VII. Vaccine Injury Compensation and Future Developments in Vaccines

> It seems safe to say that, in a decade or less, it will be possible to offer vaccines against all infectious diseases caused by viruses or bacteria. Anti-parasite vaccine, pehaps even anti-tumour vaccines, will also be available. Some may regard such a plain statement as sensational, some as natural progress (Hennessen, 1978).

If, in fact, there is likely to be an explosive increase in the number of vaccines available in the next decade, how might these new developments in vaccines affect a vaccine injury compensation program?

Table 7 lists the vaccines expected to be developed after 1976.

Most of the vaccines currently being researched are targeted at diseases that are moderately contagious at most.[1] The major exceptions are syphilis and gonorrhea. This reflects the fact that major epidemic diseases affecting the U.S. population have been controlled via existing vaccines, other public health measures, and the generally high standard of living enjoyed by most Americans. Most of the vaccines currently being researched are thus being targeted for use among specialized “high risk” populations.

Annual influenza vaccination is presently recommended for approximately 40 million people, 25 million of whom are 65 years of age or older (Foege, 1980). Thus, although influenza immunization is recommended primarily for high risk populations, it nevertheless qualifies as being widely recommended and used.

The target population for a hepatitis B vaccine encompasses health care and laboratory personnel; staff and residents of institutions for the mentally retarded and other large semi-closed institutions; patients on maintenance hemodialysis; patients requiring repeated blood transfusions or ministration of blood products; patients undergoing treatment with immune suppressive or cytotoxic drugs; and patients with malignant diseases and disorders associated with depression of immune response (Plotkin, 1978). Pseudomonas vaccine is even more of a vaccine targeted at a specific population, as these bacteria cause

problems only in persons who are susceptible to them because of other health problems.

What this means is that for many of the vaccines that might be expected to be developed in the next 10 years, the decision to be vaccinated or not will be much more of a private decision taken in consultation with one's physician, which will involve balancing the risks versus benefits for that particular individual.

There are, however, some potential candidates for mass immunization programs among vaccines currently being researched. Vaccines to protect against the bacterial agents that cause meningitis and otitis (a type of ear infection) in children are cases in point. The bacterial agents in question are streptococci, meningococci B&C, pneumococci (approximately 8 strains) and H. influenza. Of these, meningococci C and H. influenza are the most readily spread from person to person, though relative to other contagious diseases they are only moderately contagious. At present vaccines against meningococci C and H. influenza that are effective in adults and older children have been developed. Meningococcal vaccine has been used successfully against small scale outbreaks of meningitis among specific at risk populations such as soldiers. Most of the serious, lasting damage done by these bacterial organisms occurs, however, in children under age 5. For example, with H. influenza meningitis, approximatley 10% of those affected die; 30% suffer neurological damage. Thus, the benefits of a mass immunization program against these bacteria would only occur if a safe and effective vaccine could be developed for use in infants. Existing vaccines do not produce sufficient levels of immunity in children under age two, however. Apparently the immune system is still maturing in infancy with respect to these antigens. Whether or not vaccines against the bacteria that cause meningitis and otitis will become serious candidates for use in mass immunization programs thus depends on solving the problem of how to provide effective immunizations against these bacteria in infants.

A vaccine against chickenpox (varicella) has not yet been developed but is anticipated. This is a common childhood disease which, in the present state of knowledge, does not appear to have the same potential for the serious complications associated with measles, mumps and rubella. Should a disease that is highly unpleasant but seems to run its course in a short time without fatalities or residual disability be made the target of a mass immunization campaign? As the vaccine has not yet been developed, no one can know what the adverse side-effects of such a vaccine might be. Serious adverse reactions to a vaccine tend to be the same as the serious complications of the disease itself, so we might anticipate that a chicken pox vaccine would be quite safe. This does not, however, fully answer the question whether an unpleasant but largely benign disease should be made the target of a mass immunization effort.

Another potential candidate for a mass immunization program is a vaccine against cytomegalovirus. Mass immunization against cytomegalovirus in young girls, in later childhood just before puberty, might will prevent considerable mental retardation, since cytomegalovirus is the most common congenital infection (Table 8). The infant born with intra-uterine infection suffers brain damage in 10-30% of cases (Zuckerman, 1978).

Finally, gonorrhea and syphilis are obvious candidates for mass immunization programs, should effective vaccines become available.

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Table 7

New Vaccines - Expected Development After 1976

Vaccinees	Bacteria Toxoids	Virus	Other
Children	Meningococci B. Meningococci A - B Polyv. pneumococci H. influenza Caries Trachoma	Herpes simplex 1 - 2 Cytomegalo Varicella/Zoster Rota	
Adults	Bact. enterotoxoids Pseudomonas Cholera-toxoids Gonococci Syphilis Rocky Mountain Spotted Fever	Influenza, inactivated Influenza, live, att. Resp. synctytial Parainfluenza 1 - 3 Hepatitis A - B	Parasites Tumour

Sources: Hennessen, 1978 and Foege, 1980.

Table 8

Incidence of Certain Causes of Neonatal Sepsis Syndrome
(per 1000 cases)

Bacterial	1.0-3.5
Cytomegalovirus	5-20
Rubella	0.25-5
Toxoplasma	0.75-1.3
Herpes virus	0.03-0.3
Syphilis	0.1-0.2

Source: Plotkin, 1978.

1. This discussion is based on Hennessen, 1978, and discussions with NIH scientists involved in vaccine research; Drs. John LaMontague, James Hill, and Milton Puziss,