An Interview with Mr. Gilbert S. Goldhammer

Dr. Y.:

This is an interview with Gilbert S. Goldhammer at his home in the District of Columbia on August 26, 1968. I am James Harvey Young of Emory University. Gilbert, you have had a career in the Food and Drug Administration that lasted thirty-one years.

Mr. G.:

About that.

Dr. Y.:

Would you please go over your career and indicate what its nature was?

Mr. G.:

Well, Harvey, I will be glad to. I came into the Food and Drug Administration in the summer of 1935, after about five years teaching of chemistry in the New York City high school system. I was given the job of inspector, although I had a choice of a job as a chemist or an inspector, but the FDA official who interviewed me painted such a rosy picture of the inspector's job, I decided to set aside my plans to be a chemist, and, instead, I became an inspector. I worked as an inspector from '35 to '43. In 1943, I was appointed chief inspector of the Buffalo Station,

as it was called at that time. In 1945, I went to Philadelphia Station to serve as chief inspector there, and in June of 1946 I came to Washington as one of the administrative assistants to the Commissioner who was then Dr. Paul B. Dunbar. I served in the Commissioner's office until 1948 when a Division of Litigation was established and I was asked to serve in that division. I became Deputy Director of that division about four years later. The Division of Litigation, which was the name under which the division was initially established, later became the Division of Regulatory Management. In 1961, I became the Director of that division and served as its Director until 1963, when, with a reorganization and the establishment of a new Bureau, known as the Bureau of Regulatory Compliance, I became its Assistant Director for regulatory operations. I retired in December of 1964, only to be asked to serve in a special capacity to assist in the preparation and presentation of the Krebiozen case. And this I did until the spring of '66 when I retired a second time. And I've been retired from the Government since.

Dr. Y.:

You still go back occasionally to help with the training program, isn't that true?

Mr. G.:

Yes. I have developed a course in Food and Drug Law for supervisory personnel of the Food and Drug Administration, and I've given some six or seven seminars of a week's duration to FDA supervisory personnel; and I'm scheduled to give three more to FDA inspectional, administrative, and laboratory personnel during the 1970 fiscal year. In addition, I've developed a course on Food and Drug law for State officials, and I have given three such seminars of a week's duration each to State officials in charge of food and drug programs. I'm scheduled to give another one in Texas in 1970 - probably in April.

Dr. Y.:

So you still keep your hand in with the agency.

Mr. G.:

I do.

Dr. Y.:

One of the things that I was particularly interested in was the way, when you were with the bureaus, Regulatory Compliance and Regulatory Management, you developed a kind of team of experts there concerned with quackery. You may have been concerned

with other problems, too, but there was a team, as I understand it, of people who had had background in this area and had developed considerable know-how, that really regulated and managed the whole anti-quackery program of FDA. Now I would be interested in how this team came about; how it was organized; what kind of people it had on it; and how it operated; how you made your decisions; and what was involved in various ways in developing a major case.

Mr. G.:

The Division of Litigation was established in 1948 by Commissioner Charles W. Crawford. He wanted a division in FDA which would concern itself almost solely with the handling of cases that were already in court and the development of new cases which were particularly complex, or which were of national scope and importance. At that time the sixteen local field stations of the Food and Drug Administration would develop their own cases within the framework of programs set up by Washington. It was the experience of the Food and Drug Administration that, when a case was complex or one of national interest and importance, Washington, sooner or later, had to get into the picture and assume the handling of the case. The FDA field offices just weren't equipped to handle a particularly

complex case. Commissioner Crawford recognized this for a long time and ultimately, in 1948, he set up the Division of Litigation with the express purpose of overseeing the handling of all cases that were in court anywhere in the country. The field districts were to develop cases as before only if they were routine cases. But once the cases were in court, and there was intimation of contest, the Division of Regulatory Management, or its predecessor, the Division of Litigation, took over the cases and monitored them until final adjudication. We reviewed the cases thoroughly examined the available evidence, determined its sufficiency, and decided what else needed to be done to insure victory. A second function of the division was to initiate, direct, supervise, and follow through right to the end, any complex case or special investigation. Quackery is in the category of complex cases. These cases are very important, and badly prepared cases make bad law. Bad law can stymie enforcement for years to come. Those staffing the Division of Regulatory Management were men who had had long experience in the development of cases and in the art of investigation. They were knowledgeable in what it takes to make a case; in how and where the evidence can best be acquired; and in the investigational skills that are necessary

to get the evidence. In addition, they had the qualities of leadership to lead and work with diverse groups, within and outside of FDA, involved in the development of our cases, such as inspectional, scientific, and legal sections or groups.

Dr. W.:

Beside yourself, who were some of the important men who were brought in to form this group?

Mr. G.:

Kenneth E. Monfore, who was the District Director of Seattle District, Seattle Station; James C. Pearson, who was Director of Atlanta District; myself, who was infthe Commissioner's office; John T. Cain, who had many years of experience as one of FDA's ace investigators; Van W. Smart, who had a considerable amount of experience in the handling of cases in court in the Western district area as an associate or an assistant to Mr. Harvey. Mr. Harvey was the chief of the Western district which covered the western third of the country. He was brought in to Washington in 1948 to head up this newly organized Division of Litigation. Mr. Harvey is a lawyer and had years of experience as an inspector, and station and district director. Prior to 1948 the country was divided into three districts: Eastern,

Central and Western, and Harvey headed up the last. The men who staffed the Division of Litigation, and its successor, the Division of Regulatory Management, were outstanding men who had made reputations for being able to develop cases, to get the evidence and win in court.

Dr. Y.:

Right.

Dr. G.:

Now, getting back to the question of quackery, almost all quackery cases require a great deal of careful investigation. Careful planning is necessary in dealing with quackery, particularly where the product involved is one which is recommended for the treatment of chronic and pretty much incurable diseases, such as arthritis, or cancer. I mention cancer as being incurable in the accepted sense. The fact is that two-thirds of those who are afflicted with cancer are not cured. They die of cancer. So, essentially, cancer is still an incurable disease. When a product is marketed to treat such a disease, where modern medicine itself is helpless in most cases, except for some pain relief or palliative treatment, the fact that the product failed in any given case is not substantial evidence. You've got to establish that the product never succeeds; and

this is a tall order. For this reason such cases, by their very nature, are complex and difficult to prove. So, as a matter of policy, FDA decided that cancer and other difficult quackery cases were to be centrally initiated in Washington, that is, in the Division of Regulatory Management, centrally directed and supervised, and the case itself handled from Washington even after its referral to the United States attorney; which is a departure from the routine case which is initiated and handled by the local FDA District headquarters.

Dr. Y.:

They take it to the U. S. attorney themselves.

Mr. G.:

They take it to the U. S. attorney and work with the U. S. attorney until its final adjudication, with only nominal assistance from Washington. But not so in cases which are extraordinarily difficult or which are of national scope and importance, and that's when we came into the picture from the very beginning.

Dr. Y.:

In the Food and Drug Review, the house organ for FDA, in an article about you, some of the cases that were listed as "major

cases" in which you participated, dealt with such quackery investigations as the Hoxsey case and the Krebiozen case which you have already mentioned, and then there was listed the Plantation Extract case which dealt with extract, particularly false vanilla.

Mr. G.:

Yes, that was the case which...I think was the first war frauds case brought during World War II or just before World War II. It involved bribery of government officials. It did involve vanilla and other foods.

Dr. Y.:

And the case involving, or cases involving, adulterated olive oil, the incubator egg reject racket and so on. Now these were some of the cases that were listed. Would you mind selecting one of the cases that might appeal to you for the purpose and showing how the principles that you have explained in connection with this team were applied to the given case?

Mr. G.:

Well, I think the Hoxsey case is a good one. The Krebiozen case is an excellent one but there were complications in that case.

Dr. Y.:

I want to ask you about that later.

Mr. G.:

All right. So, perhaps the Hoxsey case, which, incidently, I became involved in in 1946, and from 1946, onand off, that case was an active case until 1961 when the last nails were hammered into its coffin. But, you might say, that I spent almost a lifetime on the Hoxsey case. We had three trials which went to the Supreme Court possibly half a dozen times. I said "three trials." Actually, there were four trials: One was of a suit brought by Hoxsey himself against the Postmaster General, the Secretary of HEW, and the Commissioner of Food and Drug, to enjoin them and to require them to remove from post offices our poster displayed there warning the American public that the Hoxsey treatment was dangerous.

Dr. Y.:

I understand, incidentally, that you drafted that poster.

Mr. G.:

Yes, I worked with the Post Office Department on it and I drafted it. Now, getting back to how we happened to get involved in developing a case: generally, we get word of the

existence of a quack remedy either through advertising or through alertness on the part of inspectors who, as you probably know, are referred to as the eyes and ears of FDA. The Hoxsey medication came to our attention through our resident inspector in Dallas, Texas, who noticed Hoxsey's establishment there.

Dr. Y.:

Who was he, do you remember?

Mr. G.:

Yes, Breaux, Willard Breaux

Dr. Y.:

How do you spell his name?

Mr. G.:

B R E A U X. He's now a hospital administrator. He happened to be driving past a building and he saw the sign, "Hoxsey Cancer Clinic." Having the curiosity of a good food and drug enforcement agent, he investigated and reported Hoxsey's Dallas venture to his chief in New Orleans. FDA knew about Hoxsey, but he had drifted from state to state, and Breaux's report constituted the first knowledge the Food and Drug

Administration had that Hoxsey had established himself in Dallas and was operating there.

Dr. Y.:

You may have heard about his earlier history.

Mr. G.:

Oh, we knew about Hoxsey for a long time. His father, in the Twenties, was a figure of national attention because of his sponsorship of the "Hoxide Treatment." The American Medical Association, also back in the Twenties, had an expose of the Hoxide Treatment in its Journal. It's interesting that both Hoxsey's father and mother died of cancer, and when they died Hoxsey inherited the Hoxide Treatment. The Hoxide Treatment was an external cancer preparation. It was applied to the skin where the cancer was visible. It had in it corrosive chemicals which would destroy tissue. This is known as an escharotic substance. The cancer would, in fact, be destroyed, but so would a lot of good normal tissue. Escharotics are generally not used in the destruction of external cancer since a much cleaner job can be done through surgical excision. In the expose by the American Medical Association, the great harm he had done to persons with simple cancers that could have easily been excised, was pointed out. Skin cancer, as you

know, is almost 100 percent curable, especially if it's caught in its early stages. But he caused great needless disfigurement, even death, to persons who could easily have been cured by surgery. Hoxsey's father was prosecuted by Illinois. Harry Hoxsey, his son, carried on with this escharotic, and he did pretty much what his father had been doing. And he, too, was prosecuted; West Virginia, Illinois, Iowa, Michigan, and Ohio, all took action against him. Others attempted to. He went from state to state, but he couldn't get his roots established anywhere. He was always in trouble. But when he got to Texas, he found a haven. There he solicited the aid of a doctor of osteopathy, and they set up a "clinic" with Hoxsey as the boss of the clinic, and the D. O. as the front. But it was Hoxsey's business. There was no question about that, and he got himself a good foothold in Dallas. Now, it doesn't require very much to make a success of a quack cancer remedy. Just get it rumored around that you've got something which <u>may</u> be of value in the treatment of cancer, especially in terminal cases given up for hopeless by the medical profession. Let it be known that you have something which <u>remotely</u> may be effective, and those unfortunate patients and their relatives will be battering your doors down to get the treatment. It wasn't long before the Hoxsey Clinic was growing by leaps and bounds. Once he got started, it was like

a snow ball rolling down a snow covered hill.

Dr. Y.:

He changed his plan of operation at this point in Dallas to add to the escharotic which he and his father had employed an internal cancer treatment.

Mr. G.:

Yes. Some time before he came to Dallas, he was associated with a notorious quack by the name of Norman Baker who operated a clinic in Muscatine, Iowa. Norman Baker had the internal medicine; Hoxsey had the external medicine, the escharotic; and they divided their responsibility there. Hoxsey confined his treatment to external cancer; Baker, to internal cancer, with his internal remedy. The State of Iowa stepped in, enjoined this combine, and Hoxsey set off on his own, and when he did he had an internal remedy which was very similar to the one that Norman Baker had been peddling. When he opened his "clinic" in Dallas in the mid-Thirties he had an internal medicine. And so now, he peddled treatments for both external and internal cancers. So we knew about Hoxsey. We knew he was being driven from place to place. For instance, when I was Chief Inspector in FDA Philadelphia headquarters we had just completed an investigation of his activities in New Jersey

in the early Thirties. He had to leave New Jersey in a hurry. He went to Pennsylvania, and he had to leave Pennsylvania in a hurry. As I said before, he was going from state to state and getting into trouble, but in Dallas, Texas, he was able to operate, seemingly legally. Texas State officials considered for a long time the possibility of taking action against him, and, ultimately, they did. But they lost the case in the Texas Court of Appeals. He was exonerated and, in effect, given a free hand to operate there. And there, as I say, he achieved his greatest success. In 1946, when Inspector Breaux investigated his clinic FDA again gave consideration to stopping this activity. By this time we had gotten a Supreme Court decision which was very important in shaping FDA's decision that action should be instituted. That was the Lelord Kordel decision which defined the scope of labeling. It was apparent that the literature distribution plan for Hoxsey's medications fell within the scope of the Supreme Court's interpretation of labeling, thus giving FDA jurisdiction. Accordingly, the order was given to develop a case.

Dr. Y.:

The main point there is that Hoxsey was sending his printed matter separate from his medicine.

Mr. G.:

That's right. Prior to the Kordel decision there was doubt as to whether Hoxsey's printed matter was labeling. If it wasn't, FDA had no jurisdiction over Hoxsey's operation. The way Hoxsey operated was as follows: consumer or patient inquiry about the treatment would be sent to Hoxsey by mail, and he would, in reply, send his literature which contained false and misleading statements about its value. The Supreme Court held in the Kordel Case that such literature comprised labeling, if it was labeling, and it had false and misleading statements, the drug, when shipped in interstate commerce to persons receiving the literature, was then misbranded. The Federal Food, Drug and Cosmetic Act prohibits the interstate shipment of misbranded drugs. And despite the fact that, ostensibly, a doctor, namely the D. O., who was the front for Hoxsey, was administering the drugs in his practice of medicine, and that FDA could not legally interfere in the legitimate practice of medicine, the Food and Drug Administration felt that the facts in the case, nevertheless, added up to a violation of the Federal Food, Drug and Cosmetic Act. The Division of Litigation was given the job of preparing the case. I was the one in the Division who was assigned to the case--to prepare it, initiate it, manage it, and carry it through to its completion. Remember that in a case like this, in order to win in court,

you've got to prove that the preparations are totally ineffective for cancer, and when used in or on persons with cancer, failure of cure or benefit results every single time. Now, it's a peculiar fact of life when you're dealing with quack preparations, that no matter how fantastic the preparation is, no matter how worthless it is, no matter what its composition is, and the product may be nothing more than distilled water, or, maybe, just air, no matter how worthless it is for cancer, there will be persons who will be convinced, after taking the treatment, that they were helped. It is not surprising that Hoxsey in his literature reported hundreds of patient testimonials or claimed cures and claimed benefits. Such patient acceptance and praise creates a tremendous hurdle in winning a case involving cancer quackery. Because cancer is a disease which, for the most part, is not curable, and if Hoxsey is able to convince a judge or jury that he cured <u>one</u> person, the government wouldn't stand a chance. The fact that you can prove that he failed in a hundred cases is meaningless, because it is easy enough to prove a hundred cases of failure by surgery or chemotherapy or radiation therapy. That wouldn't mean that surgery or radiation therapy are ineffective. So failure means nothing. You must prove it never succeeds. How do you overcome Hoxsey's cases of claimed benefit? The answer to this lies in a carefully planned investigation

to get all the facts about Hoxsey's operation. In cases like this the first thing we do is to pretend to be cancer patients. We write to the firm a realistic sounding letter. We tell them that someone who is dear to us, a relative or a friend, has cancer. The cancer is identified, such as cancer of the prostate, the breast, the brain, or whatever. We inquire as to whether the Hoxsey treatment will be of any benefit. The object in this is to determine, without visiting the firm, what its promotional and labeling practices are. The answer that Hoxsey sends out is labeling within the meaning of the law, if the product is then purchased, and product and literature are brought together. There is then an accompaniment of product and literature as enunciated in the Supreme Court decision in the Lelord Kordel case. This is a necessary prerequisite for a charge of misbranding or violation of the law. So, without going to the firm, we write first to get the literature, or labeling, and claims for the drugs. Let's say the first letter that he sends is non-committal. In that case, we put ourselves in the position of the patient who may have received such a non-committal letter. What would he do? I believe he would want more information. The logical thing for him to do is to write another letter and say, "I don't know from your letter whether your medicine is of value for my wife's case. I don't want to make

the trip from New York to Texas or from Seattle to Texas on the basis of what you told me. What I want to know is, can it do my wife any good?" So we send a follow-up letter which any interested person who is trying to help an afflicted cancer patient might write and generally this results in a reply which is more definite, such as, "We have helped cases like yours."

Dr. Y.:

In preparing these letters, do you get help from the Bureau of Medicine?

Mr. G.:

Yes, but fundamentally we draw upon our own knowledge and experience. We have had many instances where we've gotten copies of letters which were actually written by cancer patients or their relatives and we know what they ask for and how they express themselves. We try to make our letters as realistically sounding as possible. Hoxsey has received many such letters from actual patients or their relatives. Now the second letter received may be a little stronger than the first in claims of value of the treatment, and this would make our case stronger, because it would help to explain what the literature says. The literature may be hedged. It may be

couched in terms which allow for more than one interpretation. In this way the promoter of the treatment thinks he protects himself. He may argue, "I don't claim cure of cancer", and when a charge of violation is brought against him that is his defense, "We don't claim to cure cancer." But we try to show through what he writes in his letters that he does make such claims. So, it's very important in the planning stage to set up the back-drop of the case being developed. After getting these preliminaries, that is the letter writing phase, out of the way, we will then order the product for shipment to us.

Dr. Y.:

Would he ship direct to people?

Mr. G.:

When we first instituted our case he would ship directly to people. Later he stopped that practice and made patients come to Dallas to receive the drugs. Now we have the shipment of the product. We also have the labeling. Ordinarily this would be enough to make a case, but we don't stop with that alone. We would have several other agents write in from various sections of the country, telling them exactly what should be written. We would send to the agents copies of prepared letters, and say, "This is what you should say. Let us

know immediately when you get your reply and send it to us immediately." When the reply came in then we would write back and say, "Now follow it up with this letter." And in time additional shipments of drugs would be induced.

Dr. Y.:

Would these letters go in under real names?

Mr. G.:

Yes. Usually those of chemists or inspectors. Of course, the contents of the letters were false. But the courts have held that this is not entrapment. As long as you give the promoter the opportunity to do what he would normally do under similar situations, the falsity of the letter did not result in entrapping him into violating the law when he shipped the misbranded drug. If it is entrapment the defendant has not violated any law. By "entrapment" we mean the creation in the mind of the defendant the idea for the commission of a crime. In this case, if the federal government hadn't written to the promoter, he wouldn't have violated the law in shipping his products to our agents. Is this entrapment? The courts have said "no." This is not entrapment because, if there were a bona fide situation like the one the government created, Hoxsey would have shipped his products

under those same circumstances. So, the government merely gave Hoxsey the opportunity of doing what he would do, normally. In proving our case we would have to show by evidence what he would do normally. Now, how do we get that evidence? First, we try to find out to whom he has shipped. Many persons would come to Hoxsey from out of the state. They would park their cars outside the clinic, and they'd go in and would be given the medicines, and, in due time, shipments would also be made to them. Our men maintained surveillance at the "clinic" and copied license numbers of cars that came from out of the state. We then ascertained the identity of the owners of those cars and visited them. More often than not we encountered considerable opposition from the patients. They had been propagandized by Hoxsey about government interference. Hoxsey stressed that the government was a tool of the AMA, that the AMA had tried to get his treatment and had failed and was getting its revenge by having the government destroy the Hoxsey treatment. Hoxsey hammered away that the government was not to be trusted. He told his patients in direct terms not to cooperate with the government. But among the many patients who visited Hoxsey and who later got his medicines, were some who did cooperate. The majority did not. But it was a matter of plugging away--persisting in our efforts until we encountered a patient who was not persuaded

by Hoxsey, and such patients established for us a pattern of behavior and activity by Hoxsey in their cases which fitted almost exactly the pattern in the shipments of Hoxsey drugs induced by the government.

Dr. Y.:

You did this by having the lists checked and then sending inspectors out to these homes?

Mr. G.

Exactly. The assigned inspector was told that he should expect to meet with opposition; that many would not let him in the house or talk to him once they learned that he was an inspector. He was instructed to be polite and sympathetic, and that he was not to get into any arguments. Rather, he should solicit their cooperation. But if cooperation were not given, he should not become overly persistent nor do anything which might be offensive, or subject to misinterpretations, or lead to an accusation of harassment. In this type of investigation you simply had to persevere with visits to hundreds of people. If you could find two or three who were cooperative, you could make a showing that what happened in the case of the government's induced shipment is precisely what happens in the case of actual cancer patients who get Hoxsey's medicines. And we did find an

adequate number to show a pattern. Therefore, our induced shipments were taken out of the category of entrapment. When our evidence of shipment and labeling was complete, we made an official inspection of Hoxsey's clinic. Even before that, however, we enlisted the help of several cured cancer patients to get them to do undercover inspections. They went to Hoxsey under our instructions and guidance with the story that they had had cancer. Their hospital records and their medical records showed that they had cancer, and these were taken and shown to Hoxsey. The cured cancer patients pretended that they were fearful that their cancers were returning; and they inquired, "Will your medicine prevent its return?" Invariably, they were told, "Yes, it would." In addition, one Food and Drug inspector was sent from Alabama to Texas to visit Hoxsey as a possible cancer patient. He was perfectly healthy, but he told Hoxsey that he feared he had cancer. He left the clinic with a statement from one of Hoxsey's physicians that "You came to us in the nick of time. You have cancer of the lung. You can't live more than six or eight months. We think we can save you." From the Hoxsey Cancer Clinic this inspector went to doctors of our choosing for a complete check-up and, of course, he had no detectable cancer of any kind. This case illustrates how Hoxsey sets the stage for claiming a cure. Many a hypochondriac with a

cancer phobia, coming to Hoxsey, was falsely told he had cancer and had only a short time to live. He took the Hoxsey treatment. He didn't die, and after the Hoxsey treatment all supposed evidence of cancer disappeared, and here is a case of cure for Hoxsey. The inspector who posed as a patient was perfectly healthy. He's alive today. He testified about his experiences at the clinic at the trial of the case instituted against Hoxsey. His testimony was very impressive. I relate this to show another aspect of our planning to gather evidence to show how far Hoxsey would go in this quackery venture. After the official open inspection, we try to correlate our samples and our witnesses' statements with what the inspector observes in the plant. In that inspection he talks to patients, gets their names and addresses, finds out about their conditions. In addition, of course, he determines the labeling; he tries to find out the compositions of the products, the financial aspects of the venture, etc. He makes as complete an inspection as he possibly can.

Dr. Y.:

He tells them who he is at this point?

Mr. G.:

Oh, yes, he tells them who he is. However, Inspector Gulledge who went in as a potential cancer patient, did not tell them he was with the Food and Drug Administration. He went in simply as an individual who was fearful that he had cancer. They confirmed his fears that he had cancer, which of course, he didn't have. We sent another inspector to the clinic in the same way with a pretense of cancer of the prostate. They confirmed it. He had no cancer of the prostate; we knew he had no cancer of the prostate, but he went in there with the declaration that he had certain symptoms and they told him that he had cancer of the prostate. Which led us to believe that anybody who went to the clinic with the feeling that perhaps he had cancer was informed that he did, in fact, have cancer. Then his failure to die would illustrate the effectiveness of the Hoxsey cancer treatment. Hoxsey had hundreds and hundreds of persons who felt that they were benefitted by the treatment. Now we had our samples; we had our literature; we had information as to what goes on in the clinic; we had our official open factory inspection; and we had our bona fide patients. Our next task was to show that the Hoxsey treatment never ever helped anybody. This meant we had to find out one way or another the name and address of every person who Hoxsey claimed was benefitted. If we left one such

person uninvestigated, we would lose the case. Therefore, it became very important to learn from Hoxsey or any other source the identity of those who were represented to have been benefitted by the Hoxsey treatment. Hoxsey was mighty proud of his claimed benefits and he publicized them for promotional purposes. He had a booklet with perhaps fifty pages which had the names and addresses of persons who allegedly had been benefitted, classified by type of cancer. Hoxsey advised persons to whom he mailed this booklet, "If you have any questions, write to these people." This was his means of convincing doubters who were wavering about taking the treatment that they should take the treatment. I should say, by that time, the Hoxsey Clinic had grown from a clinic with one doctor to a clinic with twenty-six doctors. It had all the trappings of a hospital...X-ray machines...X-ray technicians...It had the appearance of being a bona fide clinic, whereas, it was nothing but a house of quackery. We were able by digging up almost everything that Hoxsey had written, everything that Hoxsey had said about his treatment publicly, every publication that Hoxsey had had printed, to amass the names of hundreds and hundreds of claimed cures or benefits.

Dr. Y.:

How many did you have to investigate? You say, "hundreds and

hundreds."

Mr. G.:

I wouldn't be surprised, Harvey, if it totalled over a thousand Now this was an enormous undertaking. And, yet, we had to do it, if we were successfully to squelch Hoxsey's treatment. It meant going to the satisfied patient and getting his co-operation. How could we get his cooperation in the light of the antagonism engendered by Hoxsey? We went to Hoxsey and said to him, "Look, we are going to investigate your cases in which you claim benefit. We have to do this because we have an obligation to decide whether or not your treatment is of any value. Now, can we say to them that you gave us their names; that we are investigating your treatment; and that we'd like to know from them what their experience with the drug had been? Is that all right with you, Mr. Hoxsey?" Mr. Hoxsey took the bait and agreed because he felt that these people would give strong testimonials for the Hoxsey treatment, and would convince the government to give its blessings to the treatment. I'm sure he felt he would get FDA off his back if they visited and talked to the patients who felt they had been cured or helped. After all, they were his strongest supporters. Consequently, we were able to go to these people and say, "The government is investigating the Hoxsey treatment,

Mr. Hoxsey has given your name as that of a person who has used his treatment. Mr. Hoxsey says he has no objection to our interviewing you, and your giving us information as to your experience." With this approach the patients became completely cooperative, whereas before, they were antagonistic. Before, they would slam doors in our investigators' faces. But now, they gave us everything--names of their physicians, the hospitals they stayed at, and their complete histories. This was exactly what we needed. And we investigated these cases of claimed benefits thoroughly. We visited the physicians who treated before Hoxsey, the hospitals where they were treated, etc., and in this way, we were able to adduce evidence to show that in not one of these cases was Hoxsey justified in claiming benefit.

Dr. Y.:

Were there any cases in which these patients had never been to any other physician except Hoxsey?

Mr. G.:

Yes, there were instances of that sort.

Dr. Y.:

How would you tie those down to prove that there had been no

benefits?

Mr. G.:

There was no biopsy. Consequently, there was no conclusive evidence of cancer. As long as there was no evidence of cancer, it is entirely possible, and even probable in these particular cases, that cancer did not exist. Hoxsey can not claim benefit from his treatment if he hadn't established that the patient had had cancer. Hoxsey's Clinic did not do biopsies. Hoxsey's philosophy was, "Do not let them cut. Do not let them burn." By that, he meant use X-ray. "Because cutting spreads the cancer and X-rays burn and barbecue." So he could not espouse that theory, and at the same time, have biopsies taken of these persons who came to him.

Dr. Y.:

They did do a few biopsies, didn't they?

Mr. G.:

On one or two skin cancers, they did biopsies to establish that they had cancer, only for propaganda purposes. They knew that if the cancer were small, very small, the cancer could be removed, so that where a person had a very small cancer, they'd have the cancer removed during the biopsy to establish the

presence of cancer of the skin, but the removal of the cancer cured the patient. Then they would apply the escharotic. The escharotic would eat away a lot of additional tissue and guarantee the removal of the cancer, but would disfigure a person. We had any number of instances in which simple early cancers, that shouldn't have left even a scar if removed by surgery were treated by Hoxsey with the escharotic which caused great destruction of normal tissue with consequent disfigurement. One man who thought Hoxsey had cured him of cancer had his chin completely eaten away. He had a simple early lip cancer that was probably cured by the biopsy, and the escharotic wasn't necessary at all. Hoxsey used it anyway, as I say. When the patient testified, he could hardly talk. Half of his chin was gone. Yet he testified that Hoxsey cured him. So, we were able to show that in every instance Hoxsey was not justified in claiming benefit. We showed that all claimed benefits fell into one of three classes: (1) the patient never had cancer, or (2) had cancer and was adequately treated before taking the Hoxsey treatment, or (3) had cancer, went to Hoxsey, and died. But Hoxsey continued to publicize the testimonials that patients wrote after a month or two of the treatment, that they were feeling much better under the Hoxsey treatment, and Hoxsey never took the trouble of keeping himself posted on their actual condition.

Any number of these persons who had been so loyal to him were dead within two or three months after starting his treatments. Now, the fact that they were feeling better really didn't mean anything, because generally they went to Hoxsey after surgery or X-ray therapy because they didn't feel well after the surgery or X-ray treatment, for a protracted period of time. Not everybody recovers from surgery immediately. The same is true with X-rays. To some it's followed by a period of protracted discomfort, and just about the time they had given themselves up for lost and thought the surgery or other treatment was non-successful, that's about the time that the body was about ready to take a turn for the better; but by that time the patient had gone to Hoxsey. He took the Hoxsey treatment, but was already recovering from the previous treatment. His feeling better was attributed, of course, to the last medicine he had taken, which were the Hoxsey drugs. So it is not strange that Hoxsey was able to get testimonials from persons who really had cancer that the medicine was helping them. But at any rate, we were able to develop a very strong case to show that the Hoxsey treatment was misbranded and that it had never benefitted anybody.

Dr. Y.:

Now up to this time your team in Washington had been sitting there writing these letters, setting this network of inspectors at work investigating each of these individual cases.

Mr. G.:

That's right.

Dr. Y.:

And all of this data had been pouring in at headquarters.

Mr. G.:

Right. Now this data would be reviewed, and where there was some ambiguity, the inspector would be required to clear up the ambiguities, to complete the medical records, and then a decision was ultimately made as to which cases we wanted to present in court. These were not simply cases of failure, because a case of failure doesn't mean anything. We put on cases to show that the claim of benefit in the labeling for these cases was not true. In other words, the claim of benefit for these cases was a false statement, and if we could prove it to be a false statement, then the product was misbranded by that false statement and was illegal. We made a selection of thirteen such cases for presentation at the

trial in Dallas. These were their prize cases that they had proclaimed as cures in their labeling. We decided we would put on those thirteen cases. Now this involved a tremendous risk because the patients in these thirteen cases attributed cures to Hoxsey.

Dr. Y.:

So they were all witnesses for Hoxsey.

Mr. G.:

Actually they were our witnesses since we put on their cases but they were very hostile to the government. In cross-examination, they would say unequivacally that Hoxsey cured them. But, nonetheless, we felt that we could establish in an injunction suit, and that's what we filed in Dallas, that these thirteen cases were falsely represented to have been cured or benefitted by the Hoxsey treatment, thereby, establishing at least one aspect of misbranding. Now, the other cases we investigated were to be used only in refutation, in rebuttal. We anticipated that Hoxsey would put on so-called benefits, persons who would testify that they took the Hoxsey treatment, that they were given up for lost, that Hoxsey cured them. To win, the government would have to devastate such testimony and this was done in rebuttal when the government presented the

true facts about their cases.

Dr. Y.:

Now in some cases you could count on the judge restricting testimony by laymen along lines like that.

Mr. G.:[th]

Yes.

Dr. Y.:

But in this particular case, you were aware ahead of time you couldn't count on that.

Mr. G.:

Yes, in the case that we brought in Dallas in 1949, November of 1949, we knew that the senior judge in charge of all civil cases, Judge Atwell, would preside. Judge Atwell, it was rumored, and I might say, later confirmed by statement of Hoxsey's attorney, was a patient of Hoxsey, and he believed that he had been cured of cancer by Hoxsey after taking the Hoxsey treatment. Now, this was rumor, as I said, but we were well aware of it. Later, in 1961 or 1962, it was confirmed. I might deviate a little to tell you about the injunction suit that Hoxsey brought when the warning poster I

mentioned earlier was issued and placed in federal and state buildings and in post offices. Hoxsey sued for an injunction in Federal Court, Washington, D. C. to restrain us from using that poster and to make us take down the posters. At that time Judge Holtzoff, the judge who heard Hoxsey's injunction suit, was addressed by the attorney for Hoxsey who made this statement, and these are about the words that he used: "Judge, you know Judge Atwell. He thinks very highly of this treatment." And he held up the Hoxsey pills--the internal treatment. "Judge, as a matter of fact, Judge Atwell takes these pills. And he thinks they helped him." Now this is in the record of that case. So Hoxsey's attorney, himself, confirmed what was rumored in 1949. By the way, Judge Holtzoff refused to grant Hoxsey's request for an injunction of us. The poster is on exhibit in the Medicine display of the Smithsonian Institution in the section devoted to Quackery. To add to our difficulties in Dallas, Judge Atwell, the year before in 1948, had decided a case which Hoxsey had brought to recover damages of one million dollars against the Hearst publications, the American Medical Association and Dr. Morris Fishbein, then the editor of the Journal of the A. M. A. Allegedly, they had all called Hoxsey a quack. In that case Judge Atwell ruled that Hoxsey cured cancer. Having so ruled in April of 1948, we had every reason to believe that he would rule similarly, no matter what

evidence we put on, in 1949 when we brought our case. Yet we brought the case knowing full well we would lose. We planned to put on as strong a case as possible; build the best possible record in the hope that the anticipated adverse findings of Judge Atwell in our case would be reversed by a court of appeals. And so we concentrated on developing a case which was unbeatable.

Dr. Y.:

Now, just let me ask you. You got all the evidence; you were ready to bring the case. Now, what is the procedure that is involved in your group in Washington getting the case set up in Dallas?

Mr. G.:

All right. Now we were ready to go. The next question was: "What kind of case shall we bring? Shall we prosecute?" This would be a criminal case where proof beyond a reasonable doubt is required. It would be in Texas. Nobody had ever beaten Hoxsey in Texas. Many had sued him. The State of Texas and many persons had sued Hoxsey for malpractice, for fraud, but he had never lost a case in Texas. We took due cognizance of that. So we set aside the idea of prosecution. We could proceed by injunction, or we could seize the product. We decided

that since injunction would mean going before Judge Atwell this, too, was risky. The decision was reached that we would try seizure where he shipped across the state line in a sufficiently large amount to justify seizure. We found such an amount in Colorado in the hands of a doctor of osteopathy. We seized, in the hope that Hoxsey would contest; but Hoxsey was too foxy; he was too smart. He didn't contest. He made no appearance, and he let the seizure go by default so there was no trial. Our strategy failed. Our plan was to provoke a trial outside of Texas where we would stand a better chance of getting a just hearing, but Hoxsey apparently saw through our plan. If there was to be a trial he wanted it in Texas. The only other alternative then was to proceed with a complaint for injunction. And this we did. We prepared a form of complaint in our office and sent it to the General Counsel's office where it was perfected and sent to the U. S. Attorney General with a request for the institution of injunction.proceedings. The Department of Justice concurred, and sent the complaint and request for injunction to the U. S. Attorney in Dallas. He, too, concurred, and filed the complaint. The case came up before Judge Atwell. Judge Atwell at the time was about 80 years old, and he did not accept the government's contention that a lay person suffering from cancer is not qualified to testify about his

condition or about any betterment of his condition from any therapy given. The Judge felt that a person who has cancer knows this perhaps better than anyone else. We felt that proof of the existence of cancer can only be established through competent expert medical testimony and proof based on microscopic examination of tissue taken from the patient, and that the patient's knowledge as to his condition was of a hearsay nature, and hearsay testimony is not admissable in a court of law.

Dr. Y.:

Well, after you'd spent these months gathering all this material with the big network of inspectors working on it, you had the data assembled. Now did you check this out with Billy Goodrich's office here in Washington before you took it down to Texas?

Mr. G.:

Yes. As I said before, we prepared our concept of the case with a recommendation which went to Billy Goodrich, our General Counsel. In doing so, we even went so far as to prepare a proposed complaint and the General Counsel's office, of course, revised it, polished it, gave it its finishing touches, and sent it to the Attorney General, where it was further considered,

and then sent to the United States attorney in Dallas, Texas. Again it was reviewed by him so that there was check upon check to be sure that the case was a sound one. The United States attorney then gave his acquiescence, and the case was filed.

Dr. Y.:

Now when it's filed and then about to come to trial, do you go down with a staff from headquarters?

Mr. G.:

I and a member of the Bureau of Medicine went down to Dallas for that case with an attorney from the General Counsel's office. This man was Goodrich's first assistant, Joe McGuire. The physician of the Bureau of Medicine who accompanied us was Dr. Gordon Granger. We constituted the team that worked with the Assistant United States Attorney in the preparation and presentation of the case. It was our duty in the Division of Regulatory Management, at that time the Division of Litigation, to prepare a fact sheet for the testimony of each government witness. This was given to the United States Attorney in Dallas who would have something to take home and study. Rather than to tell him verbally who the witnesses are and what they would testify to, we prepared the testimony in writing for each

witness in a form that would make his use of it easy for him in his preparation of questions.

Dr. Y.:

He has a terrific job. You've been working months on it, and then he has a short time relatively to get familiar with it, and yet he's the man who's up there and can't make a mistake.

Mr. G.:

He does all of the interrogation. You are right. He cannot make a mistake. Consequently, the burden upon us is great to prepare him adequately so that he can capably handle the case. He is not a physician; he's not even an expert in Food and Drug law, because the United States Attorney or his assistants, and this was an assistant in the United States Attorney's office...

Dr. Y.:

Who was he, do you remember?

Mr. G.:

A man by the name of Harrel, H A R R E L, I believe. It's necessary for him to prosecute cases of all sorts under the law--income tax, interstate commerce, Federal Trade Commission,

any act on the books. Consequently, he cannot be an expert in all phases of criminal law, and generally, he is certainly not an expert on Food and Drug law; but, if he is properly prepared by us, he can do a creditable job, and he did. He did an excellent job. Now, as I mentioned before, it was our idea to put on so strong a case that any adverse decision by Judge Atwell would be overruled by a Court of Appeals. Judge Atwell, during the course of the trial, made many errors in law. He permitted witnesses for the defense to testify that they had cancer, that they were treated by Hoxsey, and that they were either cured or benefitted. Hoxsey did not put on any physicians for these patients, but relied solely upon the testimony of Dr. Durkee who was the doctor of osteopathy who served as the front for Hoxsey. This exposed Atwell to a reversal, because certainly a patient is not in a position to testify whether or not a certain drug benefitted him. And this the courts have held consistently. That was a question of law. But to get a reversal on the facts, that's a really hard thing to do. The Courts of Appeal have consistently taken the position that the trier of the facts had the right to decide his concept of the facts, and "Findings of Facts" of the judge sitting in a case, such as this one, which was an injunction case, are almost never reversed. This is so because the Judges of the

Courts of Appeal are not present at trial and do not listen to the testimony for the facts. They are to decide the validity of the findings upon a record, and they have said consistently that the trier of the facts is in a better position to judge the facts than the Court of Appeals because the trier of facts is able to decide for himself the credibility of the witnesses. He can tell by the witnesses' demeanor, whether they give evasive answers, by their facial expressions, etc., whether or not the witnesses are telling the truth. This is not available to the Court of Appeals. So the Courts of Appeal have been very loath to reverse judges on findings of facts. And that's what we were up against. Judge Atwell, after hearing some hundred witnesses in about a six-day period, found as the facts that Hoxsey cures cancer and that his treatment is at least as good as surgery, radiation, or chemotherapy. Judge Atwell ruled against us and refused to grant the injunction. But our case was so good, it was so strong, that the Court of Appeals, when we appealed, held the judge would have had to be blind or deaf not to have seen, heard and understood the evidence that the government had put on. The Court of Appeals said that they had a distinct feeling that a miscarriage of justice had occurred here. They reversed Judge Atwell on

the findings of fact, which, as I say, was a rare thing indeed. So, our strategy paid off, and we did get the injunction. This was appealed by Hoxsey to the Supreme Court, but the injunction was sustained and Hoxsey was enjoined. But this didn't stop him.

Dr. Y.:
Now, I'd just want to ask a few more questions about the trial. You also had expert witnesses, besides the witnesses whom you used to try to show that this had done no good.

Mr. G.:
Yes.

Dr. Y.:
For them.

Mr. G.:
Right.

Dr. Y.:
The patients of Hoxsey. Now, were these expert witnesses also assembled as a task of your team at headquarters?

Mr. G.:

They were assembled by the team, but they did not become a part of the team.

Dr. Y.:

Yes, but it was your responsibility to select the best possible witnesses to...

Mr. G.:

That's right.

Dr. Y.:

...describe what real cancer therapy was and to criticize the kind of therapy that Hoxsey was giving.

Mr. G.:

Yes. This was part of our role. We not only decided which witnesses were necessary, but we actually went out and solicited their cooperation and engaged them as expert witnesses. Then as another aspect we also planned animal studies or whatever investigations could be made in the laboratory or perhaps in a hospital to show the inefficacy of Hoxsey medications. When it comes to cancer therapy, you can't have a clinical trial, because you're dealing with a quack remedy

and in order to determine its effectiveness in a clinical trial, you would have to take a cancer patient off competent therapy. This would be deadly to the patient if a quack remedy is substituted so we don't do it. The next best thing is to see how it works on animals with cancer, and we did undertake a clinical trial at the Jackson Memorial Laboratories in Bar Harbor, Maine. Jackson Memorial Laboratories are nationally known. They experiment with mice and rats. They have developed colonies or strains of mice that are in demand for research purposes throughout the country. For instance, they had a colony of mice, every female member of which would develop spontaneously cancer of the breast, and these were the mice that we used the Hoxsey treatment on to determine whether 1., it would retard development of cancer of the breast and 2., whether it would have any effect on the course of the disease. And, of course, it didn't. That testimony was put on during the course of the trial. We did this, knowing full well that there are limitations to the applicability of animal work to the evaluation of therapeutic agents in human beings. But still, it did show, that in no way did it alter the course of the cancers in the mice. Then we engaged an individual who had done work on the role of potassium in cancer, Dr. Max Goldzhier, an endocrinologist, from New York, who had done extensive work on potassium and

its effect on terminal cancer. He concluded from his work that there was a godd likelihood that potassium enhanced the growth of cancer.

Dr. Y.:

Now the point of that was that potassium iodide was part of Hoxsey's internal cancer treatment.

Mr. G.:

That's right. Seventy-five grams of potassium iodide was in a dose of Hoxsey's internal cancer remedy, so that not only would you not expect the Hoxsey treatment to be of any value, but there was also the possibility, remote or not, that the potassium in the drugs would enhance the growth of cancer. So, that was another aspect of the case that was presented. At any rate our strategy did pay off and we did win.

Dr. Y.:

Now, you were there at the trial.

Mr. G.:

Yes.

Dr. Y.:

And I presume, in addition to the briefing that you had given the Assistant District Attorney prior to the trial, there were lengthy nightly meetings to get things sharpened up for each day's...

Mr. G.:

Yes. We would anticipate cross-examination in our own case, and plan ways of meeting it. When the defense case was on, we planned cross-examination. We anticipated the testimony of the witnesses and planned for cross-examination of those witnesses. That was a very important role in preparing the United States attorney. In addition to that, we sat at the counsel table, and we would transmit notes to the United States attorney to keep him from erring. If he committed an error, or if he failed to cover a point, or if something of significance arose by reason of the examination of the witness which had not been previously discussed with the United States attorney, we would prompt him. So we served a vital role sitting there at his elbow to guide him and to make sure that all of the evidence went in.

Dr. Y.:

Now, Hoxsey, himself, in this case, did he appear as a

witness in his own defense?

Mr. G.:

No. He did not. He relied entirely upon Joe Durkee, the D. O.

Dr. Y.:

You did, nonetheless, have an opportunity to observe Hoxsey to some degree during the course of the trial?

Mr. G.:

Yes. He sat at the counsel table with his attorney.

Dr. Y.:

Trying to do the same kind of job for his attorney that you were doing for the district attorney.

Mr. G.:

Yes.

Dr. Y.:

I've been interested in Hoxsey as a person. How would you describe him and his demeanor and the way he behaved himself while you had an opportunity to observe him?

Mr. G.:

I had an opportunity to observe him on two occasions. We had another trial of the Hoxsey treatment up in Pittsburgh, Pennsylvania, in 1956, after Hoxsey was instrumental in opening a Hoxsey Cancer Clinic in Portage, Pennsylvania, a little mining town about seventy-five miles from Pittsburgh. He's an impressive fellow. There isn't any question about it. He's tall and he is not shy. He's quite aggressive. His love of money is considerable. I had one little experience in the trial up in Pittsburgh where, during a recess, I was on my feet, giving myself a rest after having been sitting all morning. I was flipping a dime in the courtroom, and the dime got away from me and rolled halfway between me and Hoxsey. Hoxsey saw me approaching the coin, but he approached faster, bent over, picked up the dime, just as I was getting ready to bend over, turned his back on me, walked over to his side of the courtroom, and loudly proclaimed, "You see, I'm always lucky in a courtroom." And he put the dime in his pocket. So he owes me a dime.

Dr. Y.:

Well, that's a good, vivid, symbolical illustration, I think. I've read lots of things that Hoxsey wrote or that were

written over his name. These are written in pretty good English. From other things that I have heard, I've had the feeling that perhaps something of the coal-mining background that Hoxsey had earlier in Illinois before he got underway on this Hoxsey promotion...on his cancer promotion...might have stuck with him. When he spoke in conversation, were there evidences of this? Did he speak good English?

Mr. G.:

Yes. He spoke acceptable English. It wasn't English that a college professor would use but he was articulate. His English, I'm sure, if it were reduced to print as he spoke it, would be full of grammatical errors, but he could get his point across. You know, of course, he had nothing more than an eighth grade education. And apropos of your point as to what sort of a man he was, let me tell you what his lawyer told me he was. He told me during the course of the trial in Pittsburgh that Hoxsey was par excellence the con man. Now, that was his lawyer's words, not mine. In his office, he had a little placque which read, "The world is made up of two kinds of people: those that take and those that get took." Now, for one who's in the habit of taking, the way he was, this thing had particular significance, I think. This was his philosophy.

Dr. Y.:

Right. Did you get the idea that he was in any sense a crude man?

Mr. G.:

Yes. In a way he was quite crude. He wasn't polished, by any means.

Dr. Y.:

A blunt man.

Mr. G.:

A blunt man. But, in today's world, this is quite acceptable. You listen to people on television in high positions, and they're just as crude as he was. In his day, in those days, I think it was unusual for a man who was crude to achieve any great success in politics or in the professions. But judging by today's standards, I'd say, he was quite acceptable in his demeanor and speech.

Dr. Y.:

He must have talked with patients. Of course, he did talk with patients, as you found out, and he must have had a salesman-like persuasiveness in his manner of speech.

Mr. G.:

Yes. And that persuasiveness was attributable to the fact that he gave hope to these people who came to him. Many of them had been told by their physicians that their conditions were hopeless and that modern medicine could do nothing more for them. They went to him and he gave them hope. He criticized the medical profession for giving up on these patients, and whereas he did not promise that he would cure them, he would make statements which would encourage hope. He would tell them, for instance, that "While I can't promise you that I'm going to help you, I have helped dozens of cases just like yours." This is enough. So this was his charm, in that he was kind to these unfortunate people and he gave them hope. He would encourage them, tell them, "Don't worry, we'll help you." But that wasn't motivated--I'm convinced of this--by any humane or humanitarian impulse. He was looking for the income to be derived from this person who was about to be taken.

Dr. Y.:

Did the words of his attorney that he was a con man agree with the impression you got that he wasn't like some people who may be called "quacks," persuaded by his own gospel. You have the feeling that he was aware most of the time that he really was...

Mr. G.:

I would think so. As a matter of fact, I think it was his attorney who told me that he was convinced, that is, his attorney was convinced, that if Hoxsey ever came down with cancer, he would not rely upon his own medicine to help him, but would go to a doctor and have surgery.

Dr. Y.:

I heard a rumor the other day that Hoxsey is in some Texas establishment with cancer.

Mr. G.:

I heard that rumor, too. It may be more than a rumor. You might check this out with Brandenburg who asked that an investigation be made to establish if it was a rumor or not.

Dr. Y.:

I see. So that is being looked into.

Mr. G.:

That is being looked into, from the standpoint of interest more than anything else.

Dr. Y.:

Sure. From the point of view of the issue of Hoxsey's integrity or lack of integrity, wasn't there some episode in connection with the death certificate of his father which might throw light on that point?

Mr. G.:

Yes. The death certificate of his father actually on file at the State Health Department in Illinois showed that his father had died of cancer. In his book, "You Don't Have to Die", Hoxsey stated that the death certificate of his father had disappeared from the State Health Department's files because it showed that the cause of death was not cancer. The death certificate that Hoxsey had published in his book showed that a Hoxsey, but with initials different from his father's, had died of cancer, and he contended that this death certificate wasnnot for his father's death. We got hold of the authentic death certificate at the Health Department as it was filed, and it was identical to the one in his book in all details, except that the initials of his father were changed on Hoxsey's copy, apparently by Hoxsey, before he photographed the death certificate for incorporation in his book as a photograph of the death certificate. The initials did not match those on the original death certificate for Hoxsey's

father. This was how Hoxsey thought he would get around the fact that his father, who was touting a cancer treatment himself, died of cancer.

Dr. Y.:

One of the other things that I wanted to ask about related to the Krebiozen case, particularly your estimate of why it was that after the long, long trial in Chicago, and as a result of the trial in Chicago, the jury reached the verdict that Dr. Ivy and the Durovic brothers were not guilty in a criminal case of violating the law, when earlier it had been established that Krebiozen, chemically speaking, was a product that could in no way have any influence upon the course of cancer.

Mr. G.:

Yes. We had a very unfortunate jury. We started off with a panel of three hundred. When the judge announced that the trial would take about three months, actually it took nine, he gave those who felt that they could not sit at a long trial the opportunity to be excused. That one operation alone, reduced the jury panel down to about one hundred talismen. In other words, we lost two hundred prospective jurors, and these were probably our best jurors.

Dr. Y.:

The ones who would have had good jobs and...

Mr. G.:

That's right--who felt that they couldn't spare three months. Those who felt that they could spare three months, you wondered, you questioned what kind of people they were that they can spare three months; perhaps they were retired. But I think we lost our best people when that occurred. Now, you've got to remember, too, that the people in Chicago had been besieged and bombarded with propaganda about Krebiozen both pro and con. I doubt that there was any thinking person in Chicago who hadn't heard of Krebiozen and who hadn't, by this time, had some idea of whether they felt it had any real merit or not. Surely, the people in Chicago who had cancer were very apt to wind up using the Krebiozen treatment because it was home-based.

Dr. Y.:

And there were enough doctors there who were using it.

Mr. G.:

Yes, because of the influence of Dr. Ivy. If Dr. Ivy had not been involved, there wouldn't have been any issue. But because of Ivy and the confidence he instilled, doctors from Chicago,

were, mostly at the insistence of their patients and their relatives, getting Krebiozen. Now, for each person getting Krebiozen, there are many, many persons who know about it. Consequently, to me, it seemed a little bit strange that we had jurymen who ultimately got on the jury who professed not to have heard of Krebiozen and, therefore, they were uninfluenced by the propaganda, and could decide this case without bias, and that they had formed no opinion. Most amazing to me, was that there were persons on that jury who said that they had never heard of Krebiozen. I felt that either they were lying or that they must be awfully ignorant. What intelligent person would not know, at least know, about Krebiozen? Yet, there were persons on that jury who said that they had never heard of it. So, we did not have an A-1 jury, and we knew this. We knew right from the start that this was a very poor jury to decide this very important case.

Dr. Y.:

Did you really know very much about the background and the educational level of the jury members?

Mr. G.:

No. We had their occupation listed, nothing more. But you've got to remember this: that where the occupation indicated a

high degree of intelligence, like attorney, the defendants challenged them, made sure that any person with any education was not on that jury. And they had a great many challenges, because there were four different attorneys there, each representing a different defendant, and each attorney was entitled to his full quota of challenges, giving them an enormous advantage over the government who had only the number of challenges to which one attorney was entitled. They had four times as many challenges. Anyone with intelligence, apparent intelligence by reason of the position held, was automatically dropped from the jury. So, this, too, contributed to lower the level of the jury. Now, that was one aspect. Yet, notwithstanding that, there were at least six persons on that jury who were persuaded by the government's case to the point where they were for conviction of all defendants. There were, however, five who were against conviction. Now, of those five, one, who turned out to be the foreman of the jury later, was a person whose wife had had cancer, who had heard of the Krebiozen treatment, and who had considered using the Krebiozen treatment for his wife in the event that there was a recurrence of cancer of the breast. The breast had been amputated and, apparently, there was no recurrence, so he never was faced with the need in the two years between operation and jury service to use the Krebiozen. But he later admitted to newspaper people

that he had considered taking his wife for Krebiozen in the event that there was any return of the cancer and that he at that time felt that Krebiozen had value. Yet, he sat on the jury, and he had lied in the voir dire on the part of the judge as to whether he had heard of it or had any preconceived ideas. Now that was one. Another thing was, one of the members of the jury by the name of Butkowski was an official of the International Meatcutters Union. He was characterized by the jury people who were for conviction as the "Hammer Man" on the jury. From the very start, with the very first government witness, this man attacked the government to the other jury people. Despite the warning of the judge with each recess that the jury was not to discuss the case among themselves nor were they to discuss the case with anyone else, that they should, under no circumstances, permit anybody to talk with them, as soon as there was a recess, no matter who the government witness was, Butkowski would attack them as liars, egg heads, stupid. This International Meatcutters Union, where he was on the board of directors, and was one of the members of the executive committee, and a high official, had taken a position publicly with respect to the Krebiozen case. As a matter of fact, over union headquarters which he had to go into, every time he went to his office, was a big sign that said: "Krebiozen should be given a government test." During the course of the

trial, there was a meeting of a local of this union in Peoria, Illinois. Ivy and Marko Durovic attended this meeting during the course of the trial. It was also attended by this jury man--Butkowski.

Dr. Y.:

During the course of the trial?

Mr. G.:

During the course of the trial.

Dr. Y.:

While it was in recess.

Mr. G.:

It was over a weekend. Ivy and Marko addressed this local and this union leader was there. During the course of the trial, on two occasions, every member of the jury was circularized with pro Krebiozen leaflets. This circularization was by mail; the letters bore the return address of this union.

Dr. Y.:

You have no idea why the union took this position?

Mr. G.:

Many unions did. I think the American Federation of Labor took a position which was pro-Krebiozen as did Senator Humphrey, as did Senators Douglas, Proxmire, Hart, Kefauver. They all took positions to get special treatment for Krebiozen from the Secretary of Health, Education and Welfare.

Dr. Y.:

Was this out of respect for Ivy that Senator Douglas had and then the other senators out of respect for Senator Douglas?

Mr. G.:

I would say so. It would be my guess. Now Senator Javits also was approached to take a similar stand, until one day his staff man called us on the phone and wanted to know about this petition that Senator Douglas was sending around to the other members of the Senate, asking the Secretary of Health, Education and Welfare to set aside the requirements of the law as to Krebiozen and to permit interstate shipment of Krebiozen. He wanted to know, "This is a little irregular. What are the facts?" We gave him the facts and Senator Javits withdrew. But prior to that he had gone along with Senator Douglas. Now during the deliberations of the jury, and this we got from the jury people, at the first ballot, and almost throughout the

deliberations, it was six for conviction and five for acquital, and one who said she'd go with the majority. She was indifferent. Didn't care either way. Whichever way the majority went, she'd go. And that's the way this thing remained day after day. I think they were out for eight days when they apparently reached an agreement to get out of this impasse. This was Saturday, the 29th of January, I believe, 1966. They agreed that they would acquit Ivy and Marko and convict Stefan Durovic, Dr. Phillips, the Krebiozen Research Foundation and Promack Laboratories on counts which they would decide after Ivy's and Marko Durovic's acquital. Now this "Hammer Man" insisted that before they deliberate further as to what they should convict Stefan Durovic and the others on, that they go in and acquit these two people. This was done. When the jury came back to deliberate--this we got from those who were for conviction--those who were for conviction discovered that they had been double-crossed. This guy from the union said, "You misunderstood us. We haven't said that at all. We had no agreement to convict anybody." That was his position, and they were stuck.

Dr. Y.:

They were hung then, at least for the time being.

Mr. G.:

They were hung, yes. And all the time, they had been asking the judge to let them go because they were hung up. The judge would say, "No, keep on deliberating; reach a verdict; it's your responsibility." Then, they came back, and found themselves in a position where they had let go some of these defendants. When they saw the hopelessness of it, they again told the judge, and again the judge told them to continue their deliberations. This was about the sixth or seventh time that they appealed to the judge to declare a mistrial because of lack of agreement. That was on Saturday when they found Ivy and Marko Durovic not guilty. On Sunday, a woman in the jury got sick. Now those for conviction feel--she was one for acquittal--that she didn't really get sick; she feigned sickness. At any rate, they took her out in an ambulance, and this chap from the union is reputed to have said, this is what we were told by the jury people, that "If she dies, this will be on your consciences. You are the cause of it." Thishe told to those who were for conviction.

Dr. Y.:

Because they kept her there so long.

Mr. G.:

That's right. He tormented them further with the question:

"And how can you as Christians ever sit in a church again," or words to that effect. This is what we were informed when we spoke to some of those jury people who were for conviction. Well, as it turned out, she was back Monday. Thatwwas on Sunday, she was back Monday, well. In the meantime, the shock of this made those for conviction feel that they had to get out of this thing. They were going to make one last appeal to the judge that they were hung and that they should be let go. They did, that Monday morning, and that Monday the judge said, "No, go back." This was about the ninth day, maybe the tenth day, I don't know. It was a long time. Well, they didn't go back in. They felt resentment; they threw in the sponge; to get out they voted for acquittal. As they were coming out of the jury chambers, one woman who felt very strongly for conviction, heard Butkowski say to the foreman,..."Boy, I never thought we'd swing it all the way like we did." And she told us that she felt like slapping his face. Instead, she burst into tears and the accounts of the acquittal in the newspapers have it that she had tears streaming down her face. Well, she later told us what had occurred. She heard this remark and this so infuriated her that she burst into tears, and she came into the Courtroom with tears streaming down her cheeks. Now, this Hammer Man, Butkowski...

Dr. Y.:

How do you spell the name?

Mr. G.:

B U T K O W S K I. He had been charged with contempt of court and he plead "not guilty" and the matter is awaiting trial. (Butkowski was later convicted and given a three-year prison sentence.)

Dr. Y.:

On what grounds?

Mr. G.:

On grounds that he obstructed justice.

Dr. Y.:

Because he hadn't admitted earlier that he had had some connection with Krebiozen?

Mr. G.:

No. Because of his failure to comply with the requirements of the court, that he not discuss the case.

Dr. Y.:

I see.

Mr. G.:

And that there he was down in Springfield with some of these defendants during the trial.

Dr. Y.:

I see.

Mr. G.:

For that convention of the union local. That and the fact that he was constantly hammering away at the witnesses of the government when he was under court instructions not to discuss the case at all, right from the start. And the fact that his union had taken a position on Krebiozen and there was that sign over headquarters.

Dr. Y.:

And this case still awaits trial?

Mr. G.:

Yes. Now you ask how it is that this occurred? Well, this is how it occurred: Much of what I have told you here is public information.

now. It was all reported in a series of articles in the St. Louis Post-Dispatch, written by one of that newspaper's ace reporters, a fellow by the name of Collins, his full name slips me at the moment. But what I've just told you is public.

Dr. Y.:

And does he allege that there was anything behind the position of these pro-Krebiozen jury people?

Mr. G.:

No. He doesn't. Of course, the whole thing is mighty unfortunate.

Dr. Y.:

He doesn't allege that the Krebiozen forces got to and bribed the witnesses or anything...?

Mr. G.:

No. There is nothing like that alleged. What motivated Butkowski, I can't say. The government was doomed from the start.

Dr. Y.:

Now, this case differs from the Hoxsey case in that it was a jury trial.

Mr. G.:

No. In the first Hoxsey case, that is, the case involving the injunction in Texas, that was before Judge Atwell without jury. But the second trial, which involved a tremendous seizure of all of Hoxey's medications in Portage, Pennsylvania, was a jury trial.

Dr. Y.:

Yes. I was thinking of the first Hoxsey case in Texas. There you could appeal.

Mr. G.:

Yes.

Dr. Y.:

Would it have been possible to make the same kind of an appeal to a circuit court after a jury trial case?

Mr. G.:

Only in a seizure case. But in a criminal case there is notappeal if the government loses. To reverse an acquittal would be double jeopardy.

Dr. Y.:

That's what I thought.

Mr. G.:

Consequently, we simply had to accept the verdict. It's an unfortunate thing that the judge was so insistent upon the jury returning a verdict.

Dr. Y.:

You think it would have been better had he recognized the impasse and called it a hung jury and permitted, therefore, a new trial to have been brought?

Mr. G.:

One of the jury women, the one who had tears in her eyes, told the Assistant United States Attorney who handled this case and Mr. Palmer, one of FDA's inspectors, that she felt that this was a very poor jury and that the government could not prevail with a jury of this poor quality and that she was very anxious that the government have another chance to prove its case. She was going to hold out for a hung jury, but the way things developed, they were the weaker ones, she said, and they couldn't hold out in the face of the aggressive attacks. They were sick. There was an epidemic of the grippe going around. They were not immune. They

were imprisoned. They could go only between the courthouse and the hotel. They had had it.

Dr. Y.:

And this had gone on for nine months?

Mr. G.:

Nine days. The trial had gone on for nine months. But the deliberations were for nine days, and they were imprisoned in this room with a lot of antagonism built up, and the judge wouldn't cooperate with those who were for conviction. They just felt such resentment that they threw the sponge in and said, "The heck with it."

Dr. Y.:

Of course, the judge didn't have to explain his position? He was hopeful that he could get a verdict and avoid another long trial.

Mr. G.:

That's right. But it was no secret that he wanted a conviction. He was convinced beyond any question that this was one of the greatest frauds ever perpetrated upon the American public. He was sorely disappointed in that jury.

Dr. Y.:

But somehow he didn't, at that point, couldn't he realize what was happening in the jury?

Mr. G.:

He didn't recognize that it was hopeless for the government. He did not foresee that, if anything, instead of compromising in favor of the government, the compromise would be against the government. He didn't recognize this.

Dr. Y.:

And your feeling was that your evidence was every bit as persuasive as the evidence had been in the case connected with Hoxsey.

Mr. G.:

It was the strongest evidence ever put on in any case within my experience and the members of the United States Attorney's office assigned to the case have said the same thing.

Dr. Y.:

It was not only the kind of medical evidence with respect to the cases of people who hadn't benefitted or hadn't been cured, but in this case, you had fraud.

Mr. G.:

We put on tremendously persuasive evidence of fraud. Absolutely irrefutable.

Dr. Y.:

Did this relate to such things as the number of ampules that they had bought compared with the amount of medicine that they asserted that they had?

Mr. G.:

That's right. That was one thing. The money they made was another. There were many aspects of fraud.

Dr. Y.:

Things of that sort.

Mr. G.:

They said they had enought so-called Krebiozen powder to make only two hundred thousand ampules of the injectable solution. That's all they had, and yet they bought well over a million ampules. I can't recall the exact figures, but it certainly was well over a million ampules and used them. Now where did the Krebiozen powder come from? And then, what was the substance Krebiozen? Their refusal to give us samples of the powder was suspicious.

Ultimately they did give us a sample, and what did it turn out to be? Creatine monohydrate. Their purchase of horse meat was suspicious. We know we can make creatine from horse meat. We've made it. Why were they buying horse meat? They were supposed to have the blood. Krebiozen, they claimed, came from the blood of horses.

Dr. Y.:

In other words, your assumption there was that they were making it out of the horse meat and not out of this tedious, complicated process that they claimed they were making it out of, injecting something in the horses and then taking the blood.

Mr. G.:

The evidence is clear to us that they made nothing. But when they were pressured to give samples to the government, they had to give it something. They gave creatine which they made from horse meat. But creatine doesn't dissolve in mineral oil. We never found any creatine in mineral oil. But we did find 1-methyl-hydantoin, a creatine derivative, which does dissolve in mineral oil, if you add a little amyl alcohol, and we found the amyl alcohol in the ampules of Krebiozen. Now what is the significance of this? The significance is: they had given the government creatine and they could expect the government to look for it in the mineral oil

Krebiozen powder was supposed to be dissolved in. They knew creatine doesn't dissolve in mineral oil so they put this creatine derivative 1-methylhydantoin into the mineral oil instead of creatine. The amyl alcohol was added to increase the solubility of 1-methylhydantoin. I'm sure they never imagined that the government would be able to discover and identify such small amounts of 1-methylhydantoin and amyl alcohol in the mineral oil. They thought the 1-methylhydantoin would surely confound the government chemists and convince them that a substance Krebiozen did exist. And so, when we had samples examined by our chemists, this unknown something was discovered which we established ultimately, in a beautiful piece of research work, to be 1-methylhydantoin. We were able to prove that Promack Laboratories, that is the Durovics, had a supply of 1-methylhydantoin. We knew they also had creatine because the commercial laboratory which they hired to analyze certain unknown substances were given coded samples of creatine and 1-methylhydantoin. The laboratory was told that the sample, which turned out to be creatine, was Krebiozen powder. This commercial laboratory reported to the Durovics that it was creatine monohydrate. Once the government discovered that the Krebiozen given to them was creatine in the powder form, or 1-methylhydantoin in the mineral oil, there was no longer any need for Dr. Durovic to carry on his pretense. Immediately after that the Krebiozen solution again became pure mineral oil. Prior

to their giving us the sample of creatine the injectable liquid labeled Krebiozen was pure mineral oil. After they gave us a sample of the powder which we established to be creatine, they dissolved 1-methylhydantoin and amyl alcohol in the mineral oil. After we discovered this, Krebiozen once again became just mineral oil. The only time it contained anything other than mineral oil was for a short period of time in 1963 when it contained the 1-methylhydantoin.

Now as far as the FDA is concerned, and it convinced the United States Attorney and the Justice Department of this, Krebiozen is nothing but mineral oil. It never was anything but mineral oil, and everything else were the props of a con man. As a matter of fact the United States Attorney, in his summation, said he was struck with the similarity between Krebiozen and the fairy tale of Andersen, "The Emperor's Clothing." The government attorney read Andersen's fairy tale to the jury in summation. The story starts off, "Two foreigners who were swindlers came to the city of this kingdom." The government attorney told the jury that that's exactly what happened here. Two foreigners who were swindlers came to Chicago from abroad. They pretended to make Krebiozen. They brought the props to suggest its manufacture, but Krebiozen was never made. It was only mineral oil, and the Krebiozen cloth was just spun out of nothing.

Dr. Y.:

And in connection with the fraud point, didn't you also have some evidence that there had been tampering with medical records?

Mr. G.:

Oh, yes. A person who had cancer of the bladder took Krebiozen, then went back to Argentina where he died, of...cancer of the bladder...in 1956. The Krebiozen Research Foundation records showed him as being alive and examined in 1959, had him again examined in 1961, and claimed he was free of cancer--thanks, of course, to Krebiozen. This false record was given to the National Cancer Institute as evidence of Krebiozen's efficacy.

Dr. Y.:

And you checked with the death records?

Mr. G.:

We went to Argentina.

Dr. Y.:

Did you go?

Mr. G.:

No. I was supposed to go but the Krebiozen case came up and someone

else batted for me.

Dr. Y.:

I see.

Mr. G.:

But, we actually went down there and we brought up the sister, two sisters, who testified, and we got, of course, a certified copy of the death certificate and his medical records. His sister testified that he died in 1956. Krebiozen Research Foundation carried him on their records as having been examined in '59 and '61. They may have felt "Well, who's going to go down to Argentina to check this?" We did. So that was one. There were, oh, any number. We alleged two or three such falsifications of records which we charged as being criminal acts because the false records were submitted to the National Cancer Institute. The one involving the fellow down in Argentina... the death in Argentina, is one of them. But there were many of them; many records which didn't jibe with the actual medical facts.

Dr. Y.:

Now, one of the truly intriguing questions that underlies this whole episode, and it makes it the kind of episode that it

became with the stature and a magnitude of its appeal, is unquestionably the fact that Dr. Ivy lent his reputation, which had been a very high reputation, to it. From your observation of the trial and your examination of all the records getting ready for the trial, did you reach any judgment as to why this sort of thing occurred?

Mr. G.:

I did, yes. The testimony of Ivy and the facts of the case indicated that Dr. Ivy embraced Krebiozen with almost no knowledge about it, with no knowledge about the promoters, the Durovics. He worked with a physician by the name of Krasno, Louis Krasno, and they conducted a study with this. They didn't know what it was; its composition was completely unknown, and yet, they embraced it without knowing its composition, and they conducted a study of the most superficial type on dogs and human beings. No scientist in his right mind would accept either the type of study that was done or the results as having any validity. And yet, on the basis of that absolutely insignificant work, they concluded that Krebiozen had tremendous merit and justified intensive study. Now, in March of 1951, Ivy announced to the world in a convening of physicians and members of the press at the Drake Hotel in Chicago that he had studied Krebiozen and that it had sufficient merit to warrant further investigation by the

medical profession, and he presented to the medical profession a booklet with a chart showing the patients, identified only by initial, the disease, the treatment, and so on. It was an interesting tabulation. Now during the trial, we tore that apart and showed that there were downright falsifications in that chart. One of the doctors, for instance, had written to Ivy and said, "You've completely distorted" (it wasn't Ivy's patient, but it was this other doctor's patient, whom Ivy was permitted to observe)..."You've completely distorted my medical facts on this man. He didn't benefit; he got worse." This was after the booklet was published. Ivy never retracted. There were a number of patients who had died of cancer and were shown in this chart as being alive and well. He knew they had died, because one of those who had died was Dr. Pick's wife, and Dr. Pick was one of the doctors who was working with Ivy on this thing. Ivy knew Dr. Pick's wife was dead. Certainly, Dr. Pick knew his wife was dead, and yet there they both were on the platform at the Drake Hotel not saying anything when they spoke of the results of their study of Krebiozen. So you ask me whether I drew any opinion or any conclusion about Dr. Ivy and what motivated him. My own personal feeling was this, that Dr. Ivy had reached a stage in his life where he was about to retire on a very small pension. Here was a man who was active all his life and he apparently never made very much money; after all, he was

for most of his life a college professor. Although he's an M.D., he was not a practising M.D. He had five sons, four of whom he sent through medical school, and I don't think he was in a position to accumulate too much wealth in the course of his professional activity. He was now reaching a time in his life when he would have to consider retirement on a small pension. Durovik came along and, perhaps there was a lot of wishful thinking on the part of Ivy, he embraced this preparation, perhaps he had visions of a Nobel prize. Even as late as the trial in this Krebiozen case, Ivy sued the government, the United States Attorney, to keep this trial from being held. He sought an injunction to keep this trial from coming up. And among his contentions was that if he were convicted, and he felt that there was a good likelihood that he would be convicted, he would probably be the only Nobel prize winner who ever spent time in jail. I think that's rather interesting, in that it suggests that that's maybe what he had in mind when he embraced this. He hadn't achieved that; he had achieved fame and respect, but not the Nobel prize. Maybe this was on his mind. Maybe that's whyhhe embraced it. Here was his opportunity. I don't know whether he made any money out of this thing. The evidence at the trial showed that he had deposited a sum approximately equal to his take-home pay as a university professor; I think what the evidence showed was twelve hundred dollars

a month, perhaps fourteen hundred dollars a month, each month, that would be deposited. And that was equivalent to his salary minus his deductions as his take-home pay. Nothing else went into this account for years, and then suddenly in 1957, a hundred and ninety thousand dollars went into this account, including, of course, those fourteen hundred dollar checks. And then in another year, soon after that, there was a hundred and sixty-four thousand dollars that went into his account. This was a lot of money, and this is in the evidence. Now, whether it indicates that he got paid from Krebiozen, I don't know. We weren't able to prove that. He denied it. But the fact is that he had tremendous stock holdings. Maybe he made it on the market. Nobody knows, but certainly he had at least a quarter of a million dollars in stocks. This was in the evidence. It all came about by a question asked by the defense attorney when he had Ivy on the stand. He asked Dr. Ivy, after having portrayed him as a man of no great means, who was now retired after having devoted a lifetime on the campus, "Dr. Ivy, what do you live on?" And Dr. Ivy, in furtherance perhaps of this thesis of giving the impression of being a poor man, said, "Well, I have a small pension, and I contributed to this pension, and the state contributed to this pension, and then some income that we have from our invested savings." All of which gave the impression of being very, very small. I think the pension was around six thousand dollars a year.

Well, that opened it up, and actually he had had twelve thousand dollars, I don't remember whether it was twelve thousand or fourteen thousand, in dividends from the stocks. He didn't mention that. He says, "Return on the investments that we've been able to make from our savings."

Dr. Y.:

Now, on cross-examination, they found out what the sum was.

Mr. G.:

Yes. It was twelve thousand dollars. Well, we had known this. We had his income tax report; he knew we had his income tax report. But whether he made any money out of the Krebiozen venture, I don't know. I rather suspect that perhaps he had hopes when he embraced Krebiozen of obtaining recognition as a Nobel prize winner.

Dr. Y.:

I have talked to people who have had the feeling that he was the sort of personality who, once he got involved in a thing like this, would become more hardened in his defense of it rather than admitting perhaps that he had made an initial mistake.

Mr. G.:

I think he is incapable of saying "I was wrong." I gathered that from his testimony. He was on the stand a long time, subjected to rigorous cross-examination. In my opinion, he turned out to be a deplorable witness. It was sad. It made me sad to see a great man responding in the manner that he was responding to questions from the United States Attorney. So I gathered that he was very stubborn and incapable of admitting error on his part. What you had gathered, I think is true, that the more criticism heaped upon him that the stronger became his determination not to abandon Krebiozen.

Dr. Y.:

There was another Chicago scientist whom I wanted to ask you about. He was a physiologist at the University of Chicago, Anton J. Carlson. Now in the research that I've done, I have found that many times Professor Carlson served as a prosecution witness for the Food and Drug Administration, sometimes in quackery cases, sometimes in other kinds of cases. While you were with the Litigation or Regulatory Compliance part of the Food and Drug Administration were you involved in any cases in which Professor Carlson was a witness?

Mr. G.:

Not while I was with the Division of Regulatory Management. By then, Carlson had gotten sick. He'd had a heart attack, and he was considerably less available as a witness. I might say that Ivy was a protege of Carlson. He was a disciple of Carlson and Carlson was very proud of him until Ivy embraced Krebiozen.

Dr. Y.:

I might say that a friend of mine, a medical school dean, who knew Carlson, once met him in his latter years, after he had his heart attack, at a convention in Atlantic City, so he told me, and he posed the question to Carlson as to what had happened to Ivy in connection with the Krebiozen situation. According to my friend, Carlson took his hands and clutched his chest and said, "Thank God, I have my trouble here instead of here," and on the last phrase he moved his hands from his chest to his head.

Mr. G.:

I've heard that story, too.

Dr. Y.:

So that that's true that Dr. Ivy was a student of Professor Carlson.

Mr. G.:

Yes. And Dr. Carlson tried very diligently to persuade Ivy to give up Krebiozen, which he felt was madness on Ivy's part. And some of Ivy's friends and colleagues banded together and tried to persuade Ivy to give it up. Later on, Ivy accused them of an insidious motive in that. He didn't accept their efforts in the spirit in which they made them, namely, to persuade him that this was suicide for him...professional suicide for him to pursue this. But instead of accepting it, he resented it and attacked them later. But coming back to Carlson, I did have occasion to be on a case in which Anton Carlson testified. I had heard of Carlson. He had a great reputation as being the dean of physiologists in this country, but I had never met him and I didn't know him. The case in which he and I both testified was a case brought by the government against maple syrup which contained lead. The lead was picked up in the sap during the collection of the sap in those days, because of the use of receptacles to collect the sap which were made of an alloy of tin and lead known as "ternplate". Now if the sap is a little acid, the tin and lead would dissolve into the sap, and then when the sap is concentrated down to syrup, of course, the metal, the lead in the tin also concentrates down. And so most of the syrup which was packed in Vermont that year, and this was 1938, was contaminated with lead. We had seized a good part of Vermont's

output, practically ruined the industry up there, and there was a contest. The defense was that the syrup was not going to be shipped from the state of Vermont to other states in the condition in which it was at the time of seizure. It was going to be deleaded, put through a process where the lead would be precipitated down, the product filtered, and the product would be free of lead. This was their contention.

Dr. Y.:

At the time it entered interstate commerce.

Mr. G.:

At the time it entered interstate commerce, it had lead. You see, whereas Vermont ships out a tremendous amount of maple syrup, labeled as Vermont maple syrup, only a small part of it is actually produced in Vermont. A good part of it is produced in New York, Ohio, Pennsylvania, and shipped in bulk to Vermont, where it's blended and repackaged and shipped out as Vermont, pure Vermont maple syrup but actually, its origin is New York, Ohio, Pennsylvani_, other areas, other places.

Dr. Y.:

Some of it came from Canada, you said.

Mr. G.:

Yes. Now...are you familiar with this case?

Dr. Y.:

Not in detail about the case, but a little about the situation.

Mr. G.:

Yes. Well. As I say, the farmers who were collecting the sap, were the persons who were responsible for the contamination... We had the right to seize and we did, to be sure that any de-leading would be done under our supervision. It wouldn't be left to them. This was before the days of voluntary compliance. And we did maintain, we felt, that this was the way to do it. If you want to be sure, you seize it and then it's done under your supervision. They pay the cost of supervision, then you know it's gone out without any lead. The lead was too serious. Now, Dr. Carlson was brought in to testify about the hazards of lead in any food product, even in minute amounts.

Dr. Y.:

What was the name of the case? Do you remember?

Mr. G.:

It was United States versus so many drums of maple syrup. I can

give it to you if you want it, I mean, if you are interested. I can give you the title.

Dr. Y.:

I can find it, I think, but being a seizure case, that was the way it was instead of, of course, the name of...

Mr. G.:

That's right. It was a consolidated seizure. It represented many carloads of maple syrup which came in from these other states into Vermont. We seized them piecemeal as the cars came in, and we had all of them consolidated up there for trial. Now there was a curious incident that occured with me in connection with that. This seizure was being tried in Vermont which is the home of Vermont maple syrup, and the seizure was being tried in a small town, I think it was Barre, Vermont, a very small town. The jury was composed of the farmers, for the most part, of Vermont, who had a personal loyalty and pride in Vermont maple syrup, and the United States attorney, recognizing this, had instructed all witnesses not to talk to any stranger, because he might be a local sympathizer of the maple syrup people. He gave us a blanket order. He didn't want us to talk to anybody. "If you don't know them, don't talk to them." Well, I had testified, and right after my testimony, a recess was called, and we

all went to this country hotel with a long porch and rockers. After lunch, we sat out there waiting for time to go back to court, and I sat down. Before very long, this fellow, whom I sized up to be a local yokel came over. He was smoking a corn cob pipe. He was very dishevelled. His suit was unpressed; one cuff was turned down; and he sat next to me and, in an accent, said to me he had heard my testimony and thought it was brilliant. I said, "Thank you." And then he continued to talk about the case. Being mindful of what the United States attorney had told me, I said, "I'm sorry, but I can't discuss this case with you." But that didn't deter this fellow. He just kept on talking about the case, and I said, "Now look, I can't discuss it with you. I'm sorry. I wish you'd stop discussing the case. You can talk about anything you want to talk about but not about the case." Still, he continued talking about the case, and I said, "Look, I'm under orders. I'm sorry. I hope I don't offend you." And I got up and walked away. When we got back into court, the very next witness called was Dr. Anton J. Carlson. This local yokel walked down the aisle in the courtroom to take the stand, and he was the great Dr. Anton J. Carlson.

Dr. Y.:

He enjoyed the joke enough that he hadn't tipped his hand to you.

Mr. G.:

No. He had not said anything.

Dr. Y.:

Well, now, how was he as a witness? Do you remember that?

Mr. G.:

Terrific. He spoke in a Swedish accent. It isn't "Jesus"; it's "Yesus." It isn't Jumpin Jiminy; it's Yumpin' Yiminy, but he was very articulate, very dramatic and he impressed me tremendously. He was an excellent witness on the dangers of lead.

Dr. Y.:

Did you get any evidence from this case as to his skill in handling the cross-examination that came after he had given his testimony?

Mr. G.:

Oh, he was one step ahead of the defense attorney or rather the claimant's attorney. Always one step ahead of him. Dr. Carlson knew just what was coming. He knew just how to parry the questions, how to answer them, yet without giving the appearance of being flippant or insincere or anything else. He was very good. He was one of the most impressive witnesses I've ever had the

pleasure of listening to.

Dr. Y.:

I certainly gathered that from the cases that I have read, including a few instances of the way he was able to make a question on cross-examination turn out to be a point for the government rather than a point for the defense, by the way that he answered the question.

Mr. G.:

He'd be a man that I would hate to have to cross-examine. As I say, at the time I saw him, he was probably in his prime--that was in 1938--and full of confidence. I have seen many expert witnesses, however, who were brilliant men. In that Hoxsey case, up in Portage, Pennsylvania, we had a brain surgeon from Mayo Clinic who testified for us, and a brain surgeon, you'd imagine, is a man who has nerves of steel. This man testified, and I later spoke to him, congratulated him, and told him what a wonderful job he had done testifying. He said, "Did my nervousness show?" I said, "Not particularly." He said, "Let me tell you, I've had operations where I've had to stand on my feet and operate for hours and hours and hours. The fifteen minutes that I was on the stand was one of the most gruelling experiences I have ever had."

Dr. Y.:

Well, in a speech once, Billy Goodrich said that doctors fear the witness stand almost as much as lawyers fear the operating table, and I guess that's a good example.

Mr. G.:

That's right.

Dr. Y.:

An inspector, such as you were for a number of years, and then even after you went into headquarters, you were also a witness, has always to be prepared to be a witness, and so this kind of problem of knowing your facts and then of being able to stand up against the kind of hammering that comes in cross-examination, is one of the basic requisites of a good inspector, isn't it?

Mr. G.:

It certainly is. All cases are difficult to win. Never is the expression...,"a chain is as strong as its weakest link" more applicable then to a court case. You can have the most solid case in the world, but if there's one minor weakness, you will lose your case. The inspector must not make a mistake on the stand. A mistake can be fatal. He's got to know his facts; he's got to be able to anticipate the cross-examination and have

the right answers. Not only must he speak the truth, but he's got to give the impression that he is speaking the truth. So his demeanor has to be impeccable. Little things affect the jury, the way the man knots his tie, for instance. But if he in any way gives the impression of not telling the truth, no matter how sincere he is, no matter how truthful, if he gives the impression of not telling the truth, his testimony is lost. So, he not only must tell the truth, but he must tell it in a way that is believable. We prepare our witnesses very carefully. We go over their testimony with them before they testify. We review their testimony but we don't rehearse it. But we have to go over their testimony with them. We try, at that time, to smooth out things, eliminate those elements which might work to their disadvantage when they take the stand. We have written booklets or brochures on the deportment of the witness in the courtroom, not only in the courtroom but anywhere around the courtroom, because you never know when you are exposed to a juryman. He's the one who is deciding the case, so you cannot take anything for granted. You've got to be on your best behavior at all times. I've seen this happen: where horseplay or a wisecrack was made about the judge or about a juryman in an elevator during a lunch hour break, and there was the judge on the elevator at the time. You may not recognize the judge when he's out of his judicial robe. He may look like a different person. I have

seen this happen. Some witness made a comment about the judge, and there was the judge standing right next to him. The witness didn't know it. Now if this is done about a juryman, God help you if that juryman is there. So it's little things like that that your case sometimes hinges on. The inspector has to be on his toes at all times, and on his best behavior, dressed conservatively, and he must do all the things that are necessary to create an impression of credibility.

Dr. Y.:

In connection with inspectors, you mentioned that one of the members of the team that was assembled to oversee these cases was a man who could get the evidence when other people had a hard time doing it. Now, that's the impression you have among your colleagues at the Food and Drug Administration. It's the impression that you had as an inspector, as you were coming up, that you were very able at ferreting out hard-to-secure evidence, and you were certainly in some of the difficult areas, such as New York City. Do you remember any experiences that illustrate this point where you were working on a case that was very hard to crack and you managed to find some way through by some ingenious method?

Mr. G.:

Well, first of all, it takes imagination, and a suspicious turn of mind, and persistence. Now, first, as to imagination. Let me give you two illustrations that I was involved in which point up the question of imagination. I was once in a warehouse between Thanksgiving and Christmas, and some barrels came in while I was there, while I was on the delivery platform. This was a cold storage warehouse. I was waiting for something else, I don't recall what. An Armour Packing Company truck pulled up and a number of barrels were unloaded. And just out of curiosity, I asked the warehouse foreman, "What's in these barrels?" He said, "Turkeys." At that point, imagination came into play. What in the world were turkeys coming into a warehouse for between Thanksgiving and Christmas. Turkeys should be going out of a warehouse between Thanksgiving and Christmas. My suspicions were aroused. You have to have a suspicious turn of mind to be a good inspector. I requested that the barrels be uncovered and I looked into them. The barrels contained decomposed and rat defiled turkeys the equal of which I never saw before and have never seen since. The meat was rat nibbled, with rodent excreta everywhere. There was actually a layer of rat excreta pellets in one of the barrels, together with rat-gnawed decomposed turkeys. The manager of Armour and Company was trying to salvage them. He had permitted them to go bad, and he brought them to the warehouse

for freezing. Now, he wasn't going to throw good money after bad by freezing them unless he had some ulterior motive. He had trucked them from Fall River, Massachusetts, to Providence, Rhode Island. The next day the shipment was seized and the firm was prosecuted and convicted in time. Suspicion and imagination resulted in the interception of this adulterated food.

Another instance: I passed by another warehouse in New York City, and out there in the street, awaiting garbage collection, were barrels of labels. The labels read: "Crab meat. Geisha crab meat" or something, "Product of Japan." At that time there was a strong anti feeling in this country about Japanese goods. "Let me see about this," I thought. So I went into the warehouse and, sure enough, there I found some people busily stripping off labels from cans of Japanese crab meat, and putting on another label, "Product of the U. S. S. R." The U. S. S. R. at that time was our ally; Japan, our foe. They fished for crab meat in the same waters, off Japan and Siberia, Vladivostock, right there, so the waters are the same and it's the same crab meat. The owners of the crab meat couldn't sell it as a product of Japan and so relabeled the cans to falsely declare the country of origin to be the U. S. S. R. This, of course, was misbranding. It's not the most serious violation of the law, but it is a violation.

Dr. Y.:

Your curiosity paid off. Didn't you have something to do in developing the Plantation Extract Corporation case?

Mr. G.:

It takes imagination and suspicion to spot a violation and then determination. You can't take "no" for an answer. Now, the Plantation Vanilla case is one in point. It was the first war frauds case and it involved bribery of War and Navy Departments officials. FDA inspectors had gone into the Plantation Extract place time and again, on suspicion and on competitors' complaints because Plantation undersold everybody in the vanilla extract business. Yet, when Plantation's vanilla extract was examined, it tested out just like normal vanilla extract, and the question that the industry was raising was, "How can they sell it at these prices and make a profit?" Inspector after inspector visited Plantation's plant and came out with nothing. Now, I went up there, and I just didn't accept any of their stories. I just didn't believe what they said. I've got to decide the facts on what I myself observe and what our laboratory tells me. And so when they showed me a product called "J. B." which was supposed to be oleo resin of vanilla, which could be used, that's a legal product, and they showed me invoices to show, "Here it is, oleo resin of vanilla," and it's called "J. B.", I

wouldn't accept their word for it. I took samples of it, but I also took samples of other lots marked "J. B." One was oleo resin of vanilla, the other was oleo resin of St. John's wort. Oleo resin of vanilla is the resin of vanilla beans costing eleven dollars a pound; oleo resin of St. John's wort is the resins of a weed, St. John's wort, costing six cents a pound. And these resins were used for the vanilla resins. They are very much alike in appearanceaand properties. Now everybody else had gone out there and reported this "J. B." and accepted the invoices, you see. So that's it: persistence and not swallowing everything that's told you, especially where the industry says: "How can they do it?"

Dr. Y.:

This was a situation in which, by mixing some real vanilla extract with an extract of this oleo resin of St. John's wort, they got a product that tasted like vanilla extract and...

Mr. G.:

Well, it was a little bitter. So they added sugar.

Dr. Y.:

But by the chemical examinations that prevailed at the time that were used to test, it checked out.

Mr. G.:

Plantation's vanilla looked just like pure vanilla extract, and when tested in the laboratory it couldn't be distinguished from the genuine product. Ultimately we broke the case and several defendants went to jail for their fraudulent scheme. Now, we had an orange juice fraud in Houston, Texas where the analysis clearly showed it was watered.

Dr. Y.:

Is that the Cal-Tex case?

Mr. G.:

Cal-Tex case. We went in for an injunction on the basis of the laboratory test which showed the juice was watered. We lost. It was apparent that we couldn't win on the basis of just laboratory work. We had to have supplementary evidence. How do we get it? Our New Orleans District wrote in to the Division of Regulatory Management and said, "What can we do?" "Can we use a marker to be introduced into the adulterants for tracing purposes?" We said, "No." They asked again, "Well, what can we do to break this racket?" Since the District was asking for advice, we studied the problem. Here is where imagination comes in. We knew we couldn't get anywhere by factory inspections. We tried that and found the firm too clever for us to get any

evidence of watering. We told our New Orleans District, "See if you can't get a place to rent close enough to the factory so that you can observe what's going on in the factory yard every day." They were very fortunate to get an apartment directly to the rear of the yard. They paid for a month's rent and there they observed the operations and they were able to make a clear cut case of adulteration by watering and use of cover-up adulterants.

Dr. Y.:

That was where they were bringing in the sugar...?

Mr. G.:

That's right. Once we got some leads by spying, you see, then we were able to follow through and get other leads. It was a spy job. The inspectors watched that place day and night, and got the evidence through that means. They used field glasses. They took photos and movies of what they observed. It takes imagination; it takes suspicion; it takes persistence; and often it takes persuasiveness. Sometimes you talk your way in. You disarm the guy. You play dumb, like a fox. You so disarm the guy that his guard goes down and you get your evidence.

Dr. Y.:

Because the law is such that you couldn't demand?

Mr. G.:

No, we couldn't demand. Or, let us say, I am going to a bank as part of our investigation, and I question an officer of the bank. Now the instinct of the banker is, "I've got to protect my client." If I were a banker I certainly would protect my client. I mean, there's a trust there. I wouldn't give out any information to a government agent. But yet we are successful in getting information. How is it that we are able to go into a bank and get the banker's cooperation? Very often the records of a bank reveal very important evidence necessary for the proof of a crime. You could subpoena a bank's records if everyyou get to a grand jury investigation, but how do you know whether you've got a case sufficiently strong to present it to a grand jury? You'd like to know whether the bank does have any evidence. A skillful, tactful, persuasive inspector will get cooperation of the bank, whereas another man, going in for the same thing, may strike out completely and get nothing. So, it is true that one inspector goes to a plant and apparently sees nothing and hears nothing, and another inspector going to the same plant uncovers a very serious, perhaps even fraudulent, violation. It's the make-up of the inspector, his intelligence, his acuity, his

persuasiveness, his articulateness, his knowledge of human behavior and how to get things out of a person.

Dr. Y.:

Another area where persuasiveness obviously is important, it seems to me, is within the Food and Drug Administration at the time efforts are being made to determine allocation of resources, which always certainly has been for the Food and Drug Administration a very difficult task, since most of the time it hasn't had enough resources to do the kinds of tasks the laws assigned it to do. So one of the problems that I've been interested in is the problem of decision-making within the agency. One part of that decision-making has been divvying up the resources among the different projects that have been set up for the year, and, I suppose, to some degree, this is determined by people sitting down and debating what are likely to be the key problems of the biggest magnitude for the year that lays ahead and so on. You say, you went to Washington while Dr. Dunbar was still Commissioner?

Mr. G.:

Yes, in June of 1946.

Dr. Y.:

And then Mr. Crawford followed him, and Mr. Larrick followed Mr. Crawford. You, in your position of responsibility, had dealings

officially with them and were part of the decision-making process that went on about what the Food and Drug Administration should be doing with its resources, and whether or not it should undertake a given kind of campaign, and so on. Would you mind talking for a little while about these men as personalities and as administrators?

Mr. G.:

All three had tremendous savvy in Food and Drug enforcement. They had a keen understanding of consumer needs: what the consumer wanted in the way of protection--they themselves, before becoming Commissioner, had had almost a lifetime of work in enforcement of the Food and Drug act and the Food, Drug and Cosmetic Act. They knew so well the reaction of industry; they could anticipate the reaction of industry; they knew where the difficulties would arise. I had a tremendous respect for all three of these men. I think that the public was very fortunate in having men of their calibre heading up the Food and Drug Administration. I think that the public got a terrific bargain in enforcement. We had a small staff. Morale? I never saw morale as high in any governmental agency, in any organization as it was in FDA. You would think that each man had a private stake, a business stake, in the organization. Nobody was taking any graft or bribes. It wasn't a

monetary stake. It just was that under their leadership, FDA's rank and file took great pride in its work, and it was imbued with the feeling that the law was to be given its utmost scope of protection. I have a tremendous respect for all three men. I think that, perhaps with the exception of the last few years of Larrick's career in FDA, for the most part the organization was a terrific organization.

Dr. Y.:

Right. Now, how did they differ in their personalities, in the way they went about their task of leadership?

Mr. G.:

Mr. Crawford was the idealist. He had very lofty ideals. I think, of the three he was probably the most consumer-conscious. He was the one who wanted us to extend the law as far as possible in order to give protection and to test out the law. He was of the philosophy that if we won all of our cases, then we were not giving the public the full benefit of law enforcement. We should lose some. That was his feeling.

Dr. Y.:

He had been the one who had had the most to do personally with the drafting of the 1938 law.

Mr. G.:

That is right. He worked with Ole Salthe, who was an administrative assistant to Senator Copeland, and together they framed the Food, Drug and Cosmetic Act. As I say, he was the idealist, and yet, I know that he would criticize employees of the Food and Drug Administration in high positions who took the position that all violators were despicable characters. No. He felt that the violator, despite his violations, deserved at least respect. And I know he passed some disparaging remarks in my presence about men in high positions in the Food and Drug Administration would who cast disparaging remarks about a violator because he was a violator. But yet he was a vigorous enforcer. Now Dunbar was a very practical, level-headed administrator. He knew Congress; he knew how to deal with Congress; he had the confidence and respect of Congress. As I say, to me, what characterized Dunbar most, was his hard-headed practicality. He never let himself get off on fanciful flights. It was all down-to-earth, everything. Now Larrick was a diplomat. He was more of the politician, perhaps the placator. I don't think he had the idealism of Crawford. He had a lot of the practicality of Dunbar. But Larrick was beset with a lot of problems--tremendous problems which his predecessors didn't have. Organizational disputes arose within the organization. There was reorganization that was instituted by Crawford which functioned beautifully while Crawford

was Commissioner and beautifully up to a time when Larrick was Commissioner. But then, conflicts arose in Larrick's later days within FDA. I don't know what would have happened if Crawford were still there at that time. He might have settled the problems of Food and Drug. But the conflicts which later arose were very detrimental to the morale of FDA personnel throughout FDA.

Dr. Y.:

This was internal as well as all the pressures that arose outside.

Mr. G.:

Yes, this arose simultaneously with the external pressures, with Congress coming into FDA. It is certainly sad that these internal disputes arose. I think that Larrick was aware of them, but he hoped that they would pass over. Larrick was a man of tremendous know-how, and he had the respect of industry. He may have been somewhat of a compromiser. I don't think there was anything inherently wrong in that, but apparently he was blind to what was happening in his own organization. He either wouldn't believe it or he hoped that it would pass over. But he was, nevertheless, a good administrator.

Dr. Y.:

One of the other aspects of your duties at Regulatory Management was to have certain liaison with certain of the Congressional

committee. Is that not right?

Mr. G.:

Yes, that's right. The Kefauver committee, as you know, around 1960, started to investigate the pricing of drugs to determine whether there were monopolistic practices in connection with new drugs that had passed clearance with FDA. And that brought FDA into the scope of Senator Kefauver's investigations. Since the hearings that Kefauver was conducting were a quasi-judicial type of thing, it was Larrick's thought that the Division of Regulatory Management who lived with court cases would be the most logical division in Food and Drug to work with the committee. And so all requests from the committees were funneled through our Division, and we had to provide the material and the information for the committees. Now this was not always a pleasant thing, because often the committee would ask for information which the General Counsel's office and perhaps the Secretary's office felt should not be given to the committee. The question that came up early in our dealings with the committee was, "How much information from new drug files should the committee have?" The Federal Food, Drug and Cosmetic Act prohibits the giving to anyone of information which, as a trade secret, is entitled to protection, except to a court or to the Secretary of Health, Education and Welfare. This is what Congress had written, and here we had a Senator

from Congress asking for information which fell squarely within the scope of that prohibition. Yet Congress wrote the prohibition and Congress was now asking for information within the scope of that prohibition. The Senator felt that he should have such information. However, the attorneys in the Food and Drug Administration and even the Secretary's office stated that the Senator couldn't have it, because of the prohibition. Indeed, I, in the Division of Regulatory Management was caught in the middle. And this was rather an unsavory position to be in. I think this controversy over what may or may not be given to a Congressman or Senator, that's in the new drug files, was responsible for the Food and Drug Administration acquiring the reputation up on the Hill of being obstructionist and recalcitrant. Now I recognized that, and I did everything that I could in my power to placate the committee members and I think, in time, we worked out a compromise which was satisfactory to them.

Dr. Y.:

Did you do your dealing in this diplomatic mission with members of the staff or with Senator Kefauver himself?

Mr. G.:

On one occasion I had a conversation with Senator Kefauver, but almost exclusively it was with members of the staff.

Dr. Y.:

Was that Mr. Dixon?

Mr. G.:

Mr. Dixon...yes. He was chief of the staff. Yes, and I had some dealings with him and John Blair, the economist, and Goodwin and Irene Till and Dr. Wayles Brown and a number of others...Schaeffer... quite a number of others. On another occasion, the committee delved into possible malfeasance on the part of Dr. Welch, who was the head of the Antibiotics Division at the time. And this was a rather unpleasant experience where we had to provide not only to the committee but also later to the FBI information concerning activities at the Division of Antibiotics, and Dr. Welch's activities, too. And then later on, we had other committees, we had the Fountain committee, we had the McClellan committee, and the Humphrey committee--we had much dealing with the Humphrey committee. It was my job to give to these committee members the feeling that we were cooperating with them, and I think that by and large, our dealings with the committee were fruitful both to the FDA and the committee. My own reaction was that Kefauver was doing an important job in the investigation and that it was absolutely our duty to cooperate with him to the fullest to the extent that the law permitted.

Dr. K.:

Certainly. In connection with the Kefauver committee, reading the industry reaction both within the hearing and in publications, one gains the impression that industry believed or sought to let the public think they believed that Kefauver was interested in building his own political image for his own political future, rather than being genuinely sincere about the kinds of problems involving drugs that he was investigating. From your association with the members of the staff and with the Senator, the time you talked with him, do you believe that this image from industry was wrong or right?

Mr. G.:

Oh, I think that Senator Kefauver was sincere. There was nothing ever in my observation of Senator Kefauver during the hearings or in his statements to the Senate which would lead me to believe that he wasn't sincere, but I'm not going to be so naive as to say that he might not have had in addition to this sincerity a desire to uplift his image and promote himself, and I would say the same thing about Senator Humphrey. But I think that all the staff people there were sincere. They were impatient with us; they wouldn't brook any hesitation on our part or apparent reluctance on our part to provide the information. They made great demands upon us which required a considerable allotment of manpower to

dig up the information, and sometimes we wondered whether we could, under the law, provide the committee members with the information they were asking for. They were impatient whenever we questioned this. They acted like policemen, almost, in their dealings with us and at times a little high-handed. But I wouldn't say that they were not sincere.

Dr. Y.:

Was the decision with respect to what could be given to them and what could not under the law, made at the Secretary's level?

Mr. G.:

Sometimes at the Secretary's level; sometimes at the Commissioner's level. And if it was cut and dried, it was even done at my level, where something had already been decided and they simply wanted information along the lines of the decision. Then, of course, I felt free to give it to them, but if it was new, it was either the Commissioner or the Secretary who decided whether the information should be provided.

Dr. Y.:

But there was a kind of general policy line that the lawyers in the Secretary's office worked out, that you had to operate on.

Mr. G.:

Yes. That's right.

Dr. Y.:

Was this a written document?

Mr. G.:

No. It was perhaps in the form of an interview memorandum, telephone conversation memo, or it might have been a letter to the Senator in connection with an inquiry that he made. We did insist, for the most part, upon written requests and this, too, was troublesome. The Secretary's office wanted a written record of these requests, and this generated, for a time, some rather hard feelings among some of the congressmen. They felt this was an unreasonable request; they felt that time could be saved by picking up the phone and calling for the information. I know in the case of the Humphrey committee that even though the request for a written request had been made to them, and for a time they did comply, there would be a tendency for that committee, particularly Cahn, Julius Cahn, to drift away from that requirement. He would simply pick up the phone and put the request to me by phone. And after a while I thought, that where there was precedent and where it could be handled conveniently, I did. I felt they had an important function.

Dr. Y.:

But you didn't have a document from the lawyers that said, "Such and such information you can give whenever it's asked for. And other kinds of information, you can't give without seeking permission."

Mr. G.:

No. I had no such document. But if it had been the decision of the Secretary's office that we may give them certain information with respect to a certain drug in the new drug file, then I felt and the Commissioner felt that in a similar situation involving another drug, we could give the same kind of information under the same circumstances.

Dr. Y.:

So long as a certain breach in the trade secret sanctity had been made, up to that line then and subsequently, you felt you had a right to go.

Mr. G.:

Exactly. But you know, something peculiar happened when Fountain got to investigating FDA. We had worked a compromise out with the Kefauver committee enabling them to get certain information from the new drug file. And then Fountain came along and asked

for the same kind of information and, for some reason, which I will never understand, the Commissioner's office said, "No!" Well, now the Fountain staff people knew that we had given information of this kind to the Kefauver committee. They felt that we were discriminating against them. As a matter of fact, one of the staff members told me that he felt that we were discriminating against the Fountain committee. Well, we got that ironed out and in time gave them the same kind of information. But it's a lapse like that, you see, that creates the hard feeling that did exist between the Fountain committee and FDA. They genuinely felt that we were giving scoops to the Kefauver committee and were withholding information that the Fountain Committee ought to have. But, after a while, though, we got very friendly and I think we had a very harmonious relationship.

Dr. Y.:

Certainly. The 1962 Law was a very important document that came from that particular set of hearings.

Mr. G.:

The Kefauver hearings. Yes.

Dr. Y.:

Let me ask you a question about quackery which was certainly one

of the most central of your interests. You worked hard; you won a multitude of cases; and yet the job really never ended. It wasn't the kind of battle perhaps in which total victory was possible. Am I right about that, and if I am, what comments do you have to make about it?

Mr. G.:

You certainly are. Well, first, it is amazing how the failings of human beings crop up when quackery is attacked...Emotion... prejudice, and blindness often seem to prevail as against reason. I've seen that in operation a thousand times. I've even seen it operating among people whom I know to be intelligent, educated, discriminating, knowledgeable, and aware. Yet, when it comes to matters of health they react as emotionally, and as blindly, and as without reasoning as any uneducated fourth grader. And this is a barrier to easy enforcement. Because I have seen cases time and again lost in court...good cases, important cases...lost in court because of the myopia and prejudice of a judge, or a juryman, who acts in the same emotional way.

Dr. Y.:

Are there other cases besides the Hoxsey Case and Judge Atwell that you could cite?

Mr. G.:

Oh, yes, there are. It crops up all the time. Now Atwell took the position that a person certainly ought to know whether he's been benefitted. He ought to know what ails him. After all, he's the man who has the ailment, and if he doesn't know what's wrong with him, who does? That was the way Judge Atwell viewed it but that's an unthinking way of looking at it. I don't know what ails me when I feel ill, and I rely upon a physician who tells me what my ailment is and I accept his word. He may be wrong, but I accept his word. But under any circumstances, I'm the last one in the world who is qualified to say what my ailment is. And yet, I have seen a number of judges who pursued the line that was taken by Judge Atwell, that the patient is the best judge of what he has, and the best judge of whether a drug is helping him. I don't have to tell you how much psychology and emotion enter into a man's appraisal of whether he is benefitted. Certainly, scientifically, one can not accept as the final word what a patient says about his condition and about how he is progressing. And yet judges will adopt the attitude that the patient himself is the best person to testify about his condition and have not only allowed such testimony, but have also been persuaded by it and ruled against the government. Now in a criminal case, there is no appeal. Fortunately, in the Hoxsey Case, which was a civil case, there was an appeal, and Judge Atwell's misconceptions

were sharply criticized by the Court of Appeals on what a lay witness can say about his condition in his testimony.

Dr. Y.:

What are some of the other major quackery cases that you worked very hard building up to get to court in which the public was rendered a disservice when, for reason of this myopia either on the part of the judge or the jury, you lost them?

Mr. G.:

We had a case in Oklahoma involving an arthritis preparation, and the testimony of the government was essentially the testimony of experts plus a minor clinical study. The testimony of the defendant was primarily the testimony of satisfied users. The government's case from a scientific standpoint was overwhelming. The judge, Judge Chandler, now deceased, ruled against the government, acquitting the defendant. It was a criminal case; there was no appeal. And in chambers, the judge said, "You can't accept the word of an expert." He had no confidence in the word of a physician. He had seen too many instances in which they were wrong. He preferred to place his credence upon the persons who used the drug, that is, lay users.

Dr. Y.:

What was the product?

Mr. G.:

It was an arthritis preparation. I can't recall the name of the preparation. But we know that arthritics will always get relief from a drug they're trying for the first time, because of wishful thinking. The symptoms of arthritis are not unrelated to psychosomatic elements, and if the patient is promised relief, he hopes for relief, and he will actually find some temporary relief in anything new, no matter what it is. Sooner or later, he may become disillusioned with the drug, but for the beginning at least he's satisfied with it, gives a testimonial, testifies about it, and the court is persuaded. Now the court should know better. Then again when it comes to matters of health, everybody seems to be an expert. In the Krebiozen case, for instance, people in all walks of life protested the Government action. They disregarded what the government experts said about Krebiozen and assumed the role of self-styled experts, declaring the government to be biased or the government had an ulterior motive. They became the experts, organizing mass movements, to protest and obstruct the government investigation. Yet, they demanded a government-sponsored test for Krebiozen. All kinds of people, without qualifications, were telling their fellow citizens that the country's top physicians were wrong, that the government was wrong, that the scientists were wrong. They declared they were right. Krebiozen was effective.

Dr. Y.:

Quite a few members of Congress put bills into the hopper in support of Krebiozen?

Mr. G.:

Right. And they acted as though they were the experts. In matters of health, it seems that, especially with a controversial product, everybody but the expert is the expert. And this is something that we seem to have a lot of trouble with everytime we investigate or plan action against a controversial quack remedy.

Dr. Y.:

Now, in connection with the tremendous scale of operation such as Hoxsey's became and such as Krebiozen became, we are better off, we became better off as a result of the passage of the Kefauver-Harris Law, than we had been before, as far as public policy is concerned, did we not?

Mr. G.:

Yes.

Dr. Y.:

Even though the criminal case which you discussed was lost.

Nonetheless, the regulations of the Kefauver Law permitted the closing down of distribution of Krebiozen in interstate commerce.

Mr. G.:

Yes. With the Kefauver Law we were able to charge a violation of law which we weren't able to charge before. There are provisions of the law now which require, in the case of new drugs, that the drug be shown to be effective. Before the Kefauver amendment only safety had to be shown for new drugs. Well, we couldn't initially do anything about Krebiozen when Krebiozen was nothing but mineral oil. We couldn't show that it was unsafe. But when Kefauver's bill became law requiring the showing of efficacy, then we had Krebiozen licked.

Dr. Y.:

You even had them before, going into court on a problem of efficacy because...they themselves wouldn't agree to the kind of regulations that were set up in connection with the testing that preceded a new drug application.

Mr. G.:

Yes. That's right. We could have gone after them under commercialization, that this distribution was not for the purpose of bona fide investigation but for commercialization, and they were commercializing

the product. However, be that as it may, for one reason or another, FDA did nothing until after the Kefauver-Harris Amendment went into effect. And I might say this: that although we lost the case, the disclosures and the exposures of the trial convinced the medical profession throughout the world that Krebiozen was nothing. Nothing at all. And Krebiozen is today practically off the market, even though the sponsors were not convicted.

Dr. Y.:

Is it your feeling that the stronger provisions of the Kefauver Law will really permit the Food and Drug Administration to prevent any remedy that makes the kinds of claims that were made in the Hoxsey and Krebiozen cases from zooming to big-scale interstate commerce?

Mr. G.:

It's a question of whether FDA will enforce the law. If they do, yes. The law is such now that we should never have another Hoxsey Case or another Krebiozen case if the law will be enforced vigorously and promptly. If it's permitted to drag on, as it was in the Krebiozen case...Krebiozen could have been stopped effectively under the Public Health Service Act, biologicals provisions. This was represented to be a biological, and as such, it had to be licensed.

If the law had been enforced, and an insistence upon licensing made, under penalty of law, Krebiozen would have either gone off the market, or its sponsors would have complied. But, of course, they couldn't have complied. So it would have gone off the market.

Dr. Y.:

What held up the efforts to bring Krebiozen to book?

Mr. G.:

I think, frankly, there was too much politics involved. I hate to say this, but the government was intimidated by Senator Douglas and other senators whom Ivy got to assist him. Krebiozen became a "hot potato" and rather than challenge it and perhaps bite off more than it could chew, the Government preferred to let it roll on. Well, let's not rock the boat.

Dr. Y.:

Had you, in Regulatory Management, made the concrete suggestion, "Let's try such and such," and then were turned down?

Mr. G.:

Well, no. Long ago, the Food and Drug Administration had been told by the Secretary, Ovata Culp Hobby, that Krebiozen is

unquestionably a biological, which, of course, was a false premise, because it wasn't anything, really; it was just mineral oil, and it was a food and drug product, and not a biological. We were told by Secretary Hobby that since Krebiozen is a biological, the Division of Biological Standards will handle it. It was a biological by pretense only. The Division of Biological Standards did nothing and Food and Drug was told "It's not your baby." Initially, Ivy said, "It's a biological." But then when he was told he has to have a license, and in order to be licensed under the biological act he had to show efficacy, he switched, and said "It's a hormone. It is not a biological." And he submitted paper after paper to establish that this was a hormone and, therefore, subject to the Food, Drug and Cosmetic Act, and he went so far as to file a new drug application for it as a hormone, which was never approved. But the Department of Health, Education and Welfare was not persuaded and since the Secretary had said, "This is a matter for the Public Health Service and not the Food and Drug Administration," FDA's hands were tied.

Dr. Y.:

So you gathered information, but you couldn't go beyond that.

Mr. G.:

That's right. Whenever anybody wrote, we told them, "This is a

matter for D. B. S., the Division of Biological Standards, and we are forwarding your letter to the Public Health Service, the National Institutes of Health." And that's the way we routinely... Right up to '63, this was the way we answered letters. Tens of thousands of them. We were derelict. FDA was derelict. We could have stopped this.

Dr. Y.:

But of course, Secretary Hobby went out long before that, but you just presumed that the same policy was...

Mr. G.:

Oh, yes. We were never told that Secretary Hobby's policy was changed. We had no evidence as to the composition of Krebiozen until our 1963 analysis. However, we were forced into the case by Krebiozen supporters' insistence upon a government-sponsored clinical trial. Well, finally, they goaded Boisfeuillet Jones who was a special assistant to the Secretary on medical matters to the point where Boisfeuillet said, "Okay, boys, if you want the test, we're going to give you a test. But, first, we've got to have certain information. We're asking FDA and DBS to go out there to Chicago and get that certain information." That's how FDA ultimately got into the Krebiozen picture and as you know our trip out to Chicago with DBS to get the information ultimately

led to the fraud indictments.

Dr. Y.:

According to John Minor who is a medico-legal officer in the California state set-up, there is a good deal more quackery now, and still a more tremendous amount that is intrastate than is interstate. Did you find as you were closing down one big operation after another that there was a deliberate effort on the part of the quacks who were contesting to get into intrastate operation?

Mr. G.:

Yes. And some of them got into trouble. Lelord Kordel, as you know, has been in trouble with Food and Drug on a number of occasions. He's a health food lecturer. Now, initially, he shipped his product in interstate commerce with labeling, and we proceeded to take action on that. Then, when he was convicted of that, in an attempt to beat the law, he took off the labeling. He had no written, printed or graphic matter accompanying his product which could misbrand his products. But, instead, he would make speeches about his products. Now the product, let us say, was produced in Chicago. When he went to Detroit, in advance of his trip to Detroit, he would ship from Chicago whatever he thought he could sell in Detroit, and then we would give his lectures in Detroit

and he would extol the virtues of these products which had been shipped from Chicago. As you know, the courts have held that oral statements may serve to misbrand. Even though labeling is written, printed or graphic matter accompanying the article, still there is a gimmick in the law which enables you to charge misbranding if you make oral claim for a product, and the directions for use for the conditions that you are claiming the product to be effective for are not stated on the label. So he misbranded his products by these oral claims. Let's say the product was simply Vitamin A, but in his speeches he said Vitamin A was good for this, that or the other disease. You go to the label, and find there are no directions for use for these diseases which he says Vitamin A is good for. The product then is misbranded for lack of directions for its use because the directions don't tell you how to use the product in treating the claimed disease. And in that way, through a squeeze play, we are able to prosecute him. He then realized that he had to do something more drastic to get out from under the law, so he thought he would go completely intrastate. This is what he did. If he were going to Detroit to make a speech, he would set up an outfit in Detroit which manufactured the products. Now he got away with this for a while since this is purely intrastate; it is all produced in the state of Michigan and his speeches are made there. But then we got court decisions which held that, if any of the ingredients move in interstate commerce, even though

they are compounded into what might be regarded as a separate article, it is still the same article, says the court, and it has moved in interstate commerce. Lelord Kordel was recently convicted in Detroit in this attempt of his to circumvent the law by going intrastate. But you can't go intrastate anymore, if the ingredients move interstate.

Dr. Y.:

So if he gets out of jail, he'll probably make his product within a state with products that he digs out of the ground.

Mr. G.:

That would be the only way he could get out of it. But a propos your question, "Are they driven to an intrastate business?" The answer is, "Yes." But they've got to be careful. It's difficult to be completely intrastate now. You've got to be sure that everything...

Dr. Y.:

Presumably the box...

Mr. G.:

Everything significant...not the box, no, the article. It's the article. Now the article...the ingredient has to be a significant ingredient. For instance, let us say we have a mixture of

amphetamine and phenobarb in a tablet, and let us say, the excipient moved interstate, the starch. I don't believe that we could hold that the article is starch. The articles, amphetamine and phenobarb, they would have to move interstate.

Dr. Y.:
So that there are limits to the way in which this kind of Mr. Crawford logic can be expanded.

Mr. G.:
Right.

Dr. Y.:
Not to the very periphery. As I understand it, the Food and Drug Administration now has an organization in which there isn't so much of a central team to manage the cases from the center that you had. There may be central managements for major national promotions like the diet pills.

Mr. G.:
There is still a Bureau of Regulatory Compliance.

Dr. Y.:
Right.

Mr. G.:

But they don't have this corps of experts. It doesn't exist anymore, and I'm just wondering whether FDA can mount a really tough case like they had consistently mounted in the past. As a matter of fact, since the abolition of the Division of Regulatory Management, the pace of the development of cases of national scope and importance has dropped into the cellar. There are now very few, whereas before, FDA was constantly coming out with big cases.

Dr. Y.:

They also aren't working on cases, because of budgetary limitations, which are only threats to the pocketbook and not threats, as they say, to health. But I was wondering, do you see any kind of hazards in this from the point of view of quackery closed-in-on breaking lose as it were in some way?

Mr. G.:

I think the Kefauver Law requiring the showing of efficacy for new drugs will effectively curb new quackery, if the law's enforced. I must say that, because we could have curbed Krebiozen. We didn't. We let it become a monster. We let it victimize and kill many, many people for lack of adequate treatment while they were experimenting with K- biozen. And we did nothing about it. I

can't say anything more than that we were derelict. Conceivably, that kind of dereliction could occur again, but if the law's enforced...

Dr. Y.:

As it was in Rand Anti-cancer Vaccine Case.

Mr. G.:

As it was in Rand, exactly. There's no reason why we should have another Krebiozen, or any big quackery outfit.

Dr. Y.:

Then it would be a matter of the smaller fry operating within the states.

Mr. G.:

Yes. I would say so. You could close in rapidly on a firm who's selling a quack remedy under the New Drug provisions. The government doesn't have to show lack of efficacy. All it has to show is there's no showing of efficacy by <u>them</u>. It's the difference between our having to show that the product is worthless. The burden is upon them to show efficacy.

Dr. Y.:

And that, of course, is an infinitely different thing; then they have a burden of the magnitude that you had when you had to show that there wasn't a single case that turned out right for them.

Mr. G.:

That's right.

Dr. Y.:

Well, you've been most kind to spend your afternoon today in talking about these questions that you've devoted such a long time to working on, and still are interested in and active about, and I want to thank you very much, Gilbert.

Mr. G.:

You are welcome, Harvey. My pleasure.

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