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**ORAL PRESENTATION TO THE SUBCOMMITTEE ON HUMAN RIGHTS  
AND WELLNESS OF THE COMMITTEE ON GOVERNMENT REFORM:  
“THE SV40 VIRUS: HAS TAINTED POLIO VACCINE CAUSED AN  
INCREASE IN CANCER?”**

I have represented, and am still representing, individuals who have been paralyzed, killed, and or severely damaged as a result of the Orimune vaccine manufactured, sold and distributed from 1962 until the year 2000. Though attorneys are advocates, and I am an advocate in the courtroom for my clients,, I have left my attorney’s hat in Philadelphia and have come before this committee to raise questions as someone who has authored peer reviewed articles in the medical literature on the issue of SV40 and human cancers.

There is a history of negligence involving this vaccine manufacturer and the regulators, who are the employees of the Government agency charged with the responsibility of insuring the safety, purity and potency of vaccines. In 1988, the United States Supreme Court in a unanimous decision, (Berkovitz v. United States, 486 U.S. 531) held that under federal government FDA regulations, the vaccine manufacturer must conduct a variety of tests to measure the safety of vaccines at each stage of the manufacturing process. (Exhibit 1 - a copy of the regulations) Upon completion of the manufacturing process, and the required testing, the manufacturer is required to submit a license application to the FDA. In addition, the manufacturer must submit the data

showing that the tests were performed and that the test passed all of the safety standards. A license can only be issued by the FDA upon a showing that the vaccine manufacturer has met the standards designed to insure the continued safety, purity and potency of the vaccine prescribed in the regulations. **Berkovitz** at p. 540-542.

In a question and answer at oral argument between one of the Justices of the Supreme Court and the Solicitor General, the following took place:

Q. [Supposing the DBS] did not make any examination of the application at all, or any determination other than some papers have been filed and I will now issue the license. “Would that comply with the regulations?”

[Counsel]: No it would not comply with the regulation.

Q. It would violate a mandatory duty..., wouldn't it

[Counsel] In the extreme instance you are talking about..., it would definitely violate that regulation.” Tr. of Oral Arg. 34-35.

**Berkovitz**, 486 U.S. at 544 n.10.

That extreme case is exactly what happened with the Sabin Oral Poliovirus known as Orimune manufactured by Lederle Laboratories owned by American Cyanamid, and today known as Wyeth Lederle – the vaccine safety tests were not submitted, the regulators did not look, and infants in the United States became paralyzed, or died, and there are now clear instances of cancer reported in the children and individuals who received this product.

Since there are three types of wild poliovirus, there was a need to create three vaccines. Trivalent polio vaccine contained all three types combined. This manufacturer was the first to combine all three polio types into a single live oral polio vaccine known

as OPV. Between 1964 and 1977, Lederle had become the largest manufacturer of OPV in the United States and claimed to have 84% of the market. After 1977, it was the sole manufacturer until the vaccine was no longer sold in the United States. See FDA Docket No. 86N-0027.

Up until today, no scientist has had the complete data to challenge all of the assertions made by this vaccine manufacturer. Wyeth/Lederle has demanded in every lawsuit that all documents be marked confidential and could not be revealed to the scientific world. The documents that you will be seeing today are not the full complement of the documents which will tell a frightening story of contamination of live oral polio vaccine with a monkey virus known as SV40 – they are documents not under seal which were collected, from other litigation across the country, from the United States of America during litigation, and from litigation with the vaccine manufacturer in cases involving victims of this oral polio vaccine.

Within weeks of being licensed, in 1962, American Cyanamid made the following two promises to the consuming public, the scientific world, and the medical profession:

Orimune 1, 2, and 3 are produced and tested in accordance with the regulations of the United States Public Health Service for production of Poliovirus Vaccine, Live, Oral. The manufacturer makes no representation or warranty, express or implied, with respect to the merchantability or fitness for use of these vaccines other than that they have been produced in accordance with the standards for their production prescribed by the United States Public Health Service and applicable thereto at the time of their release by the manufacturer.

Can Oral Polio vaccine Cause Other Diseases?

The safety regulations discussed above include many general safety tests. There are also tests designed especially to detect certain potentially pathogenic organisms, such as the vacuolating agent (SV40). Every production pool of Orimune is carefully tested many times for SV40, and any lot in which it is found is rejected.

(Exhibit 2)

Both of these claims were, and are false.

Today it is my intent to present evidence to prove that these statements repeated and reaffirmed at the presentation of Wyeth/Lederle at the SV40 conference, held in January 1997 under the auspices of the FDA and the N.I.H., were factually incorrect and intentionally misleading so as to keep the scientific world from conducting a thorough investigation.

This vaccine manufacturer, when it presented at the 1997 conference, and when it thereafter published its presentation in scientific journals, knew that the entire scientific world, which were all involved in a debate about SV40, would rely, as they had in the past, on their statements as to the safety of this product and that it could not possibly have contained the vacuolating agent SV40.

American Cyanamid, in both its presentation and, thereafter, in a scientific publication, has stated the following: “The cell culture substrate is prepared in primary monkey kidney cells obtained from green monkeys that do not harbor SV40 virus.”

(Exhibit 3) That statement was and is false. The only known manufacturer in the world who did not do blood tests on their monkeys to determine the presence or absence of SV40 is this manufacturer. In a sworn deposition given on October 2, 2002, the now head of the biological quality control, stated the following:

Q. Did you ever see a serological test conducted to determine whether or not a African Green monkey was infected with SV40?

A. I may have done – it may have been done for investigative purposes only.

Q. Once or twice?

A. Yeah, a couple times.

Q. But it was never done as a matter of routine; is that correct/

A. Correct.

(Exhibit 4)

The vaccine manufacturer assured the scientific world that a single appearance of an adventitious agent such as SV40 at any stage of testing, results in the rejection of the cell batch. This statement was repeated from 1962 through 1999, and is now being stated in various courtrooms where litigation has been commenced against this vaccine manufacturer. As an example, in a Request for Admissions filed in a lawsuit now pending, this vaccine manufacturer answered a Request for Admission with the following assurance:

REQUEST FOR ADMISSION NO. 33:

American Cyanamid cannot insure if the alleged neutralization for SV40 from the Sabin Original Merck material Type II was successful.

RESPONSE:

Defendants object to this Request as it assumes SV40 was present in the Sabin Original Merck material Type II, an unproven conclusion. Expressly reserving, and without waiving their objections, and subject to them, defendants respond that they are not insurers but that they neutralized Sabin Original Merck Type II and tested it for the presence of adventitious agents. These tests were negative and subsequent testing on vaccine produced using the progeny of SOM Type II have been negative for SV40.

The internal standard operating procedures for this company do not provide for automatic rejection when an adventitious agent even when SV40 is found in the test results. This vaccine manufacture engages in repeat testing, and only in the extreme case where five failures in a row are recorded do they reject the harvest;; anything short of this is eventually tested into compliance. (Exhibit 5 - As of 1983 where two failures were permitted, which was modified as time progressed.)

Everyone in the scientific world has assumed that, from 1960 onward, once SV40 had been discovered in the Rhesus monkey kidney tissues utilized to produce oral polio vaccine, that Rhesus monkeys were abandoned and African Green monkeys would be utilized. The rate of SV40, and other adventitious agents, in Rhesus monkeys in the

hands of this vaccine manufacturer is somewhere between 50-60% of all monkeys rejected. (*Results of Testing Production Lots of Oral Poliovirus Vaccine*, Exhibit 6)

According to the vaccine manufacturer's internal records, African Green monkeys had about a 10% chance of being infected with SV40. (Exhibit 7) It also notes three different harvests, each of which showed the vacuolating agent, and this material was distributed throughout the United States.

In an authoritative text *Oncogenic Viruses*, Third Edition, by Ludwik Gross, M.D. F.A.C.P., he advised that the rate of Rhesus monkeys being infected with SV40 was at a much higher percentage. See Chapter 23, "Oncogenic Potency of Simian Virus 40 (SV40)," p. 829-887. (Exhibit 8)

In 1997, this vaccine manufacturer, through its presentation both orally and in writing, reconfirmed to the entire world what it had previously advised that: "All subsequent working seed strains have been prepared in CMK cells [African Green monkey] and screened to assure they are free of SV40 virus." That statement is utterly false. At no time did the regulators correct this misstatement. The master seeds were only prepared in Rhesus monkey kidneys, and as Dr. Sabin stated: "The three types of the large lots produced by Merck Sharp & Dohme in Rhesus monkey kidney cell cultures contained SV40." *WHO Report 1969*. (Exhibit 9)

The production seeds utilized by this vaccine manufacturer for the Type I and Type II components, of both the monovalent and trivalent vaccine utilized from at least 1960 until the beginning of the 1980s, were prepared only in Rhesus monkey kidney tissue and not African Green monkey tissue. (Exhibit 10) The following seeds were

prepared in the Rhesus monkey kidney tissue: 3101, 3102, 3107, 2107, 45B52, 1102, and 45B51.

Not only were Rhesus monkeys utilized to produce seeds, they were utilized in the 1980s and early 1990s to produce the actual oral polio vaccine that was administered to millions of American children who were compelled to take that vaccine by state law, and were encouraged to take that vaccine by the federal regulators, by the vaccine manufacturer, by the Centers for Disease Control, and by an uninformed and misled Academy of Pediatrics. (Exhibit 11)

In litigation involving a young girl (the daughter of a Lieutenant Commander in the US Navy), the vaccine manufacturer claimed in August 2003 that after reasonable inquiry, and based upon the information presently known, or readily obtainable, they cannot admit or deny whether Rhesus monkey kidneys were even used to produce their seeds. (Exhibit 12)

This vaccine manufacturer claims that they are continuing to engage in a search to determine the species of the monkeys used to manufacture their seeds. For the ease of the Committee, and for this manufacturer who has been searching for these records for nearly a decade, I have submitted the monkey records showing that each single monkey used to make their seeds in the 1960s through the 1970s was a Rhesus monkey. The documents which I have submitted are documents that came out of the files of this vaccine manufacturer. The audacity to claim that it does not know what it used, in and of itself, is reprehensible. One can only question how this vaccine manufacturer was able to fool the supervising regulators for over 40 years. The utilization of rhesus monkeys

kidney tissues that were prepared in the 1980s and utilized in the 1990s with the blessing of the regulators is administered in doses of vaccine into the mid-1990s. (Exhibit 13)

In a letter authored by Merck & Company to the Surgeon of the United States, Merck & Company admitted that their seeds contained SV40 and, therefore, they could not assure the Surgeon General that it could be safely removed (completely removed); therefore, they refused to produce the vaccine for commercial use. Dr. Sabin in correspondence directly with this vaccine manufacturer stated that he could not be sure that his original seed material for the Sabin Original Type III was free of SV40. (Exhibits 14 and 15)

By the year 1969, everyone knew from the reported literature, that all of the Merck Sharp & Dohme seeds contained SV40. This historical fact again was repeated in 1973 in a report given by Dr. Sabin.

As to the seeds that were utilized between the 1980s and up until 1999, those monkeys, especially for the Type I and Type II components, were monkeys that had been subject to a prior experimental test. The regulation is clear that experimental monkeys cannot be utilized as the source of material for production, let alone for production of a seed.

Monkeys that have been used previously for experimental purposes shall not be used as a source of kidney tissue in the manufacture of vaccine. (Exhibit 1)

This vaccine manufacturer in litigation is still searching for the test results of its master seeds, the test results of the initial seeds, and the test results showing the successful neutralization required by the safety regulations. This vaccine manufacturer is

still looking for the serological test data. It is still looking for the waiver that they claim to have sought and received from the Government to use experimental monkeys.

The government of the United States of America – the FDA - has been searching for the same records, and amazingly cannot find records for twenty-two out of a total of twenty-six seeds which were utilized in the manufacture of Orimune from 1960 through 1999. The seeds that cannot be found are the master seeds, production seeds that were utilized between 1961 and 1980, the master seeds and intermediate seeds utilized between 1980 until 1999. The only reason why I believe neither the regulator nor the manufacturer can find the test results, is because they do not have all the safety tests required by the regulations and by the Supreme Court in **Berkovitz v. United States**.

When questions were asked by another regulatory agency, the government of Australia, as to the seed testing results for the master seeds, the technical superintendent of polio production of this vaccine manufacturer responded as follows:

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.

(Exhibit 16)

Until the year 2000, no one published in peer reviewed journals any challenge to the promises and assurances of this company that it fully complied with the FDA's regulatory system. Everyone assumed that the vaccine manufacturer, and the regulators, fully implemented the regulatory standards.

In a memo authored by Dr. I. S. Danielson, the responsible head of this vaccine manufacturer, he noted in a discussion with a physician from Wilmington, Delaware, the following:

He [the physician] stated that we do not say in our package circular that our vaccine is free of SV40 while Pfizer's does. I said that I had not even thought of this because the regulations require that demonstrable SV40 cannot be present; therefore, it went without saying that our vaccine is SV40 free.

(Exhibit 17)

Having been involved in litigation concerning the safety of Orimune, I knew that the statements made were false. I submitted an article which was peer reviewed by doctors and was published in *Anticancer Research* in December 2000 to bring his issue to the attention of the scientific world. (Exhibit 18) Since that time, not a single FDA regulator, or the vaccine manufacturer's employees have proven that any of the contentions raised in that article were erroneous. (Exhibit 19)

In July 2002, I was given the honor of presenting to the IOM a powerpoint documentary presentation showing the presence of SV40 in released products of this manufacturer, a copy of which is available to the members of the committee. The IOM wrote in its report, in October 2002, the following:

Claims have been made that some oral polio vaccines might have been contaminated after 1963 (Kops 2000). The committee urges that FDA or other agencies address these claims to try to resolve the uncertainty regarding the possibility of exposure to SV40 after 1963. Appropriate assumptions about exposure are essential for conducting valid epidemiologic analyses of the risks that might be associated with contaminated OPV.

(Exhibits 20 and 21)

How has the vaccine manufacturer and the regulator responded to this demand of the IOM – with silence, no testing and no interest in revealing to the scientific world the truth.

Only Congress can correct and reaffirm the statutory command of the Vaccine Public Health Act, which was passed in 1902 to protect children who were compelled by

state law to be vaccinated. The duty was to **insure** the safety, purity and potency of the vaccine. Congress in 1902 understood what the word **insure** meant - Congress in the year 2003 understands what the world **insure** means. The only ones who do not understand it, and who are disregarding this mandate, the law of the land, as enacted by Congress, are a vaccine manufacturer interested solely in profits, and the regulator who was complicit in numerous violations of the safety regulations not only as to SV40, but in every aspect of the safety of the Orimune vaccine.

If any of my statements are inaccurate, I invite the representatives of the regulators, and/or the vaccine manufacturer, to present their evidence that supports compliance, and to present the documents which support their assertions.

I thank you for inviting me to discuss this issue and I will be happy to respond to any questions.