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THE SV-40 VIRUS: HAS TAINTED POLIO VACCINE CAUSED AN INCREASE IN CANCER

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SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

of the

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTH CONGRESS

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C O N T E N T S

THE SV-40 VIRUS: HAS TAINTED POLIO VACCINE CAUSED AN INCREASE IN CANCER

WEDNESDAY, SEPTEMBER 10, 2003

House of Representatives,
Subcommittee on Human Rights and Wellness,
Committee on Government Reform,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:30 p.m., in room 2154, Rayburn House Office Building, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton, Watson, and Cummings.

Staff present: Mark Walker, staff director; John Rowe and Brian Fauls, professional staff members; Mindi Walker, professional staff member and clerk; Nick Mutton, press secretary; Sarah Despres, Tony Haywood, and Jeff Baran, minority counsels; and Cecelia Morton, minority office manager.

Mr. Burton. Good afternoon. A quorum being present, the Subcommittee on Human Rights and Wellness will come to order, and I ask unanimous consent that all Members and witnesses' written and opening statements be included in the record, and without objection so ordered. I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record, and without objection so ordered. And we may have some other Members that may want to come. I don't know. We have invited them who are interested in the vaccination issue. If they come I ask unanimous consent that they be allowed to participate and we'll enumerate them as they come assuming they are here.

Immunization to protect people from infectious diseases was one of the greatest public health advances of the 20th century. I don't think anybody argues with the fact that it's made us the luckiest people in the world as far as health is concerned. However, immunization is a very different medical procedure than treating an active disease or injury. Immunizations introduce a potentially disease causing agent into a healthy body and all experts agree that no immunization is without risks.

This is a situation where government policy overrides individual rights. With very few exceptions, immunizations are mandatory. Infants and young children have absolutely no choice in the matter and their parents rarely have a choice. Government mandates require vaccination before admission to day care, school or college. Just last week, here in Washington nearly 10,000 children were turned away on the first day of

school because their immunization records were not up to date. They couldn't go to class until they got their shots.

Those in military service get another battery of shots. When freedom of choice conflicts with government edicts, the government nearly always prevails. Because immunizations are mandatory, government agencies at all levels have a duty to exercise the utmost care in the approval, administration and post administration surveillance of vaccines. In fact, the Public Health Act of 1902 imposed a duty upon the Public Health Service to, ``ensure the safety, purity and potency of vaccines.'' ``Ensure'' is a very strong word. However, doing anything less is a breach of the public trust and could destroy the public's confidence in vaccines.

The development of the polio vaccines in the 1950's and early 1960's was especially welcome because of the devastating toll of death, disability and suffering that polio caused. I can remember my mother wouldn't let me go outside, was worried about flies getting in water that might infect you. And I remember those horrible, horrible machines that children had to live in for the rest of their lives. It was just tragic. So the polio vaccine really was beneficial to mankind as well as U.S. citizens.

However, some parents and a growing number of scientists now believe that the government did not ensure the purity, potency, and safety of some of the polio vaccines and that a breach of the public trust did in fact occur. There is no dispute that millions of Americans received polio vaccines that were contaminated with the virus called Simian Virus 40, or SV-40. There also is no dispute that SV-40 is capable of causing cancer, but there is a major dispute as to how many Americans may have received the contaminated vaccine, with estimates ranging from 4 million to 100 million people. There is also a major dispute as to when the polio vaccine supply got cleaned up. In addition, nobody knows how many people got sick or died because of the contaminated vaccines.

This subcommittee's efforts to give a full and fair hearing to this important issue today are somewhat impaired by the lack of participation by some key Federal health agencies. The Food and Drug Administration informed our staff that they were having trouble locating FDA staff with sufficient knowledge to be of much help and that they needed more time to study it. They promised to submit a statement for the record within the next 2 weeks. Well, we'll anxiously watch for their statement and we will give the appropriate FDA personnel the opportunity to appear before this subcommittee down the road when those things have been located.

The Centers for Disease Control and Prevention indicated that they don't keep records on things that happened 40 or 50 years ago and that they could not be very helpful. That in and of itself raises a serious question in my mind. We're not talking about the common cold here. We are talking about polio, the most devastating epidemic of the first half of the 20th century. We're talking about tainted vaccines that were given to millions of American children and young adults, and I think the FDA and CDC need to look a little harder for their records.

The National Cancer Institute has sent a representative in the person of Dr. James Goedert. Did I pronounce that right?

Dr. Goedert. Goedert. The 'o' is silent.

Mr. Burton. OK. We thank you, Doctor, for your appearing and we thank your agency for sending you to testify today. I also want to thank the other witnesses that are here to testify

and I look forward to hearing your testimony. And I understand Dr. Engels is here with you. We appreciate you coming, Doctor, and we will accept testimony and answers of questions from you as well. And I want to thank the other witnesses who are here and look forward to hearing their testimony.

[The prepared statement of Hon. Dan Burton follows:]

[GRAPHIC] [TIFF OMITTED] T1047.001

[GRAPHIC] [TIFF OMITTED] T1047.002

Mr. Burton. Would you gentlemen please raise your right hands and stand?

[Witnesses sworn.]

Mr. Burton. Doctor, we'll start with you. Dr. Goedert. Go ahead, Doctor. And we would like to keep our testimony as much as possible to 5 minutes because we want to get on with questions and we may have more votes.

STATEMENT OF DR. JAMES GOEDERT, CHIEF OF VIRAL EPIDEMIOLOGY, NATIONAL CANCER INSTITUTE, ACCOMPANIED BY DR. ERIC A. ENGELS

Dr. Goedert. Mr. Chairman, I appreciate the opportunity to appear before you. My name is James Goedert. I'm a physician, a graduate of Loyola University Medical Center, in Maywood, IL, with training and board certification in internal medicine and medical oncology. Like everyone here, I have seen suffering and death from cancer, including close family members. To reduce suffering and death from cancer I have dedicated my professional career, over 23 years with the National Cancer Institute at the National Institutes of Health, conducting research on the causes and prevention of cancer.

Today we consider two related but scientifically distinct questions: Is cancer associated with the inadvertent contamination of the early polio vaccines with SV-40, and do people with cancer have evidence of SV-40 infection irrespective of the source? We have and continue to take both questions seriously. Our current Division Director, Dr. Joseph Fraumeni, immediately recognized the potential impact of polio virus contamination with SV-40. In 1963 he studied and found no difference in cancer risk associated with the use of the contaminated vaccine. As you know, cancer, can take years to develop so this study could not be the final word.

During the ensuing 40 years, we and many others have continued to study populations exposed to SV-40 contaminated vaccines, including children, the offspring of women vaccinated during pregnancy, military servicemen and the population of Denmark. Though some of these studies are ongoing, one point is clear. They have consistently found that recipients of SV-40 contaminated vaccines do not have an increased risk of cancer.

Turning to the second question of SV-40 in people irrespective of the source, the reported detection of SV-40 DNA in two types of brain cancer in children and in mesothelioma and osteosarcoma tissue prompted us to initiate laboratory studies. In 48 mesotheliomas from the archives of the Armed Forces Institute of Pathology we found no SV-40 DNA despite the use of two laboratory methods, each able to detect 10 or fewer molecules of SV-40 DNA. Other highly experienced laboratories also did not detect SV-40 DNA in mesothelioma. Still others were detecting SV-40 DNA in a wide variety of tumors and at the same time at extraordinarily high rates in normal blood and tissue samples.

It should be noted that our studies and those of others use the PCR technique, a very powerful method for detecting minute amounts of DNA, but one also prone to false positive results if handling procedures and negative controls are lacking.

To clarify the disparate results we and our colleagues at the Food and Drug Administration organized an international SV-40 working group, including laboratories that had previously detected SV-40, some that had not and some that were new to the field. Fundamental to the international working group study was the development of the study protocol that is included in our written materials. This protocol is the end product of extensive in-depth face-to-face discussions and correspondence. All of the participating laboratories and other collaborating units contributed to the development of its specification.

Three results from the international working group study are of note. First, the PCR assays were highly sensitive and specific in SV-40 positive and negative control specimens respectively. Second, SV-40 DNA was detected reproducibly in zero of 25 fresh frozen, optimally handled mesothelioma tissues. Third, despite what were thought to be adequate safeguards SV-40 DNA contaminated a batch of normal cells in one laboratory and SV-40 DNA contaminated the PCR reagents in a second laboratory. These events illustrate the ease with which a few DNA SV-40 DNA molecules can creep into an experiment and be detected by PCR.

The bottom line of the international working group study is that the SV-40 PCR tests worked well but there was no reproducible detection of SV-40 DNA in mesothelioma. We also evaluated the possibility that SV-40 is circulating in people without cancer. In 166 urine samples from men in Washington, DC, or New York City we compared the prevalence of the two human polyoma viruses, called BK virus and JC virus, to the prevalence of SV-40. We found that 14 percent of these men were excreting BK virus, 34 percent were excreting JC virus and not one was excreting SV-40. Even in people with advanced HIV/AIDS we found no excretion of SV-40. This work and other studies would indicate that SV-40 does not circulate in the general population today.

Our results should be considered in the context of the report of the Immunization Safety Review Committee of the National Academy of Sciences Institute of Medicine [IOM], as included in our written materials. This is as prestigious a body of scientists as can be assembled. Our approaches and findings are wholly consistent with the IOM's conclusions and recommendations which we endorse. IOM concluded, ``that the evidence is inadequate to accept or reject a causal relationship between SV-40 containing polio vaccines and cancer.'' The IOM had five research recommendations that are provided in our written materials and that I will gladly discuss.

To conclude, we remain committed to identifying the causes of cancer. If SV-40 was found to cause human cancer tests could be developed, people could be screened and perhaps even treatments could be improved. However, our work and that of excellent research centers in the United States and Europe currently reveals no association between SV-40 and cancer in people. We do not consider the matter settled, as new technologies could afford new insights. Irrespective of new technology, future studies must adhere strictly to tightly reasoned, stringently defined research protocols. We invite others to replicate the international working group study,

including successful masking and sufficient numbers and types of positive and negative controls.

In sum, on the basis of the available data we do not have evidence that SV-40 causes human cancer. Only through rigorous, disciplined and transparent science will we find the insight and the means to prevent and relieve the suffering of the cancers being considered by the committee today.

That concludes my statement. I'll be pleased to answer any questions.

[The prepared statement of Dr. Goedert follows:]

[GRAPHIC] [TIFF OMITTED] T1047.003

[GRAPHIC] [TIFF OMITTED] T1047.004

[GRAPHIC] [TIFF OMITTED] T1047.005

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[GRAPHIC] [TIFF OMITTED] T1047.020

[GRAPHIC] [TIFF OMITTED] T1047.021

Mr. Burton. Thank you, Dr. Goedert. And, Doctor, can we just rely on you for the answering of questions unless you have something----

Dr. Engels. Yes.

Mr. Burton. OK. Thank you. When did government health agencies first discover that SV-40 was in the polio vaccine supply?

Dr. Goedert. The virus itself was discovered in 1960. And in 1961, Dr. Eddy detected an occurrence of cancer in rodents that were injected with the vaccine preparation.

Mr. Burton. Hamsters I think, wasn't it?

Dr. Goedert. Newborn hamsters.

Mr. Burton. You're saying that there's no proof that the

SV-40 that was in those vaccines has caused cancer? Is that what you're saying?

Dr. Goedert. I'm saying that the issue remains open because essentially the criteria for causality certainly have not been fulfilled in terms of reproducibility, specificity and many other criteria, so I think it remains an open question.

Mr. Burton. You know we've had some real problems with the FDA and other agencies in the past because there's been concern that there's too much influence exerted by pharmaceutical companies on our health agencies, and I'm not saying that's the case with you, Doctor, but it's real troubling because 60 laboratories I understand around the world have done testing and said that the SV-40 is a cause of cancer, and I can't understand how 60 laboratories could be wrong and the FDA be correct.

Can you explain it to me? And these are not fly by nights. These are some leading scientists. Let me give you just a few names, OK? Dr. Carbone. He said that they found SV-40 in a large portion of tumors. Some of the percentages were 60, 63 and 41 percents in three tests. Dr. Cristaudo. He found cancer in--or SV-40 in 72 and 52 percent of the cancers in two tests. Dr. DeLuca. He found 86 percent. Dr. Mayall found 45 percent. However, Dr. Strickler, I guess he worked for you at one time and is now a consultant or does consulting with the FDA, or does he have some relationship with the FDA now?

Dr. Goedert. I'm unfamiliar with him.

Mr. Burton. Who's he with now? Albert Einstein Institute. Does he do any contracting or anything with you?

Dr. Goedert. Dr. Strickler is a former postdoctoral fellow from my branch who is a--I believe an assistant professor at Albert Einstein College of Medicine in New York, and we have until recently collaborated with him on a number of projects subsequent to his departure from our group.

Mr. Burton. Yes, sir. Well, Dr. Strickler evidently has done some research on this, and he showed that in 1996 there was no evidence that the SV-40 was in any tumors and was the cause of these cancers. And in 2001 he said the same thing. Now, how do you account for the fact that your scientist, he was working for you I think at the time, couldn't find any trace of SV-40 tumors when eminent scientists that I just mentioned to you and many others from 60 different laboratories around the world found many cases of its existence? Why is there that inconsistency? Scientists look at, you know, a lot of the same data. I mean your scientist says no and 60 other laboratories say yes and eminent doctors from those laboratories that have done extensive research say yes. Why that inconsistency?

Dr. Goedert. Mr. Chairman, I think reasonable people can disagree, and I'm sure that each individual believes in his or her own data. But the data are contradictory and the field is unsettled. There are 11 studies like ours that find no SV-40. There are four serological; that is, antibody, studies that find no difference between people with cancer and people without cancer. The studies that have found SV-40, not all of them, but many lack the controls and the maskings of specimens that we require to have confidence in our results. Some of the others are internally inconsistent and contradictory and they typically have not been replicated. I mentioned during my opening statement that our own study with nine laboratories had two instances, two events where SV-40 contamination occurred. I think this is the most likely but not the sole explanation for

why SV-40 may be detected but not actually related to the tumor.

Mr. Burton. You know, sometimes our health agencies and even the executive branch and other areas come before our committee and they have what I call selective memory loss or they use terminology that equivocates on an issue, and I know you don't want to do that doctor, but I do want to read something to you.

The institute, the NCI, reassured the medical community over the years that there was no evidence of cancer caused by contaminated polio vaccine. However, in referring to study after study, the Institute of Medicine report of October 2002, just last year, said, ``weaknesses in the study limit its contribution to the causality argument.''

Were the National Cancer Institute's reassurances over the years that polio vaccine did not cause cancer linked to these now discredited studies?

Dr. Goedert. Mr. Chairman, the Institute of Medicine concluded that the data are inconclusive with respect to causality, taking into account all of the available information. Epidemiologic studies are not perfect and it would be more challenging if we had found an association with cancer in a study that was less than ideal.

Mr. Burton. Well, the IOM says that there were weaknesses in the study and it limited its contribution to the causality argument. Now that you know that study has been partial--and those studies have been partially discredited, what is our health agency going to do to try to fix the problem and is there any new research methods that you guys are proposing over there that wouldn't be inherently flawed?

Dr. Goedert. Mr. Chairman, no single study is going to be perfect. We endorse and are following through with the recommendations of the IOM panel. The first recommendation, and we agree it's the most important, is the development of the serological tests that can more clearly define who is likely to be infected and uninfected with this virus. We are working with two university groups on this effort and are following through with the application of a number of different studies.

That said, we have always maintained that the question remains open and we do not say that there is no chance whatsoever that this virus is associated with cancer. We have said that there is no evidence of an excess risk of cancer related to exposure to the contaminated vaccines.

Mr. Burton. Let me ask just a couple more questions and then I'll yield to you and I'll give you as much time as you like. Eminent doctors, three tests by Dr. Carbone, 60, 63 percent and 41 percent of the cancers they looked at had the SV-40; 72 and 50 percent by Dr. Cristaudo; 86 percent by Dr. DeLuca; 45 percent by Dr. Mayall. The IOM report of October 2002 indicates that the biological evidence is strong, strong, that SV-40 is a transforming virus capable of causing cancer. Does the NCI agree with that?

Dr. Goedert. Yes, Mr. Chairman, we do. In animals and in test experiments.

Mr. Burton. In animals?

Dr. Goedert. In hamsters.

Mr. Burton. In hamsters.

Dr. Goedert. Sure.

Mr. Burton. Does the NCI consider a human being an animal?

Dr. Goedert. Mr. Chairman, I'm sorry. Maybe I misunderstood your question.

Mr. Burton. Well, you said in animals they found that there was a causality.

Dr. Goedert. I believe the conclusion----

Mr. Burton. In hamsters you said.

Dr. Goedert. I'm sorry, Mr. Chairman. I'm losing it.

Mr. Burton. No, you said in hamsters that the evidence was strong that the SV-40 was a cause of tumors, and you said in animals. You said the tests in animals. You were being generic instead of saying hamsters. You said tests in animals.

Dr. Goedert. Well, I believe that it's not 100 percent limited to hamsters. I believe there was some lesser evidence in other rodents.

Mr. Burton. Other rodents. OK. But you're talking about animals. Or rodents.

Dr. Goedert. Yes, sir.

Mr. Burton. Are human beings animals? Are we considered animals biologically?

Dr. Goedert. Mr. Chairman, I think that perhaps gets into a little bit of a philosophical question.

Mr. Burton. Well, I'm talking about from a biological standpoint. The point I'm trying to make is this. If it causes tumors and cancers in rodents and hamsters, if you have other eminent scientists around the world saying that it causes tumors and cancers in human beings, if 60 well known laboratories around the world say that they have scientific evidence that caused cancers and the only one that we know that is saying that no, it didn't, there's no evidence of it, is Dr. Strickler, who used to work for you, that would lead one to believe that there's something wrong. Either the same tests aren't being utilized by our health agencies, or else they're not looking at it fairly.

Dr. Goedert. Mr. Chairman, there are 11 studies that have found no SV-40 in those tumors. There are four studies that found no difference in antibody between people with cancer and people without cancer, and the nine laboratories in our studies, none of those were government laboratories, and several of those had previously detected SV-40 and were unable to do so when they met our stringent criteria with respect to the blinding of the specimens and the reproducibility.

Mr. Burton. Well, let me yield to Ms. Watson and I'll get back to you in a minute.

Ms. Watson. Thank you so much, Mr. Chairman. Mr. Chairman, immunizations against infectious disease is undoubtedly one of the greatest achievements of our public health. As a result of universal immunization, many diseases that just decades ago threatened sickness, disability and death to large segments of the world's population are no longer serious threats to the public health. Polio is among the greatest examples. Polio primarily affects children under the age of 3 and results in the paralysis of the limbs and/or the respiratory system.

Today, because of immunizations, we are on the verge of global polio eradication. Just seven nations remain polio endemic, with 99 percent of the cases occurring in India, Nigeria and Pakistan. Only funding shortfalls for the World Health Organization's polio eradication initiation stand in the way of global eradication.

Because of the importance of immunization, it is critical that the safety of our vaccine supply be protected against contamination, whether deliberate or inadvertent. With respect to SV-40 contamination of polio vaccines, the Federal health agencies maintain that SV-40 has not appeared in either

intravenous or polio vaccine after 1963. Because the vaccine in current use is free of SV-40, the Institute of Medicine in a report released last fall stated that it does not recommend a policy review of polio vaccine on the basis of concerns about cancer risk for exposure to SV-40. Our hearts go out to the victims of cancer and their families who have reasons to believe that SV-40 may have contributed to cancer in their cases, and it is important that we learn as much as we can about the risk of SV-40, sources of human exposure to SV-40, and all biological factors that contributed to development of cancer in humans.

What should not get lost in this discussion today is how vitally important it is that all children and adults receive the vaccinations they need to protect them from the serious health consequences of infectious disease. According to the Centers for Disease Control and Prevention, just 65.5 percent of U.S. children ages 19 to 35 months of age receive all of the vaccinations they should. Numerous States lag well behind the national average.

Maintaining the public's trust in the safety and effectiveness of vaccine is a necessary and important objective that requires vigilance by our Federal health agencies. It is unfortunate that we will not hear from the FDA and the CDC and the Institute of Medicine today. Nevertheless, I hope that today's hearing will play a constructive role in the effort to ensure that the public health benefits of immunization can fully be realized and that vaccines are as safe and effective as they can be.

I must apologize for missing the first part of the testimony. But I am concerned about the discussion I've been part of. And that is we have a section of the scientific community saying that SV-40 can contribute to the onset of cancer and we have a segment of the scientific community saying there's no data that concludes that. What I would like to know, Doctor, what steps do you see needed to be taken to implement a research agenda that could prove one way or the other? I think we need to take it out of the realm of guessing and continuing to use it if there is speculation that it is cancer, contributing to the onset of cancer. And the tests that have been taken and that you have noted, were these tests adequate in your opinion? And can they ensure all the public that polio vaccine is free of SV-40?

So can you address what is needed down the pike and how we can ensure the public?

Dr. Goedert. Madam Congresswoman, as I said in my opening remarks, there's two related but scientifically distinct questions. One has to do with the risk of cancer in people who received contaminated polio virus vaccine, and the other is the association of cancer in people with SV-40 with cancer irrespective of how they may have gotten it.

You're posing a third question which has to do with the safety of the current polio virus vaccines. The FDA would be the people most qualified to answer that. I can tell you information that I have from my preparations here is that since 1963 every lot of vaccine has been tested and certified as free of SV-40 and containing no viable SV-40. In addition, using PCR technology, the FDA itself found no SV-40 DNA molecules in lots that were released between 1972 and 1996. Comparable data have been developed by the FDA equivalent in the United Kingdom and in fact even by Dr. Carbone himself, who the chairman mentioned earlier was unable to detect SV-40 DNA in the current lots, at

least current as of when they did them, probably the late 1990's, were unable to detect any trace of SV-40 DNA in those vaccine lots.

With respect to the research agenda, would you like me to address that?

Ms. Watson. Yes, I would, because I'm hearing conflicting information. The Chair read off a group of scientists who came to a different conclusion than the one that you just reiterated. I possibly would like to see a collaborative effort. And so do you have any suggestions as to how we could get on a research agenda where we could combine findings and come to some final conclusion?

Dr. Goedert. Madam Congresswoman, our nine laboratory study which we initiated with the FDA and brought together all of the scientists who had an interest in this field in January 1997 was the--resulted as this SV-40 international working group in which nine laboratories participated, some who had previously detected SV-40, some who had not and some laboratories that were new to the field. This was a very tightly structured endeavor, highly collaborative and some were very unhappy with the result in that those who had previously detected SV-40 were unable to do so in the study that they collaborated in and that we all collaborated in.

We endorsed the research recommendations of the IOM, of which there were five. The second of those has to do with development of sensitive specific and standardized tests for detection of SV-40 DNA. SV-40 DNA PCR is a highly powerful but difficult to standardize procedure and similar issues came up with other PCR assays with previous agents, be it hepatitis C or HIV and the like. The first recommendation was actually this antibody test kind of thing, and we endorse that and we are working with other university laboratories on that. With those technologies, I think that the third and fourth and fifth recommendations can be implemented, which has to do with the evaluation of people and specimens prior to 1955 to evaluate current populations in terms of transmission and to advance the question of the vaccine recipients. And I think the weakness that the chairman was mentioning has to do with the lack of perfection. We can be very highly confident with respect to the exposure of the vaccine recipients, but having a blood test would be helpful.

Ms. Watson. I'm thinking prospectively, and I know that the field of science is always evolving, and I would think 1997's results are not conclusive because we are hearing to the contrary. So what I would like to hear, and maybe you're not prepared to even comment, is how could we plan a research agenda that would use specific serologic tests for SV-40, and maybe you're not prepared to address that. But I would like to see us use probing minds because there's too much, as I would think now, inaccuracies, and too much conflict as it addresses the results of various studies. And so to take it out of the realm of speculation and this confusion, I would like to see you come up with a new research strategy that all of you collaborate on for 2000 and beyond. Well, let's say 2003 and beyond.

If you're not ready to respond to that, I can understand, but I'm throwing out a recommendation. I'm just hearing from too many people. I understand there are some parents that either have testified or will testify and I think as scientists we ought to continue to research so that we could once and for all make conclusions that will hold.

Thank you, Mr. Chairman.

Mr. Burton. Let me just followup. What I would like to do because we're going to be running short of time. We're going to have more votes. Could we submit to you questions for the record to be answered by you and sent back so we can review them?

Dr. Goedert. Certainly.

Mr. Burton. OK. Well, then we'll do that. Let me just ask, followup on what the Congresswoman just said. You know, there were 60 laboratories that conducted tests that showed a contrary result. We have scientists around the world, eminent scientists that disagree with the results that you folks base your findings on, and many of these scientists are every bit as eminent if not more eminent than Dr. Strickler--is it Strickler or Stricker? Stricker I guess it is--who as I stated earlier was working for you. When you're following up on what Representative Watson suggested, would it be possible for you to contact those scientific laboratories and those scientists who had contrary results to take a look at their findings to find out if there's something that you missed, and we would be very happy to give you the names of those laboratories as well as the scientists involved so that you wouldn't rely just on what you folks found, but also what these other laboratories and eminent scientists found. Would you be willing to do that?

Dr. Goedert. Certainly, Mr. Chairman. The nine laboratory study that we did included laboratories, the preeminent ones that had previously found positive results. They did not when they----

Mr. Burton. You said nine. There were 60. How come you didn't talk to the other 51?

Dr. Goedert. Well, some--I'll be happy to if you send me the names of the other ones.

Mr. Burton. We'll send that to you.

And the other things I'd just like to conclude with is that many Congressmen and Congresswomen--and I'm not speaking for Congresswoman Watson, I'm speaking for myself--are a little bit suspicious of some of the results of tests and other things that we've seen coming out of FDA and HHS, and I'm not pointing this at you, Doctor, or Doctors. But we have seen the results that came back that show results that are unbelievable. And we've been stonewalled on other issues where there might be lawsuits filed against pharmaceutical companies that have had research projects that have worked with, I think, with our health agencies. And so we're just a little bit suspicious of those things. That's why when we hear these results, and I hope you--if you wouldn't mind, I hope you'll stick around a little bit and hear some of the information from these parents and other scientists. I think Dr. Gazdar is here, I think he's going to testify. I think he was on the other side of this issue at one time. I wish you could just listen to what they have to say and maybe that would illuminate the issue a little bit more and maybe help in getting to the bottom of this.

Dr. Goedert. I'll be happy to do whatever I can.

Mr. Burton. Thank you sir, very much. Any other comments?

Ms. Watson. Just before you step away from this panel I would just like to thank you for being here, and I want all of you to keep your minds open and I think that our environment, and I'm talking about comprehensive environment, is so full today with contaminants. It indeed is affecting our health to the point that there are new mutations and I'm concerned about this. More people are coming up with cancer, and we must look

at everything that we spray into our environment, that we put on our soil, that we ingest, that we use intravenously.

And so I don't want closed minds. We can't depend on research that was done years ago. We must think about our future and what we might contribute to it. So I would hope that you would agree just to keep flexible and we certainly understand and we know the shortfalls of money and we know where our focus is. But we would support you in coming up with a strategy for new studies. We will give you guidance and direction, I'm sure from the standpoint of this committee, as to what we'd like to see. And we'll even work for the funding. So blue sky, if you will. I used to say that to bureaucrats. You know, if you had all that you needed, what would you like? And I tell you they were in such little tight boxes they couldn't even--blue sky. So we're giving you such opportunity with our support to take another look and work in a collaborative way to save our people and particularly our children.

Thank you so much.

Mr. Burton. We will get you the names of the laboratories and the names of these other eminent scientists who have differing views and hopefully you can followup with them and cross-check their results with the results you've had and maybe additional studies, as Representative Watson suggested, would be done to make sure that we get to the bottom of this. In any event, I hope you'll stick around just a little bit and hear what these other folks have to say. It might be illuminating. Thank you very much.

Our next panel is my good friend Barbara Loe Fisher. She's the cofounder and president of the National Vaccine Information Center. Ms Eileen Grabinski, she's the mother of an injured child. Mr. Stanley Kops, he's an attorney from Pennsylvania, and Dr. Gazdar, whom I mentioned a few moments ago, who's a therapeutic oncology professor, I guess professor, at the University of Texas Southwestern Oncology in Dallas.

Would you all please stand and raise your right hands?

[Witnesses sworn.]

Mr. Burton. As I said to the first panel, because we are going to have a whole bunch of votes I would like to try to keep the testimony to 5 minutes for each one of you so we can get to the questions, which I think might be a little bit more illuminating, and let's just go right down the line.

OK, we'll start with Ms. Fisher. I don't know what the reason is for that but evidently you have more influence with John than anybody else. Go ahead.

STATEMENTS OF BARBARA LOE FISHER, PRESIDENT, NATIONAL VACCINE INFORMATION CENTER; EILEEN GRABINSKI, MOTHER OF AN INJURED CHILD; STANLEY P. KOPS, ESQ., ATTORNEY AT LAW; AND ADI GAZDAR, PH.D., UNIVERSITY OF TEXAS SOUTHWESTERN ONCOLOGY, HAMON CENTER FOR THERAPEUTIC ONCOLOGY

Ms. Fisher. My name is Barbara Loe Fisher. I'm the mother of a DPT vaccine injured son and cofounder and president of the National Vaccine Information Center. I've spent the last 21 years working with other participants to prevent vaccine injuries and deaths through public education.

The story you're 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

dying from cancerous tumors that contain a monkey virus which appears to have contaminated that polio vaccine. At the heart of this story is a violation of the public trust and the informed consent ethic.

I began speaking and writing about monkey virus contamination of polio vaccines 10 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. Between 1994 and 1997 I submitted several Freedom of Information Act requests to the government regarding testing of certain lots of oral polio vaccine for monkey virus contamination. It was in 1960 that a 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 SV-40, or Simian Virus 40, the 40th monkey virus to be discovered. Sadly, though, the American people were not told the truth about this in 1960. The SV-40 contaminated stocks of Salk polo 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.

At a conference on SV-40 and human cancers held by the National Institutes of Health in 1997 there was no disagreement among both government and nongovernment scientists about this fact. The only disagreement was whether SV-40 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. Nongovernment scientists working in independent labs around the world said yes. But the scientists connected with the U.S. Government said no.

As you have already pointed out, Mr. Chairman, the Institute of Medicine and highly credentialed nongovernment scientists in multiple labs around the world continue to identify SV-40 in human brain and lung cancers of children and adults and are finding that SV-40 is also associated with bone cancers and non-Hodgkins lymphomas. The majority of these independent scientists have concluded that, yes, SV-40 does cause human cancers.

Up until this hearing to date the world scientific community has assumed that the only polio vaccine that was contaminated with SV-40 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 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 SV-40 infected rhesus monkey kidney tissues after 1963 the oral polio vaccine was made using African Green monkeys, which are rarely infected with SV-40. The vaccine manufacturer and government officials have insisted that the switch from rhesus monkeys to African Green as well as testing protocols to detect SV-40 prevented SV-40 from contaminating oral polio vaccine after 1963.

However, you will be presented with evidence today that suggests, one, the original seed stocks of oral polio vaccine were made using the rhesus monkey and were contaminated with SV-40; two, the major oral polio vaccine manufacturer did not adequately test their master seed stocks which reportedly contained SV-40 but used them to produce vaccine released for

use by American children from the 1960's through the 1990's; and, three, Federal regulatory agencies either did not know or knew and did not do anything about evidence that SV-40 contaminated oral polio vaccine was released for use by the public from the 1960's to the 1990's.

If SV-40 contaminated rhesus monkeys were used to produce original oral polio vaccine 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 SV-40 does cause human brain, lung and bone cancers, then this could explain why children today, who were not born before 1963 and never got SV-40 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 SV-40 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 did not enforce the rules.

Since 1999, the United States has discontinued use of the live oral polio vaccine and American children are now getting a killed vaccine that is reportedly SV-40 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 the cancer causing monkey virus and that the vaccine manufacturer knew it and government health agencies looked the other way?

It is important because if it's 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 ensure that the vaccines do not contain animal viruses or other contaminants.

I've just ended a 4-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 the government. But 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 ensure the safety of vaccines are good enough.

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 and 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 the use of cancer cells to produce vaccines since 1954. But active consideration is now being given to lift that ban despite the acknowledged risks of contamination with adventitious agents, including residual DNA

and RNA.

There is frank admission that the limitations of technology and lack of scientific knowledge means there can be no guarantee that vaccines will not be contaminated with substances that could prove harmful to humans 1 day. Nevertheless, there are discussions about creating allowable thresholds for adventitious agent contamination of vaccines being made out of cancer cells that could contain residual DNA and RNA.

I don't 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.

Mr. Burton. Ms. Fisher.

Ms. Fisher. I know. I'll wrap up here.

Mr. Burton. Well, you can submit the rest of it for the record, but what I'd like to say is that those hearings that you were a part of----

Ms. Fisher. I was on the committee.

Mr. Burton. I would like for you to give us copies of those transcripts if you could.

Ms. Fisher. I have.

Mr. Burton. OK. And with that can you submit the rest of it for the record?

Ms. Fisher. I will. I just would like to thank you Chairman Burton for everything you've done to hold these hearings in the past 2 years, so that we can have a safer vaccine system.

[The prepared statement of Ms. Fisher follows:]

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Mr. Burton. Thank you very much.

Ms. Grabinski.

Ms. Grabinski. Hi. How you doing?

Mr. Burton. You have a child that you feel has been damaged by the vaccine?

Ms. Grabinski. Yes, I do and I brought him with me. He's sitting in the wheelchair there.

Mr. Burton. Your son's in the wheelchair over there?

Ms. Grabinski. Yes.

Mr. Burton. OK. Thank you. Mark. OK.

Ms. Grabinski. Right. His name is Mark Marino.

Mark was beautiful, healthy baby when he was born. He was growing up normally the way you would expect any normal child to grow up. He wasn't any different than my son Joe. He received routine care that babies get, including his vaccinations with the oral polio vaccine known as trivalent. Shortly before Mark's tumor was found by the doctor he was not acting right and I knew something was wrong.

Marks' tumor turned out to be a rare tumor. His hospital stays were nightmares every time he had to stay for surgery. We always had it in our minds he would never come out alive because the doctors told us it was a rare tumor. Mark had to have part of his skull removed to save his life, and now he has to wear a helmet every day for the rest of his life.

When Mark was born and when tests were done to see his intelligence, they were pretty good but after his operations they deteriorated and now he has limited ability. This limitation lasted from age 5 to now. When he was 5 I was told he was functioning somewhere between 3 and 5 years old. Nothing has changed since then.

Mark loves to paint, draw and to go out with other people, but we cannot go out often because he is in danger of having epileptic occurrence. Since the first surgery Mark has been a toddler. He never grew up. He rarely participates in family functions and when he does he has to be constantly supervised.

I try to keep him busy because he's with me 24 hours a day. He can do simple chores. He can mix the salads for dinner, sweep the kitchen floor on his knees. He thinks he cleaned the whole house. He can put away the cans after shopping. He's so proud of himself after he does the chores it's the biggest thrill of the day for him. He talks to his stuffed animals. They are his friends who he can count on being there for him every day. He takes them almost everywhere he goes.

He watches TV, but only cartoons. In his mind he believes that 1 day he will be in a cartoon. He gives his painting and coloring pages to people he meets to show them he loves them and he thinks they love him also. You know they love him back. He paints rocks and sea shells or anything that he can paint gold. The pirates in his cartoons hunt for gold, so he hunts for gold. The only difference is he gives his gold away.

He says his prayers at night and has a picture of God on his wall. He knows that God is his friend and the only one who can help him. And he never loses his faith. He is convinced that God hears him and will help him. We have to learn every day how to cope with every aspect of his life.

I have never been bitter about my son's condition until recently. Because I cannot go out a lot, I spend a lot of time on the Internet. On one of the Internet searches, I found out about there was an issue of SV-40 and childhood tumors. Eventually I found out that Mark's tumorous material was available at the hospital where he was treated. The materials were tested, and I was advised that the SV-40 was found in his tumor. What I thought was an act of God I know now was what--I'm sorry, I'm a little nervous--I now learned was an act of man.

I am not a scientist or a lawyer; I'm just a mother, and I feel cheated and robbed out of my life, my son's life, our entire family's life by someone who'd use a childhood vaccine in an unsafe manner and allow my child, along with many other

children, to be exposed to this virus. I can only hope that Mark's prayers to God will be answered by the scientists and maybe there is something that can be done to reverse his condition.

My reason for testifying here today is for two reasons: to tell the story of my brave son and to ask Congress to do whatever is necessary to protect children like my son from ever having to face what he has faced and from what our entire family has faced.

Thank you.

Mr. Burton. Thank you, Ms. Grabinski. And I don't think there is anything that we could say that will help the situation, but you have our prayers and our gratitude for what you go through.

Ms. Grabinski. Thank you.

Mr. Burton. Mr. Kops.

Mr. Kops. Good afternoon.

I have represented and still represent individuals who have suffered injuries from the Orimune oral polio vaccine that was utilized in the United States from 1962 until 1999 when Orimune vaccine, oral vaccine, could no longer be sold in the United States for immunizations.

The history of this negligence of both the vaccine manufacturer and the government can be found in reported decisions. The Supreme Court in 1988 in a unanimous decision written by Justice Marshall, found that if the vaccine manufacturer and/or the regulator failed to look at the test results and failed to determine what those test results showed, the government did not have any permission to do so. They did not have the discretion to avoid that review. In fact, at oral argument, I believe it was Justice Scalia who asked the following question of the Solicitor General: Supposing the government did not make any examination of the application at all, or any determination other than some papers have been filed and now we will issue a license; would this comply with the regulatory system?

Counsel for the government: No, it would not comply with the regulation.

Question from Justice Scalia, I believe: It would violate a mandatory duty wouldn't it?

Counsel: In that extreme instance you are talking about, it would definitely violate the regulations.

That could be found both in the transcript of oral argument and at footnote 10 to the opinion.

What I am here to testify today is that's exactly what happened. They did not look, the regulators, and the vaccine manufacturer did not submit test results. This is a white-and-black situation. Either the test results exist and they can be produced, or they do not exist because they were either not performed or performed and the results were so horrendous that they would rather not submit the test results than submit those that prove the exact points that this committee is investigating.

There are three types of wild polio. Therefore, there was a need to create three different vaccines. The IPV, the killed vaccine, was always a trivalent product. As to the oral polio vaccine, they were first made as individual monovalent pools and then later combined as a trivalent vaccine.

Between 1964 and 1967, a single manufacturer in this country, Wyeth-Lederle had 84 percent of this market. In 1977 it had 100 percent of the market. Up until today, no scientist

has had the complete data to challenge the assertions made by scientists and by the vaccine manufacturer. In fact, I heard today in the testimony of the head of the NIH cancer epidemiology session that all vaccines after 1963 did not contain SV-40. That is just wrong. They did contain SV-40 because there are test results that I have, which now the committee has, that show the positive vacuolating agent in released product. Those were the test results that were shown to the IOM, the Institutes of Medicine.

I have been lucky to have had the honor to represent people like Eileen and Mark and others, and during that representation when it was only about polio, I was given the actual test results of various products which show that they were positive for SV-40. You could see that in exhibit 21. The use of Rhesus monkeys, something that this vaccine manufacturer guaranteed the entire scientific world that it never used in manufacture, is in fact exactly what they used.

If you look at exhibit No. 11, there is a released monovalent pool of this manufacturer. It shows that the monkeys utilized were Rhesus. It shows in a subsequent exhibit, No. 13, that on January 15, 1990, American Cyanamid requested from the regulators permission to release five monovalent pools, all made in Rhesus monkeys. The pool numbers 263, 265, 283, 501, and 509. I see I'm over my time so----

Mr. Burton. Can we get into this a little bit more, Mr. Kops, in the question section?

Mr. Kops. Certainly.

Mr. Burton. This is a pretty voluminous bit of information you sent from Lederle Laboratories, and I think we're going to have to digest this over a period of time, but we have some questions we'd like to ask you about that.

[The prepared statement of Mr. Kops follows:]

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Mr. Burton. Dr. Gazdar.

Mr. Gazdar. Mr. Chairman, members of the committee, I welcome this opportunity to address you on the subject of SV-40 contamination of the polio vaccine and the role of the virus in the causation of human cancers. I've spent more than 35 years my entire professional life studying the cause of human cancers. Twenty-three of those years were spent at the National Cancer Institute.

As you have heard, several reports from laboratories around the world have demonstrated the presence of footprints of SV-40 virus in a certain select group of human tumors. You've also heard that approximately 10 percent of these reports have been negative. The virus has been associated with four types of human tumors, approximately 40 to 50 percent of these four types. These four types are brain tumors, bone tumors, mesotheliomas, and lymphomas. Three of these are very rare or relatively rare tumors; however the incidence has been increasing. Of great interest, injection of the virus into hamsters results in an identical tumor spectrum.

It defies belief that this is a coincidence that three of these rare tumors are caused by injection of the virus into hamsters and the same rare tumors in humans have also been associated with this virus. I estimate from published data that approximately 113,000 Americans will suffer from these tumors this year and 64,000 will die from their disease. Thus, approximately 50,000 tumors that occur in this country this year will contain evidence of the virus in their tumor tissues.

SV-40 is one of the most potent cancer-causing agents discovered for human cells. It's--because of--perhaps it's the most potent transforming agent, cancer-causing agent for human cells. It is widely used in laboratories, raising the spectrum that it may--its presence in human tumors is due to laboratory contamination. I was highly skeptical of the reports, and finally I decided I had the tools to investigate and, what I thought, settle the matter.

Using a technique of microsection, taking single glass slides of tumor and adjacent nonmalignant tissue, I could selectively remove the tumor cells from that glass slide as well as the nonmalignant tissues from the very same slide and analyze these independently. To my amazement, I found the virus in approximately 50 percent of human mesotheliomas and its almost complete absence in adjacent nonmalignant tissues. These experiments, in my opinion, ruled out the possibility of contamination of laboratory artifact.

I went from a skeptic to a believer. My assessment was supported by a review conducted by a panel of scientists of the National Cancer Institute chaired by Dr. Pagano and May Wong. This panel concluded that it is proven that SV-40 is present in some human tumors, and it ruled out the possibility that these were caused by laboratory artifacts. An international meeting of scientists, 80-odd scientists, held in Chicago in 2001 and chaired by two eminent scientists who never worked in this field, came to the same conclusions.

However, the presence of virus in the cancer does not prove causation because the virus may be an innocent bystander or it may be one of the causes of the tumor. To link a given agent

with the cancer, one relies on both epidemiology and molecular tests demonstrating not only the presence of virus but some effect of it. The epidemiology studies, as you've heard and the Institute of Medicine has investigated, have been flawed. They're flawed because we cannot identify in these studies which subjects receive vaccination in the years under study. Also, we don't know which batches of virus were contaminated, whether the batches contained high marks of virus or low marks of virus.

For these reasons, the Institute of Medicine has declared that all epidemiology studies have been flawed and, in fact, suggest that no further epidemiology studies be performed until these deficiencies can be corrected. They did conclude that the biological evidence is strong that SV-40 is a cancer-causing virus and that the biologic evidence is of moderate strength that SV-40 exposure could lead to cancer in humans under natural conditions.

Recent molecular studies from my laboratory have convincingly demonstrated that the virus-positive tumors have different biologic properties than similar tumors that lack the virus. These studies I believe demonstrate that the virus is not just a bystander in these tumors but is having an important biologic effect, in all likelihood contributing to the causation of these tumors.

Why have we failed to make greater progress in this field? Why are we sitting here before this committee arguing whether this virus plays a role in cancer or not? It is because we have failed to make--to make progress because of a complete lack of funding, because of lack of direction from our government agencies to fund these very important issues.

Never once has the National Cancer Institute and National Institutes of Health issued a request for proposals that specifically address these issues. This lack of major funding has hampered progress and needs to be addressed. And I thank you for this opportunity.

[The prepared statement of Mr. Gazdar follows:]

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Mr. Burton. You say there's no funding done to followup and to really study this issue?

Mr. Gazdar. There's been no targeted funding. There's been a very minimal amount of funding to a handful of investigators.

Mr. Burton. That raises the issue of whether or not the pharmaceutical companies, Lederle that produced these vaccines that may have caused these cancers, doesn't want that explored because of the possible liability that might ensue from lawsuits. And I think Mr. Kops is probably familiar with that since you were involved in litigation.

What paper were you talking about there?

There was a study, a paper on the absence of Simian Virus 40 in human brain tumors from northern India and that paper states, ``Our results do not support a role for SV-40 in human brain tumors in northern India.'' And as I understand it, several of the people that supported that study, five of the co-authors of that paper have disassociated themselves from that. And is that correct and why would they do that?

Mr. Gazdar. I believe you are perhaps talking about the

study that Dr. Goedert talked about, the multi-lab study. Those--that----

Mr. Burton. That's not the India study?

Mr. Gazdar. No.

Mr. Burton. Is this the one that Dr. Simpson was involved in?

Mr. Gazdar. Strickler.

Mr. Burton. Strickler.

Mr. Gazdar. He's been involved--I'm not sure he was involved in the Indian study. Dr. Engels, who was here, was the lead author on the Indian study. He can address that issue. But it's the multi-laboratory study that Dr. Goedert spoke about which has been attacked as flawed--being highly flawed in both public and in writing, and several members of that nine-lab panel have withdrawn their association because they felt----

Mr. Burton. Of the nine people, five have withdrawn their names as I understand it.

Mr. Gazdar. I'm not sure of the exact number.

Mr. Burton. Dr. Lednicky, Butel, Gisani, Jones, and Gibbs. Does that happen very often?

Mr. Gazdar. Not to my knowledge.

Mr. Burton. It's highly unusual, isn't it?

Mr. Gazdar. That study took several years to get written up and published, partly because the members of that committee could not agree on the study design, how it was carried out, on the interpretation, etc.

Mr. Burton. But you believed after, Doctor, and you say you were very skeptical at the outset on whether or not this SV-40 virus was a possible cause of tumors and cancers in people. Your attitude has changed dramatically since you actually did all this study yourself?

Mr. Gazdar. That's right. In fact I call myself a skeptic, but frankly I simply could not believe that a monkey was suddenly turning up these rare human tumors.

Mr. Burton. But now you believe that it can?

Mr. Gazdar. I am firmly convinced that it not only is that but it's playing a role in the causation of tumors.

Mr. Burton. It's causing tumors?

Mr. Gazdar. Yes.

Mr. Burton. What do you think we ought to do as a Congress to deal with this problem if our health agencies continue to stonewall and say we've had all kinds of tests and nothing shows up and eminent scientists have said no and there's just nothing to it? What would you suggest we do?

Mr. Gazdar. I feel you have a part to persuade our government agencies to take a more proactive role in this issue and certainly to supply targeted funding to settle the issues. Three different committees, one convened by the NIH, by the Institute of Medicine, and this international meeting I mentioned in Chicago, have all recommended greatly increased funding to settle not only these issues but to develop new methodologies so some of our deficiencies can be corrected.

Mr. Burton. Do we have copies of those?

We'll take a look at those and we'll write a letter to our health leaders urging them to follow that and to do that funding. But I will tell you I am convinced that our pharmaceutical companies have undue influence over our health agencies because of the liability exposure, and you can bet your bottom dollar that there will be every reason thrown up against us to try to stop us from getting to the bottom of this. Because we've had other cases--Ms. Watson and I have had

cases involving mercury in vaccines, and the amount of opposition that's thrown up because of the possibility of lawsuits is just phenomenal. But what I'd like to do is have from you any recommendations that you can make so that we can submit those to HHS, FDA, and CDC to try to get them to fund that, and we'll try to keep the pressure on them to make sure that happens.

Mr. Gazdar. I'll be glad to do that, Mr. Chairman.

Mr. Burton. Mr. Kops, you had a lawsuit that evidently did not prevail. Can you tell us a little bit about that and what happened?

Mr. Kops. Yes. That is a lawsuit involving a young boy who died at the age of 2. Dr. Gazdar testified in that lawsuit unequivocally that the child died from SV-40. The court had a hearing to determine whether or not there was evidence, sufficient evidence given by Dr. John Lednicky, one of the world famous scientists who is one of the scientists that the chairman has quoted from, testify that he too was under the medical certainty that this boy died from SV-40. The problem was could we prove that the given dose that this child received from an individual fill was SV-40 contaminated? We proved that the monovalent harvest were positive, positive for an adventitious agent. When the drug company reported it to the government, they said, We know what that adventitious agent is, it's a phony virus, not SV-40. Of course, they forgot to produce nine other tests which proved it couldn't possibly have been a phony agent. But the judge, hearing the arguments made by the lawyers for the drug company claiming that Dr. Lednicky's opinion was faulty because he did not do a test on the same trivalent product, therefore he would not accept his testimony.

I believe the judge was wrong. The method that this doctor used, world famous, was the identical method that the drug company uses to determine the presence or absence of SV-40. Also, the court failed to take into consideration the fact that other monovalent pools failed for specifically SV-40 and were released. The test results show it there, and the product goes out the door.

Mr. Burton. Can we get a summary of that case from you with the relevant aspects of it so that we can take a hard look at that as well?

Mr. Kops. Yes, I will be happy to do so.

Mr. Burton. Ms. Grabinski, I think your testimony was sufficient, so we won't ask you any questions.

And Ms. Fisher, you and I will talk privately later because you know we work on this.

Ms. Watson.

Ms. Watson. I just want to associate myself with something that the Chair said. I'm sitting here right now and I have a ring on, supposedly gold, and I'm having a reaction in my mouth because I have mercury amalgams, Mr. Chair, in my mouth and I'm going through the process of having them removed. It's quite a long process. I have to go out of the country to have it done, and I've already made two visits. I have four more to go.

The reason why I mentioned that is because mercury in your system, I don't care what the ADA says, is a contaminant and places those who have it at tremendous risk. I am intent on getting back to the bottom of this thing, and I do have a piece of legislation that the Chair has so kindly co-sponsored with me, and we expect to be successful.

I want to continue to take a look at those kinds of toxic

materials, fluids, substances, particles or whatever that we put into the human body. Now, the question was raised do we consider ourselves to be animals? Well, biologically, physiologically, there's an answer to that. We test on animals and apply those tests to humans. So I am absolutely 100 percent committed to further research because I do think there is a connection, Mrs.----

Ms. Grabinski. Grabinski.

Ms. Watson [continuing]. Grabinski, to your son's current condition and something that went into his system. I see more and more of that. My background is as a school psychologist. I had to test youth, and I can tell you we keep a record of inoculations. We keep a record of those who are in special education. I tested them to establish an IQ, make recommendations. So I'm a continuing researcher. I mean I've been in politics, took a different direction, but I'm hoping to continue that as we struggle to find the truth.

And so my question to you, Mr. Kops, is as you represent the parents and the victims, have you been able to establish legally a course of action that we can take? And I have had various industries in front of my committee when I was in the Senate because we found that silicone in breast transplants indeed were harmful to many women's health. We found also, and it was in the early 1980's, that the testing on breast cancer was done on men. How ridiculous. And so there's a continuing evolution that I mentioned. And so we had to go to court and we put companies out of business because the jury found on behalf of the victims. And we had to--we took case law and then we made it into legislative policies, and I want you to know from the cases you've had--I want to know from the cases you've had where do you see us going with this.

Mr. Kops. Well, I've had two different types of cases, one where the individual received the polio vaccine themselves and became paralyzed, and where their parents changed a child's diaper and became paralyzed. Those cases ended up in the Berkovitz and Sabin cases where the court held that the regulator did not enforce the regulations and the vaccine manufacturer, the same one, did not comply with the regulations.

As to the cancer issue, the problem is that no one has gone back and looked at the records. I have said in a published peer-reviewed article that appeared in the year 2000 that there are no test records. Dr. Engel was at a conference or a hearing at the IOM and he asked me a question. I was one of the people who were allowed to present a power point. He said, ``Do you mean to say that all the epidemiological studies that we have conducted up to now are flawed?'' I said, ``Absolutely. Just go back and look at the records. You will see positive proof that SV-40 was not removed from the seeds, was not removed from the product, and released product contained the vacuolating agent SV-40.'' I offered to send Dr. Engels this material after the hearing.

I can tell you as of this day I have not received a request from Dr. Engels for that material, but it's now before this committee, some of it.

Mr. Burton. You know, you hate to point fingers at any individuals because government service is a real high calling as far as I'm concerned, and most times they're not paid enough and they work long hours and they do a lot of work that the people on the street don't know about. But, you know, when our health agencies stonewall Members of Congress and keep us from

getting information, it sure raises a lot of questions.

You know, this Dr. Strickler, he--one of the favored labs that he uses for the tests that he does is funded in large part and does a lot of work with Merck, Pfizer, and Wyeth, and while that doesn't apparently look like a conflict of interest, it certainly does raise some questions.

So, you know, I don't know that we can conclude a lot more from this hearing today, but what I'd like to do is have our staff contact you and get as much information as possible and we will followup on this and we will have more hearings on this, I promise you, and we will try to get from our health agencies information that they say does not exist or is hidden in the archives someplace. And we will be prepared to, if necessary, issue subpoenas to get that information.

Mr. Kops. Thank you very much, sir.

Mr. Burton. Do you have any final comments before we adjourn? Any additional information that you have, be sure to get that to us.

Mr. Kops. I have submitted a written document which contains much more information and I would ask that it would become part of the record.

Mr. Burton. Without objection, so ordered.

And we will take a hard look at this and probably get back to all of you before long.

Mr. Kops. Thank you very much.

Mr. Burton. Thank you very much. We stand adjourned.

[Whereupon, at 4:01 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

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