

SV40 contamination of vaccines

- Oral polio-vaccines were required to be free of SV40 since 1961
- Injected polio-vaccines were required to be free of SV40 since 1961, but contaminated vaccines were sold until 1963
- During litigation against Lederle I obtained documents indicating that SV40 was present in their product well after 1961

Documents obtained during litigation

- These documents indicate that the Lederle product was never freed from SV40
- That Lederle did not follow the mandatory Code of Federal Regulations
- That Lederle knowingly distributed SV40-contaminated vaccines
- That Lederle never tested whether the neutralization procedure worked

Documents from litigation

- Lederle put me under a confidential order which prohibits me to distribute most of these documents
- Therefore, if you want to see the Lederle documents proving what I will state, you need to ask them directly or to ask them to allow me to show the documents to you

Sources of SV40 contamination

- Vaccines can be contaminated because the seed used to manufacture is contaminated
- Because the monkey kidney cells used to manufacture are contaminated

How contamination is detected

- Contamination is detected by observing the appearance of vacuoles or other cytopathic effects in cells incubated with tissue culture media and/or seed

Seed contamination

- The following representative documents show that
- the vaccine master seed was contaminated
- that the three monovalent pools derived from these master seeds were contaminated,
- that Lederle was aware of the contamination

Lederle poliovaccines

- Between 1961 to 1963 only manufactured monovalent vaccines (there are three types, I through III, each representing a different strain of wild poliovirus)
- 1963 to 1967 manufactured both mono and trivalent vaccines (the combination of all three types of Sabin monovalent vaccines)
- After 1967 trivalent replaced monovalent

Lederle poliovaccines

- Regulations were not followed
- Following slides show representative problems of type I and II monovalent vaccine pools.

Interoffice Memorandum between Mr. S. S. Aiston, Technical Superintendent of Polio Production Lederle and Mr. W. P. Cekleniak, dated March 14, 1979, states the following:

“It should be made clear that Lederle did not test the original Sabin seeds for extraneous agents or neurovirulence since only 50 ml or less of each seed were provided by Dr. Sabin. It was presumed that if progeny of these seeds proved to be free of extraneous agents and have satisfactory neurovirulence the parent seeds were satisfactory”.

Interoffice Memorandum between Dr. James L. Bittle and Dr. I. S. Danielson, Responsible Head, both Lederle scientists dated November 8, 1961, stating the following:

“... the following is a summary of the incidence of SV40 found at the PCB2 level of the 15 lots released for clinical trial. Lot No. 114, Lot No. 216, Lot No. 317” (utilized and sold in the USA from 1962 until at least 1964).

MANUFACTURING RECORD – TYPE I – MONOPOOL
 114 – HARVEST NO. 1110 – RHESUS MONKEY J071 – PCB 2
 Pooled Fluids taken from 25% Production Control Vessels
 Fourteen Days after Viral Inoculation of Production Vessels
 Sec. 73.113 Code of Federal Regulations. (Slide 1 of 3)

	<u>CPE Observed on Day</u>			
	<u>Sample</u>		<u>TC Control</u>	
	<u>6</u>	<u>14</u>	<u>6</u>	<u>14</u>
CMK 1.17.61	0	CPE	0	0
(Retest)	0	CPE	0	0
CMK 3.21.61	0	0	0	0
(Retest)	0	0	0	0

MANUFACTURING RECORD – TYPE II – MONOPOOL 216 –
 HARVEST NO. 2128 – RHESUS MONKEY L087 – PCB 2
 Pooled Fluids taken from 25% Production Control Vessels
 Fourteen Days after Viral Inoculation of Production Vessels
 Sec. 73.113 Code of Federal Regulations.(Slide 1 of 2)

<u>System</u>	<u>CPE OBSERVED ON DAY</u>			
	<u>Sample</u>		<u>TC Control</u>	
CMK 118	<u>10</u>	<u>14</u>	<u>10</u>	<u>14</u>
	0	VA	0	0
	0	VA	0	0
CMK 122	0	VA	0	0
	0	VA	0	0

Monkey contamination

- To prevent contamination manufacturers stated that all working seeds were prepared in SV40-free green monkeys
- Their own test showed that 10% of those monkeys were infected with SV40
- Furthermore, Rhesus monkeys were used to prepare type I and II seeds from 1961-1980.

Conclusions 1

- Seeds were prepared in rhesus kidney tissue and not African green monkey tissue for type I and II. This increases the risk of contamination
- 10% of green monkeys were SV40 infected
- Seeds were not tested for SV40
- Some seeds were not neutralized for SV40
- Seeds neutralized were not tested to see if the neutralization worked

Conclusions 2

- SV40 contamination was detected in all 3 monovalent types by Lederle
- Lederle ignored contamination and proceeded to release contaminated vaccines
- This failure to follow regulations continued until 1999