

**VACCINES AND RELATED
BIOLOGICAL PRODUCTS
ADVISORY COMMITTEE**

MAY 27, 1998

**STATEMENT OF
THE IMMUNE DEFICIENCY
FOUNDATION**

PRESENTED BY MIRIAM O'DAY

Good Afternoon, my name is Miriam O'Day, I am Vice President of the Immune Deficiency Foundation. The Immune Deficiency Foundation furthers education and research into the Primary Immunodeficiency Diseases. The IDF is a national organization dedicated to improving the lives of some 40,000 individuals affected with primary immunodeficiencies in the US. IDF works closely with the Informed Parents Against VAPP, and supports it's efforts.

Primary Immunodeficiencies are a group of nearly 70 different disorders. Most patients present clinically with an increased susceptibility to infection, these infections can be chronic or unremitting and unusually severe. As a group, primary immunodeficiencies are more common than both childhood leukemia and lymphoma together.

I am here today to endorse the use of a black box warning label listing the potential adverse side effects of the oral/live polio vaccine. I would like to elaborate further on the reason the Immune Deficiency Foundation supports this initiative.

In September of 1996, the Centers for Disease Control and Prevention (CDC) accepted its advisory panel's recommendation to change the routine childhood polio vaccination schedule to decrease the occurrences of vaccine associated paralytic polio (VAPP). The CDC now recommends that U.S. children receive two doses of injectable polio vaccine (IPV) *killed virus*, followed by two doses of oral polio vaccine (OPV) *live virus*. Previously, the common polio vaccine protocol consisted of an all OPV schedule. The Immune Deficiency Foundation has endorsed and continues to support this recommendation. Also, households with immune deficient persons should have their children vaccinated with the IPV because the live oral poliovirus (OPV) is excreted in the stool and may pose a risk to individuals with a compromised immune system.

The Immune Deficiency Foundation in cooperation with the CDC and John Hopkins University is currently conducting a study to determine the amount of live vaccine that may be present in current stool samples of immune deficient patients. The objective of the study is to determine if some immunocompromised patients who received the oral/live polio vaccine as children but did not develop VAPP may still carry the live poliovirus.

The US has been free of the wild poliovirus since 1979. The only remaining cases of polio in the US since 1979 are associated with the live virus in the oral polio vaccine.

Infants with primary immunodeficiency disease are at a significant risk for vaccine-associated paralytic polio (VAPP); IDF is concerned that if a sequential schedule is not followed, OPV may be administered too early. It is also very important to take into account the age at which most patients with primary immunodeficiency disease are diagnosed. In most cases, the diagnosis of a primary immunodeficiency disease is **later than the first 6 months of life** and in many cases is not made until age one or older, and in addition 70 percent of patients surveyed by IDF have no known family history. Furthermore, the OPV prescribing information does not provide for administration of the third dose before 12 months, although this is a common practice among pediatricians. The use of a black box warning which is heeded by physicians would allow these children the opportunity to be diagnosed before a vaccine associated injury. We could eliminate the needless risk from the oral vaccine during the two and four month series of immunizations.

The goal of adding inactivated polio vaccine to the accepted schedule was to minimize the number of cases of VAPP, many of which occur in babies with primary immune deficiency, we believe it would be prudent for this Advisory Committee to support the black box warning on the live/oral polio vaccine. The boxed warning is necessary to advise physicians and parents of the possible risk of VAPP.

The National Immunization Program (NIP) continues its public service campaign aimed at educating parents and Pediatricians regarding the advantages of the killed (IPV) vaccine in the first year of life. Parents are urged to understand these differences allowing for an informed decision, which best suits, their child. However, physician education remains a key element in the total healthcare decisions and a black box warning will assist many physicians with awareness of an issue they may have previously ignored.

I would encourage this Advisory Committee to support the black box warning on the oral/live polio vaccine.

Thank you