An Interview With Mr. Boisfeuillet Jones

This is an interview with Mr. Boisfeuillet Jones, President of the Emily and Ernest Woodruff Foundation, being held in his office in Atlanta, Georgia, on January 26, 1968. I am Harvey Young, Professor of History at Emory University.

Dr. Y.:

Boisfeuillet, you went to Washington at the call of President Kennedy in 1961. Is that right?

Mr. J.:

That is correct--January of '61.

Dr. Y.:

And you went as assistant for matters pertaining to health to the Secretary of Health, Education, and Welfare.

Mr. J.:

The position was a statutory one, the title "Special Assistant to the Secretary for Health and Medical Affairs." It was an advisory position at the right hand of the Secretary to oversee medical and scientifically related activities.

Dr. Y.:

And you stayed there during Kennedy's presidency and into Johnson's presidency until July of 1964 when you came back to Atlanta accepting

this position as President of the Woodruff Foundation.

Mr. J.:

That's correct.

Dr. Y.:

One of the key agencies involving health that was under your administrative responsibility then was the Food and Drug Administration.

Mr. J.:

That's correct.

Dr. Y.:

And at the time that you went there, one of the key problems that confronted the agency was the choice of a new medical director. They had been without one for some time, as I understand it, and had been urged by the Second Citizens Advisory Committee to get one of the highest competence and ability, and so this was a problem that was, in a sense, laid in your lap rather quickly after you got on the scene. What's the story of the search to find the medical director?

Mr. J.:

Commissioner Larrick, who in my judgment was a very able public servant and administrator and who did a very good job with FDA over a long period of time, was considered to be oriented primarily

toward enforcement rather than toward scientific investigation, scientific appraisal of FDA responsibilities. I think the competence of FDA scientifically was underrated. Nevertheless, the scientific community felt that in terms of new drugs, particularly, there was a lack of competence on a broad front properly to evaluate the effects of drugs. Mr. Larrick was quite aware of this and undertook to find a strong director for the Bureau of Medicine in the FDA under whom the medical activities, the evaluation of new drugs and the like, came. His director had resigned and he had been without one for a while. Mr. Larrick had difficulty identifying the individual he wanted. At one point along the way he did identify three people, any one of whom he thought might satisfactorily do the job. Of these three, he picked one and recommended him, Dr. Charles May. I advised him to go ahead and make contact with Dr. May, determine whether or not he would be available. Meanwhile, it seemed that he would be. There would be the normal field investigation of Dr. May before appointment to a major position of this kind. Dr. May was then a research professor of pediatrics at New York University and had been very prominent in research, particularly in the use of drugs, pharmacology, through the years. He looked good on paper. Commissioner Larrick determined that Dr. May would be available and that he would be very interested in having the job. When the preliminary field investigation came in, there were some questions, not as to

Dr. May's scientific competence, but as to some broader judgments and personal traits that indicated he would have some difficulty, perhaps, in securing support from the scientific community in behalf of FDA scientific evaluations. It seemed very apparent to some of us that the job the FDA had to do could not be done alone by FDA personnel. Panels of experts from the scientific community, primarily the academic community, would be required for sophisticated judgments on complex questions having to do, say, with drugs or with the effect of products regulated and approved by FDA. These questions that seemed to be raised in connection with the preliminary investigation led to the need for a full field investigation of Dr. May. This would require several months. While this investigation was going on, Dr. May became somewhat restless at a delay, after having been approached. There were some interests desirous of having Dr. May in the job, particularly those who, both within and outside of FDA, were critical of FDA's scientific competence. Dr. May, when there was delay in his appointment, finally said through Mr. Larrick that unless he had word by such and such a date he would ask that his name be withdrawn from consideration. This matter was presented to Secretary Ribicoff by me. The Secretary said he would not waive the requirement for full field investigation, as he had the right to do, on the basis of information then available. This was relayed back to Commissioner Larrick by me. A week or so later, word came back that Dr. May would be able to

delay his decision at least several months longer.

Dr. Y.:

He kept his name in the pot.

Mr. J.:

He kept his name in the pot. Meanwhile, Secretary Ribicoff had resigned and Secretary Celebrezze had replaced him before the full field investigation was completed. When this report was available, which obviously was a very confidential document, but one that is usually--is always--available for a major appointment, when this report was made available to me I went over it myself and then had Commissioner Larrick review it. In my judgment, because of qualities other than scientific competence that had to do, again, with judgment and ability to work with other people primarily, it seemed to me unwise that Dr. May be given that kind of responsibility. In answer to a direct question from me as to whether he thought Dr. May could handle the job and whether he would be successful in it, Commissioner Larrick said that he thought the chances were about 50-50 that he would be successful. I then said, "Commissioner Larrick, would you be willing to appoint a man in a major job of this kind you thought had only a 50-50 chance of being successful?" He said, "In this case, yes, because I have no other alternative." I disagreed that that kind of percentage would be in the public interest for that important a job. However, the whole matter with

the full report was presented to Secretary Celebrezze who, on consideration, but without much hesitation, said he would not approve the appointment. Commissioner Larrick then said he had done all he could to fill the job; he'd have to leave it in the hands of others. That meant that I had the responsibility then to identify a person acceptable to Commissioner Larrick and to the Secretary who could be appointed to the position. That was the story of Dr. May at that particular time.

Dr. Y.:

Now, this was used later on by certain groups, the fact that Dr. May was not appointed, in a way to rather belabor both the Agency and the Secretary's office, wasn't it?

Mr. J.:

Yes, it was. This was done in a committee hearing of the Senate Sub-Committee on Government Operations, chaired by then Senator Hubert Humphrey at a public hearing at which he had Dr. May testify along with Dr. Nestor, the disgruntled employee of the Bureau of Medicine of FDA, whose testimony was put together in collaboration with Mr. Julius Cahn on Senator Humphrey's committee staff. This matter was mentioned in the public hearing very strongly by Senator Humphrey who said that he understood Dr. May's testimony before his committee was very good and incidently, I thought so myself, in contrast to Dr. Nestor's which I didn't think was good,

but Senator Humphrey referred to the excellence of Dr. May's presentation. He said he understood that he had been blocked as the medical director of FDA. He couldn't understand why this was so; he intended to find out who was responsible and to get to the bottom of it.

Dr. Y.:

You were there that day yourself.

Mr. J.:

I sat in the hearing. I was not testifying that day. However, after several attempts to discuss the matter with Senator Humphrey, attempts which I think were blocked by his staff who didn't want me to deal directly with the Senator, although I saw him socially several times, each time saying that I'd like to see him. He was very cordial but I never got an appointment for this purpose. On the third occasion, however, the Senator said he wanted to see me and would work it out if I'd call a certain person on his staff, which I did, and I did get an appointment and in a very short period I explained the whole May situation to him.

Dr. Y.:

This was while you were in a car, I think you said.

Mr. J.:

Well, my appointment was interrupted, even before I got to it, by a

call from the White House requiring Senator Humphrey's presence and our conversation was in his car riding from his office in the Capitol Building to the White House.

Dr. Y.:

He seemed persuaded?

Mr. J.:

Well, he said that "If I'd known what Dr. Nestor's testimony was going to be, I wouldn't have had him testify". I said, "Mr. Cahn of your staff knew what the testimony was going to be, and I was surprised that they would have that kind of testimony under those circumstances." In any event, I explained the situation concerning Dr. May to Senator Humphrey.. There was never any further public mention of it from Senator Humphrey or his staff, and some months later, when I saw the Senator in an entirely different context, he volunteered a statement to me. He said, "Bo, I have learned more about the situation concerning Dr. May and I agree that he should not have been given the job".

Dr. Y.:

Now, to go back: When you had decided and the Secretary had agreed that this appointment shouldn't be made, the task of finding a medical director was placed in your lap?

Mr. J.:

Yes. I might add that we had a lot of pressure from those who were sponsoring Dr. May to explain why he wasn't appointed, and we took the position that we never explained why anybody wasn't appointed as there were many people who were not appointed to public office. We would defend any appointment that was made.

Dr. Y.:

What was the nature of the motivation of the groups that were critical?

Mr. J.:

Dr. May had made something of a name for himself for being a very strong advocate of tight controls over new drugs and products put on the market by pharmaceutical manufacturers, and it was assumed by those who were very heavily consumer-oriented or anti-business that there was undue influence from manufacturers which blocked Dr. May's appointment. This was absolutely untrue. It had nothing to do with it at all.

Dr. Y.:

It was entirely an impersonal evaluation of Dr. May's fitness for the position?

Mr. J.:

That's correct. And Senator Humphrey was one of the strong consumer advocates.

Dr. Y.:

Now there were representatives of the press in this camp. Is that right?

Mr. J.:

Well, particularly, I think Mr. Mintz of the Washington Post. Besides him, I don't identify off-hand others in this camp.

Dr. Y.:

Within the Food and Drug Administration, there were people who sided with this faction?

Mr. J.:

A few.

Dr. Y.:

On what grounds?

Mr. J.:

These were professional judgments which I was not qualified as a non-professional to evaluate, but the issue seemed to be that the leadership and the consensus on evaluation of certain drug products, for example, reached by the Bureau of Medicine was not compatible with the ideas of one or two or three of the team making the evaluation, and, instead of accepting the judgment of the department of which they were a part, they would criticize their colleagues to people like Mr. Cahn of Senator Humphrey's staff, and the staff

of Senator Kefauver who was very much interested in drug matters. In effect, they were staying in the organization and criticizing the organization of which they were a part. This did not seem to be proper procedure. As a matter of fact, Mr. Cahn as staff member for Senator Humphrey asked Commissioner Larrick for permission to talk with Dr. Nestor and one of his associates in the preparation of material for Senator Humphrey's committee, presumably critical of certain decisions made by FDA. Commissioner Larrick agreed that Dr. Nestor and any other of his staff could say whatever they wished to the committee staff, but he would like a transcript of what they said or have a representative present during the questioning. Mr. Cahn objected to this saying that it would lead to incrimination if the FDA didn't like it. The matter was referred to me by Commissioner Larrick and the Secretary backed me. "We would be glad to have them give you any testimony they want, but we have a right to know what it is they say, no matter how critical, with assurance that there will be no adverse procedure affecting these career people." Mr. Cahn said that if we didn't allow the private interviews, he would have no recourse but to have open hearings and have it all come out in the open. I told Mr. Cahn myself that we would much prefer the open hearings, however critical, to a star chamber session. The hearing at which both Dr. May and Dr. Nestor appeared and at which time Senator Humphrey criticized the failure to appoint Dr. May as Director of the Bureau

of Medicine for the FDA was a direct outgrowth of that episode with Mr. Cahn.

Dr. Y.:

So that Dr. Nestor could say, and the records show what he did say, what his own opinion was. Do you have the feeling that there had been personal collaboration between Mr. Cahn and Dr. Nestor prior to his testimony?

Mr. J.:

Well, there usually is with a staff member and a witness--not exactly collaboration but comparing of notes and agreement on the area to be covered. I feel, in this case, that there was a very close consultation. This is only illustrative of the type of pressure to which the regulatory agency was subjected by the staff of a committee of Congress exercising a legitimate function of the committee.

Dr. Y.:

Of course. And there were real problems about the scientific competency of the agency which did need to be confronted, of which the selection of the proper medical director was one?

Mr. J.:

With this background, then, the selection of a director for the Bureau of Medicine became a very sensitive matter both scientifically and politically. So that we had to be absolutely certain to get an

individual of considerable stature and prestige in the scientific community, to overcome this type of sniping, this type of criticism as to the scientific competence of the FDA, some of which, I might add, was justified.

Dr. Y.:

You were actually wishing the same kind of man as your critics were wishing from the point of view of rigor and quality?

Mr. J.:

No difference there, and Commissioner Larrick was in full agreement. He just couldn't get one.

Dr. Y.:

Now, what was the procedure you followed in seeking to make this appointment?

Mr. J.:

Immediately I got in contact with the leading pharmacologists of the country, primarily in academic circles, one by one to express the Department's deep concern that the leadership of this very important regulatory activity of FDA be in the hands of scientific competence of the highest order. I made it very clear that it would be necessary for the scientific community through panels of experts to participate with FDA in scientific judgments related to the evaluation, particularly of new drugs, as they were presented

for approval by FDA. The sophistication of chemical compounds, the very rapid development in this field through research sponsored by pharmaceutical houses, and outside of the commercial range also, was such as to require the best of judgment as to side effects, deleterious effects, weighed against the beneficial effects. The FDA, neither then nor ever, would have the full range of competence to make these sophisticated judgments. Therefore, the scientific leadership had to be such as to secure sympathetic response from the experts in the country wherever they may be, particularly in the academic institutions. Through association contacts, through individual contacts, we reached personally, probably a hundred of the leaders of pharmacological competence that were not directly related to business that would be regulated. We offered the job actually to about five or six of the top people.

Dr. Y.:

As an indication of the quality, could you give some of those names?

Mr. J.:

Yes. Dr. Harry Dowling, University of Illinois; Dr. Dickinson Richards who had retired as Chairman of the Department of Medicine at the College of Physicians and Surgeons of Columbia, who was a Nobel laureate. I could mention others; these are illustrative of the types of people whose competence we felt was required.

Dr. Y.:

The fact that they didn't take the position didn't indicate anything about their attitude toward the agency? The reasons were purely personal, I take it.

Mr. J.:

In both cases, the reasons were personal, so much so that I waited in each instance three or four months trying to get their situation such that they could accept the position. In both instances, reasons of health militated against it. In the case of Dr. Richards, I might add that President Kennedy himself at our request talked with Dr. Richards to encourage him to accept the position. The only reason he didn't was because of the advice of his physician by virtue of the fact that Dr. Richards had had a heart attack some months previously and it was felt that the pressures of the job would be too much for him. This is the kind of competence we were seeking, and there were several others whom we sought to recruit of the same calibre generally. And I think the word got around in scientific circles, and I said so directly to about 100 in one group, there was no point in having that particular group continue to criticize the scientific competence of FDA until some among their number were willing to take some responsibility for this area of FDA activities. This hit a responsive chord and the academic community became interested in helping find the right person. We finally found the right person in my

judgment in Dr. Joseph Sadusk who was then at George Washington University in Washington, who had had a distinguished career in medicine, both as a clinical practitioner, as a faculty member at Yale and at George Washington University, who had been chairman and still was of AMA's--American Medical Association's--divisional council--

Dr. Y.:

On drugs?

Mr. J.:

No, on legal medicine. Dr. Dowling had been chairman of AMA's Council on Drugs at one time. Dr. Sadusk was in the same calibre of leadership we were seeking, and by great assistance from Dr. John Parks, Dean of the George Washington School of Medicine, under whom Dr. Sadusk was then working, with full cooperation of the University, after considerable meditation, Dr. Sadusk agreed to undertake the job. When he came into it, I think he did extremely well, in identifying the problems, in attracting the scientific community, and it was very shortly after he took over that I, myself, resigned to return to Atlanta.

Dr. Y.:

The matter in connection with the medical director is just symptomatic of problems that, according to the record, the Food and Drug Administration had in the realm of developing its scientific

competence to the level that was required by the drug picture of our day. There had been criticisms in a couple of Citizens Advisory Committee reports about this, so this was solving one problem in a certain sense, the appointment of Dr. Sadusk, but there is some indication that it may not have been a complete solution, since the key administrators remained people who had come up through the ranks in the regulatory side and for whom quite naturally the increasingly complex scientific problems that were confronted must have been somewhat overwhelming. They needed the best advice that they could get.

Mr. J.:

My impression was as Dr. Sadusk came into the position and he was received with a great deal of warmth and appreciation. Of course, Commissioner Larrick was fully a participant in the choice and selection of Dr. Sadusk when I was able to identify him as one available, and as far as I could tell the whole FDA staff, including those in the Bureau of Medicine, responded to this kind of leadership.

Dr. Y.:

Now, after you had come back to Atlanta, Mr. Larrick decided that he would retire as Commissioner of Foods and Drugs and, by this time, there was a new Secretary of Health, Education and Welfare, Secretary Gardner, and the task of selecting Mr. Larrick's successor

confronted him. A committee was set up to chose the new Commissioner of Food and Drugs and you were a member of this committee. As it turned out, it seems to me, this was one of the most important transitions in the leadership of the Food and Drug Administration of all its history since 1906, because it was the first time that the new Commissioner was chosen from outside the agency rather than from having risen within the ranks of the agency and it was the first time, too, for, oh, 40 years, at any rate, that a man of scientific training became the new Commissioner. I think it's important in the historical record to reflect on how this committee, of which you were a member, went about the task of selecting the new Commissioner after Mr. Larrick had submitted his resignation.

Mr. J.:

I think the first thing I should say is that the committee was not to select but only to identify appropriate condidates for the Secretary to consider. The committee met several times. It put into consideration names which the individual members of the committee themselves wished to see considered. It accepted recommendations from whatever source names came.

Dr. Y.:

Did a good many names come in?

Mr. J.:

Not too many, really, but enough for a considerable breadth of selection.

Dr. Y.:

Did you sense that industry, the different segments of the regulated industries, presented what might be considered candidates?

Mr. J.:

No, my own feeling, and this is impressionistic, because you never can rely completely on motivations that others have, in terms of your appraisal of them, but my own impression was that the regulated industries, particularly the pharmaceutical industry which had been publicized pretty largely through new drug regulation problems was very anxious to see competence. They didn't much care about individuals so long as they felt that there was good administration and a sense of fairness. And as far as I could tell they were not interested in trying to influence the selection in one direction or another, but only to try to help suggest strength in their position from the standpoint of both administrative competence and fair judgment.

Dr. Y.:

Many of their journals argued pretty strongly that the choice should be made from within the agency.

Mr. J.:

This may have been so. It didn't influence the committee one way or the other. The committee would have preferred, I think, as I would as an administrator, to promote from within. This leads to morale-building, it recognizes experience, rewards those who have contributed. But the committee was not bound by this, although it would have preferred to be able to recommend an appointment from within.

Dr. Y.:

As I read what little has come out in connection with this, particularly the document the committee itself submitted, I get the idea that before the committee really tried to pick a person, it drew up a pretty comprehensive list of criteria as to the qualities that the person picked should have.

Mr. J.:

Before names were even listed, the committee, in its first meetings, decided on this procedure, that is, a listing of criteria on which selections would be made and then would consider individuals against this list of criteria. Obviously, no individual would be 100 percent responsive to each criterion listed, but the criteria were important in objective judgment as to the type individual should be in the job.

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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