

**THE CENTER FOR DISEASE CONTROL AND PREVENTION
ADVISORY COMMITTEE FOR IMMUNIZATION
PRACTICES**

**ATLANTA, GEORGIA
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**STATEMENT ON THE RISK OF LIVE POLIO VACCINE
IN PATIENTS WITH PRIMARY IMMUNODEFICIENCY**

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Let me begin by introducing myself. My name is Terry Harville and I am a pediatric immunologist currently practicing in Athens, Georgia. My practice is devoted to the diagnosis and treatment of patients with primary immunodeficiencies. I am here today representing the Immune Deficiency Foundation. Let me begin, therefore, by telling you something about primary immunodeficiency diseases and the Immune Deficiency Foundation.

As most of you know, the primary immunodeficiency diseases are a group of nearly 80 different disorders that are intrinsic to the immune system and result in immunodeficiency. Most patients present clinically with an increased susceptibility to infection, and have an unusually high number of infections, have chronic or unremitting infections, have infections that are unusually severe, or have infections with organisms of relatively low virulence - a point especially relevant to today's discussion, since patients with primary immunodeficiency diseases may develop complication from liver viral vaccines.

The Immune Deficiency Foundation was founded in 1980 to further education and research into the primary immunodeficiency diseases and thereby improve clinical care and prognosis of these patients. It is composed of over 20 chapters and support groups representing nearly 50,000 US patients. Its Medical Advisory Committee is composed of 20 physicians who specialize in the care of patients with primary immunodeficiency diseases; their function is to advise the Foundation on its many medical programs.

As most of you know, patients with Primary Immunodeficiency Diseases are at risk for developing vaccine-related poliomyelitis. For this reason we are here today recommending that this Committee endorse an all IPV schedule. In June of 1996, the first steps were taken when IDF presented testimony to ACIP supporting the move to a sequential schedule. However, at the time, IDF's representative Jerry Winkelstein, MD, Chair, Medical Advisory Committee stated that "the ideal immunization schedule for poliovirus for the undiagnosed patient with a primary immunodeficiency would include no live oral poliovirus."

Our recommendation today of changing polio immunization protocols to an all IPV schedule is based on the following:

FIRST, in a national patient survey conducted by the Immune Deficiency Foundation to which nearly 2,000 primary immunodeficient patients responded it was learned that the age of diagnosis was as follows. 50% of primary immunodeficient patients have a pediatric onset, of those 75% are diagnosed after their first birthday. There is a study in the medical literature on the clinical presentation and course of patients with X-linked agammaglobulinemia, we found that the average age of diagnosis was 2.5 years in familial cases and 3.5 years in non-familial cases. In fact, nearly 25% of patients were not recognized to be immunodeficient until after 4 years of age. Equally important, symptoms

referable to their immunodeficiency did not develop in over half of the patients until after 9 months of age. In another primary immunodeficiency in which vaccine-related polio has been reported, common variable immunodeficiency, the average age of onset is even later, occurring in adolescence.

SECOND, 71.5% of primary immunodeficient patients responding to the Foundation's national patient survey report an absence of a positive family history.

It is our experience that many pediatricians believe that primary immunodeficient patients are diagnosed soon after birth and present with a positive family history. This prevailing attitude among physicians continues to place these patients at dire risk. In fact all children are at risk even with the use of the sequential schedule.

Finally, the use of oral polio vaccine among the general population preserves a reservoir of live poliovirus potentially affecting all immunocompromised individuals, including those receiving the vaccine as well as those who are passively exposed. Since the only cases of polio occurring in the US since 1979 are associated with the oral vaccine, it is imperative that the US government move to an all IPV schedule.

As you address these issues, if you plan to convene a working group, we ask that IDF be included, since we have a relevant and important view on this topic.

Thank you for the opportunity to voice these concerns, I would be glad to answer any questions.