Vaccine Supply and Liability

Vaccines are dramatically effective tools for the prevention of disease. Through the appropriate use of vaccines, smallpox has been eradicated from the face of the earth. Several other serious diseases of childhood—diphtheria and poliomyelitis for instance—have been brought to the vanishing point. We are on the way to eliminating measles and rubella from the United States. In spite of this remarkable success story, the nation is facing a crisis in which the supply of vaccines in the United States is now threatened to an unprecedented degree.

The dilemma arises because vaccines, like other drugs and biologics, are not perfect. A small proportion of persons who receive vaccines may not be protected by them, and an even smaller proportion of persons may be injured as a result of vaccination. Every effort is made to develop the safest possible product, but it has not been possible to remove all risks from vaccines. Persons may be injured even though they received a vaccine manufactured according to all applicable government standards and passed by the Food and Drug Administration.

In increasing numbers, however, those who are injured are turning to the courts to seek compensation through the tort system. They seek compensation which typically includes amounts for medical and rehabilitative expenses, missed wages, pain and suffering and, often, punitive damages. The suits are usually brought against the manufacturers and often seek multimillion dollar awards.

In recent years, both the number of suits brought against manufacturers and the amounts of money sought in each case have increased dramatically. In 1978, only one suit was brought against manufacturers of diphtheria and tetanus toxoids and pertussis vaccine (DTP), and it asked approximately $10 million. In 1984, 73 suits were brought against DTP manufacturers. Of that number, 28 suits asked specific amounts, of which the average was more than $45 million (*1*). One manufacturer has reported 97 law suits filed against the company alone in 1985.

Faced with the increasing number of suits and the escalating amounts of money involved, manufacturers have found it increasingly difficult and expensive to obtain liability insurance. One manufacturer of DTP (Connaught, Inc., of Swiftwater, PA) was apparently unable to obtain liability insurance at all for a period of 10 months in 1984–85 and consequently stopped distributing vaccine during that time. More recently, the other remaining commercial manufacturer of DTP (Lederle Laboratories of Pearl River, NY) stated that due to the reluctance on the part of insurance companies to offer coverage for vaccines, Lederle may be unable to secure liability insurance after the current policy expires on June 30, 1986. The president of Lederle, Robert B. Johnson, stated in a letter to the American Academy of Pediatrics, "As a result of this extremely tenuous situation, we are left with no option but to consider withdrawing from the DTP vaccine market"(*2*).

The increasing litigation is making it less and less attractive for manufacturers to stay in the marketplace. To study the problem and recommend solutions which would assure a continuing supply of vaccines in the United States, the Cabinet Council on Human Resources formed a Working Group on Vaccine Supply and Liability, in March 1985, which I chaired as Acting Assistant Secretary for Health. Membership of the group included representatives from the White House, the Office of Management and Budget, the Department of Justice, the Department of the Treasury, the Council of Economic Advisers, and the Department of Health and Human Services. The group issued its report in July 1985(*3*).

Recognizing that there are several issues involved, including (*a*) the question of whether injured individuals have any significant difficulty in obtaining compensation in an equitable and timely manner and (*b*) whether there were disincentives to manufacturers to develop new and improved vaccines, the group focused on the closely intertwined issues of vaccine supply and cost.

From its review, the Working Group found that punitive and noneconomic damages are the large, and generally unpredictable part of many vaccine-related awards. There is little justification for punitive damages in cases of vaccine-related injury, since vaccines are strictly regulated under Federal law. The group also concluded that a cap on noneconomic damages (pain and suffering, mental

anguish, emotional distress, and so forth) was reasonable if set at a generous level. Noneconomic damages are based on subjective judgment, and they have a significant effect on vaccine cost. By contrast, economic damages vary somewhat from State to State and case by case, but they generally fall within a broad range for particular types of injuries.

After examining several options, the Working Group recommended that the Administration seek the enactment of legislation to ban punitive damages in vaccine-related injury cases and to place a generous but reasonable cap on all noneconomic damages. This recommendation has been forwarded to the Congress, but corresponding legislation has not as yet been introduced. However, at least 2 proposals are presently being considered in the Congress (S5827 and HR1780) which address problems of vaccine compensation. One of the proposals (S5827), as introduced, does not appear to help the problem of liability exposure and consequently has been opposed by manufacturers. The other has features which would limit liability exposure but has other features which do not seem acceptable to parents or trial attorneys.

The problem is complex. Developing a reasonable solution will be difficult and will require close cooperation among all parties. It is imperative, however, that we have a continuing supply of life-saving vaccines.

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References

1. Hinman, A. R.: DTP vaccine litigation. Am J Dis Child. In press.
2. Letter dated February 12, 1986, from Robert B. Johnson, president, of Lederle Laboratories Division, American Cyanimid Corporation, to Martin Smith, MD, president of the American Academy of Pediatrics.
3. Report of the Cabinet Council on Human Resources Working Group on Vaccine Supply and Liability. Issued July 1985.

Health Problems of Minority Groups: Public Health's Unfinished Agenda

The three excellent articles in this issue of *Public Health Reports* pertaining to the health status and access to care of Hispanics raise thought-provoking issues for any serious observer of minority health.

• One is struck by the limitations in the data and the resulting constraints on the number of questions we can answer. The Hispanic population is heterogeneous by country of origin, by income, by genetics, by length of residence in this country, and by conditions of entry (for example, immigrant, refugee, migrant agricultural laborer, undocumented worker). All of these factors (and others) correlate in various ways with health outcomes, yet to date we are primarily dependent on small sample or anecdotal reports to address questions which require this sort of fine-grained data. During the Task Force on Black and Minority Health (*1*), we also struggled with data limitations for Hispanics, Asian-Pacific Islanders, and the non-Indian Health Service Native American population. Because it is larger and has a long historical presence in the country, the black population is better characterized. Inconsistencies in ethnic identified data collection by the States, overaggregation of minority data, and insufficient representation of minorities in national surveys have all been problematic in the past.

• Andersen and colleagues raise many important points in their article on access and financing. Three points deserve amplification: (*a*) the serious problems among Hispanics and other minorities around the lack of health insurance, (*b*) the importance of culturally sensitive and culturally appropriate health care sources, and (*c*) the still highly disproportionate underrepresentation of Hispanics, blacks, and Native Americans among physicians and other health professionals after two decades of ameliorative efforts.

• A third important issue raised by these articles is the differentials in health status among the four major minority groups. It is often assumed that the health problems among minorities are overwhelmingly the result of poverty. Yet the data presented in these three articles as well as in the Task Force Report (*1*) indicate that the aggregate health status of Asian-Pacific Islanders, blacks, Hispanics, and Native Americans differ from one another. The Task Force data were recently summarized in the MMWR (see table, *2*). As compared with whites, overall black mortality rates are substantially worse, Hispanic and Native American rates are somewhat worse, and Asian-Pacific Islander rates are somewhat better. Within these