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The National Foundation-March of Dimes  
Subcommittee on Health  
Senate Committee on Labor and Public Welfare  
June 30, 1969

The National Foundation-March of Dimes is pleased to have been invited to present its views on proposals to the Senate for the control of communicable disease. Our interest in immunization is well known and extends back to 1938, the year in which The National Foundation was organized by Franklin D. Roosevelt to lead the fight against poliomyelitis.

During an era in which government support of health research and development was minimal, The National Foundation was the principal source for the funding of major advances in virology and immunology which culminated in the licensure of the Salk vaccine in 1955 and the elimination of epidemic poliomyelitis as a public health problem in the United States. Underlying all the developments leading to subsequent virus vaccines were the laboratory techniques perfected in poliomyelitis vaccine research.

Since 1958 The National Foundation-March of Dimes has been dedicated to the prevention and amelioration of birth defects which are this nation's primary problem of child health. An estimated seven per cent of the liveborn -- some 250,000 each year -- have defects which are evident during infancy. Through programs of laboratory and clinical research, medical care, professional and public education, and community service, this organization strives to advance the fight against birth defects.

S.1662 addresses itself to the problem of the control through vaccination of certain communicable diseases of childhood, namely, poliomyelitis, diphtheria, whooping cough, tetanus, measles and rubella. S.2264 adds to this list tuberculosis, venereal disease and other communicable diseases determined to be of national significance.

With the exception of rubella, existing prophylactic measures have brought each of the specified diseases under control to varying degrees -- from virtually complete control in the case of poliomyelitis to less-than-adequate control for tuberculosis, measles and the venereal diseases. Our particular interest, however, is directed to the prospects for prevention of rubella, since the recent approval of a vaccine for this disease represents a significant step forward in the fight against birth defects.

Rubella is usually a mild childhood disease but may cause serious defects in the unborn baby when the mother is infected in the early months of pregnancy. Young children are the principal source of the infection of pregnant women. Epidemics of rubella occur in the United States at irregular intervals of 6 to 9 years. The last major epidemic, in 1964, caused an estimated 50,000 abnormal pregnancies, resulting in some 20,000 live-born babies with birth defects and about 30,000 fetal deaths.

The consequences of rubella in pregnancy are varied and unpredictable. Spontaneous abortion, stillbirth, live birth with one or more anomalies, and normal infants are represented in the spectrum. Virtually every organ may be involved, either temporarily or permanently. Cooper and Krugman, in a review of 271 abnormal infants followed to age 18 months, found congenital heart disease in 142 (52%), confirmed or suspected hearing loss in 140 (52%), cataract or glaucoma in 107 (40%), severe or moderate psychomotor retardation in 65 (24%), and neonatal thrombocytopenic purpura in 85 (31%). The mortality rate was 13% (35 infants).

Thousands of victims of congenital rubella from the 1964 epidemic and from subsequent outbreaks of the disease have been cared for at the 107 Birth Defects Centers supported by the March of Dimes. Many of these children continue to require intensive medical and educational

services if they are to realize their full potential.

With widespread immunization of children with the new rubella vaccine, this tragedy may not be repeated.

In our view, however, there are formidable obstacles to the rapid and widespread use of the rubella vaccine in time to prevent another wave of rubella babies which may occur as early as 1970 or 1971.

Some of these obstacles are educational in nature; others are fiscal. On the educational side, the idea of vaccinating children against rubella to protect unborn babies from birth defects will not be easy to get across. But public understanding is crucial if the vaccine is to prevent another epidemic. Accordingly, The National Foundation has pledged itself to render voluntary service when requested by health departments and medical societies to foster public understanding and acceptance of the vaccine, as supplies become available. A review article on rubella has been mailed to 145,000 physicians and other health professionals throughout the nation, and millions of educational flyers are being readied for widespread public use.

We are confident that educational measures such as these, undertaken in cooperation with other voluntary health agencies, organized medicine and public health departments, can and will overcome the barriers to public understanding and acceptance.

As for the fiscal obstacles, however, we are less optimistic. There are approximately 56 million children aged 1 to 14 in the United States. This is the target group for rubella immunization. If 75% of these boys and girls are to be vaccinated -- and I believe that we can achieve this level of participation -- some 42 million doses would be required initially. If as much as half this amount were to be administered on a private,

fee-for-service basis -- and I personally view this as a probable upper limit -- then governmental sources will need to furnish at least 20 million doses to achieve primary protection against another epidemic. At current prices, this is equivalent to \$30 million, exclusive of necessary laboratory, surveillance and administrative costs.

In view of the cyclical nature of rubella epidemics and the consequent need to achieve rapid vaccine coverage, neither of the legislative proposals under consideration appears to be entirely adequate to meet this challenge. The appropriations authorized in S. 2264, however, more nearly approach the requirements.

S. 2264, moreover, would permit expeditious use of rubella vaccine through the well-established mechanisms of the National Communicable Disease Center which has proven its competence in earlier programs authorized under the Vaccination Assistance Act. The coming rubella epidemic, whether it strikes next year or the year after, constitutes a real emergency for the more than 4 million American babies who will be conceived that year. Under the circumstances, it would seem ill-advised for the federal government to approach the problem of rubella prevention along a circuitous route which involves untried and necessarily slower administrative mechanisms.

In urging your favorable decision on S. 2264, we should like to call your attention to the need for amendment of the measure to comprehend the prevention of another disease which constitutes a more serious threat to children than most of the others included, and for which there is an effective vaccine. This is hemolytic disease of the newborn due to Rh incompatibility, otherwise known as erythroblastosis fetalis, or more simply, Rh disease.

Unlike the vaccines for the other diseases, this vaccine prevents, instead of fostering, immunization, in this case the immunization of Rh

negative mothers against the Rh positive blood of their unborn babies. Each year an estimated 250,000 women and their families in the United States face the possibility of having an affected child.

Prevention of Rh disease now is possible with the use of a specially prepared blood fraction known as Rh immune globulin. This product has been available to hospitals since June 1968. Injected into an unsensitized Rh negative mother soon after the birth of an Rh positive baby, the Rh immune globulin effectively prevents her sensitization and the possible development of the disease in a subsequent Rh positive baby. About 8.4% of white maternity patients and 4.1% of Negro maternity patients are candidates for this vaccine.

With optimal use of this vaccine, the incidence of Rh disease can be expected to decline continuously from year to year, so that in 20 to 25 years the present pool of sensitized women of childbearing age will be exhausted, thus eliminating the disease as a public health problem.

Our surveys of hospitals and our consultations with state public health departments, however, indicate that in many parts of the country substantially fewer doses of the Rh vaccine are being administered than are needed to eliminate the disease. While the situation differs from one community to another, we estimate that nationally about one out of every 4 women who need the vaccine is not receiving it. The reasons for underutilization of this preventive are varied, but since the vaccine is relatively expensive, cost may be a serious obstacle for many low and moderate income families, especially in areas where public programs of medical assistance are absent or inadequate to meet this need. For this reason, we ask you to consider the inclusion of Rh disease in any vaccination assistance measure you approve.