Vaccine Production

[Excerpt from a Letter to Representtive Dan Burton from a parent of a vaccine damaged child. Found at: www.ouralexander.org/BurtonSV40 Letter (2003).doc]

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 passage (1) 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." (2) Dr. Salk then passed this strain through fourteen living monkeys and two cultures of monkey testicular cultures. (3) 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. (4) 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. (5) 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. (6) 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. (7) 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. (8)

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. (9) 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. (10) 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. (11) 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…" (12)

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. (13) It was estimated that 10% to 30% of the vaccines contained live SV40. (14) 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). (15) Incredibly, this agency did not order a recall of any of the SV40-contaminated vaccines. (16) The tainted vaccines continued to be administered until 1963 when they were all used and replaced by allegedly SV40-free vaccines as required by the new federal regulations promulgated in 1961. (17)

Footnotes:

1. 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.

2.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. Fancis and Mack.

3,4,5,6,7,8 Id.

9. 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).

10. 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).

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

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

13. 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].

14. Id.

15. 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.

16. Immunization Safety Review, supra note 45, at 21.

17. Id. 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.