

**Immune Deficiency Foundation Statement before the  
FDA Blood Products Advisory Committee  
December 13, 2001**

Good morning. My name is Jonathan Goldsmith, MD and I am the Vice President, Medical Affairs of the Immune Deficiency Foundation. IDF is the national organization dedicated to improving the lives of primary immune deficient patients through research and education. I would like to address an issue that has become extremely important to our community as a result of the increased threat of biologic terrorism. I am speaking of the potential adverse impact upon our community that could result from a broad scale preemptive Smallpox vaccination program should one become necessary.

I would like to point out that the risk that we are currently focusing on is the impact on our community from the vaccination program itself. Because the vaccine contains a live virus, it is highly probable that many immune compromised individuals may be vaccinated or unintentionally exposed to the virus through household and casual contact and may suffer significant morbidity and mortality. Additionally, the persistence of the virus in some individuals with immune deficiency and its ability to spread to others could pose further risks to our community.

In an effort to understand this potential impact and to develop strategies to maximize the protection of at-risk populations such as primary immune deficient patients, the IDF has assembled an expert working group. Our intention, given different vaccination scenarios is to recommend strategies to reduce the risk of adverse effects should a public vaccination program become necessary. One such strategy may involve the use of an immune globulin containing Vaccinia antibodies to provide transient passive immunity against the vaccine virus.

We are also conducting a series of meetings with government officials involved in developing the national strategy for dealing with bioterrorism, including individuals from the FDA, in an effort to voice our concerns and provide input from our experts. Our goal is to help develop a policy that provides the maximum protection for US inhabitants while at the same time reducing the adverse impact on at-risk populations.