

News From...



## The Subcommittee on Human Rights and Wellness

Chairman Dan Burton (R ~ IN)

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### **“Preventing Another SV-40 Tragedy: Are Today’s Polio Vaccine Safety Protocols Effective?”**

Washington, D.C. - Immunization to protect children and adults from infectious diseases has been one of the greatest public health advances of the 20<sup>th</sup> century. However, no immunization is without risk. It has been widely acknowledged that millions of Americans may have received contaminated polio vaccines. Those vaccines contained the Simian Virus 40 (SV-40), which many researchers believe is capable of causing cancer. There is, however, great dispute over how many Americans may have received the tainted vaccines, and when the hazardous contaminant was finally removed.

As part of his continuing investigation into vaccine safety and efficacy, Congressman Dan Burton (R-IN), Chairman of the House Government Reform Subcommittee on Human Rights and Wellness, will hold a hearing entitled, **“Preventing Another SV-40 Tragedy: Are Today’s Polio Vaccine Safety Protocols Effective?”** **The oversight hearing will be held on Thursday, November 13, 2003, in Room 2154 of the Rayburn House Office Building at 2:00 p.m.**

Stated Chairman Burton, “Because the Federal government mandates vaccinations be administered before admitting individuals to day care, public schools, universities, or the military, I believe our various health agencies have a special duty to exercise the utmost care in the approval and administration of vaccines, as well as the post-administration surveillance of vaccines. After all, it is sound public health care policy to err on the side of caution when the safety and well-being of our citizens is at stake.”

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. However, 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 same malignant cancers that SV-40 causes in lab animals.

The development of the Salk Polio Vaccine in 1955 and the Sabin Polio Vaccine in 1962 were significant medical achievements because of the devastating death toll, disability,

and suffering that polio caused. Soon after the discovery of the Salk vaccine in 1955, mass vaccinations against polio were undertaken. It is estimated in the U.S. that by 1961, 90 percent of all persons under 20 years of age and 60 percent of those 20 to 39 years of age had received at least one inoculation.

Initially, the tissue cultures used in the polio vaccine came from the kidneys of the macaque monkey, about 60 percent of which are infected with SV-40. In the early days of polio vaccine production, the laboratory tests that were available could not detect the SV-40 virus. At least 26 other simian contaminants were detected and eliminated, but SV-40 slipped past the quality control testing procedures and was inadvertently introduced into the vaccine pool.

Soon after scientists first discovered the existence of SV-40 in 1960, they also discovered that SV-40 produces cancer in hamsters. When reports first surfaced that SV-40 could cause cancerous tumors, the United States government, starting in 1961, instituted a screening program requiring that all new lots of polio vaccine be free of SV-40 because of concerns about possible adverse effects on human health. However, already produced and contaminated vaccines were never removed from the market, and they continued to be used until as late as 1963.

Due to the controversy, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) commissioned an independent report by the Institute of Medicine (IOM) to provide objective assistance in reviewing emerging immunization safety concerns. The IOM report, published in October of 2002, concluded that the evidence was inadequate to conclusively establish whether or not the contaminated polio vaccines caused human cancers. The IOM committee did recommend continued public health attention to the matter in the form of further targeted biological research.

The Subcommittee has invited representatives from the National Cancer Institute (NCI) to reappear before the Subcommittee in the hope that they might better explain the 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. Additionally, the Subcommittee has invited representatives from the FDA and three polio vaccine manufacturers to present evidence that supports compliance with safe manufacturing protocols, and that supports the assertion that all polio vaccines have been, are, and will continue to be SV-40 free.

### **PANEL ONE WITNESSES:**

**Dr. William Egan**  
**Acting Director for the Office of Vaccines Research and Review**  
**U.S. Food and Drug Administration**

**Dr. Robert Hoover**  
**Director, Epidemiology and Biostatistics Program**  
**Division of Cancer Epidemiology and Genetics**  
**National Cancer Institute**

**PANEL TWO WITNESSES:**

**Representative, Wyeth-Lederle Pharmaceuticals -Invited**

**Representative, Merck & Co. - Invited**

**Representative, Aventis Pasteur - Invited**

This hearing is a follow-up to the Subcommittee's hearing of September 10, 2003, entitled "*The SV-40 Virus: Has Tainted Polio Vaccine Caused an Increase in Cancer?*" For more information regarding this ongoing investigation into vaccine safety and efficacy, or to see hearing resource materials, please visit the Subcommittee's website at [www.reform.house.gov/WHR](http://www.reform.house.gov/WHR).

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