Polio Policy: A Bitter Pill to Swallow

By RICK WEISS

Nine-year-old Kevan Berkovitz, paralyzed from the neck down and breathing only with the help of a respirator, is — depending on how you look at it — one in 10, one in 170 or one in 2.7 million.

Kevan is one of about 10 children in the United States each year who become paralyzed with poliomyelitis. And he is one of approximately 170 petitioners whose appeals were decided by the U.S. Supreme Court this term. Kevan's case was of interest to the High Court for one awful reason: Of the 2.7 million doses of oral polio vaccine given to U.S. children during his first few months of life, he got the one dose that inexplicably became virulent, ravaging his central nervous system and paralyzing him for life.

Legal scholars took note of *Berkovitz v. United States,* a vaccine-liability case decided in June, because it affirmed that the federal government could be sued, under certain circumstances, for vaccine-associated injuries. But the case also interested biomedical researchers and federal health officials, because it served as a reminder of a lingering, tragic flaw in an otherwise stunning success story in the war against polio. For of the 10 or so cases of polio that originate in the United States each year, every one is caused by the oral polio vaccine itself.

The problem is inherent in the popular vaccine, which is made of a living, weakened strain of poliovirus. Developed by Albert Sabin and used widely in the United States since 1962, the vaccine has virtually eliminated the disease in this country. Rarely, however, a dose of the weakened poliovirus undergoes a genetic transformation a few days after a person swallows it. Reverting to its original, virulent self, the virus causes the disease it was designed to prevent.

With the number of naturally occurring U.S. cases of polio having dropped to zero since 1980 from a peak of 20,000 per year in 1952, the annual reprise of vaccine-induced paralysis is distressing. Some find it especially difficult to accept in light of the availability of an injectable killed-virus vaccine — equally effective and incapable of causing the disease — developed by Jonas Salk and approved for use in the United States since 1955. Although parents can choose either vaccine for their children, national policy has encouraged using the oral vaccine. As a result, the injectable form accounts for less than 1 percent of the polio doses given in the United States each year.

Unfortunately, the total eradication of polio is not simply a matter of switching vaccines. Indeed, a recent report by the National Academy of Sciences' Institute of Medicine (IOM) recommends no change in the current national policy of primary reliance on the oral vaccine — even though health officials blame the vaccine for more than 100 cases of paralytic polio between 1975 and 1986. The IOM decision reflects the difficult immunological and bioethical considerations unique to the battle against the poliovirus.

Public health officials have made remarkable gains in reducing the incidence of polio in countries where one or both of the vaccines have been widely distributed. And although worldwide some 250,000 individuals each year become paralyzed with the disease, immunization levels are now estimated at about 50 percent among children in the developing world. With a full-scale effort, says the World Health Organization, eradicating the disease might be possible by the year 2000.

In countries where polio has already been all but eliminated, health officials face a more subtle challenge: how to design a national polio vaccine policy that prevents reintroduction of the wild virus from other parts of the world and still minimizes the number of vaccine-induced cases of paralysis. The problem provides a study in altruism and ethics because of a peculiar — and very useful — characteristic of the oral vaccine.

Since the oral polio vaccine contains a live, if weakened, strain of poliovirus, it lives and multiplies in the human digestive tract for up to three weeks. During that period it is shed from the mouth and excreted in feces, spreading through the environment. Individuals who come in close contact with a recently vaccinated person are exposed to the virus and in many cases become immunized without ever getting vaccinated.

This so-called "herd immunity" is a great public health benefit, since even in the United States large numbers of individuals remain unvaccinated — including as many as 50 percent of urban poor children. Moreover, by loading the environment with nonvirulent strains of poliovirus, a society can alter its entire microbial ecology to essentially "crowd out" more virulent, wild strains. In addition, health officials fear that a recommendation to switch to the less convenient, more painful, injectable vaccine would result in fewer people actually bothering to get vaccinated.

Thus the difficult balance facing U.S. health officials: While the injectable, inactivated poliovirus vaccine (the newest, enhanced version is known as E-IPV) carries with it no risk to individuals, it also fails to "donate" protection to other members of society. And without that more widespread protection, more cases of wild-type polio might occur. The terribly bitter aspect of this is that a handful of "altruistic" children become paralyzed for their role in maintaining a more healthy general populace.

Various advisory committees have reconsidered U.S. polio vaccine policy periodically over the years. Last fall, the U.S. Public Health Service asked the IOM to update its recommendations, last revised in 1977. The update was requested because of a number of developments in the past few years, including recent improvements in vaccine technology and the growing number of individuals whose immune systems may be compromised because of infection with the AIDS virus. (Health officials have long recommended that immunocompromised individuals — because they may be more susceptible to vaccine-induced paralysis — rely on inactivated vaccines and avoid close contact with people recently immunized with the oral polio vaccine.)

The IOM released its report in May, recommending essentially no change from current policies. It expresses optimism, however, that within two to five years the Food and Drug Administration will approve a vaccine that combines an E-IPV with the diphtheria-tetanus-pertussis (DTP) vaccine, which most children already get. By tacking an E-IPV onto the first two or three DTPs routinely given to children — typically at 2 months, 4 months and 18 months of age — then following up with subsequent oral doses, many of the benefits of both polio vaccines would be realized, the report says.

Such a schedule, the report concludes, "would reduce or even eliminate cases of vaccine-associated paralysis," and might solve once and for all one of the more painful dilemmas in modern public health. □