Q Campaigns took force. The government had special committees for surveyance of the administration and ultimate effect of the vaccine, and I wonder if you would address yourself to some of the attendant problems that came out of this advance.

A There was actually one basic committee involved. I guess it was the surgeon's general's committee which was operating through the center for disease control of then called the communicable disease center in Atlanta and there were people assigned in the various states in which mass vaccination campaigns were occurring to follow what was happening after the administration of the vaccine and the paralytic cases that were occurring. And, it was clear that when used in the face of an epidemic that you obviously had to expect cases of paralytic polio to occur in those who received the vaccine because you knew that many people were already infected in the epidemic by the time they got the vaccine because there were certain criteria that had to be established. But the big problem and the reasonable problem that this committee faced, and I was a member of this committee, was to decide which cases of paralysis that occurred let's say within four to five days after the administration of the vaccine and again there were discussions of what the period should be in let's say, the subsequent thirty days. Could be or would be considered concurrent or perhaps could have been caused by the vaccine itself and that required frequent
meetings, analysis of data reported in different states, and it so happened that there were a certain number reported. Of course the same thing occurred every year when Salk vaccine was being used very extensively because very soon after mass vaccination came into being the use of Salk vaccine in the United States almost came to a halt but the criteria that were used for Salk vaccine association were not used for live polio virus association. There was all kinds of language that you couldn't say that just because something occurred after vaccine was administered that it was caused by the vaccine. But nevertheless the impression was that well there is certainly a probability and that you had to consider epidemiological factors that you couldn't decide in any one case whether it was or was not. Now, in the case of the Salk vaccine as I documented in one of my dissenting opinions there were some hundreds of cases that occurred within thirty days after administration of Salk vaccine and some occurred first in the inoculated arm. And it was assumed and the statements was always made by the public health service that because it was said now if you make any qualifying statements you are going to interfere with the acceptance of the vaccine and that will prevent the elimination or coming down on the paralytic polio itself. So there was a great hesitation to be critical. You see it is Basil O'Connor had a very strong influence and there is a certain justice to that. There is a fine balance between warning the public of a possible risk and having the vaccine accepted sufficiently--any vaccine--to produce the overall public
health impact that you were looking for. And then of course the Salk vaccine had the horrible situation of the Cutter Incident in which because of the premature and too heavy pressure the vaccine was used which produced paralysis itself. It could be proved to produce paralysis in I forget what the ultimate number was over a 100 persons. But then it was tacitly assumed that with sort of making a little stricter the controls that what happened in the Cutter incident was finished. That now it was killed, killed, killed. And this is still being repeated. It is a killed vaccine. Therefore it cannot produce polio but that is not true because in the curve of inactivation by any chemical you have a place where a certain small proportion of virus particles remain uninactivated. And you may never detect it if you use ten monkeys or twenty monkeys or fifty monkeys inoculated directly in the brain. But if you use a million people you will detect it. And particularly when you use the most highly virulent strains for making the killed virus vaccine as was done with the Salk virus vaccine. There was still a high probability and in my judgment that what happened in the Cutter incident was an iceberg that was sticking way out and later on what happened was that much of the iceberg was submerged and it was still occurring. Yet, the public health service never raised any question that cases that happened particularly within a week or ten days or something like that, started paralysis in the arm was caused by the Salk vaccine. However, with the live virus vaccine not only were there questions of diagnosis because in the
first place not everything that is paralysis is necessarily polio. And not everything that is clinically paralytic poliomyelitis is caused by polio. And not everything that is caused let's say by polio virus is necessarily the type which you have to isolate at the time from the intestinal tract. And for many of the cases no polio virus was isolated at all. But the specimens that were being obtained were not always good. So there were really very difficult problems for the committee to establish. And at one point in the situation because the types were given separately at the time: First type 1, then type 3, then type 2. There was a predominance what appeared to be a predominance, and they were small numbers of type 3 cases so called. Not type 3 cases but after the administration of type 3 vaccine. Some of those cases later on turned out not to be polio. The viruses that were isolated after administration of a dose of type 3 vaccine as they were tested for neural virulence in monkeys by the division of biologic standards itself was they were not virulent viruses. And if you would go out on the street and take a thousand persons who had been fed type 3 vaccine we know from the studies on the volunteers at Chillicothe, even if they are already had previous natural infection that some of them would excrete virus. In other words if somebody had a traffic accident and you would test them within a month, maybe six weeks, after he had had a dose of type 3 vaccine, you would isolate type 3 vaccine from it because they even multiply more than the others and for a longer period. So, there were many instances where you isolated type 3 but it was of course an attenuated strain
but no attention was paid to that. And the thing was that epidemiologically it was perhaps more than type 1. Of course in retrospect now it is very evident that we were dealing with a period when paralytic strains were still spreading. Let's take now the real polios that were occurring and that sometimes, let's say the type 1 could cause the disease. The infection, the original infection, but by the time the patient developed paralysis let's say ten days later, and he had had a dose of type 3 vaccine five days before, the virus which you found in his intestinal tract was type 3. It was not the one that infected him. But there were ways of detecting this. Some of these things we learned in methods in preliminary studies. At any rate, there developed a situation in which it was thought perhaps the risk of type 3 was too great in certain age groups. So, there were judgements made that there is a certain risk and the risk is greater with type 3. And it just so happened that with trivalent vaccine that was used in Canada, and there were some cases, again, of type 3 virus isolated and when you gave trivalent type 3 is the dominant one. So there were problems of stopping it and then starting again. But as we have seen now those were basically problems connected with a situation in which the viruses were still spreading. You had not yet eliminated it and you will see in one of my papers which you can consult on that in which I analyze each and every case separately. There were patients that were put down as having been caused by the attenuated virus vaccine who had had five doses of Salk vaccine before.
You see, and the probability of it being actually a case of paralytic polio was very very slim. And then there were also simultaneously cases that occurred in some, in Michigan still in the early stages that had gotten Salk vaccine that were discounted. It was a very difficult period. As a matter of fact there was a different committee then appointed. I forget whether it was by the Academy of Pediatrics separately to go over--are these cases paralytic polio. Many of the people on the committee were not clinicians. They were not trained in the clinic. And I remember taking certain cases and discussing it with Dr. Aring who was then president incidentally of the American Neurological Association, and there was one case particularly which the whole committee said this was polio. We said, I said it wasn't polio. I took it blindly to Aring and I said you tell me as a clinician, would you make a diagnosis of polio on this. And he said no. And a year later that case turned out to be a multiple sclerosis. There were all of these difficulties in the early stages which now once paralytic polio has been eliminated. I mean the paralyzing strains, there is no evidence that type 3 is any different from any other strains.

Q What I find interesting about this period is the fact that really good, very good virologists were taken aback by what they called the associated cases with--.

A It is quite natural. You see this is unlike any other vaccine and I think this is perhaps just what had to be done as I look back on it this way. But, what we can see now in retrospect is that it was irrational. And the probability
judgements were incorrect. And the so called epidemiologic guidelines fell down as they often do. And when one, when I analysed them case by case as I did at that time, that that held up better than the so called epidemiologic association. Now, is it possible that once in five million or in ten million or whatever, something like this may happen. Well, it is hard to say. I don't see how immunologically compromised persons can really change the situation in the intestinal tract. But nevertheless, with all the things and whatever uncertainties remained, and the estimate of a potential not possible but potential risk are now so miniscule that at a meeting that just was held at the end of 1975 by an independent committee of the scientific group on virus disease of the World Health Organization the judgement of this committee at the end of 1975 was expressed in the following words. Excuse me just a moment. Page 17.

Under poliomyelitis they said, Evidence continues to accumulate that polio virus vaccine is one of the most effective and safest vaccines.

Q But you know there is an interesting problem of what is an acceptable risk for certain diseases. People accept ten, a hundred deaths as an acceptable thing. We, for example, accept hundreds killed on a July 4th weekend in automobile accidents. We will not accept let us say one polio case in a million. Why is that.

A Who says we will not accept it. It was accepted. Even the possibility was accepted because what was found that either you choose to continue with some thousands of cases continuing or if there is a risk. Suppose when we ran, we grant that risk.
And if at that cost you eliminate the disease altogether, except for that minimal risk, which do you choose as the public health thing. Now there are other consequences now of course which have come up as part of the total malpractice business in the United States and there is a classical case that shows the problem in our legal culture at least.

As I said paralytic polio viruses continued to be brought into the United States from México. Mexico. This is the problem we will have to consider, the difficulties in control in other parts of the world. México has not been able to eliminate the dissemination of paralytic strains so that when hundreds of thousands of migrant workers and their families come in through Texas and California to work in this country they bring in paralytic strains in with them and they had been over a period of years, although it isn't occurring now. Some little outbreaks on the border. And in Texas, in one instance there was an outbreak and mass vaccinations were immediately introduced to try to halt it, and an eight month old child developed paralytic polio during a period when others were, other unvaccinated children were developing polio. And the virus that was isolated from it. There are certain markers by which one can identify. Were shown to be the epidemic strains. It was not the vaccinated strain. And so nevertheless the company that produced this vaccine that was used in this mass campaign was sued a very large sum of money. And although the most unusual mottling of experts, and I wasn't one of them. I refused to testify in these cases because everybody would say
Oh, you are biased. I didn't want to go. But others said this is a case that was obviously acquired in the natural course of events. Nevertheless, the jury acting on the principle, well, here is a poor child that has been paralyzed. Here is a big corporation. Give it. The legal basis, why did the judge pass on that. He said that the, and again, the old quotations which have now been disproved by the Public Health Service's so called advisory committee are quoted again and again you see. Parents should have been quoted of the danger even if it is one in a million or one in five million that there was in giving this vaccine, and they were not. But it was not caused the experts said by this vaccine. But nevertheless they were awarded. And then it went to a higher court and the higher court upheld it. The situation has reached a point where Phiser for example that was the first one who made vaccine has gone out of the vaccine production business of any kind. Because all sorts of things that may happen when millions of persons get something. There are suits now in connection with measles vaccine, with German measles vaccine, with all sorts of things. And there isn't really enough money. It becomes too much of a strain on insurance. And this is something that will have to be dealt with.

There were also problems in other parts of the world where vaccine was still being used while strains were being—paralyzing strains were circulating. And there too was the question raised first the type 3 wasn't as good and second that type 3 was perhaps more dangerous and well, you know the world health organization also had its own surveyanse committee
elsewhere in the world and things came in after an analysis. But it was always from certain countries you see. The same vaccine presumably prepared the same way used in Japan and England and Europe, etc. without the consequences if something happened in Hungary or Rumania you see. And there were also some questions arose as to whether or not the control of the Russian made vaccine was as good as we liked. I had no control over them. Nobody had any control over them. That is another problem that I don't want to go into. But at any rate, after all of these considerations this is what the W.H.O. committee said as I have indicated before.

And some analyses that were made recently pinpoint the W.H.O. committee still continues surveyance of that sort. But they have invariably evaporated. As a result of this, and again, an attempt was made to develop other strains in Czechoslovakia and they were used. Presumably strains that would be less neural virulent or more stable. And then they were used in Poland and somewhere else and many cases occurred. So a little bit like my experience when I made those cold variants, cold adapted mutants and found that they were worse than these strains even though neurologically on neural virulence tests in monkeys they were so much better, they turned out to be worse. on use. So we went through periods with that behind the iron curtain countries. And that has now been given up. Attempts have been made but it didn't turn out well.

Poland, to cite another example. Koprowski who studied medicine in Poland and even though we were both born in Poland there is a difference. He speaks Polish and I don't. And I
remember we were both called in by the Ministry in 1958 and he gave them a big spiel and they decided well. We were both Jews so you see. And they decided for national reasons they were going to use Koprowski's strain. And they went along and it just didn't work out well. And finally they came to me. Would I give them my strains. Yes I gave them my strains. But still they had problems in proper production and so on. But you see the iron curtain wasn't solid. On the other hand, in Yugoslavia they went into production in Belgrade and in Serbia and did a very excellent job not only providing the vaccine needed by themselves but also in Latin America and various other places. Still, even in Yugoslavia, which is a divided country in which you have Slovinia with Zagrad as the capital and they will never do anything that the Serbs do. They made their own vaccine and they did it from Koprowski's strain.

Q Was there much--you know, just as an aside. I don't want to lead you astray. Was there much conflict let us say between yourself, Cox, and Koprowski in this period.

A Well, I would say conflict to the extent that they continue without the really extensive studies after the judgement was made in the world and in the country, Cox not so much but Koprowski continued to cry out at the injustice. But it was based on dispassionate studies I would say that wouldn't perhaps. I find myself in the position that Koprowski and Cox was because I don't work that way. Because if the judgement had been the reverse I probably would have behaved the same way and it is understandable but the point of the
fact is that the issues ultimately were not decided by an individual. The issue in the United States was decided by a separate committee set up by the American Medical Association not by somebody else or--. The issue of not making any more Salk vaccine in the United States by the manufacturers was decided by the doctors, by the people who were using it and by independent committees despite all the things you know that during the Salk vaccine days were said, well, this might destroy public confidence. We have a situation now in the United States which is extraordinary. For 250 million people there are supposed to be only four cases. Four or five in 1975 and '74 we reached a point of reported cases. And I am never sure that are all really polio because. Just because you isolate a polio virus let's say after vaccination. Especially it doesn't mean that that caused disease.

Q Were there markers available for in vitro diagnosis of whether it is a vaccine virus or--

A Well there are all sorts of markers but some of those markers change on multiplication in the intestinal tract. But there have been developed markers which are very interesting because it was found by highly sophisticated neutralization tests that the vaccine strains had particular slight antigenic differences as well as virulent differences. And for type 1 and 2 when they went back to the banks of strains of virus that were isolated before live virus vaccine was introduced it was found that you could rarely encounter a naturally occurring type 1 or type 2 strain that had the identity by these
special tests of the vaccine strains. On the other hand for type 3 it didn't hold because a very large percentage of the naturally occurring virulent strains that were isolated long before vaccine was being disseminated, vaccine strains were being disseminated they had the same things. There are other markers altogether. But the most important marker is namely whether it is really the virus that you isolated is virulent or not. And in the first report of the Public Health Service the surgeon general's advisory committee, they did not mention that the five type 3 cases that were reported whatever it was that they isolated virus, that they had tested in the monkeys and that they were not virulent. I had to get that information out and I published it. There were all sorts of shenanigans. But at any rate, there is reason for some of them and no reason for others but it was a very, very dramatic period chiefly because one was dealing here with as I said before, a vaccine different from any other vaccine, a vaccine which after multiplication was able to get out of the body and spread to others. It was not true of yellow fever, not true of measles, not true of German measles, not true of smallpox except by contact you see with pustules and so on. So that it was necessary to do that. But the benefit of it is also very great.

For example, information that CDC did not publish as yet but whether they will ever publish it I don't know. One of the great problems in the United States now is the fact that with polio actually having been for all intents and purposes eliminated that many families do not have their
children vaccinated. In Italy it is compulsory. In Belgium it is compulsory and so on. In the United States it is not. So there are many areas in the United States where almost 50% of the children have not received any vaccine at all of any kind. And naturally the public health service now goes out and campaigns it is necessary to vaccinate your children at this, this, this, this. But what has happened is the Center for Disease Control sent out people to areas to test the blood of children who had not received vaccine but are living in communities where let's say 50, 60% of the children are getting vaccine and not in mass campaigns, but as an ongoing activity. And they found that the vast majority of the children who were not vaccinated also at that time, that they were getting it by contact. And this was the beautiful thing of this revolutionary vaccine because it immunized not only those who received it but a considerable proportion of those who did not receive it. So that then there was also the question of well how about disease you see, that might be acquired as a result of a contact infection. The virus becoming more virulent in the intestinal tract of let's say the child who gives it and then giving it to the parent who did not have it or some other child. Well, there were a certain number of so called secondary cases reported subsequently. It didn't occur in whole areas and then you get an occasional one. And to my, in my judgement, the proof is not satisfactory that there has been such contact cases really. Because, as in the original thing that occurred, I said you would have to assume that in 50 million or so who
got the vaccine in one part of the country, that there was no danger at all. And that among one million who got it in Nebraska, there was this special strain. There were all sorts of things that when you deal with huge populations that occurred. But ultimately in spite of all this we are down to a situation in the United States now which after real elimination of the paralyzing strains and having built up a barrier against the new paralyzing ones that are being introduced constantly we end up with something like four or five out of 250 million people. So that these were all situations that had to be discussed, had to be considered because it was a different kind of vaccine from any other that has ever been used.

Q Do you know what I find of interest in you know, it is off to the side I admit. In the early days of polio it was very difficult to make a diagnosis. Frequently they would mix it up with cerebral spinal meningitis and then the notion was that people knew how to make a diagnosis of polio and here in the early 1960s again it is very difficult to make a diagnosis of polio.

A I think that that is not quantitative. It should be remembered that poliomyelitis clinically, and even pathologically is an entity that has a multiplidiology that when you make a diagnosis of poliomyelitis clinically even you are not automatically saying that it was caused by polio virus because as we learned later coccisacki A-7, echo 6 and certain others could produce similar lesions and sometimes even persisting
paralysis. So that the first job is to make a diagnosis of poliomyelitis on clinical grounds. And the difficulties that present themselves are in small numbers of cases. In an epidemic the probability of a correct diagnosis is very high but not absolute. For example, during my own many years of studies on central nervous system manifestations when I was doing autopsies I remember a case during a polio epidemic, and I think it was in Portsmouth, Ohio, a child was rushed in to get it to a respirator because there was an epidemic and it was brought in and I did a regular autopsy. The child turned out to have Guillan Barré Syndrome, Landrey's paralysis and not polio. So that sometimes it isn't easy and there was a feeling that well, alright, if you examine the spinal fluid properly you can make a diagnosis but there are always the fringe cases. And the statement was said, in the old days well not every case of poliomyelitis even early after onset needs to have inflammatory cells in the cerebral spinal fluid. Well it isn't true on the base of probability. If in the first seven days of the disease there are no cells so to speak inflammatory cells above the few that are always present the probability is 90% against it being polio because we then study for example Romulus Alvarez continued that study in Mexico in which every child with paralytic poliomyelitis that came in for a period of five years had a complete autopsy done and virus was searched for. And during that period it turned out that 50% of the children who died of poliomyelitis with a clinical diagnosis, on pathological examination turned out not
to have poliomyelitis. And we published a paper together because I helped to do the neural pathology on it and identified new pathological syndromes. Something that causes the change either in the scitoplasma of the neuronal anterior horn cells and another group in which the change is in the nucleus and it is not clinically it was polio. But pathologically it was not and clinically one of the main points there was that they did not have inflammatory cells in the cerebral spinal cord. It was not an inflammatory disease and yet they occurred. There they were. In Mexico. And from one of these patients Romulus Alvarez isolated type 1 virus. It wasn't a vaccinated child. He isolated type 1 virus, polio virus from the stools of that child yet there was nothing in the central nervous system. There was no pathological change of poliomyelitis so that other things can simulate it. And sometimes an early attack of myelitis caused the first manifestation of multiple sclerosis can be diagnosed as poliomyelitis. So these things occur so that when you get down to smaller numbers and they don't occur in mass the probability of making a mis-diagnosis is even greater.

Let me again draw on my experience. In 1963 I was called to Ceylon now Serulanka (?) and they had a tremendous epidemic of poliomyelitis there and they got a lot of vaccine from the Soviet Union, oral polio vaccine and when I arrived to stop the epidemic and when I arrived in January of 1963 in Colombo. I think it is Colombo. Yes there is Colomo. Yes.
A What greeted me on arrival. There was a big headline in the paper. Six year old child of the richest man in Ceylon who had had seven doses of Salk vaccine during her life and then had five doses of Sabin vaccine because her father was killed (?) to get it. She died of polio. What good are the vaccines. And on analysis it turned out that that child just as one of the children I mentioned previously was rushed to the Children's Hospital in Cincinnati from Portsmouth Ohio, had had Guillan Barre disease and not polio.

So you see there are these various other possibilities.

Q Alright. Look at what happens. Let us say, they say the child clinically looks like a polio. You do a pathological examination.

A If he dies.

Q If he dies and you say it is Guillan Barre syndrome. Do people accept that. Do even other scientists accept that?

A Well, when you have an autopsy there can be no question. We had, however, a very interesting situation that occurred in Czechoslovakia, because Czechoslovakia beginning with 1960 when it carried out its first mass campaigns really completely eliminated polio from the country. But after I think a couple of years a 29 year old woman developed paralysis. She was not vaccinated. Whether she had gotten it from somebody who was--she hadn't been out of the country. And there was a division of opinion among the clinicians. Some of them said Guillam Barre Syndrome. Some said transverse myelitis. Some said this is polio don't try to pull the wool over our eyes. This
is polio. So then it came up an autopsy was done. She died. And again the pathologists said oh this is polio. And then they had to sent it around to an international group of neural pathologists. I also got the slides. It was a clean cut case of tranverse myelitis. What is the difference between tranverse myelitis and poliomyelitis. In poliomyelitis as the title suggests, only the grey matter is involved. You get destruction of the anterior horn cells and then an inflammatory response to these destroyed cells. In the transverse myelitis you get an inflammatory response across, in the white matter and in the grey matter. And if you look very carefully in the grey matter although there is a lot of inflammatory response most of the nerve cells are intact. And it was a case of transverse myelitis. The cause of transverse myelitis is still unknown. Sometimes a multiple sclerosis begins as a transverse myelitis. But even there you see the clinician--they have very good clinicians in Czechoslovakia--disagreed. Then even the pathologists disagreed and it took an international group of neural pathologists to finally rule overrule the Czech pathologist in that hospital. Yet this was a case of transverse myelitis.

Q Now one of the things that intrigues is soon after Burney who was then the surgeon general accepted the vaccine it wasn't licensed yet, you wrote him a long letter speaking of the political necessity of producing this vaccine as a humanitarian--.

A What do you mean by political. I don't have the letter in front of me and I don't understand what you mean.
Dr. Albert Sabin; July 4, 1976; side 3; page 20

Q What I am saying is that the only people who were producing vaccine for export at that time in the summer of 1960—the Russians were already producing—

A This is the summer of what?

Q 1960. We were already producing vaccine for export and you had pointed out to Burney that it would be important that the United States also do this.

A Do you have that letter here?

Q I happen to have that letter here.

A I have just seen this exchange of correspondence between the surgeon general and myself in October of 1960 and I think the correspondence tells the story of what I proposed. Basically the surgeon general replied that my recommendations that the United States take the initiative in producing large quantities of this vaccine not only for itself but also for the underdeveloped parts of the world that cannot afford it and so on which is contained in the correspondence was not accepted, for reasons that the surgeon general mentioned. I want to continue however and say that many years later the World Health Assembly voted that it should become the responsibility of W.H.O. to see that countries that cannot afford to have vaccination against polio and polio was still continuing in many parts of the world should be provided somehow to the officers of the world health organization. I would like to say at this point however, that it would be much more important to discuss at this point what the problems are of eliminating poliomyelitis in different parts of the world, the role that not only ecological conditions
but also organizational and administrative sophistication of health services play in administration of vaccine in certainly, influence the course of events. Let me only say at this point because I, there will not be a place to say it later because I hope that we can discuss the problems of eradication in different parts of the world and before that I would want to say this. For the record, and you can put it in wherever it would fit.

That in 1972 when I had narrowly escaped death by having open heart surgery and I realized at that time after recovery it wasn't right that I should have the sole responsibility for deciding of who is in a proper position to produce oral polio vaccine and who is not. That it would be necessary for some agency to have charge of the vaccine because I had personal contracts except for the Soviet Union which hadn't signed one but a gentleman's agreement between Chumakov and myself. China which got the strain from Chumakov before the Soviets and China broke relations. I had contracts with more than twenty individual pharmaceutical companies that gave me the right to withdraw the privilege of their producing vaccine if they didn't follow certain requirements. And then I realized that that couldn't continue. The basic vaccine strains, the seed I had turned over to the Bureau of Biologics and also some of my very original material, not a large number of cubic centimeters. It was stored in a frozen state by the bureau of biologics in Washington and I thought that some international committee should have the job of deciding who should be authorized or given the privilege of making vaccine. Mind you there is never
any money involved on this and who should not. The problem is particularly acute because of the following situations. For example, in 1972 I was president of the Wiseman's Institute in Israel and indirectly Egypt which had been receiving vaccine from the Soviets for years and it would not really eliminate polio in any way for one reason or another--had passed word--I think they were already breaking with the Soviets to the W.H.O. that they would like to have my strains to produce oral vaccine themselves and that they would be helped by the Maurier Company in--

Q From France.

A They would get technical help. And so a decision had to be made and I was the only person really to do it and I knew that if I would say no I would be accused of bias. There was also a special request from Poland anew. There was also a special request from India. There was a request from Iran. I went to Iran and fortunately in Iran I was personally very delighted and able to give approval.

Q I have to change the tape.

END OF TAPE