

June 7, 2003

The Honorable Dan Burton
Chairman of the House Government Reform
Subcommittee on Human Rights and Wellness
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

By Facsimile

Letter to Demand a Congressional Investigation and Hearing on the Introduction of Simian Virus 40 (SV40), a Cancer-Causing Monkey Virus, into the American Population From Contaminated Polio Vaccines

Dear Representative Burton:

I am writing this letter on June 7, 2003. Exactly seven years ago, on June 7, 1996, my son Alexander was born. He would die in my arms 30 months later in a little motel room in Houston, Texas as we, his parents, tried desperately to save his life. This letter is written in commemoration of Alexander's short life and the injustice that befell him and the cause of the brain tumor (medulloblastoma) that killed him.

This letter is also the result of four long years of struggle by myself and my husband to find out why our beautiful healthy young son would be stricken by cancer. Now, our lawsuit against the manufacturer of the oral polio vaccine, American Home Products, (i.e. Lederle), has come to a close.¹ As a result, much of the information that has been under a protective order for over three years has been entered into the public record through *our* legal documents filed with the Federal Court for the Central District of California in Los Angeles.² What happened to Alexander is not an isolated event. We contend that his death was caused by a Public Health Disaster that has befallen others and will continue to kill children until it is addressed.

On August 12, 1999, we wrote you when you were Chairman of the Committee on House Government Reform in support of your investigations into pediatric vaccines - *Vaccines; Finding the Balance Between Public Safety and Personal Choice*. In this letter we described how various childhood vaccines contain known carcinogens and yet not a single vaccine is tested for carcinogenicity. While shampoos and cosmetics are tested to see if they cause cancer, incredibly, biological substances that are squirted or injected into healthy infants and children have never been tested.

¹ The case was Horwin v. American Home Products, American Cyanamid Company, Lederle Laboratories, Case No. CV00-04523 WJR (EX), United States District Court for the Central District of California originally filed on January 31, 2000. The District Court Judge decided that the testimony of the plaintiffs' experts on the issue of whether SV40 caused Alexander's tumor was admissible under the Daubert standard. (United States District Court Central District of California Tentative Ruling Case No. CV00-04523 WJR (EX), Daubert Motion, Thursday May 8, 2003.) Nonetheless, the judge excluded critical evidence related to the source of SV40 because it believed that it could require that all exhibits used to qualify a witness under Daubert be identified in a FRCP Rule 26(a)(2) disclosure. After excluding critical evidence, the court decided that since there was no direct evidence that the dose of Orimune administered to Alexander was contaminated that the expert's opinion was inadmissible under Daubert. As a result, the judge granted the defendant's (Lederle's) motion for summary judgement.

² The defendant asked for and was granted a Protective Order. As a result, all of its production documents cannot be quoted directly or shared with Congress, the media, or health authorities. However, our motions and pleadings are in the Court Record and have not been put under a Protective Order. Therefore, we are able to cite our own arguments set-out in these papers. We believe this Protective Order should be lifted because public health interests should take precedence over the interests of pharmaceutical companies.

On June 7, 2000, My husband and I also appeared before your Committee to discuss the FDA's control of effective non-toxic pediatric cancer therapies in *Cancer Care for The New Millennium - Integrative Oncology*. During our sworn testimony we described how Alexander suffered enormously and unnecessarily as a result of the administration of four toxic but ineffective chemotherapy drugs (vincristine, cytoxan, etoposide, and cisplatin - Protocol CCG 9921). We described how the FDA would not allow our son to have access to a non-toxic cancer therapy that offered him the best chance of saving his life. We presented photographs to your Committee that demonstrated how Alexander struggled to stay alive and then suffered a horrific death.

From your own considerable effort in investigating vaccine production, testing, and safety you know that childhood vaccines contain formaldehyde (i.e. formalin), mercury (i.e. thimerosal), aluminum, and other toxic substances. In addition, vaccines can also contain animal viruses – contaminants from the animal substrates upon which the vaccines are manufactured. One of these viruses, a monkey virus called Simian Virus 40 is carcinogenic and found its way into the oral polio vaccine (OPV) and the inactivated polio vaccine (IPV) in the late 1950's and early 1960's. Such an event was not surprising because monkey kidneys contain a multitude of simian viruses and the polio vaccine is grown on monkey kidney cells.

The oral polio vaccine is a "live" trivalent vaccine which means that it contains three strains of poliovirus - Types I, II, and III, and each strain is attenuated (i.e. weakened). Dr. Albert Sabin, who was responsible for the creation of the licensed OPV, had to passage³ his poliovirus strains through a myriad of animals and animal host cells in order to attain the right virulence—strong enough to illicit an immune response, but sufficiently attenuated so as to not cause polio in the recipient. For example, Type I has the following lineage:

In 1941, Drs. Francis and Mack isolated the Mahoney poliovirus "from the pooled feces of three healthy children in Cleveland."⁴ Dr. Salk then passed this strain through fourteen living monkeys and two cultures of monkey testicular cultures.⁵ In 1954, the strain (now called Monk14 T2) was given to Drs. Li and Schaeffer who subjected the virus to nine more passages through monkey testicular cultures.⁶ Next, the strain (now called Monk14 T11) underwent fifteen more passages in monkey testicular cultures, eighteen passages in monkey kidney cells, two passages through living rhesus monkeys skin, and additional passages through African Green monkey skin and monkey kidney cell cultures.⁷ This strain was now called MS10 T43 and LS-c. In 1956, Dr. Sabin took this virus and passaged it through seven cultures of African Green Monkey kidney cells.⁸ That same year, the pharmaceutical company, Merck, Sharp & Dohme, passed the strain (now called LS-c, 2ab/KP₂) through a rhesus monkey kidney cell culture.⁹ The resulting material was called Sabin Original Merck (SOM) and was provided to Lederle in 1960 as the seed material to manufacture its polio vaccine.

Types II and III were created in a similar fashion.¹⁰

³ Passage is defined as the introduction of infectious material into an experimental animal or culture medium followed by recovery of the infectious agent. Dorland's Medical Dictionary, 25th edition, page 1146.

⁴ A.B. Sabin, A.B. & L. Boulger, *History of Sabin Attenuated Poliovirus Oral Live Vaccine Strains*. 1 J. BIOL. STAND. 115, 115–18 (1973). The Mahoney virus was isolated in 1941 by Drs. Francis and Mack.

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

Once the strains were isolated, the pharmaceutical companies needed a method to propagate the viruses in order to produce the vast quantities of vaccine needed for nation-wide immunization campaigns. This required a substrate upon which the poliovirus could be efficiently grown and harvested. Kidney cells from rhesus monkeys were chosen because they were found to be an effective growth medium.¹¹ A small quantity of poliovirus could be added to the minced kidneys removed from these monkeys and within a few days, large quantities of poliovirus could then be harvested from these same monkey cells.

Between 1959 and 1960, Bernice Eddy, Ph.D., of the National Institute of Health (NIH) examined minced rhesus monkey kidney cells under a microscope.¹² These were the cells of the same species of monkeys used to create and produce the oral polio vaccine. Dr. Eddy discovered that the cells would die without any apparent cause. She then took suspensions of the cellular material from these kidney cell cultures and injected them into hamsters. Cancers grew in the hamsters.¹³ Within a few months, the virus responsible for creating these cancers would be isolated and identified by Dr. Eddy and other scientists. Because it was the 40th simian virus found it was named simian virus 40 (SV40).

According to the FDA:

The discovery in 1960 that a DNA tumor virus, designated simian virus 40 (SV40), was an inadvertent contaminant of rhesus monkey cells, and consequently the poliovirus and adenovirus vaccines that were made in these cells, was a watershed event in vaccine development...¹⁴

By 1960, the Salk injectable polio vaccine (IPV) had been administered to about 98 million American children and adults, and Sabin's oral polio vaccine (OPV) had been administered to about 10,000 Americans and millions in the USSR where the clinical trials had been conducted.¹⁵ It was estimated that 10% to 30% of the vaccines contained live SV40.¹⁶ The federal agency in charge of vaccine licensing and safety at the time was the Division of Biologics Standards (DBS) of the National Institute of Health (NIH).¹⁷ Incredibly, this agency did not order a recall of any of the SV40-contaminated vaccines.¹⁸ The tainted vaccines continued to be administered until 1963 when

¹¹ M.R. Hilleman, *Discovery of Simian Virus (SV40) and its Relationship to Poliomyelitis Virus Vaccines*, in SIMIAN VIRUS 40 (SV40): A POSSIBLE HUMAN POLYOMAVIRUS, 94 DEV. BIOL. STAND. 183–90 (F. Brown & A.M. Lewis eds., 1998).

¹² Bernice E. Eddy, *Tumors Produced in Hamsters by SV40*, 21 FED'N PROC 930, 930–35 (1962) [hereinafter Eddy I]; Bernice E. Eddy et al., *Identification of the Oncogenic Substance in Rhesus Monkey Kidney Cell Cultures as Simian Virus 40*, 17 VIROLOGY 65–75 (1962) [hereinafter Eddy et al. II]; EDWARD SHORTER, THE HEALTH CENTURY 195–99 (1987).

¹³ Eddy I, *supra* note 34, at 930; Eddy et al. II, *supra* note 34, at 65.

¹⁴ Simian Virus 40 (SV40): *A Possible Human Polyomavirus*, Developments in Biological Standardization Vol. 94, 1998.

¹⁵ INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, IMMUNIZATION SAFETY REVIEW: SV40 CONTAMINATION OF POLIO VACCINE AND CANCER 4, 21 (Kathleen Stratton et al. eds., 2002), <http://www.nap.edu/books/0309086108/html> (last visited May 26, 2003) [hereinafter IMMUNIZATION SAFETY REVIEW].

¹⁶ *Id.*

¹⁷ National Institutes of Health (NIH) Division of Biologics Standards (DBS) was a forerunner of today's Center for Biologics Evaluation and Research (CBER). Paul Parkman, Harry Meyer, Jr., MD Lecture, CBER Centennial—Slide Presentation (Sept. 23–24, 2002), at <http://www.fda.gov/cber/summaries/cent092302pp.htm> (last visited May 26, 2003). “The transfer of DBS to the Food and Drug Administration took place in 1972.” *Id.* The DBS became the FDA's Bureau of Biologics (BoB). *Id.* “Later incarnations of this organization included the Center for Drugs and Biologics (CDB) and finally, the present day Center for Biologics Evaluation and Research (CBER).” *Id.*

¹⁸ Immunization Safety Review, *supra* note 45, at 21.

they were all used and replaced by *allegedly* SV40-free vaccines as required by the new federal regulations promulgated in 1961.¹⁹

In 1961, federal regulations were implemented to ensure that SV40 would no longer contaminate the polio vaccine. Despite these regulations, we contend that the OPV has been sporadically contaminated with SV40 for the last four decades. As a result, we allege that some of the children who have been administered the contaminated vaccines have been stricken with cancer and others are at risk. The main points are summarized below:

- 1) SV40 (Simian Virus Number 40) is a cancer causing monkey virus found in the kidney cells of Rhesus and African Green Monkeys. The kidney cells of these two species of monkeys comprise the substrate that has been used to create poliovirus strains and manufacture the oral polio vaccine for four decades.²⁰
- 2) SV40 is a human carcinogen for brain cancer and mesothelioma and it is a suspected carcinogen in osteosarcomas (bone cancers) and Non-Hodgkin's Lymphomas.²¹
- 3) Alexander was administered the OPV in November 1997. He was diagnosed with a brain tumor in August 1998. Alexander died on January 31, 1999.
- 4) Four independent laboratories using DNA testing and laser micro-dissection found SV40 in Alexander's brain tumor.
- 5) SV40 has been found in the cancers of many other children. Pediatric brain tumors and other childhood cancers including osteosarcomas (bone cancer) and Non-Hodgkins Lymphomas have been found to contain SV40.²²
- 6) When Alexander was born on June 7th, 1996, I had his cord blood saved and stored by a private laboratory. The cord blood was the blood shared by Alexander and myself at the time of Alexander's birth. We had this blood tested for SV40. This marked the very first time the cord blood of a child with an SV40 positive brain tumor would be tested for SV40. To the astonishment of the scientists it was negative for SV40. This suggested that at the time Alexander was born he had not been exposed to SV40.
- 7) It is known that SV40 can be spread through contaminated blood so my husband and myself underwent a battery of tests from 2000 to 2001. Using a variety of sophisticated DNA tests to isolate the genetic fingerprint of the SV40 virus including Polymerase Chain Reaction (PCR), the scientists checked blood, urine and semen multiple times looking for any trace of SV40 (even antibodies). The scientists were once again surprised. Despite the repeated tests by leading SV40 laboratories both in the United States and Europe, we had absolutely no trace of SV40.
- 8) The scientists concluded that Alexander did not get SV40 from his parents, nor did he give SV40 to us.

¹⁹ *Id.*

²⁰ A.B. Sabin, A.B. & L. Boulger, *History of Sabin Attenuated Poliovirus Oral Live Vaccine Strains*. 1 J. Biol. Stand. 115, 115–18 (1973).

²¹ Adi F. Gazdar et al., *SV40 and Human Tumours: Myth, Association or Causality?*, 2 Nat. Rev. Cancer 957, 957–64 (2002).

In addition, in July 2002, the National Academy of Science Institute of Medicine (IOM) Immunization Safety Committee convened a study into SV40 and cancer which culminated in a report published in October 2002. According to the IOM report "SV40 Contamination of Polio Vaccine and Cancer": The committee concludes that the biological evidence is strong that SV40 is a transforming [i.e., cancer-causing] virus, . . . that the biological evidence is of moderate strength that SV40 exposure could lead to cancer in humans under natural conditions, [and] that the biological evidence is of moderate strength that SV40 exposure from the polio vaccine is related to SV40 infection in humans. See Immunization Safety Review: SV40 Contamination of Polio Vaccine and Cancer.

²² John A. Lednicky and Janet S. Butel, *Simian virus 40 regulatory region structural diversity and the association of viral archetypal regulatory regions with human brain tumors*, Semin Cancer Biol. 2001 Feb;11(1):39-47. Bharat Jasani, et al., *Association of SV40 with human tumours*, Semin Cancer Biol. 2001 Feb;11(1):49-61.

- 9) The original oral polio vaccine (OPV) seed stocks created by Dr. Albert Sabin and used to make OPV since 1961 were known to be contaminated with SV40. In fact, SV40 was isolated from Sabin's OPV seeds - the original material used to make OPV for four decades.²³
- 10) Dr. Sabin had admitted that OPV seeds were contaminated with SV40 in a peer-reviewed scientific publication.²⁴ Dr. Sabin wrote, "The three types of the large lots produced by Merck, Sharp and Dohme in rhesus monkey kidney cell cultures contained SV40."²⁵
- 11) Lederle, the sole American manufacturer of OPV for many years, received their OPV seeds from Merck, Sharp and Dohme. There is no evidence that Lederle ever tested their seeds for SV40 nor discarded their presumably contaminated seed stocks.
- 12) There are Lederle documents (not under a protective order) that demonstrate that their early OPV vaccines were contaminated with SV40.²⁶
- 13) Lederle did not use the SV40-neutralization procedures recommended by Dr. Sabin.²⁷
- 14) Monkeys used to produce OPV were not tested for SV40 by Lederle because of economic considerations.²⁸
- 15) After reviewing all of the Lederle records and the Lederle systems in place, our expert concluded that the contamination detected in the OPV material ultimately administered to Alexander was SV40.²⁹
- 16) The medical literature is unequivocal – the pediatric brain cancer rate in the U.S. has been climbing at a rate of approximately 3% for the last four decades.
- 17) A recent study has demonstrated that 11% of Americans are currently infected or have been infected with SV40.³⁰

SV40 is not only responsible for causing the cancer, but also for making these particular cancers incurable. Orthodox cancer therapies such as chemotherapy and radiation can **not** cure an SV40 positive cancer. Pediatric brain cancers and other solid cancers have been found to contain SV40. SV40 binds with the tumor suppressor genes p53 and RB and stops tumor cells from undergoing apoptosis (programmed cell death).³¹ Apoptosis is what radiation and chemo depend on to work in order to trigger the cancer cell to die.³² Exposing SV40 positive cancer cells to chemo and radiation does not kill the cells but simply creates more genetic mutations - making the cancer more

²³ See Sara Stinebaugh and Joseph Melnick, *Plaque Formation by Vacuolating Virus SV40*, *Virology* Vol. 16, March 1962 ("The strain of virus (SV40) used was isolated from Sabin's lot of type 2 oral poliomyelitis vaccine . . ."); Asaria Ashkenazi and Joseph L. Melnick, *Induced Latent Infection of Monkeys with Vacuolating SV40 Papova Virus: Virus in Kidneys and Urine*, *Proceedings of the Society for Experimental Biology and Medicine*, Vol. 111, October-December 1962 ("The [SV40] virus used was isolated from Sabin's seed stock of type 3 oral polio-vaccine. . .")

²⁴ A.B. Sabin, A.B. & L. Boulger, *History of Sabin Attenuated Poliovirus Oral Live Vaccine Strains*. 1 J. BIOL. STAND. 115, 115–18 (1973).

²⁵ *Id.*

²⁶ These documents are attached as exhibits to the Declaration of Stanley P. Kops in Support of Plaintiff's Motion For Reconsideration (Case No. CV-00-04523 WJR (Ex) Pending in the U.S. District Court for the Central District of California.)

²⁷ Declaration of Stanley P. Kops in Support of Plaintiff's Motion For Reconsideration (Case No. CV-00-04523 WJR (Ex) Pending in the U.S. District Court for the Central District of California.)

²⁸ From *Brown v. Lederle*; Civil Action 73-1920. Deposition of Dr. Ronald Vallancourt of July 24, 1975. Dr. Vallancourt, the responsible head of American Cyanamid, testified that the reason for the lack of testing of the monkey sera for SV40 was based on economic considerations.

²⁹ Declaration of Stanley P. Kops in Support of Plaintiff's Motion For Reconsideration (Case No. CV-00-04523 WJR (Ex) Pending in the U.S. District Court for the Central District of California.)

³⁰ D.E. Rollison, et al., *Serum Antibodies to JC Virus, BK Virus, Simian Virus 40, and the Risk of Incident Adult Astrocytic Brain Tumors*, *Cancer Epidemiol Biomarkers Prev.* 2003 May;12(5):460-3.

³¹ S.D. Conzen, et al, *Identification of a novel antiapoptotic functional domain in simian virus 40 large T antigen*, *J Virol.* 1997 Jun;71(6):4536-43; J.W. Ludlow, *Interactions between SV40 large-tumor antigen and the growth suppressor proteins pRB and p53*, *FASEB J.* 1993 Jul;7(10):866-71; Michele Carbone, et al., *The pathogenesis of mesothelioma*, *Semin Oncol.* 2002 Feb;29(1):2-17.

³² THE CHEMOTHERAPY SOURCE BOOK 4 (Michael C. Perry ed., 3d ed. 2001). One tumor gene in particular, p53 is designed to kill cells through apoptosis or "cell suicide" so that mutated cells do not lead to cancer through uncontrolled multiplication and metastasis. Chemotherapy and radiation depend, to a large degree, on p53. *Id.*

aggressive. The bottom-line is that SV40 causes human cancer, stops orthodox cancer therapies (i.e. chemo and radiation) from providing any benefit, and can make the cancer even more aggressive.

Despite these facts, children diagnosed with cancer are not given a choice of whether they should undergo debilitating and toxic chemo and radiation. Alexander should have been tested for SV40 upon his diagnosis, not after he died. He should not have been administered ineffective and unnecessary chemotherapy which provided no benefit and only made him suffer. Children with SV40 positive cancers (or p53 mutations) should not be used as guinea pigs and profit centers for pediatric oncologists, hospitals, and pharmaceutical companies.

A Congressional Hearing should be immediately convened to examine how a federally policed vaccine program has introduced a deadly monkey virus into countless American men, women and children for the past 45 years and what the public health consequences have been of this tragedy.

This government investigation should demand to know:

- Why a vaccine manufacturer was allowed to use vaccine seed stocks for four decades that came from a source contaminated with SV40?
- Why did this manufacturer violate federal regulations and allowed contaminated vaccines to be released?
- Why weren't sophisticated tests to detect SV40 during OPV production and to eliminate the virus ever required by the federal government?
- Why aren't children with cancer tested for SV40 *when they are diagnosed, not when they are dead*, because an SV40 positive cancer means that chemo and radiation will be ineffective?
- Why is there a significant percentage of Americans (children and adults) walking around with evidence of having had an SV40 infection and what does that mean for their risk of cancer and chances for a successful treatment?

Like our son, many children are already dead, victims of this virus, and many adults will be stricken later. Time is of the essence, not for our beloved Alexander anymore, but for other children who are infected with this cancer causing virus.

Sincerely,

Raphael Moreau-Horwin M.A., M.F.S.

Michael Horwin, M.A., J.D.

www.ouralexander.org

cc: Barbara Loe Fisher, Co-Founder & President of the National Vaccine Information Center