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Our Last Vaccine?

A writer in the *New York Times* termed the recent swine influenza immunization program a "sorry debacle." What happened, and what are the implications?

The new strain of swine flu isolated at Fort Dix represented a serious potential public health hazard. Virologists and public health officials responded rapidly and with expertise drawn from years of experience and research. Vaccine strains were developed with amazing speed and distributed to manufacturers. The government—perhaps in part politically motivated, but also mindful of the well-known difficulty of mass immunization by private means—made the startling and courageous decision to underwrite the cost of a mass immunization program.

The real problems which are common to all vaccines and to other biologics in the United States today, then began to surface. First, in a mass immunization effort, there are two very real hazards. One or more batches of vaccine may be imperfect and produce unexpected side effects. With current methods of detection and reporting, even infrequent side effects will be apparent. This hazard is minimal in the United States today because of the stringent controls required by the Bureau of Biologics of the Food and Drug Administration. Nevertheless, the possibility always exists. Second, and perhaps more troublesome, is the certainty that deaths and other complications will occur coincidentally with vaccine administration. In the litigious climate that exists in the United States, these events will inevitably result in lawsuits, each of which may result in a judgment as large as $1 million to $10 million.

Who properly should bear the risk of such suits, and the cost of their defense? After lengthy deliberation, the government made the momentous decision, in the case of influenza vaccine, to assume this responsibility. Otherwise, not a single dose of vaccine would have been released.

A major problem inherent in making vaccines, other biologics, and new drugs available in the United States is here put into sharp focus. The problem is liability. Until this problem is understood, faced, and solved, innovation in preventive medicine will slow down to an unacceptable crawl.

A manufacturer who proceeds with dedication, expertise, and courage to make a new vaccine available, investing time, effort, and money to satisfy the most stringent FDA requirements that both the safety and efficacy have been proved beyond reasonable doubt, still must face the realization that if the product is not widely used, he may never be able to recoup even a fraction of the cost of the development, validation, and licensing. In the case of vaccines, where widespread use is likely, he also will have to bear an intolerable risk of litigation for even coincidental adverse events.

As a result, an important segment of the biologics industry in the United States is moribund; effectively only one U.S. vaccine manufacturer remains willing to embark on the development of a new vaccine. Plants and research facilities lie empty, or are sold to foreign firms; research and development efforts are at a standstill. Exciting new vaccines are ready for development—hepatitis B, gonorrhea, syphilis, malaria, to name a few. They may never be available in the United States.

What is the solution? Two possibilities might be considered. One would have the government undertake to bear legal responsibility for all products that it has licensed (and therefore tested and approved) unless negligence in manufacture or administration can be proved. The second would have the government itself or nonprofit government-supported organizations take over the responsibility of manufacture and distribution of biologics. This approach has been widely used in many countries, such as Sweden and France, and in certain states, such as Massachusetts. Perhaps a combination of those approaches would permit America to return to the forefront of preventive and curative medicine.—ALFRED M. PRINCE, *New York Blood Center, 310 East 67 Street, New York 10021*