Dr. Y.:

Now, was this a kind of consensus conversation in which....

Mr. J.:

Oh, yes. It was a very small committee and everything was reached by consensus.

Dr. Y.:

You sat around and talked about the qualities that the Commissioner should have--somebody kept notes and....

Mr. J.:

That is correct.

Dr. Y.:

Made an organization, a listing of these, that were submitted to you so that you all shared in this drawing up of the list?

Mr. J.:

That's correct.

Dr. Y.:

When the list was drawn up, it certainly was a list that put scientific competence of the agency, which we've been talking about in connection with the medical director, very high as a responsibility either of the new Commissioner or of his Deputy or of an assistant or associate commissioner of science.

Mr. J.:

The committee recognized the importance of having excellent scientific competence somewhere very high in the policy level of FDA, and it had to be one of the top two or three positions in the judgment of the committee.

Dr. Y.:

Now, after the list was drawn up, what was the procedure toward winnowing the list of names that you had acquired from various sources?

Mr. J.:

This then became a subjective analysis of objective data. I can't describe how a group of five or six people evaluate these things, any more so than you do how a jury arrives at a decision.

Dr. Y.:

The committee was a group session, by conversation, talking the names over one by one?

Mr. J.:

And relating the data concerning one individual to the criteria that had been established.

Dr. Y.:

Dr. Goddard, I take it, rose from the discussion to the level of choice on the part of the committee as a person to recommend to

the Secretary.

Mr. J.:

This is correct. I might say, referring back to the earlier part of our conversation, that Dr. Goddard was one of those with whom I discussed the position as Director of the Bureau of Medicine. I gave you two names--Dr. Goddard was a third one. He was then Director of the Communicable Disease Center of the Public Health Service, where he had done an outstanding job. He was well known for the competence of his administrative procedures and the vigor of his interest in public health and health protection matters. Again, Dr. Goddard was one of those who, for health reasons, was unable to take the job, but it was the health of a member of his family, not of himself, and by the time the committee considered this proposition, it had been determined that this problem had been resolved, and that Dr. Goddard, if he were selected and if he were interested, could make the transition.

Dr. Y.:

Did the White House have any role at all in this selection?

Mr. J.:

None at all. Obviously, the White House was greatly interested because this was a matter of public debate in some segments of the press and a matter of concern to important members of Congress. Therefore, the White House was concerned but it did not participate

or have a hand in the decision, leaving the judgment to the Department.

Dr. Y.:

And so, of course, I presume that when the Secretary made the decision, the White House was informed and agreed before the formal offer was made. Is that true?

Mr. J.:

Well, I don't know because I was then only a consultant, but I would presume, as is true in major appointments of this kind, that White House clearance is a customary procedure, properly so.

Dr. Y.:

Surely. The White House expressed its interest by announcing the appointment, as I understand it, in any case. Did you personally talk to Dr. Goddard about this as an official representative of the committee, while it was in the discussion stage?

Mr. J.:

When it was close to decision, the Committee informally authorized me to determine whether or not Dr. Goddard was in a position to accept the place or would be interested in it. This was because I knew personally of the fact that he could not move to Washington before. I did make inquiry of Dr. Goddard directly, and he explained the situation which had been a deterrent before as now being removed,

that he, if he were wanted, would be available. One of the plus factors concerning Dr. Goddard was that he was a career officer with the Public Health Service, and one of the concerns was that the FDA and the Public Health Service needed to operate in as close collaboration as possible since they were sister agencies in the same Department and had supplementary or parallel responsibilities which, if not carefully understood, could be competing or duplicating responsibilities. I think there was some considerable satisfaction that a competent person in the career service, in the Public Health Service, acceptable to the FDA people, too, as we learned by discreet inquiry, was available, although this was not the determining factor by a long shot.

Dr. Y.:

Surely. One reads over the list of criteria and then thinks of Dr. Goddard's background and sees why he would be a strong choice for the committee to come to. I'd like to go back to the period when you were in Washington. One of the major problems that the Food and Drug Administration wrestled with for a long time was the problem of Krebiozen, and I remember from perhaps the first time that I saw you in your office there that this was one of your major problems that related to the agency--was the matter of Krebiozen. You had a letter on your desk about it when I came in that day. One of the things about the Krebiozen problem that went on over a number of years, that made it trickier than other promotions of

unorthodox cancer cures, so-called, was that it was bolstered so strongly by Dr. Andrew Ivy whose scientific reputation was known, and another reason was that it was supported so strongly by Senator Paul Douglas of Illinois. Did you have any personal contact during your concern with this problem with either Dr. Ivy or with Senator Douglas that you could talk about, and I'd be interested in your own speculation as to their motivations in being involved in a matter of this kind.

Mr. J.:

I think I should say first that when I was established in the position in Washington, Commissioner Larrick made known to me that FDA had been concerned for some years with the distribution of Krebiozen as a new drug distributed for experimental purposes which was within the law generally. He said that the feeling generally was that it was worthless; that the National Institutes of Health of the Public Health Service, particularly the National Cancer Institute, felt the same way about it, but that they were not able effectively to evaluate Krebiozen and it was a problem for them. I said: "Well, if it's been a problem this long, why haven't the two agencies done something about it?" I got no satisfactory answer, so I said: "Well, it's time to do something about it". Then the new drug regulations came out which tightened the basis upon which experimental drugs could be distributed and this gave an opportunity for FDA to review Krebiozen as a new drug being

used for experimental purposes. Regulations required the submission of data having to do with the manufacturing standards of this particular product. The experimental program for its use, the competence of the people who were managing the use, the reporting system, and the like. There was some question as to whether this was a drug under FDA regulatory supervision or a biological under the supervision of the NIH which had the biologic standards...

Dr. Y.:

Branch?

Mr. J.:

Yes, a branch of the Public Health Service administered under NIH. So I got representatives of the Public Health Service and FDA together to discuss the matter and there was enthusiastic response toward a proper evaluation of Krebiozen or an effort to halt its distribution in the absence of conformity with requirements for the use of experimental drugs by the sponsors of Krebiozen. That's the way the matter started. Dr. Andrew Ivy had been a very highly distinguished research scientist in cancer chemotherapy. He published many research papers. He, for some years, had been the leading proponent of Krebiozen for use in the treatment of cancer. The real producers were two brothers known as Durovic--D U R O V I C--. It was virtually impossible to get from the Durovic brothers or from Dr. Ivy information on which an evaluation could be made of the

product, that is, standards of production, so that the government agencies would know that a product they tested would be the same product that would be produced the next time under the same standards. It was very difficult to get samples and impossible to get any information as to standards of production for the product. I won't go into detail, but Senator Douglas had been a very close personal friend of Dr. Ivy and had great confidence in Dr. Ivy and felt that Dr. Ivy would not be supporting this product unless Dr. Ivy had good scientific reasons for it. The controversy had gone on for a long time. There were hundreds of people who, we found, were paying or making contributions to the Krebiozen foundation, so-called, voluntarily for Krebiozen which was then administered to them, sometimes by their own physicians, but always on the demand of the patient who may have been beyond hope in terms of known methods of therapy, surgery, radiation and chemicals. When their own doctors had given up hope of cure or even control of the condition, then the victims and their families would look to any source they could that offered hope. Krebiozen was this source of hope for many of them. The FDA, then, launched an investigation. The evidence eventually was such as to support an indictment of the Durovic brothers and of Dr. Ivy. The case was tried, one of the longest trials in Illinois history, and the jury exonerated these people, although FDA kept the product from distribution in interstate commerce.

Dr. Y.:

The company submitted a plan for investigational use before a certain deadline, but then before the deadline came, they withdrew the plan again. Now, in the course of this tortuous series of events, did you try to dissuade Senator Douglas from his commitment?

Mr. J.:

It was the other way around. Senator Douglas, through pressure on President Kennedy, had sought to have FDA and the department of HEW cease and desist the unfair persecution of the promoters of Krebiozen or else to give it a fair test at the Cancer Institute. A fair test in Senator Douglas' nomenclature was impossible because the National Cancer Institute could not get the basic data on which to make a test. All it had were case histories prepared by Dr. Ivy and his associates which could not be evaluated.

Dr. Y.:

Expert committees looked at them and decided.

Mr. J.:

Well, we set up an expert committee, both in house, that is, full-time scientists at the National Cancer Institute in Bethesda, and experts in the field from primarily academic institutions all over the country. They took a hundred and some-odd case histories

that Dr. Ivy had submitted and supplemented the case histories with full hospital records secured with permission of the patients' families through FDA agents. A full record on each and every case was there and there was absolutely no basis, according to the report of the National Cancer Institute's select committee, to justify the claim that there was efficacy in the use of Krebiozen for cancer. Meanwhile, the FDA did get samples, very small samples, of the product called Krebiozen, subjected this to analysis and with a stroke of great, good luck based on highly competent scientific study, they did discover that, in addition to mineral oil, which was the base of Krebiozen, there was a product in it which turned out to be nothing but creatine--C R E A T I N E--which is a product normally in the blood anyway. This product could be bought very inexpensively from supply houses, chemical supply houses, but the Durovics claimed that this was a product prepared from the blood of horses that had been innoculated through a procedure. Well, the evidence that FDA investigators got fully substantiated indictment against these people. My own personal feeling is that only the emotion of cancer patients who thought they were being helped by Krebiozen and the age and previous reputation of Dr. Ivy saved Dr. Ivy and the Durovic brothers from paying the full penalty for this kind of alleged fraud.

Dr. Y.:

Well, when Senator Douglas brought pressure on President Kennedy, did he come over to see you then? Did the President refer him...

Mr. J.:

No. This matter was referred to me by the President, and Senator Douglas met, probably more than once, but at one time with Dr. Kenneth Endicott who directed the National Cancer Institute, and Dr. Endicott agreed with Senator Douglas on the basis on which the National Cancer Institute could give a clinical test of Krebiozen. Senator Douglas agreed that if the Durovics and Ivy did not agree to this, then he was through. The Durovics did not conform, although they claimed they did. They did not supply the samples. They did not give the basis upon which the product was produced to assure the product tested could be reproduced by them, without revealing their secrets even, and Senator Douglas never accepted the fact that the agreement had not been lived up to, although he was pretty sure of it. Some months later while--this went on for a long time--some months later after Mr. Johnson became President, almost immediately, in a short while, at least, Senator Douglas again sought to remove this investigation through pressure from the White House. I happened to be in the office of Mr. Feldman, Special Assistant to the President, when the President called him and wanted to see him. Senator Douglas had just called the President about Krebiozen, and Mr. Feldman said, "You come go

with me". He told the President he had the man who knew most about it there. I explained to President Johnson what the matter was. He said, "Well, you call Senator Douglas and tell him I've referred it to you and you go see him." I made an appointment then with Senator Douglas, which was my first direct contact with him, and went over at 4 o'clock in the afternoon and sat with him and his administrative assistant until 7 o'clock that night for three solid hours. During that time, discussion on the matter...it was quite clear that Senator Douglas was involved because of loyalty to his friend, in my judgment. Senator Douglas did say to me, at one time, he said, "The Durovics may be crooks, and I'm inclined to believe they are, but I think Dr. Ivy is sincere." Well, I never could quite equate this feeling with his continued public support backing of the product Krebiozen.

Dr. Y.:

You did have a feeling when you went away that, despite your best efforts, you really hadn't gotten through to him anymore than others who tried had done?

Mr. J.:

This is quite correct. He said, "I don't say that Krebiozen is effective. All I say is that it ought to be tested." And yet when, having agreed to the ground rules on which any drug could be tested, he would not accept the fact that the Durovics had

not conformed to the requirements for an adequate test. This was where I think Senator Douglas was wrong, as did nearly everyone else who experienced this whole episode.

Dr. Y.:

And that was your only personal conversation with Senator Douglas during the course of the series of events about Krebiozen?

Mr. J.:

Yes, that's correct. I had some extended correspondence with him and did talk to his administrative aide once or twice.

Dr. Y.:

In this conversation, your effort was to lay out the data that had been accumulated as factually as you could?

Mr. J.:

Yes. At that time, we didn't have as much data as we acquired later when we really swung into full investigation of the matter, but it was enough to illustrate that the Durovics and Dr. Ivy were not operating in the generally accepted pattern of responsible scientific activity.

Dr. Y.:

Did you have any personal conversation with Dr. Ivy during the course of all this?

Mr. J.:

Yes. Dr. Ivy and the Durovic brothers came to see me prior to filing the new drug application as required by law as of a certain time, and I had present the responsible people from both FDA and the National Cancer Institute, a full-dress meeting. We laid out the requirements of the new drug regulations for an experimental drug concern. They agreed that they would submit an application which they did. But prior to the time of an evaluation of their application, they withdrew it, and it was quite obvious to me and to the experts who were concerned that they withdrew because they knew they could not stand up to the investigations that would come from their submission of data. It then became an emotional fight, a publicity campaign, this kind of thing and very strong criticism of FDA and its methods. The FDA, in my judgment, performed superbly as did the National Cancer Institute, and I think that there wasn't any question but that the facts justified the indictment and, I think, conviction.

Dr. Y.:

It looks to me as if this tape is about finished, so I'm going to turn it off with appreciation for your time and recollections.

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