

Oral Presentation  
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Subcommittee on Human Rights and Wellness  
U.S. House Government Reform Committee  
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“The SV40 Virus: Has Tainted Polio Vaccine Caused An Increase in Cancer?”

My name is Barbara Loe Fisher and I am the mother of a DPT-vaccine injured son and the co-founder and president of the National Vaccine Information Center. I have spent the last 21 years working with other parents to prevent vaccine injuries and deaths through public education and defending the right to exercise informed consent to vaccination. (Coulter HL, Fisher BL. 1985. *DPT: A Shot in the Dark*. New York: Harcourt Brace Jovanovich.; Attachment 1 – Allen A. May 6, 2001. A Shot in the Dark. *New York Times Magazine*; Konrad W. and Ginsburg EH. June-July 2000. Who’s Calling the Shots? *Offspring Magazine*.)

The shocking story you are about to hear involves a pharmaceutical company which used monkeys to make polio vaccine, government health agencies responsible for making sure the vaccine was not contaminated with monkey viruses, and individuals who are now are dying from cancerous tumors that contain a monkey virus which appears to have contaminated that polio vaccine. At the heart of this tragic story is a violation of the public trust and the informed consent ethic. It is a story about what happens when the legal and moral duty for industry and government to insure that a vaccine will not harm individuals is

sacrificed to insure acceptance and mass use of a vaccine by the entire population. It shows what can happen when Congress, which has oversight authority over federal health agencies, blindly trusts and fails to verify.

I began speaking and writing about monkey virus contamination of polio vaccines ten years ago when questions were raised in the medical literature about whether the use of monkeys infected with monkey viruses to produce oral polio vaccines was responsible for HIV and the AIDS epidemic. (Attachment 2: Kyle, W.S. 1992. Simian retroviruses, poliovaccine, and origin of AIDS. *The Lancet* 339: 600-601.) Between 1994 and 1997 I submitted several Freedom of Information Act (FOIA) requests to the government regarding testing of certain lots of oral polio vaccine for monkey virus contamination (Attachment 3 – Correspondence between BL Fisher and FDA) During the course of my research I discovered that it was well known that the first polio vaccine produced in the 1950's – the inactivated polio vaccine created by Jonas Salk – was made using rhesus monkeys that were infected with a monkey virus called simian virus 40 or SV40.

It was in 1960 that an NIH scientist named Bernice Eddy discovered that rhesus monkey kidney cells used to make the Salk polio vaccine and experimental oral polio vaccines could cause cancer when injected into lab animals. Later that year the cancer-causing virus in the rhesus monkey kidney

cells was identified as SV40 or simian virus 40, the 40<sup>th</sup> monkey virus to be discovered. (Shorter, e. 1987. *The Health Century*)

Sadly, the American people were not told the truth about this in 1960. The SV40 contaminated stocks of Salk polio vaccine were never withdrawn from the market but continued to be given to American children until early 1963 with full knowledge of federal health agencies.

Between 1955 and early 1963, nearly 100 million American children had been given polio vaccine contaminated with the monkey virus, SV40. (Institute of Medicine, National Academy of Sciences . 2002. *Immunization Safety Review: SV40 Contamination of Polio Vaccine and Cancer*. Washington, D.C.: National Academy Press)

Today, U.S. federal health agencies admit the following two facts:

1. Salk polio vaccine released for public use between 1955 and 1963 was contaminated with SV40; and
2. SV40 has been proven to cause cancer in animals.

In fact, at a conference on SV-40 and human cancers held by the National Institutes of Health in 1997, which I attended, there was no disagreement among both government and non-government scientists about these two facts. The only

disagreement was whether SV40 was actually being identified in the cancerous tumors of children and adults alive today and, if it was, whether the monkey virus was in fact responsible for their cancer. Non-government scientists working in independent labs around the world said, "Yes." But the scientists connected with the U.S. government said "No." (Transcript of FDA, CDC, NIH, NIP, NVPO January 27-28, 1997 *Workshop on Simian Virus 40: A Possible Human Polyomavirus*).

Today, there are scientists associated with the US government who continue to deny that SV40 causes human cancer or that SV40 associated cancers have had any effect on cancer rates since the early 1960's. However, highly credentialed non-government scientists in multiple labs around the world continue to identify SV40 in human brain and lung cancers of children and adults and are finding that SV40 is also associated with bone cancers and Non-Hodgkin's Lymphomas. The majority of these independent scientists have concluded that, yes, SV40 does cause human cancers. (Attachment 4 – Gazdar AE, Butel JS, Carbone M. 2002. SV40 and human tumours: myth, association or causality? *Nature* 2: 957-964)

And in a report published in 2001, the Institute of Medicine Immunization Safety Review Committee stated that "in light of the biological evidence supporting the theory that SV40 contamination of polio vaccines could contribute to human cancers, the Committee recommends continued public health attention in the form of policy analysis, communication and targeted biological research."

Up until this hearing today, the world scientific community has assumed that the only polio vaccine that was contaminated with SV40 and released for use by millions of Americans was Jonas Salk's killed polio vaccine, which stopped being used in 1963 because it was replaced by Albert Sabin's live oral polio vaccine. Why? Because the oral polio vaccine manufacturer and federal health agencies have told everyone that while the Salk vaccine was made using the SV40 infected rhesus monkey kidney tissues, after 1963 the oral polio vaccine was made using African Green monkeys, which are rarely infected with SV40. The vaccine manufacturer and government officials have insisted that the switch from rhesus monkey to African Green as well as testing protocols to detect SV40 prevented SV40 from contaminating oral polio vaccine after 1963. (Attachment 5: Statement of Bonnie Brock, Lederle, at Jan. 27-28, 1997 Workshop on SV40, transcript pages 300-307).

However, you will be presented with evidence today that suggests (Attachment 6: Kops SP. 2000. Oral polio vaccine and human cancer: a reassessment of SV40 as a contaminant based upon legal documents. *Anticancer Research* 20: 4745-4749. and Oral Testimony, Stanley Kops, Esq. Subcommittee on Human Rights and Wellness, US Government Reform Committee, September 10, 2003):

1. the original seed stocks of oral polio vaccine were made using the rhesus monkey and were contaminated with SV40;

2. the major oral polio vaccine manufacturer did not adequately test their master seed stocks which reportedly contained SV40 but used them to produce vaccine released for use by American children from the 1960's through the 1990's;
3. Federal regulatory agencies either did not know or knew and did not do anything about evidence that SV40 contaminated oral polio vaccine was released for use by the public from the 1960's through the 1990's;

If SV40 contaminated rhesus monkeys were used to produce original oral polio vaccine seed stocks, and if these seed stocks were used to produce oral polio vaccine that was swallowed by American children through the 1990's, and if SV40 does cause human brain, lung and bone cancers, then this could explain why children today, who were not born before 1963 and never got the SV40 contaminated Salk vaccines, are now sick and dying from cancerous tumors containing DNA from a monkey virus that was in those vaccines. Pediatric brain cancer, once rare, rose during the past few decades according to the National Cancer Institute. But we don't know how many of these children had or have SV40 in their brain tumors because nobody checks. How many of these children are sick and dying because the manufacturer of oral polio vaccine did not follow the rules and government health agencies didn't enforce the rules?

Since 1999, the US has discontinued use of the live oral polio vaccine and American children are now getting a killed polio vaccine that is reportedly SV40

free. So why is it important today to find out whether or not the oral vaccine used to eradicate polio was in fact contaminated with a cancer causing monkey virus, and that the vaccine manufacturer knew it, and that government health agencies looked the other way?

It is important because if it is true, then a precedent has been set. And that precedent may well be affecting decisions being made by government health agencies today about what kinds of animal tissue cultures vaccine manufacturers will be allowed to use to make new vaccines and what kinds of tests will be required to insure that the vaccines do not contain animal viruses or other contaminants.

Drugs and vaccines are very different. Drugs are used to cure sick people while vaccines are required by law in this country to be given to healthy people, primarily children. The standards for proof of safety and efficacy of vaccines should be higher than for any other pharmaceutical product we use.

I have just ended a four year term as the consumer voting member of the FDA Vaccines and Related Biological Products Advisory Committee. My service on that committee gave me a new appreciation for the dedicated work of a number of fine scientists employed by the FDA, who take their regulatory duties very seriously and are working hard to regulate the vaccine industry with very limited resources and limited support within and outside of government.

However, there are legitimate concerns which I and others have voiced in the past and continue to have about whether government standards for requiring vaccine manufacturers to prove the safety and efficacy of vaccines are high enough and whether the tests used by the manufacturers and the government to insure the safety of vaccines are good enough. (Attachment 7: National investigative news reports, including Wechsler P. November 11, 1996. A Shot in the Dark. *New York Magazine*.; Rock, A. December 1996: The Lethal Dangers of the Billion Dollar Vaccine Business. *Money Magazine*.; Bookchin D, Schumacher J. June 1997. The Lonely Crusade of Walter Kyle. *Boston Magazine*; Bookchin D., Schumacher J. February 2000: The Virus and the Vaccine. *Atlantic Monthly Magazine*.)

I urge this Committee and other congressional committees to carefully review the transcripts of meetings of the FDA Vaccines and Related Biological Products Advisory Committee, specifically those which were held in 1998; 2000; 2001 and dealt with adventitious agent contamination of vaccines. Vaccine manufacturers are asking the FDA for permission to use cells from human and animal cancer tumors – that is cancer cells – to make HIV and other viral vaccines in the future that would be used on a mass basis by the American population. There has been a federal ban on use of cancer cells to produce vaccines since 1954 but active consideration is being given now to lift that ban despite the acknowledged risks of contamination with adventitious agents, including residual DNA and RNA.

.(Attachment 8: Excerpt from November 19, 1998 FDA Vaccines and Related Biological Products Advisory Committee meeting, transcript pages 29-52).

There is frank admission that the limitations of technology and lack of scientific knowledge means there can be no guarantee the vaccines will not be contaminated with substances that could prove harmful to humans one day. Nevertheless, there are plans to set allowable thresholds for adventitious agent contamination of vaccines being made out of cancer cells that would contain residual DNA and RNA. (Attachment 9: Excerpts from May 12, 2000 FDA Vaccines and Related Biological Products Advisory Committee meeting transcript and Attachment 10: Excerpts from May 16, 2001 FDA Vaccines and Related Biological Products Advisory Committee meeting transcript)

I do not think Congress or the public understands any of this. There should be a much wider discussion in the larger scientific community outside of federal health agencies and the pharmaceutical industry, as well as in Congress and by the public at large before decisions are made to proceed with producing vaccines that use cancer cells and have legally allowable thresholds of adventitious agent contamination.

Past is often prologue. So much can be learned from understanding the mistakes of the past so that the same mistakes are not made in the future.

Outstanding questions about the links between vaccines, government vaccine policies and the epidemic of chronic disease in our children, including autism, learning disabilities, ADHD, asthma, diabetes and, as we have discussed today, cancer are not going away. Questions about the links between vaccines that US military soldiers are required to take, including anthrax and smallpox vaccines, and the subsequent death or permanent health problems being suffered by those previously healthy, young recruits are not going away. They will never go away when the main defense of industry and government health officials is that when anything bad happens after vaccination it is just a coincidence. I can tell you, the American public, especially parents, are not buying it. And they shouldn't buy it, especially when the kind of evidence that you will hear today suggests official government and industry denials are simply a way of avoiding taking responsibility for failing to do everything they can to minimize the risks of vaccines.

We owe it to our children and grandchildren to do everything we can to find out the truth about vaccine risks and make the mass vaccination system as safe as it can be. I believe that can only be done if Congress exercises more oversight authority over federal health agencies responsible for vaccine research, development, regulation, policymaking, promotion and monitoring of vaccine side effects. Conflict of interest legislation is urgently needed to separate government health agencies from financial and other ties with the vaccine industry so that government health officials can be free to do the job they are supposed to do:

protect the health and well being of every American and not simply protect the vaccine supply. (Attachment 11: Investigative news report by UPI reporter Mark Benjamin. July 20, 2003. *Chicago Sun Times, Washington Times*)

Before I conclude, I would like to thank you, Chairman Burton, for all you have done during the past three years to investigate and bring to the attention of Congress and the American people the fact that our nation's mass vaccination system must be reformed to make it safer. You have had the courage to stand up for those who suffer greatly when a vaccine's risks turn out to be 100 percent for them or their child and you have done it against great opposition from powerful special interest groups with vested interests in protecting the status quo. Your tireless efforts on behalf of so many will not be in vain because the truth will shine bright and clear in the end no matter how long it takes.