

**Opening Statement
Chairman Dan Burton
Government Reform Committee
Subcommittee on Human Rights & Wellness
November 13, 2003**

“Preventing Another SV40 Tragedy: Are Today’s Vaccine Safety Protocols Effective?”

Today, the Subcommittee is holding the second in a series of hearings examining the aftermath of the tragedy of SV-40 contamination of America’s poliovirus vaccine supply in the 1950s and early 1960s.

During the first half of the twentieth century, polio stuck down hundreds of thousands of people, leaving many paralyzed – some in iron lung machines – and killing many thousands of others. The worst year for the disease in the United States was 1952, when more than 57,000 polio cases were reported, and at least three thousand of those individuals perished.

Following licensure of the Salk (inactivated) polio vaccine in 1955, the incidence of the disease fell dramatically. The disease was further reduced by the advent of the Sabin (oral) polio vaccine in 1961. In fact, the last cases of paralytic polio from natural poliovirus in the U.S. were in 1979, and the most recent case from outside the U.S. occurred in 1993.

Today, polio has virtually been eliminated from the U.S. and the entire Western Hemisphere, although it remains a threat in some developing countries.

There can be little doubt that the invention of vaccine immunization to protect children and adults from infectious diseases, as demonstrated by the success of the anti-polio campaign, was one of the greatest public health achievements of the twentieth century.

In fact, immunization as a tool against disease has been so successful that it has now become almost commonplace to use it against even relatively minor disease such as human influenza.

As a society, we have become so confident in the power of vaccines that we have even created government mandates requiring vaccinations be administered before admitting individuals to day care, public schools, college or the military.

But, what we perhaps tend to forget, is that immunization is very different than administering a medicine to combat an active illness in a person. Instead of curing a disease, vaccines instead introduce a potentially disease-causing agent into an otherwise healthy body in order to stimulate an immune response. Thus there are always risks associated with taking any vaccine. In some cases, vaccines have even been known to cause the very disease they were created to prevent.

But the risks can be greater still.

In the earliest days of polio vaccine production, laboratory tests were not sophisticated enough to detect the presence of what became known as Simian Virus 40, or SV-40. At least 26 other simian contaminants were detected and eliminated, but SV-40 slipped past quality control testing procedures and into the vaccine pool, potentially infecting millions of Americans. Soon after its discovery, scientists also learned that SV-40 could cause cancerous tumors in hamsters.

So, in society's zeal to combat one disease we as a society potentially risked exposing millions of Americans to another deadly disease. As the Subcommittee learned at our last SV-40/Polio Hearing on September 10th, we are still trying to uncover the true health impact of the SV-40 contaminated polio vaccines.

For four decades, Federal government officials have insisted that there is no evidence that SV-40 is harmful to humans, or that polio vaccines produced after 1963 were contaminated with SV-40. But, in recent years, dozens of scientific studies have found the virus in a steadily increasing number of rare brain, bone and lung-related tumors – the very same malignant cancers that SV-40 causes in lab animals.

The Subcommittee's previous Hearing in September examined the intense debate raging within the scientific community between government scientists who claim that SV-40 has had no effect on the human population, and independent researchers from across the globe who believe SV-40 IS a human carcinogen.

What the government witnesses testified to at that previous Subcommittee Hearing raised serious concerns about the National Cancer Institute's (NCI) handling of research related to the presence of SV-40 in human tumors. The Subcommittee subsequently asked NCI to provide written clarification regarding several issues of concern to our investigation. Today we have invited representatives from the NCI to reappear before the Subcommittee in the hope that they might better explain and clarify the apparent inconsistencies in the research being supported by the NCI's Division of Cancer Epidemiology and Genetics regarding the relationship of SV-40 to contaminated polio vaccines.

In September, we also heard from Mr. Stanley Kops, a Philadelphia-based attorney, regarding allegations that at least one polio vaccine manufacturer may have knowingly shipped contaminated vaccine lots after the FDA's 1961 SV-40 screening regime was implemented, and that not only did said manufacturer not submit vaccine safety tests to the FDA as required, but that the FDA regulators failed to hold the manufacturer responsible for their failure to comply.

In response to these allegations, the Subcommittee has invited representatives from the FDA and several vaccine manufacturers to present evidence that supports compliance with safe manufacturing protocols, and the assertion that all polio vaccines have been, are and will continue to be SV-40 free. Regrettably, none of the vaccine manufacturing companies chose to attend today's hearing.

Because of the mandatory nature and the risks associated with all human vaccines, government health agencies have a special duty to exercise the utmost care in the approval, administration, and post-administration surveillance of vaccines.

The government must always err on the side of caution in this worthy public health endeavor. To do anything less is a breach of the public trust.

This Subcommittee will continue to pursue the historic truth in this matter to either reaffirm or, if necessary, rebuild the public's confidence in vaccines specifically and our Public Health Service in general.

I look forward to hearing from our witnesses this afternoon.