same time guaranteeing that those children who are injured by vaccines receive equitable compensation.

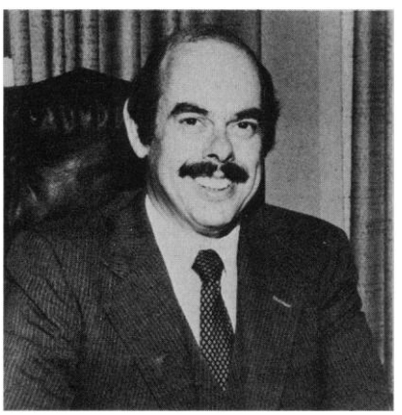
Most experts and medical organizations, such as the American Academy of Pediatrics, believe that legislative action is long overdue and that the situation is now serious. In the past two decades, several companies have stopped producing vaccine so that now there is only one manufacturer of measles vaccine, one of polio vaccine, and one of mumps and rubella vaccine. The two companies that left the market last year were makers of whooping cough vaccine and their withdrawal left only one distributor, Lederle Laboratories.

The departure of such manufacturers from the market has driven up the cost of vaccines, threatened a steady vaccine supply, and is said to dampen incentives to improve old vaccines or develop new ones. The price of whooping cough vaccine, for example, has skyrocketed more than 2000 percent in the past 2 years, from 12 cents to $2.80 per dose. Officials at the Centers for Disease Control said at a meeting in Atlanta in January that there are spot shortages of whooping cough vaccine across the nation.

Although the reasons that vaccine manufacturers leave the market are numerous, companies now cite increasing liability costs as the prominent reason. Lederle officials testified at a congressional hearing in December that 30 to 40 percent of current revenues from their whooping cough vaccine is available to cover liability costs. Claims such as these have prompted legislators and others to tackle the problem with a new sense of urgency.

For now, the short-term goal is merely to stave off a disruption in the supply of whooping cough vaccine. Lederle's insurance is up for renewal in July and public health officials are worried that Lederle and its insurance carriers may not be able to reach an agreement. But it is clear that the problem is wider.

At the heart of the dilemma is the fact that a small number of individuals are seriously injured each year by vaccines that have been properly manufactured. The combination vaccine against diphtheria, whooping cough (pertussis), and tetanus (DPT) accounts for most of the adverse side effects of all the vaccines against childhood diseases. According to an interagency government report, 5 to 20 children died annually during the past 10 years following DPT vaccination. Edward Brandt, Jr., then assistant secretary of health at the Department of Health and Human Services, testified at a congressional hearing in May that based on a population of 3.5 million children receiving DPT annually, an average of 50 suffer permanent brain damage, 9000 "collapse" after DPT inoculation, 25,000 suffer very high fevers. An average of 8 contract polio from the oral polio vaccine. About 40 to 60 children go into shock after receiving either the combined vaccine against mumps, measles, and rubella, or DPT.



Representative Henry Waxman

Public health officials stress that the benefits of vaccination far outweigh these risks. In Japan and the United Kingdom, use of DPT has dropped because of fears of severe reactions. Epidemics of whooping cough have ensued. In a major outbreak in the U.K. between 1977 and 1979, 100,000 cases of whooping cough were reported and 36 children died as a result of the disease, an incidence far higher than when the vaccine was widely used.

Although serious adverse reactions are infrequent, each case can be enormously expensive to settle. The unpredictability of court awards—which one company executive likens to a lottery—and pending lawsuits have also made it difficult and expensive to buy insurance, companies claim. In an extraordinary ruling last year, for example, a federal court in Chicago ordered Lederle to pay $10 million to a victim of its polio vaccine, of which $8 million were punitive damages. Even though the court determined that the vaccine was properly manufactured, it ruled that the company had failed to adequately warn about the risks of the vaccine. The company is appealing the decision. In the few other cases that have actually gone to trial, the court has awarded much smaller amounts, but out-of-court settlements are said also to contribute significantly to manufacturers' liability expense.

In addition, manufacturers contend that the costs of liability shrink an already thin profit margin. They note that vaccine production is difficult and lengthy and that the market for vaccines is inherently limited because they are administered only in childhood whereas drugs are usually taken repeatedly throughout life. As a result, their incentives to remain in the market have been eroded in recent years, they say.

Liability woes do not discourage all research, says one person involved in the compensation issue, but they may influence companies to concentrate on vaccines that are potentially less risky in terms of side effects and lawsuits. Merck Sharp and Dohme, for example, continues to develop new vaccines. A longtime maker of measles, mumps, and rubella vaccine, Merck 2 years ago began selling a vaccine against hepatitis B and now is testing a vaccine against chicken pox. According to this source, the company has chosen vaccines that are not likely to cause them problems.

Merck spokesman Roy Walker says that the firm is "confident" about the safety of its new vaccines. Apparently so are its insurers. The liability troubles at other companies have had "no signifi-

cant impact" on Merck's own insurance coverage, he says. However, Merck supports a federal compensation scheme, and company president Richard Lyons has claimed that liability problems are a "serious impediment" to the development of new vaccines.

The liability problem has been the principal obstacle to any solution thus far. There is a wide, continuing debate over whether the federal government should establish a compensation program for children injured by immunization. For example, a committee of the Institute of Medicine at the National Academy of Sciences is currently debating the compensation issue. The committee is planning to release a comprehensive report in March or April on factors affecting vaccine development. According to three committee members, a draft of the final report recommended a specific remedy, but some committee members later disagreed with the proposal. As things stand now, the final report might only list a series of options without advocating a particular solution.

Senator Paula Hawkins (R–Fla.) and Representative Henry Waxman (D–Calif.) are hoping to accommodate the appeals of both parents and vaccine companies. Last year, they introduced legislation that was drafted by the American Academy of Pediatrics and a group called Dissatisfied Parents Together, whose children have had serious reactions to DPT. The legislation would establish a federal compensation program, while at the same time retain a victim's right to sue. The proposal was intended to provide a faster and more equitable system of compensation than the courts offer and to provide incentives for vaccine companies to stay in business. Its main thrust, however, is opposed by vaccine manufacturers and the Reagan Administration. The legislators plan to reintroduce the legislation in mid-March, but with significant modifications.

Vaccine manufacturers and the American Medical Association have called for a federal compensation system as the sole remedy. They argue that if victims are given a choice between federal compensation or filing suit, the companies would still be vulnerable to unpredictable court decisions. They also object to a provision in last year's bill that allowed an individual to switch from the compensation program to the courts, or vice versa, in hope of landing a bigger settlement. As a result, vaccine manufacturers contend, insurance companies will still be reluctant to cover them.

The Reagan Administration opposed

Marjorie Sun

Senator Paula Hawkins

Planning for a new bill.

the compensation program as originally drafted, partly because of its potential expense. The Congressional Budget Office estimated that the program could cost $4.9 billion for the first 3 years alone. The estimate was based on an assumption that many claims would be filed since the bill would be retroactive and that $100,000 would routinely be awarded for pain and suffering in each case, plus lawyer's fees. The Administration also objected to the broad scope of injuries that could be compensated under the bill.

Senate aides say that the industry's and the American Medical Association's sole remedy proposal is totally unacceptable. But discussions are now under way among congressional staff and attorneys for the pediatrics society and the parents' group to modify the old bill. A House health subcommittee aide said that the Waxman bill "may be different" from the Hawkins' version. For example, the Waxman bill might address the pricing structure of vaccines "to make sure the government isn't paying twice" to cover liability costs—first through higher priced vaccines and second, through a compensation program. The subcommittee staff is investigating whether liability costs are as big a problem as the companies assert. So far, he says, Congress only has the companies' word that liability costs are excessive, but manufacturers have not presented any hard dollar figures to support their contention. The aide also asks whether some companies truly cannot obtain liability insurance. "I've talked to some insurance companies, and they don't know what the problem is."

Stephan Lawton, a lawyer representing the pediatricians, concedes that last year's bill "cost too much and that companies still can't predict their losses." The modified version, he said, may tight-

A Closer Look at the Legislation

The bills introduced last year by Senator Paula Hawkins (R–Fla.) and Representative Henry Waxman (D–Calif.) were broad in scope. The two legislators currently are modifying the bills in consultation with the American Academy of Pediatrics, Dissatisfied Parents Together, and industry and hope to introduce revised bills this month. The major concept of the old bills, however, which provides a victim the choice of seeking compensation through a federal program or through the courts, would be retained.

Last year's version contained the following provisions:

- The federal compensation program would cover injuries associated with vaccines against diphtheria, tetanus, pertussis, measles, mumps, rubella, and polio. Coverage is provided for medical expenses exceeding $2,500. The injured child would also be eligible for up to $100,000 for pain and suffering.
- A child would be compensated for a wide range of injuries that occur within a certain time period following inoculation.
- If a child dies, parents are eligible for compensation between $300,000 to $700,000. The money would be paid from a federal trust fund formed from surcharges placed on vaccine manufacturers.
- Better reporting of harmful effects of vaccines would be required. Public health officials acknowledge that the incidence of side effects is not well documented. The bill would require health care providers to report adverse reactions to CDC.
- There is a passing reference to vaccine research and development. The bills state that the Secretary of the Department of Health and Human Services "shall encourage" research to improve old vaccines and develop new ones. The bill would also establish a committee to advise the secretary on vaccine-related issues, including research.—**M.S.**

en the definition of the types of injuries that a victim could be compensated for, set up a federal reinsurance program in which the government would back up either the vaccine manufacturers or insurance companies, and restrict the time period in which individuals can choose between the courts or the compensation program. He said that he may propose to limit the retroactivity of the bill to 5 years, but the parents' group has resisted this proposal.

Even with these changes, one observer says, the bill would probably be unattractive to the Administration because the program would still be expensive. "I don't think the government wants to get into the insurance process," he says, adding that the real problem is not with the insurance process but broader problems with the court system that require a much more comprehensive review. "Congress should draft very narrow legislation limited just to problems linked with the whooping cough vaccine. When you're talking about kids and public health problems, it's best to legislate quickly and narrowly. Put tight limits on compensation for medical expenses, lawyers' fees, and eliminate all provisions for punitive damages."

Alternative solutions have also been raised. Alan Hinman, director of CDC's immunization division, cited several possible ways of averting a future shortage of whooping cough vaccine at the recent meeting of the agency's advisory committee on vaccines, but the group did not arrive at any recommendations. Hinman said that whooping cough vaccine could be purchased from overseas companies, or from Michigan or Massachusetts, which manufacture the vaccine for distribution within their borders. Hinman noted, however, that the state officials are also concerned about potential liability. Alternatively, the federal government could start up its own production facilities, but it would take several years to build the factories.

For the moment, attention is likely to focus on the revised bills planned by Hawkins and Waxman. Frustrated parents of injured children are vocal and the issue of compensation for their children is emotionally charged. A Hawkins aide said they are trying to get a bill out as soon as possible. The aide noted, "We're afraid that if we don't have legislation by July, Congress may overreact" and pass legislation that takes manufacturers off the hook completely.

—MARJORIE SUN

Next week: The search for an improved DPT vaccine.

Scientists Object to Loss of NSF Ethics Program

Protests have been trickling into Washington from scientists dismayed at plans to eliminate the Ethics and Values in Science and Technology (EVIST) program from the budget of the National Science Foundation.

The $1-million program, founded in 1976, has engendered a variety of studies on professional conduct and on the incorporation of research and development into policy-making. Presidential budget-makers have repeatedly sought to ax it, but it has been rescued in the past through the efforts of former NSF head John B. Slaughter and Senator Orrin Hatch (R–Utah), who chairs the committee that authorizes the foundation's budget. However, the new director, Erich Bloch, is said to endorse the decision.

The EVIST advisory committee, which was only set up a year ago, was not consulted in the decision. Its chairman, Clifford Grobstein of the University of California at La Jolla, says NSF is dodging its responsibilities and should actually be devoting far more money to ethical questions "to counteract concern that science and technology plunges mindlessly ahead regardless of fundamental values."

Gerald Holton of Harvard emphasizes that the establishment of EVIST "responded to the clear recognition that such issues should be researched by serious and qualified scholars." He says its elimination will pull the rug out from under this field just when it is coming to fruition. "Zeroing out EVIST is a signal in precisely the wrong direction" and will discourage universities from contributing to such studies, he says. And "I see absolutely no alternative sources forthcoming."

Although social sciences are no longer under wholesale attack at NSF—indeed, the budget contains a healthy boost for quantitative studies in economics—this clearly does not represent a major shift in thinking. In addition to knocking out EVIST, the budget proposal would pare down the Office of Policy Research and Analysis from $4.7 million to $2 million, which means no more research would be funded in such areas as risk analysis and technology assessment.

—CONSTANCE HOLDEN

Comings and Goings

Joseph A. Cannon, one of the few top Environmental Protection Agency (EPA) officials to be kept on after the departure of Anne Burford, has resigned to practice environmental law. His post, assistant administrator in charge of air pollution and radiation programs, will be filled on an acting basis by **Charles L. Elkins**, who has been with EPA since its creation in 1970 and is currently head of the acid rain policy staff.

Harrison Brown, a geochemist and author of several books on world problems, has been named editor in chief of the *Bulletin of Atomic Scientists*. Brown, who worked on plutonium chemistry for the Manhattan Project, succeeds Bernard Feld.

College Curricula in Disarray, Study Says

The Association of American Colleges has added a strong voice to the swelling chorus of concern about the plight of undergraduate education in the United States. In a report that minces few words, the association contends that American colleges and universities "are more confident about the length of college education than its content and purpose."*

The report, the result of a 3-year effort by a committee of academics from 18 colleges and universities, argues that undergraduate curricula have become so fragmented that they lack coherence and purpose. "The curriculum has given way to a marketplace philosophy: it is a supermarket where students are shoppers and professors are merchants of learning. Fads and fashions, the demands of popularity and success, enter where wisdom and experience should prevail," the report contends. "Evidence of decline and devaluation is everywhere," it adds.

This trend is exacerbated by the way college teachers are trained and by the academic reward system, which gives prominence to research and short shrift to teaching, the report

**Integrity in the College Curriculum* (Association of American Colleges, 1818 R Street, NW, Washington, D.C. 20009; $3).