HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Robert C. Brandenburg

Retired Director, Compliance

Regulations and Policy Staff

and

Robert G. Porter

U. S. Food and Drug Administration

Ojai, California

November 4, 1982

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. The interviews were held with retired F.D.A. employees whose recollections may serve to enrich the written record. It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration.

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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TAPE INDEX SHEET

CASSETTE NUMBER(S) 1, 2, 3, and 4

GENERAL TOPIC OF INTERVIEW: History of the Food and Drug Administration

DATE: November 4, 1982 PLACE: Ojai, California LENGTH: 186 minutes

INTERVIEWEE	INTERVIEWER
NAME: Robert C. Brandenburg	NAME: Robert G. Porter
ADDRESS: [redacted]	ADDRESS: U. S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: FROM 1946 TO: 1976 RETIRED? Yes

TITLE: Director, Compliance Regulations and Policy Staff
(If retired, title of last FDA position)

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Interviewer: Robert G. Porter

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This is an oral history interview, one of the series that has been made regarding the history of U.S. Food and Drug Administration. Today, I am interviewing Robert C. Brandenburg, retired FDA employee, at his home [redacted]. The date is November 4, 1982. My name is Bob Porter.

Porter: Bob, I think I would like, if you don't mind, to start this interview with a sketch of your career, both with Food and Drug and since. Start wherever you would like and just tell us where you were and what you did.

Brandenburg: I was a rather late-comer to Food and Drug. I was all of 29 years old when I started, since I had worked shooting Mickey Mouse for Walt Disney for quite some time previously. So it was not until December 16, 1946, that I reported for duty in the Los Angeles District, then Los Angeles Station, as a temporary war-time employee which meant that I had to pass one of those pernicious Civil Service Tests a couple of years later.

Porter: How well I remember.

Brandenburg: I took my test in chemistry, even though my major at the University, UCLA, was that of astronomy. I had minors in physics, mathematics and chemistry. I took my Civil Service test in chemistry, and surprisingly I came out fairly well. They hired me anyway.

Porter: OK

Brandenburg: I spent the first 5 years as an inspector in the Los Angeles District. It became a District shortly after I

joined it. I was then transferred as Salt Lake City Resident. I replaced there one Bob Porter who had decided that his FDA future lie in Chicago.

Porter: There is a mistake there. Somebody else decided that.

Brandenburg: Well, in any event, I spent 10 months in Salt Lake City as Resident and was then transferred to Chicago for a 6 month's temporary assignment, not to exceed 6 months I was told, to work on a case of a cancer quack and to help prepare the evidence for trial. Needless to say since I did spend 30 years in FDA, that assignment exceeded 6 months. I actually spent 5 years in Chicago. From Chicago I was transferred to Washington as a member of the Division of Regulatory Management. I had been assigned to that Division while in Chicago, but I became a full fledged member when I transferred to Washington in 1957. From 1957 to 1963 I was a member of that Division, and then it was reorganized out of existence for various reasons.

I was next assigned to the Division of, I think it was called the Division of Field Operation at that time. I only spent a couple of months there.

Porter: Probably the Bureau of Field Administration, by then.

Brandenburg: Might have been called that. As I say I only spent a couple of months in there.

I was then transferred to, I don't know the name of what they called the outfit at that time, it was Winton Rankin's

shop and he was responsible, amongst other things for Congressional Liaison. I was assigned as Congressional Liaison and spent most of 1963 and part of '64 in that job.

In late 1964 and until early 1966 I was on a special assignment to handle the operations of the FDA with respect to the Krebiozen case. There was a case of a cancer cure that was brought in Chicago. I was responsible for FDA's posture in that case.

Porter: This was probably the Bureau of Enforcement, by this time. Or am I wrong?

Brandenburg: I was on special assignment. It was under no bureau. It was a direct assignment from the Commissioner's Office. It was a rather peculiar assignment, in that FDA had retained the services of Gilbert Goldhammer, who by that time had retired. Since he was not an FDA employee, he could not be responsible for the direction of the field, in any assignments that might become necessary during the course of the trial. So, that responsibility devolved on me.

From 1966 through 1968, after the Krebiozen trial, I was a Staff Officer, most of that time, on the staff of the Associate Commissioner for Compliance. I worked on various cases that involved fraud and the submission of false evidence to the government. Part of this time I was on the staff of the Associate Commissioner for Compliance and part of the time I was assigned to the Bureau of Field Administration.

Porter: Yes.

Brandenburg: Al Barnard was the Director for a while.

Porter: Bureau of Regulatory Compliance, by that time wasn't it?

Brandenburg: As I say...

Porter: I think that is what it was.

Brandenburg: The terminology and when it changed escapes me. During this period, as I say, I handled a number of cases for one or the other unit. Can't decide which.

From 1968 to 1970 I certified antibiotics, as Director of the Office of Certification Services, also part of the staff of the Associate Commissioner for Compliance.

During 1970 I was Deputy Director of the Office for Compliance of the Bureau of Drugs. Late in 1970, until early in 1971, at the direction of the then Commissioner Charlie Edwards, I was Acting Deputy Director of the Bureau of Product Safety.

Porter: I didn't remember that.

Brandenburg: That was mainly in an effort to write necessary regulations concerning safety in toys. FDA was being sued in several courts for failure to prepare such regulations. So, my main duty was to prepare these and get them on the books, which we did. Also to defend the various court cases that had been brought against us. We did so successfully.

Then from 1971 through 1976 I was Staff Director of a staff for the Associate Commissioner of Compliance. This was

called the Regulatory... Let me go back. This was called the Compliance... We'll have to stop here.

Porter: OK

Brandenburg: Trying to think...

Porter: Let's try it again.

Brandenburg: It was called the Compliance Regulations and Policy Staff. I think you can understand why I tried to forget the name of that when you consider the acronym.

Porter: Let's see?

Brandenburg: CRAPS.

Porter: I won't say a word.

Brandenburg: Under this staff however, we had, in addition to those who reviewed all regulations from all of the bureaus for compliance with the Commissioner's policy, the Hearing Clerks Office and the office of the Federal Register Writer. I also had the Freedom of Information function to set up and staff and I set up the Regulatory Management Staff, as it was known at that time. It was under my supervision for quite some time.

Porter: I see.

Brandenburg: So during that period we were somewhat busy and all of these staffs expanded rather enormously before I retired, I am sorry to say.

Porter: Well, I imagine the Freedom of Information, particularly?

Brandenburg: Freedom of Information, as you know, is a business all in itself.

Porter: Yes.

Brandenburg: But the Hearing Clerk's Office also expanded greatly. When I inherited the Federal Register Writer function, I had 2 Federal Register Writers and I think that as of recently there were about 12 plus a commensurate staff for them. I would hope that some day they'd all decrease.

Porter: Maybe they have been "Reaganised" now.

Brandenburg: Well, I don't think it was too bad of an idea. Get them a little bit smaller than we found necessary to have them at that time.

Basically that brings me up to the day of my retirement, Bob. That is a short outline of where we have been.

Porter: That is what I want, Bob. Now, during the course of this interview I want you to talk about any incidents in your career that you would like to talk about. I would like for you to talk about people, if you would. Little, what should I say, vignettes of things that happened and especially the kinds of things that might not show up in the files. One thing that is obvious in listening to your career is that you have had a part in a lot of important cases, law suits that the Food and Drug has had over the years. You haven't mentioned the names of but one or two but I personally know that you were involved in a number...rather deeply involved in directing and gathering evidence and in the way the case was

presented in court. How about starting with those cases and taking them in, more or less, chronological order and just telling about what you did, why you did it, who you did it with and that kind of thing.

Brandenburg: Well, perhaps I was rather naive when I first joined the Food and Drug Administration. I was told that it was a law enforcement agency, and so my aim was to focus on law enforcement aspects. I did so early in my career. I had the good fortune to stumble onto some rather important evidence soon after I started being an inspector in a matter that involved Ruth Drown and her little black box.

Porter: Tell me about it.

Brandenburg: It seems that we were working up a prosecution for misleading statements concerning the theraputic efficacy of a device that had been invented and was being distributed by a chiropractor by the name of Ruth Drown. One of the places where we were lacking evidence was in direct claims from Ruth Drown concerning the efficacy of this product. A lot of the people to whom she sold it made overt claims, but we were trying to pin it down closer to home. We found that a very ardent supporter of hers, a chiropractor in Los Angeles, had died while we were trying to locate this evidence. I went to this person's place of business and found that his nephew, a poker card dealer down in Gardena, had inherited his possessions. I persuaded this person to permit us to look through

his uncle's possessions for literature that might pertain to this device.

Porter: You asked him to deal you in.

Brandenburg: He did. We found the trump card. We found the Ruth Drown Atlas which played a big part in a very hard fought trial. Amongst other things this Atlas said that those who would preserve their health, and this was an interesting part of the trial, those who would preserve their health should never pull the plug while they are in the bath tub because their energy would flow down the drain. Nor should they ever take a shower. As a defense witness, the husband of the Superintendent of the Los Angeles Board of Education testified. He was a chiropractor. Amongst the questions that were asked him was, "How did he take a bath?" He testified in all due seriousness that he got out of the bath tub, then took a long board or a long chain and pulled the plug. We hit the headlines about everyday on that one because the Atlas was full of such goodies. We did obtain a conviction in the case, and the Superintendent of the Los Angeles Board of Education lost her job.

Porter: Bob, you haven't said it and I might be wrong, you correct me if I am wrong, but wasn't the principle of this that a drop of blood on a blotter or something could be put in a machine that would not only diagnose but treat? Or am I mixed up?

Brandenburg: Right, this had similarities with a number of other machines of the same type that had been distributed. The Abrams device as an example. The persons who bought these machines were told that they should never try to take them apart. All screw holes were sealed with drops of solder to make sure you didn't. We unsoldered them. We took one apart and we found that they consisted mainly of a Wheatstone Bridge. You would rub it and form a little static and the needles would all twirl.

Well, that whetted my appetite for that type of investigation. I felt that I would rather be doing that than sampling eggs, as an example. Not to say that egg sampling doesn't have a place.

Porter: For other people.

Brandenburg: I have done my share of it.

Not too long after that, the Administration decided that overt claims were being made for vitamins and minerals by a firm called Mytinger and Casselberry for the product Nutrilite. This was a tremendous money maker. It had swept the country by storm. We knew that we were faced with a very difficult problem.

Porter: Wasn't this one of these pyramid schemes?

Brandenburg: It was the original. Not only that the firm had... Well, let me put it bluntly, political connections. They had spent lots money and those two are a hard combination to combat for what was then a small agency.

Porter: Right.

Brandenburg: The importance of this case is reflected by the fact that John L. Harvey, who was shortly to become Deputy Commissioner of the Food and Drug Administration... Let me see, William Goodrich who was the General Counsel, at that time they didn't call them General Counsel of the Food and Drug Administration, he was Food and Drug General Counsel from the General Counsel's office. They assigned Walt Simmons, who at that time was Chief Inspector the Central District.

Porter: That was Walter B. Simmons.

Brandenburg: Walter B. Simmons. Walter B. Simmons was, as I said, Chief Inspector of the Central District but he was more known for his case handling abilities since he had gone all over the country working on various important cases. These three men were assigned to the case and they needed a leg-man in Los Angeles. I was the man chosen. We worked on that case, or I worked on it in Los Angeles, for approximately two years before we obtained a consent decree of injunction.

During the case Mr. Simmons had asked if I would be willing to go to Chicago to work with him on a case involving, what we considered to be, a fraudulent cancer cure if he were able to arrange for my transfer on it. I told him that I would be willing to do it. Just let me know. I heard nothing for quite sometime. In the meantime I was then transferred to Salt Lake City.

Porter: Right. Where you and I worked together for probably three months before I left.

Brandenburg: After about ten months I suddenly received a call from my District Director and he said, "Well, I had an offer for a transfer to Chicago to work on the "Koch" case," as we knew it. He said he would advise against it because it would only be for six months and when the six months were up I would be transferred somewhere else, not to Salt Lake City, and no one could tell me where I would be or what my position would be. Well, since I had made the promise to Mr. Simmons, I told the District Director that I would take the job and then after the six months I would find out where I was.

I then went to Chicago. As you know I stayed there five years. While I was in Chicago I was at first temporarily assigned to the Washington Division of Regulatory Management. Later on, a permanent assignment to them.

Porter: Bob, we had there in Chicago three of you who were really...you were headquartered in Chicago but you were Washington people as far as the organizations you worked with. That's unusual, we don't have too much of that. Would you describe that situation?

Brandenburg: There were two of us, Walt Simmons and myself, who were assigned to the Division of Regulatory Management. Dr. Norman DeNosaquo was part of the Bureau of Medicine. He was one of three physicians who were so assigned. There was Dr. Leo Parmer in New York, Dr. Ralph Weilerstein in San

Francisco, and, of course, DeNosaquo in Chicago. Dr. DeNosaquo and Simmons and then myself, when I joined them, formed a team, a medical-inspectoral cooperative team that investigated various of these claimed cancer cures. Visiting physicians involved, discussing the matter with some of the people who were survivors and some of the relative of those who weren't. At times we would be joined by an attorney, when we felt it necessary, but during this type of investigation it was usually just the two of us. Dr. DeNosaquo and I traveled in almost every state in the Union in investigating many of these so-called cancer cures. At that time we had, perhaps uniquely, travel orders that enabled us to travel within and throughout the continental United States, and enough books of T.R.'s to enable us to do it.

Porter: Right.

Brandenburg: Mr. Simmons, Walt Simmons, became ill about the second year that I was working with him in Chicago. Very shortly after that he was forced to retire because of his health. I was then put to greater use by the Division of Regulatory Management, on various other cases that occurred in other parts of the country.

As part of this utilization of my services, I went to Pittsburgh to work on the Hoxsey Clinics there, the cases involving them. There were, as I recall, and my memory is not too clear on this. There were either two or three injunction cases that followed one another and were all intertwined.

These intertwined cases involved the operation of a cancer clinic, using the Hoxsey treatment. This clinic was headed by a state senator. Here again politics were very much involved with the matter. This case, again, was handled primarily by Gil Goldhammer who was at that time Deputy Director of the Division of Regulatory Management. Bill Goodrich acted as the attorney. I was functioning as their alter egos. The handling of a case of this type, requires this much manpower because you are constantly interviewing witnesses. They flow through very fast. It is necessary to also issue assignments, when holes are found in the evidence or when the evidence does not appear to be quite sufficient for purposes of testimony the next day. This is done on a daily basis. At times one of us, either Mr. Goldhammer or myself, would be sitting at the counsel table in court, working with the attorneys in assembling and having the evidence ready for presentation and the other one would be in the office making telephone calls to make sure the evidence would be available when needed for the next day. This is necessary in nearly every case of importance.

Porter: Now, we are talking about cases that literally extended over weeks, the actual court part.

Brandenburg: The court part of this case, I would say, we were actually in court, out of a year, we might have been in court almost eight months.

Porter: Right.

Brandenburg: This was not a year of contiguous months, but it took place over about two years.

Porter: Yes.

Brandenburg: While I was still in Chicago, I was also assigned a number of other cases that occurred in and around Chicago, or nearby, such as the Vivison Macaroni Company case in Detroit where we got involved with the macaroni being manufactured under filthy conditions. One of the very interesting facets of this case is that the inspector, when he made the inspection, took a sample of the flour as it came into the plant, from the original sacks. These are called investigational samples. They are not handled, or were not at that time, with the formality that an official sample was handled. During this trial we found it necessary to present evidence concerning the taking of the sample, the submission of it to our laboratory, the transmission of the sample from our laboratory to Washington, and the examination of the sample in Washington. In order to do this, two of the people who handled the sample, one was the Director of the Laboratories of the Chicago District, a Ph. D., and the fellow who received it in Washington was a Ph. D. had to testify, and all that they could testify to was that, "Yes, I got it and that I had sent it."

Porter: Right:

Brandenburg: So, we had high powered testimony on both ends of that. That is a case where our inspector, Vince Balanty,

was lauded very much by the judge for his extremely convincing testimony.

I also spent a great deal of time on a case that took place in Mississippi. Here again, we ran into what should have been an extremely simple matter, but which was terribly complicated by outside pressures.

A number of years before this occurred, before this incident occurred, FDA had taken action against the same product under several different names. It was a three part treatment for arthritis. It consisted of some innocuous mixtures of vitamins and a few other things that really... nothing would hurt and nothing would help. We put this firm out of business, I think they called it ABC Company at one point. It was in Florida. We put it out of business, I think, as the XYZ Company in Los Angeles.

Porter: Were the principle people the same?

Brandenburg: No. These were different people, but the same product.

Porter: They just got the idea...

Brandenburg: Just got the idea. Finally this little old widow woman, Mrs. Wier, from Jackson, Mississippi, was down in Florida visiting. She happened to be an arthritic. She was visiting this woman down there who we had put out of business, or she had heard of her. Apparently we didn't put her out of business as well as we thought we had. She was a real estate woman, Mrs. Wier, and she suddenly saw the light. She took

this back to Mississippi, the formula, and she called it Triwonda.

Porter: Oh, yes.

Brandenburg: She knew that we had taken action against the product before. So, she was ready. First of all she got a whole series of people to attest to its efficacy. You can do this with anything in the world, any treatment, you can get all the affidavits from arthritics that you want, that they are cured. Due to the nature of the disease, people do believe that they are helped no matter what it is. So she lined up her group of people. Then she managed to get herself an attorney who was not only a member of the staff of one of the senators from that state at the time, but he was also a former partner of the Federal Judge in that area. He also, he had a co-attorney who was a partner of the Judge's former partner. In other words, we were faced with a problem and we knew it. The problem was, if you bring a criminal case, and the judge throws you out of court you are, of course, out of court for good. If you bring a civil case and the judge throws you out of court, then you can appeal. So, this is one of the few cases that we brought where we knew we would be in Appellate Court for the final answer. We had to predicate our actions on that basis. Each time we would investigate the various cures claimed by this distributor. We would go to court and present our evidence, and the judge would continue the trial

at a future date. In the meantime, they would find more cures.

Porter: Now, were we going by injunction?

Brandenburg: We went by injunction.

Porter: OK

Brandenburg: This went on and on. I had, personally, ten trips to the South, including Mississippi, on this trip. Each trip took several weeks. I would go down, and through discovery we would learn the names of their new witnesses. I would go down and visit them. They had, in the meantime, retained a physician from a consulting laboratory who had gone around to visit these people and make a report on their condition. Sometimes I would be accompanied during my visit by a physician, or more often by another inspector. We would find that what we were told by the people did not correspond with what the physician said. So we would prepare our evidence and appear in the judge's court again, and this went on and on.

I'll never forget one session. The judge liked to hold court in his office overlooking the Gulf in Gulfport. He didn't have...there was no Federal Office Building there that he had an office in, I mean, no courtroom but he had an office in there. So, we would hold court in there. One session I was sitting, unfortunately, near an open window and after about 3-4 hours I suddenly found out that I had gotten a terrible sunburn. I was quite uncomfortable for the rest of

that session. We finally had, as we expected, an adverse verdict from the judge. We did make an appeal. We did win on appeal.

Porter: A lot of effort to put one little woman out of business, wasn't it?

Brandenburg: It was a tremendous amount of effort. Her attorneys made a lot of money. Enough said.

Porter: She was making money out of the product, no question.

Brandenburg: She was at the time. If we had not acted, counter to probably what was smart politically, she'd still be in business. Sending her stuff through the mail.

Following and during this session, during which we were bringing action against Triwonda, I was moved to Washington. I was on a staff of the Division of Regulatory Management there. The Division was headed, at that time, by Dr. Milstead.

Porter: Dr. Kenneth Milstead.

Brandenburg: Dr. Kenneth Milstead, the most energetic, workaholic that I have ever met in my life. He can't rest for a minute unless he is working and he is always thinking about his work.

His Deputy, at the time I went there, was Gilbert Goldhammer. There were five others who were on the staff at that time. We operated in a kind of an informal basis to

split up the cases that were assigned to the Division, because of their complexity or their propensity for making new law or for various other reasons that would be reflected by their difficulty or where the District believed that they did not have the necessary manpower to handle it. Most cases, routine cases, were not assigned to this Division. They were handled either directly by the District or at times by the Division of Case Control, I think they called it then.

Porter: I believe so.

Brandenburg: Where Les Baukin, or Harold O'Keefe, or some of the others in that Division would either handle it or tell the District what they thought should be done. Those that were shunted to the Division of Regulatory Management, were usually those where a decision had already been reached either by a District or by the Commissioner's Office, that something needed to be done about the situation. They had shown a criminal act. Or they had shown a need for court action against a product, for some reason or another.

Porter: Yes.

Brandenburg: We usually would split our cases according to the subject matter. One man would usually handle food. Those cases that involved food. Another one would usually handle a case involving drugs. Another, perhaps, those involving fraud. Most of my cases were those that dealt with fraud, false statements, or conspiracy. As an example Van Smart, who

was a member of the Division then, would handle cases that dealt with surveys and public opinions, or content analysis material. We would do this. As I say we would split up the cases on that basis, but that did not mean that at times I would not handle a case involving food. Even though Chick Palmer usually did.

Porter: Well, you were a small group and you could work on that basis.

Brandenburg: We were a small group and did mixing and matching. We predicated our actions, first of all on the evidence submitted to us by the Districts or the evidence we would find in our files of previous history from this firm. We would decide how much additional evidence was required and depending on the nature of the case involved, we would then decide what kind of a team we would need to form to handle these cases.

Porter: Yes.

Brandenburg: If the cases involved required medical testimony, we would contact the Bureau of Drugs, might still have been the Bureau of Medicine. Dr. Weinstein, Howard Weinstein at that time, headed up a group that would mainly be involved in court cases. We would ask for a man to be assigned. After we worked with him and we would tell him the nature of the case, he'd pick the man he felt had knowledge in that particular field of medicine. If it were a case involving rotten eggs, as an example, we would discuss the matter with the

Bureau of Foods and, of course, our expert was Fred Hillig in so far as the chemistry of rotten eggs was concerned.

Then we had Tommy Bartram or Pete Dunnigan or one of the other bacteriologists, who would handle the bacteriological side of it.

Porter: Yes.

Brandenburg: So, that would give us the start of the team. That would give us the man from the Division of Regulatory Management; the scientific man or men; and when we reached the point where we decided that evidence was sufficient for consideration by our legal experts, then the man from Regulatory Management would usually sit down and prepare a rough proposed action. In other words, the rough proposed information, or injunction and take it to the General Counsel's office. Either Goodrich or his Deputy Al Gottlieb, would then make a decision as to which of their men should work with this team in the preparation of this case.

Porter: Yes.

Brandenburg: By that time, usually, we would have our evidence in a fashion to be tested. We might even have been ready for presentation to the United States Attorney, after the FDA attorney assigned to the case had decided that the information or other legal papers were sufficient.

Porter: Yes.

Brandenburg: Usually they would put their whereas's and if's and and's and but's in there.

Porter: Yes.

Brandenburg: This is the way that we handled most cases was through the team effort. At times we would call in a man from the District who was most involved in the investigation and he would become part of the team.

Porter: Now, did this team hold regular meetings or...?

Brandenburg: No, usually we would be working together on almost a daily basis.

I can remember one instance however, I was bringing a case involving a "cancer quack", this was later, but it involved the same theory. I was bringing a case against a "cancer quack" in Cleveland. It was called the Rand Cancer Vaccine. I was trying to form a team to handle this matter. I already had a member of General Counsel's Office assigned to it because we were sure that we were going to go forward and we wanted to prepare the papers in conjunction with them to be ready on an expedited basis. I contacted the Bureau of Medicine, at that time, and asked for a man to be assigned to the case. The man they assigned was known to indulge quite often. I tried to get a hold of him. I had interviews with various physicians at the National Institutes of Health and others that would be involved in the case, but I wasn't able to get a hold of him...it was a period of days. So, finally, after we had conducted our interviews without him, and without his advice we were ready for trial. We returned to Cleveland and

got into court and we were in the middle of the trial and we get a call from Washington and I pick up the phone and he said, "This is doctor so and so and I thought I was supposed to work on that case with you." We told him, "Well, Doctor, we'll be talking with you and we'll let you know." Needless to say we handled that case without the helpfulness of a medical expert, but that was most unusual. Most of the time our teams functioned very adequately. It is a very good concept and we won a lot of cases, lost very few.

Porter: Yes.

Brandenburg: It was in some ways almost too successful, in that during the several years that we were working in this fashion our batting average insofar as winning cases in court was extremely good. We were constantly adding new men to our staff to handle more cases, hopefully, just as successfully.

Porter: Yes.

Brandenburg: The Division went from a Director and a Deputy and six men, to a Director, a Deputy and about sixteen men or something like that within several years. All of these people addressing assignments to the Districts, on the various cases that were being handled by this Division tended to disrupt the routine, daily workings of the Districts. Of course the people who were directing those routine, daily workings became very unhappy. I think this is one of the factors that led to the reorganization that did away with the Division of Regulatory Management.

Porter: Yes.

Brandenburg: I think we were hoisted by our own petard. We just got too successful.

Porter: Do you think that the very size became...five or six people can work together and know what each other are doing, at least to the degree that you wouldn't overburden the District or you would get together on your requests? But sixteen couldn't really do that?

Brandenburg: Exactly. I am sure that towards the end that there were complaints, from a given District that they had received six or eight requests from DRM that had people shooting off in all directions. It was, as I say, I think we just became too successful for our own good. In that, the seeds of distruction were sown.

I should mention that during this period, amongst the other kinds of cases that were being brought, we did start successfully to bring cases under Title 18. Section 1001, that is the making of false statements to the government, or withholding information from the government, in a matter under the government's purview. There had been prior to our bringing of these cases, one case, I think, brought a number of years previously but it had never been brought to completion. We first started the Title 18 cases with the "MER 29" case. That was an anti-cholesterol compound that was successful in reducing cholesterol, but also caused you to lose your hair

and caused many other even more serious problems to those who took it. At the same time we were bringing a case against a product known as Dornwall, or the producer of the product. The MER 29 case has often been held as an example of the fact that FDA did not seek heavy enough penalties for a very serious offense. The agency is being improperly maligned in that regard. The seriousness of the offense was very clearly spelled out to the Department of Justice. The firm had an individual in the firm and several co-workers had deliberately falsified animal studies. These animal studies showed the extremely adverse affects of the drug. When the results of these studies were submitted to FDA, they showed no adverse effects. This was made clear in the reports from FDA to the Department of Justice, and in the proposed indictment that FDA submitted to the Department of Justice. The Department of Justice, however, during this period had extensive discussions with the firm's attorneys, that included a former Attorney General. As a result, when the judge accepted the pleas of the firm and the individuals, he did assess the firm an $80,000 fine but he went out of his way to put the three individuals involved on a period of unsupervised probation and made a statement during the sentencing that he was sure that they were honorable men, or words to that effect. This is contrary, I know, to the evidence, but I don't know whether or not the judge was ever presented with an accurate statement of the evidence by the Department of Justice. Be that as it may.

During the same period we were also investigating a number of other cases of falsifications in the submission of results of clinical studies and animal studies on drugs to FDA, and in one case the studies involved studies on color additives. Some of these were submitted to the Department of Justice and they refused to accept them upon their evaluation of the evidence although, we and GC felt that it was sufficient.

Porter: Now, this would have been false information in connection with their...

Brandenburg: ...submissions to FDA, concerning the safety of their product. Efficacy was not the consideration right then. During this period we... I say we, in DRM I am referring to me, because these are cases that I did handle.

Porter: Yes.

Brandenburg: I handled a case against the foremost distributor of, at that time, of misbranded vitamin products in the country. It was the Royal Lee Company in Milwaukee. We had been engaged in actions with Dr. Lee, who was a non-practicing dentist, for many years.

Porter: I did a little investigating on that myself.

Brandenburg: I am sure you did. We made a number of trips to Milwaukee and we conducted a rather extensive investigation. I made a comprehensive content analysis of all of the promotional writings of Royal Lee, and since they would occupy a

good portion of the corner of this room, why, I don't have to tell you how long it took to make a content analysis of that much material, but we finally prepared the information and a proposed injunction. We were ready for trial. We had our witnesses lined up and to our amazement Dr. Lee who had been extremely litiginous up until then, pled guilty and acceded to the injunction. So we were happy to bring that situation under control and it stayed under control pretty well from then on.

During this period we also brought a case... I drew up the information against one Dr. Krebs of California who had a product called Pangamic Acid and Vitamin B15, that he was distributing for the cure of heart failure. Here again, although we anticipated a rather difficult court fight, he pled nolo contendere and was fined a considerable sum and as part of the probation for Mr. Krebs concerning this action, he was forbidden from distributing a product called Laetrile. We thought that perhaps that would bring Laetrile, which was just then becoming known as a "cancer cure", under control. However, Mr. Krebs then transferred complete control of the product to his 80-year old father who they claimed was the inventor of the product. Even though the father was found in contempt of court a number of times for shipping the product, we were never able to tie his son back to the product. Laetrile went on being distributed for quite some time.

Very interesting that when we first encountered the Krebs and their distribution scheme they were...their products were being distributed by a firm called Spicer Gerhardt in Los Angeles. Spicer Gerhardt was distributing the pangamic acid. They were also distributing a product called Syrup Leptol. Syrup Leptol had been distributed by the elder Dr. Krebs in 1919 and 1923 and FDA made seizures of it at that time. It was being held forth as a cure for the then pandemic flu, all forms of consumption, tuberculosis and any lung conditions.

They were also distributing a Krebs product called chymotrypsin which, of course, is a enzyme that is common in the human body, but they were distributing it as a cure for cancer. At that time they were not distributing Laetrile and nobody had heard of it. Chymotrypsin was self-defeating in that it demonstrated...first of all it was too common and secondly it demonstrated quite early it had no additional action above and beyond that that was already available to all humans. You make it in your body. Then suddenly Laetrile appeared. For some reason FDA has not been able to bring it under control since. Namely because for a long while it was assertively produced and distributed only outside of the United States. Any that came in, was smuggled in.

Porter: Didn't the control of that company transfer from Krebs to some Canadian guy?

Brandenburg: The son of Field Marshal McNaughton was the Canadian who was joined with, really, Krebs in promoting this

product. Krebs kept promoting it in the country but not assertively and ostensibly not distributing it. This was being made by McNaughton in Canada at the same time as the elder Krebs was supposedly manufacturing it here. We found that the two products were entirely different, when we got samples of them. Be that as it may, neither of them were effective in the treatment of cancer, nor have there been any cases that have ever shown that it had any effect.

Brandenburg: We have, I think, fairly well covered many of the more important cases that took place during those years. Bear in mind these are important cases from my viewpoint.

Porter: Sure.

Brandenburg: One very extensive and I think very productive series of actions we took involved, of all things, rotten eggs and putrid butter.

In the early 1960's FDA had complaints made to it by producers of legitimate frozen egg products that they just couldn't compete in the New York frozen egg market, because they were being undersold by frozen egg products being made by incubator reject packers, surreptitiously. These packers were located in several parts of the South, New Jersey and several other areas.

Porter: What in the world is an incubator reject?

Brandenburg: Well, that is one that the hen sits on and no chicken comes out.

Porter: I see.

Brandenburg: Or one that you put into an incubator and it doesn't hatch; it stays there for 21 days and then they take it out. There are several legitimate non-food uses for them. For example, in the tanning of leather.

Porter: Industrial rather than foods.

Brandenburg: Industrial. They are extremely disposed to being rotten or to...

Porter: Have a dead embryo in them.

Brandenburg: There are many things that can happen. But even the ones that don't smell when you break them out, are susceptible to bacterial infestation and so on.

Porter: Yes.

Brandenburg: A very accomplished organolepticist can distinguish between cans of eggs packed with incubator rejects that have not become rotted, and good eggs. But it does take a keen sense of smell. We fortunately had those types of people on our staff. I can mention Harold Post and Peter Colucio who were probably the preeminent egg smellers of their time. There were a number of others. We had enough of them so that we finally formed a team to handle this matter. Myself, Fred Hillig and Pete Dunnigan or Tommy Bartram or both of them. Fred Hillig handled the chemical part of it. Tommy Bartram and Pete Dunnigan handled the bacteriological. Fred Hillig had conducted experiments for many, many years. Not

only on eggs but on butter, too. Where he would take cream and deliberately permit it to rot and then pack butter out of it. Or he would take cream, good cream and pack butter at various stages of decomposition to demonstrate the types of acids that would form of one decomposed cream was made into butter. The types of acids that would then be present in the resulting butter. As a result of this, we did take actions against several butter manufacturers and many of the fly-by-night operators, producers and packers of rotten eggs. When I say fly-by-night many of them used just a plain, regular rotating washing machine to separate the rotten eggs from their shells and the dead embryos and whatever chicken feathers and cigar butts and whatever else may be in them. The garbage that they represented.

Porter: Seems to me they were hard to inspect because every-time an inspector arrived they weren't in operation.

Brandenburg: We'd never find them in operation. Some places it was a little dangerous too, you know.

Porter: Yes, I know they were tough people.

Brandenburg: These were very tough people and they were fighting for huge stakes. Because the difference of a couple of cents a pound, between a can of rotten eggs or a can of incubator reject packed eggs and those that were packed legitimately was an extremely potent economic force.

Porter: Yes.

Brandenburg: And as I say we were told during this investigation, we did talk to a lot of the legitimate producers. They frankly admitted that they couldn't compete in the New York market. So we evolved the system whereby we would have in the hands of the various Districts seizure papers for immediate transmittal to the nearest United States Attorney, where we could locate a truck of these rotten eggs going through. If we knew that a truck was headed for New York City from say South Carolina, we would trail the truck, determine the route as best we could, maintain surveillance or maintain surveillance at check points, such as toll gates and so on, on highways. We would have the United States Marshals ready, alerted and ready, to seize that truck full of eggs at a given point.

Porter: Then did that work often?

Brandenburg: It worked quite often. It worked very well. One rather amusing but perplexing thing happened at one point. We had such seizure papers ready. We located the truck of eggs and as I recall the driver and his assistant they were in for a cup of coffee or something, anyway in a restaurant. They spotted the Marshals approaching the truck, so they just beat it. There was the Marshal with this truckload of incubator reject eggs. They have to be kept frozen or they would decompose. There was no place to put them. The nearest thing was an Army proving ground. We finally got permission from the Army to drive this truck out on the proving ground and

just let it sit there. There was nobody who came near that truck for at least a couple of months. Those things really rotted. The owners of the truck finally got into the picture and as I recall we took action against them. That truck was out of commission for quite some time.

Well, these were interesting years, those with DRM and they were full of action.

Porter: Yes. They were years we were making a lot of actions, of all kinds.

Brandenburg: Years when we were making actions. They were years when there were weeks and weeks and weeks at a time when I didn't see my wife.

Porter: Yes.

Brandenburg: I spent too much time in too many hotel rooms and motel rooms. And on trying to catch those not too trustworthy airplanes of the time. I was younger and full of pep.

Porter: Sure, you enjoyed it.

Brandenburg: Yes, it was something that I am very proud to have done, but...

Porter: Wouldn't do it over.

Brandenburg: Not now, couldn't do it over probably. After I left. Well, DRM was disbanded as I mentioned and I was transferred to this Bureau of Enforcement or whatever they called it at that time. I decided that whatever type of assignment I received there it would not have the satisfaction or the type

of fulfillment insofar as my career was concerned, that I had had in DRM. Even though I had been in almost entirely immersed in enforcement for nearly my whole career, I was well aware that there were other aspects to the Food and Drug Administration.

About that time, I approached Winton Rankin who was then an Associate Commissioner for something, I forget what it was. But under him was the Congressional Liaision Office. I told him I would like to have a job. The man he had heading the Congressional Liaison Office was...well, first of all he was at that time the son-in-law of a senator. So he was able to get a position as a Congressional Fellow, which is very valuable to such a job.

Porter: Yes.

Brandenburg: So he was leaving for almost a year stint as a Congressional Fellow. So, I took over that spot and I handled many hearings during that period before the then Senator Humphrey and others, and FDA was regularly being called up on the Hill to answer what we were doing about people who were promoting drugs that were unsafe; what we were doing about control of those who were conducting experiments that perhaps weren't being conducted correctly, in their view. We had many hearings. That aspect of my career is one...well, it took place and we did a lot of work on it but it gave me a somewhat jaundiced view of the operations of Congress.

Porter: Yes.

Brandenburg: I've seen no reason in the interim to change that view, but be that as it may. After the Congressional Liaison position came the Krebiozen case.

During the last year or so of DRM's existence, the Division had directed a very extensive investigation of claimed cures due to the product Krebiozen which was a claimed cancer cure. The firm asserted that they had 500 absolutely provable cures, and finally presented us with files which they claimed proved this. FDA had these files analyzed by the National Cancer Institute and they said, "Well gee, there's no information in most of these". We have got to have information on these people. We then sent out a tremendous volume of assignments to gather the information that the National Cancer Institute claimed that it needed and required in order to evaluate these cases. So, one of the last functions of DRM was to send these assignments out.

Following this period of the disbanding of DRM and my activities as Congressional Liaison, it took place that NCI had examined these cases, had decided that they were worthless; that there was no proof whatsoever of the efficacy of the product. The decision was made to bring a case, of some kind, against the producers and distributors of Krebiozen. However, with the disbanding of DRM, Gilbert Goldhammer had retired from the agency.

Porter: Yes.

Brandenburg: The next man who knew most about Krebiozen and who had directed most of these investigations happened to be me. Someone had to represent the Food and Drug Administration at the trial, and be in a position to direct the Food and Drug Administration investigators and others in necessary assignments that arose during the conduct of the trial, as they always do.

Porter: Yes.

Brandenburg: So, I was called in and told that I was to handle this matter. I demurred, I said, "I have been through this. I have been a law enforcement man for many years now, let somebody else have the fun." I pointed out that I had deliberately sought a change of direction in my career because it appeared to me as though...an operation of the DRM type was no longer viable and no longer would be viable. This would be a one shot situation and I would be losing another couple of years in acquiring another facet to my career. I got a couple of weeks grace out of that but I was finally ordered to accept the position that was offered.

So during, considerably over a year, between late '64 and early '66 I worked on the case. First of all I spent most of that year in Chicago. The first part of the time I prepared alternative proposed legal papers for consideration by the General Counsel and by those in a position to make the deter-

mination. I prepared a proposed indictment and I also prepared a proposed injunction. The indictment was the route that was chosen. That's the route we went.

Porter: Yes.

Brandenburg: In retrospect, if it were my decision, I think that the better course would have been an injunction. It wasn't my decision. The course that we took was the indictment. It was the longest case in the history of the Food and Drug Administration.

The two previous longest cases were the ones that involved the Koch cancer cure. It, of course, has been exceeded I am sure in criminal cases by some of these anti-trust suits or...

Porter: Oh, yes.

Brandenburg: I think, the Krebiozen case was probably, the longest or at least comes close in the trial of a suit of this type. Needless to say, we did not prevail in court, however I think I would have to agree with Mr. Goodrich's assessment that the trial accomplished what we set out to do. It took this product off the market.

Porter: Yes.

Brandenburg: I guess that should be our main thrust. To remove a serious threat to the public health from the market whenever we can.

For me, however, the Krebiozen case ending did exactly what I thought it would do. It left me in limbo, again. I

came back to Washington and they didn't know where to put me, so they assigned me as a Senior Staff Officer on the staff of the Associate Commission for Compliance.

I did handle another case during this time. This was between 1966 and 1968. Basically what I was doing during this time was evaluating more cases wherein the Bureau of Medicine felt that false information had been submitted to it.

Porter: Oh yes.

Brandenburg: To determine if action should be taken under Title 18. I had a capable man assigned to me, at that time a fairly new man, from the Bureau of Enforcement, Paul Sage.

Porter: Oh, yes.

Brandenburg: To help me evaluate these cases. During this period, one day around Thanksgiving, I was in a local drug store and I saw a magazine that I had never read before and have never since, except that I bought a copy of it then because it had...it was Pageant Magazine and it had an article on the front about a wonderful cancer cure.

Porter: Oh, yes.

Brandenburg: The Rand cancer vaccine. Well, I had never heard of it. When I looked into the matter, I found out that there was some information in our files on it. The fact that the then Vice President of the United States had obtained from us permission to have a shipment made of this material to a friend of his in, I think it was, Milwaukee who was dying of

cancer and wanted to be treated with it. This permission had been granted. There was strong political connotations to the matter. One...In fact the Cleveland Plain Dealer was supporting this product with editorials and articles and people were flocking to Cleveland to get this treatment. There were some shipments being made.

Porter: Bob, would you spell, I didn't quite understand the name of the product.

Brandenburg: Rand cancer vaccine.

Porter: R A N D?

Brandenburg: R A N D.

Porter: OK

Brandenburg: One of the fascinating facets of this promotion was that the articles concerning efficacy which appeared on the editorial pages in the Cleveland Plain Dealer were written by the paper's business editor. It was developed during the trial that he had some shares contributed to him, of this product. Of this firm.

The trial of this case was fascinating. We determined that the man who was placed in charge of the manufacturing, promotion and the expert evaluation of the results of the use of this cancer vaccine was a graduate in the local school, of a local university or college in the Cleveland area, but that he had never had any courses in the production or evaluation of medicines. That what science courses he had taken, he had

done very badly in. The man happened to be black. He was attempting to utilize this as part of his defense, but not to very good effect since the United States Attorney who handled the case also happened to be black. He was an extremely able man. He did a beautiful job. The judge, when the trial injunction trial which we brought was completed, castigated all of the promoters and those involved, very severely. The interesting part is though, that after the trial they stopped shipping this product inter-state and they continued to produce it and to use it to treat people who came to Cleveland. The State did nothing about it. As I said, there were policital overtones that had filled the newspapers there.

A couple of asides on this. When I called for an inspection of the laboratories, one of the first steps in this investigation, we found that they were filling this product... their filling room was being supplied with sterile air by pumping air in through the top of a filter and the filter was a plain, ordinary automobile filter. As soon as the results of that inspection came in, I had shipments reported to various places. Sure enough, one of the first shipments that we got was contaminated. So, we were able to show, directly, the results of that very poor filling practice. Mr. Paul Sage worked with me all through this case.

Also, we had as our expert witness, who responded to our hypothetical questions, Dr. Jesse Steinfeld, who had also testified for us as an expert in the Krebiozen case.

Porter: Yes.

Brandenburg: Dr. Steinfeld was for a while, the Surgeon General of the United States.

Following this period, in limbo as it were, but still working on the more important cases that either came down the pike or I saw on the local magazine stand, I applied for and was accepted as Director of the Office of Certification Services, which was also part of the Office of the Associate Commissioner for Compliance. My duties there were to review first of all the production record of various firms that were having insulin and antibiotics certified, then to review their results of the testing performed on samples that they had to submit for each batch to FDA and determine whether the plant conditions warranted certification and whether the results of the samples tested reflected the conditions that we saw in the plant. This became a very interesting situation in that some of the Districts involved were where plants were producing antibiotics and the Districts were making in-depth inspections at the same time (that's when we had the so-called Intensive Drug Inspection Program). At times certain Districts would call on me to suspend Certification Services to a firm on the basis of what they found in the I.D.I.P. even though the samples that were being tested by our laboratories showed that the products involved were safe and of the correct potency.

I can't think of one instance wherein an actual sufficient evidence was presented to me to cause me to agree with

the District. Usually the evidence was transmitted to me, particularly from the New York District at the time, in the form of a very long telegram. And I had to inform the District that the telegram was fine but it's not evidence. I would request the actual report from the inspector demonstrating, by various means, the lack of control alleged and never once received it.

Porter: This must have caused some friction between you and the field people.

Brandenburg: It caused friction between me and some, a few, of the field people. I think as you may recall, this type of situation finally led to the end of I.D.I.P.

I remember making a trip to Philadelphia where Irv Berch, me, Ted Byers (someone else was with us, I can't remember now --getting old) had a meeting. You may recall too that at that time Irv Berch had been one of the initial proponents of I.D.I.P.

Porter: Yes, Philadelphia is really where it started.

Brandenburg: Yes. But during this meeting we pretty well agreed that I.D.I.P. had seen it's day. It was not long afterwards that I.D.I.P. was phased out. That was a well-meaning but rather unfortunate occurrence. Familiarity as the old saying goes, breeds contempt and an inspector gets too familiar with the operations of the firm. In most cases, I think, it did breed contempt.

I certified antibiotics for a couple of years and then the Antibiotic Certification Services were transferred from the FB8 (the building in Washington) to the building in Rockville.

There had been some meetings between the Commissioner, me and certain people who felt that antibiotic certification should be a part of the functions of the Bureau of Drugs. The leading proponent was Jack Jennings. I don't know if at that time he was seeing beyond the horizon, to where we were going to stop certification. In any event there were several meetings with Jack Jennings and the then Commissioner, Edwards, I guess, and other members of the Bureau of Drugs at that time. I can't remember if Dr. Simmons was present or not, if you can remember him. But no decision was reached until 1970 and then the decision was made to transfer the function and put it as part of another division, as a subdivision in the Bureau of Drugs. When I moved the function to Rockville it had been a separate division. For a while I was Director of the Division of Certification Services in the Bureau of Drugs but that was very short. It stopped quickly because they had already made up their mind they were going to do this job. So I was then transferred as Deputy Director of the Office of Compliance of the Bureau of Drugs. Ted Byers was Director. I functioned in this capacity for I would say, not quite a year.

Then I had been approached by Sam Fine, and Reo Duggan to accept a staff position with the Associate Commissioner for

Compliance, and I had agreed. As a matter of fact, my papers were drawn up. Just before I was due to report for duty, Sam called me in and told me that Dr. Edwards had asked that I be detailed as Acting Deputy Director of the Bureau of Product Safety. I said, "Well, if that's what he wants, that's what I'll do." He didn't delineate why, but I knew why because I knew that we were being sued by a number of consumer organizations, because we had not implemented the Child/Toy Safety Act.

Porter: Who was Director of that Bureau at that time?

Brandenburg: Sam Hart.

Porter: Oh yes. I'd forgotten.

Brandenburg: Sam Hart was the Acting Director. Sam, I am sure was not familiar with the preparation of this type of paper. I mean not all people are.

Porter: That is right.

Brandenburg: So, Al Gottlieb, Joanne Sisk, one of the attorneys in the General Counsel's Office, and I got together and with a lot of blood, sweat and tears, and a hell of a lot of long hours got these regulations written and published before Christmas. Not much before, but before. During this same period we were making appearance after appearance in court to defend ourselves against these suits. We were preparing legal papers in response to the suits, that were necessary. So, all in all it was a rather hectic situation.

The interesting side-light is that after we got those papers out of the way, and about a month or so later, I was working on matters trying to get the organization going and reorganization of that Bureau of Product Safety when one day a guy comes in and looks around. I'd never seen him before. Sam Hart had never seen him before. He says, "Well, I'm the new Director." Nobody had said "boo" to either one of us.

Porter: Gee.

Brandenburg: And that was Mr. Jensen, of whom I will say no more.

Porter: I know.

Brandenburg: But come to find out Mr. Goodrich hadn't been told about it. Mr. Fine hadn't been told. Nobody knew that Mr. Jensen was going to be over there reporting for duty as a new Director of Bureau of Product Safety. I lasted there two weeks after he got there. I called up Mr. Fine that same day and told him, "Well, I said, "Is that job I was supposed to take on a couple months ago--is that still there?" He says, "Yes". I said, "Fine, I'll be reporting for duty."

So, I got out of the Bureau of Product Safety with almost my whole skin. But we did do a job while we were there. I'm not going to apologize for it.

This brings us to the last stint or the last major operations that I performed for Food and Drug prior to retirement. Between 1971 and 1976 I was the Staff Director on the staff

of Associate Commissioner for Compliance and I was Director of the Compliance Regulations Policy Staff. As I think I indicated before, this staff had many segments. I had a corps of specialists who reviewed regulations promulgated by or offered by the various bureaus; it had the Freedom of Information function, the Hearing Clerk's function, the Federal Register's Writers, plus an oversight function for the Regulatory Management staff.

During the period, of which I am speaking, Reo Duggan was the Deputy Associate Commissioner for Compliance. He finally retired and for about...a period of somewhat over six months I functioned as the Deputy Director, also. During this period we engaged in perhaps the most feverish regulations activities that Food and Drug ever encountered because Mr. Peter Hutt happened to be the General Counsel at that time. When Mr. Peter Hutt was General Counsel he wrote regulations for almost every function of Food and Drug. Either wrote them or re-wrote them. He was a firm believer in having regulations to cover almost every activity.

Porter: What do you think of that? Do you think that is a practical approach.

Brandenburg: Not to the extent that he pushed it. I believe that he was correct in foreseeing the position of the courts, insofar as regulations were concerned, in many aspects. They were demanding that regulations be promulgated. He certainly was in tune with the Congressional intent at the time.

Porter: What was the philosophy of that? Why is that a good approach? Is it to let industry to know exactly what we...

Brandenburg: It is to let people know in minute detail what is expected of them, insofar as obeying the rules and regulations promulgated pursuant to law.

Porter: Sort of narrows our ability to use the law to protect the people, like in a very imaginative way, doesn't it?

Brandenburg: It took almost all initiative away in certain areas from the Food and Drug Administration. You had to know the regulations almost by rote, in order to be an efficient enforcer. Needless to say, since there were so many regulations, efficiency suffered.

Porter: Yes.

Brandenburg: Congress, however, at this same time was on an extraordinary regulations binge. Each law that was written during this period mandated that the enforcing agency be it Food and Drug or Environmental Protection Agency or OSHA, or whom so ever, would promulgate regulations until they never ended. The onus of passing the regulations was passed entirely to the Executive Branch, but they had to do it according to the laws that were passed. Since then the Executive Branch has been blamed for all of this extraordinary amount of regulations that they have promulgated.

Porter: Yes.

Brandenburg: But really most of the agencies had no choice. Of course I will say this, insofar as Food and Drug is

concerned, the law that has placed probably the greatest burden of promulgating regulations on the Food and Drug Administration is the Device Act. I am very much afraid that Mr. Hutt and some of his young attorneys can be blamed because they were working very closely with Congress in this respect, and they helped write that law. Almost every time that you take a breath, with respect to the Device Law, you have to pass a new regulation. That is one of the problems that the agency is faced with currently, with respect to the Device Law. I noticed in the newspapers recently that certain Congressmen have been complaining because FDA hasn't passed regulations that the law said they were supposed to pass. Well, some of those regulations are almost unpassable. They are almost impossible to draw up and... Frankly, I don't ever expect to see some of them promulgated:

Porter: Of course there is the contrary pressure from the current administration too that makes it...you have to get all sorts of clearance before you can promulgate...

Brandenburg: They are in a "Catch 21" situation.

Porter: Yes.

Brandenburg: The promulgation of regulations, in fact the approval for publication of many of them has been shifted from FDA level to the department level.

Porter: Which for all intents and purposes means the White House level.

Brandenburg: Which for all intents and purposes means that many of them never get considered. They sit.

Porter: Yes.

Brandenburg: It was our experience, previously, that whenever regulations went to the then Department of HEW that the agency that sent them there could just about figure on a year or two lag before they would ever get them cleared, if they got them cleared. Many of the agencies were very envious of the Food and Drug Administration, because of the exemption it had from clearing regulations through the department. There were always certain elements, certain people in the department who constantly were trying to take the privilege of reviewing and publishing its own regulations without department approval from the Food and Drug Administration. They were very anxious to take over the oversight functions.

Porter: Yes.

Brandenburg: This was a constant battle, as you may know for years. They finally won.

Many of the laws that were passed, in fact nearly all of the regulatory laws that were passed by Congress for the past 10 or so years have contained these provisions that mandate the promulgation of regulations. Even providing time-tables, which the agencies had to meet for sequential promulgation of the various regulations that were entailed.

And Robert, that does bring me up to the end of my career with FDA. I had retired as of July 2, 1976. From there I

went into the consulting business. The firm of Arthur A. Checchi.

Porter: Oh, yes.

Brandenburg: He was formerly with FDA. I was told by Mr. Checchi, at one point, that when he mentioned to Peter Hutt that I had joined his firm that Mr. Hutt was very surprised. He said he thought that, given my regulatory stance, I was the last person in the world that he would have thought would undertake to advise industry and to work with industry. I have had others since then who asked me how it felt to be on the other side of the fence, when I was doing consulting work. My response was that I didn't consider that I was on the other side of the fence. That the advice I gave to clients was exactly that which they would have received from me had they come for my opinion while I was still a member of FDA. And that is the case.

I have talked about many of the cases that I was involved with. There are a few that I think would bear further comment. One of them being the so-called Koch case (that's K-O-C-H, not C-O-K-E) that I worked on with Walter B. Simmons during the 1950's in Chicago.

Walter Simmons, and I might amplify upon him a little bit, was one of the very few men who reached fairly high rank in FDA (in fact, one of the very few men who were ever in an inspector - now investigator - status) who had not graduated

from a university. Walter was a high school graduate, was a product of the Boston area to start with, and wound up as an inspector in Cincinnati early in his career. He was the first inspector hired in Cincinnati. The chief of that station then was a political appointee of sorts and his main occupation was visiting his club every afternoon as I understand it, according to Walter anyway. But Walt was the first inspector hired, and George Larrick was the second in that station.

George Larrick told me that that was a rather difficult position for him in that the chief of the District (or the chief of the station) took all assignments that entailed no travel and that took place inside of the city. Simmons, exercising his seniority, took all of the assignments in a circle in the immediate vicinity of the city. The remainder of the entire area was allocated to George Larrick. Well, he managed to capitalize on that situation finally, and wound up being the boss. He told me that he was distinctly aware of his junior position in that hierarchy.

Walt Simmons had several hats to wear when I joined him. As I say he was the, what they then termed, the Chief Inspector of the Central District of the Food and Drug Administration. I won't elaborate further on that because I think the old District set up is well known to everyone.

Porter: Yes, it has been described in a number of my interviews.

Brandenburg: Walt was also the chief trouble-shooter, insofar as court cases were concerned, for the Food and Drug Administration for a number of years. When difficult cases came up anywhere, he was assigned to work them. He would direct the investigations and accumulate the evidence and with help, whatever he needed, he'd help the United States Attorneys present the cases in court. This was his first love really. He did like being Chief Inspector and keeping the little black book that all Chief Inspectors had but basically he liked court work. He had pictures of several judges with whom he had become friends posted in his recreation room, in his home. Walt had worked up two cases, then the longest cases in the history of the Food and Drug Administration against this quack cancer cure that had been devised and promoted by a physician, Dr. William Frederick Koch. The first case was about six months long. It resulted in a hung jury. The second case was five months long. It too resulted in a hung jury. Walter then set about to attempt to control this activity through the working up of a injunction, which he intended to bring against the promoters. In the meantime the promoters had ostensibly transferred control of the product to a group of fundamentalist preachers in the area. So, it was being promoted both under the guise of religion and as a cancer cure.

I was transferred, as I mentioned, from the Salt Lake City Resident post to Chicago on a temporary basis to assist

Walt in working up this case. We did a tremendous amount of work on it, along with the FDA physician who was involved in the matter, Dr. Norman DeNosaquo. We had arrived at the point where we did have an injunction prepared, a proposed injunction. We were just about ready to go to court on this matter, but Walter became ill and for some reason the promotion of the product had slowed down. Whether it was through design or just because new so-called cancer cures had come up on the horizon and the Hoxsey cure was then being promoted very heavily, this particular product didn't receive the publicity it had before. The people weren't using it to the extent they had previously and the decision was reached finally not to bring the case, unless there was a resurgence in activity. That never occurred.

Porter: I am glad you explained that, because much earlier in our interview you talked about going to Chicago and then Koch sort of got lost in the shuffle.

Brandenburg: Another case that I touched upon and mentioned to some extent was the cases against the Hoxsey cancer cure that was being promoted in a clinic in Pennsylvania. We had, as I recall, two separate cases involving that clinic. Brought to and enjoin the clinic from promoting and using the so-called Hoxsey cancer cure. Previous actions against Hoxsey and his product had already been brought in Texas. I worked on this with Gilbert Goldhammer. I was still stationed in

Chicago and I would travel to Washington, we would work on the various legal papers entailed and then we would travel to Pittsburgh and stay there until we had terminated the immediate action. This took almost a total of a year between the two trials.

I made a number of trips back and forth from Chicago to Washington to Pittsburgh and needless to say, I saw my wife at one point once in three months. Only then because I took a bus from Pittsburgh and met her in Cleveland where she had relatives.

On these trips Gilbert Goldhammer was always accompanied by his wife, Marge. Marge Goldhammer was and is, a very bright woman who was part of the team most of the time. She would make notes of the important testimony during the time it was being given so that we would be ready that evening to work on the next day's investigations or the next day's presentations or start to prepare a rebuttal to the testimony that had been given by defense witnesses. She had been a teacher of office skills previously and she was extremely knowledgeable. She knew as much about the cases as we did--just about. This of course, was the usual team, that Marge and Gil would go out on any of the cases that he was involved in, so that sometimes you might want to talk with her Bob, or your group. She could probably give you a pretty good interview concerning many of the cases that took place in which Gilbert was involved, and he was involved in many of them.

He was a product of the New York area. He'd been in New York District and other Districts up in that area. When he came to Washington he was assigned to the Division of Regulatory Management and became the Assistant to Dr. Milstead. When Dr. Milstead went on to bigger and better things as was suitable, Goldhammer took over Directorship of the Division. He held that position until that reorganization in 1963.

I made many trips with the Goldhammers myself. He had started originally handling the Triwonda case that took place in Mississippi by himself. Later I joined him and then took over all of the final activities in that case. But in the interim, I made a couple trips from Chicago to Washington and then traveled with the Goldhammers down to Mississippi. We usually drove down in our own automobiles because we were taking so many files with us that we didn't want to trust to the Post Office or anyone else.

Porter: Yes.

Brandenburg: We had all the evidence and other things in our automobiles. Good thing we didn't have a wreck.

Now Bob, we have discussed some of the personalities concerned. If you think it would be of interest I could give an outline of some of the people we worked with in Division Regulatory Management.

Porter: I'd like you to. I'd like you to, if you would, talk a little bit about Harvey and his style of operation and

management, and Larrick and Billy Goodrich, Peter Barton Hutt. I can't tell you exactly what to do because I don't know...

Brandenburg: Right.

Porter: ...your experiences. But any of these people--if you'd select them now and just tell a little bit about their management style or anecdotes about them--that would be great.

Brandenburg: Well, the Division of Regulatory Management at the time that I came into it from Chicago in 1957 was composed of Dr. Milstead, of course. There again if anyone was ever an example of how to direct your energies, he certainly was. He was extremely hard-working. His full attention was always focused on the job, and Goldhammer of course, was his Deputy. Gilbert was a very energetic and rather nervous type. Ostensibly he was calm but all you had to do was look at his fingernails to know how nervous he actually was. John Cain who had been with the Food and Drug Administration for quite some time at that point, was also a member. At about the time that I came in or shortly thereafter, Chick Palmer came in from ...he'd been stationed in Baltimore District until then as Food and Drug officer. Will Swain was a member of the staff when I came in. Then Van Smart, of course. Van was a double-barreled threat in that he was an attorney in addition to having been experienced in the Food and Drug officer's work. Josh Randolph was also a member. That was the staff at that time. Later, as I elaborated previously, the staff grew

and grew and grew. I'm afraid it grew like Topsy and we got too good for our own good.

Porter: Don't you think part of that was that even then we were getting the beginnings of a move away from the law enforcement kind of approach and more towards...

Brandenburg: Exactly.

Porter: I'm just saying that it probably wasn't entirely due to this growth. It was due to a lot of other things that were beginning to occur at that time.

Brandenburg: Well, we also at that time I think, had a misguided effort in focusing a lot of attention on the bringing of over-the-counter cases. We had a very strong push in that regard and the opponents let me say, of DRM at that time--the ones who were guiding the field, were the ones that were guiding that effort. They preferred to put more effort into that I believe, than into the bringing of cases that involved the poor manufacturing practices and other matters of that type. I know that at the time the number of actions that we brought against incubator reject eggs were the subject of some adverse comments to the Commissioner's office in that they felt that our time would be better spent by using these same people for the bringing of over-the-counter cases. So as a result, there was constant friction during that period as anyone knows who was present at the time. But yes, there was pressure on the part of industry, I think mainly the drug industry, to have a

relaxation of our efforts insofar as criminal actions or injunctive actions were concerned.

Porter: Well you know, both the first and second Citizen's Advisory Committees recommended highly a more educational and less prosecution-minded approach too, and I'm sure that that effected Larrick's management style and even more so, Goddard's after he came in.

Brandenburg: Well I think that Goddard came in with that philosophy to start with. A very interesting commentary... during this period when Goddard first came in, we had conducted an investigation of the distribution of dimethyl sulfoxide, DMSO, which is still being sold in various places ostensibly as a solvent but actually for the cure of what-have-you. This was being promoted very vigorously by the physician Dr. Jacobs, who is a professor of surgery at the University in Oregon as I recall. But we found the product being distributed indiscriminately throughout the country. We had made an investigation. We found it being shipped not for investigational purposes, but for curative purposes...being distributed to almost anyone who wanted it just for use. I had prepared an information. I'm sure that it wasn't a politically popular information or act because there were certain senators and congressmen from Oregon who were very much in favor of Dr. Jacobs. But I was convinced that we could prevail in a court case. I prepared the information in

rough draft and I presented it to Mr. Goodrich. He saw nothing wrong with the information but he sent it to the Commissioner...at that time Dr. Goddard. The Commissioner took my rough draft which was accompanied by examples of all of the evidence that we anticipated using to prove our points. In other words it was a couple of three-ring binders full of material headed by my rough draft of the information. He took it to Seattle with him and went down to Oregon and met with Dr. Jacobs. He told me personally, before he left that he was really going to have it out with Dr. Jacobs. Well, I understand from reports I received later that he had it out with Dr. Jacobs but Dr. Jacobs came out the winner because I never saw my rough draft again.

Porter: Is that right?

Brandenburg: Never did. I never did find out what happened to it and no action was ever taken against Dr. Jacobs. This really was not unexpected to me because I knew what the political situation was. So that was sort of a very good indication as to what was in store for enforcement activities from then on, I thought. When our Commissioners became political people, more so than during a period when he had really an apolitical man such as George Larrick, who even though he had to bear in mind the politics of the situation, was himself an enforcement man originally.

Porter: Right.

Brandenburg: So I knew that from then on one could anticipate very little other than that sort of a decision to be reached.

During the succession of Commissioners that we had, while Bill Goodrich was still there, I felt fairly sure that there would be some sort of continuity in at least the way that the General Counsel's office reviewed and considered recommendations for actions. But as all things pass so did Bill Goodrich. I mean at least from the scene.

Porter: Right.

Brandenburg: I understand that he's hale and alive, and well and kicking.

Then came Peter Hutt. Peter put his stamp on the Agency in an entirely different matter. Bill was no great one for the promulgation of regulations. He felt that the law said what had to be done and he wanted I think, to have the leeway to make decisions himself rather than have each one spelled out for him so that he would have to observe them in detail at each point. I believe that his philosophy was the one that should have been followed. Whether it could have been followed, in light of the attitude of the courts and congress in succeeding years, is debatable. For many years we operated, FDA did, with the law and a few basic regulations.

Of course following Bill's period and starting at about Hutt's period, there were a number of court decisions on procedural questions. Title 5, as an example, of the United States Code.

Porter: Right.

Brandenburg: Where the courts held that the agencies had to spell out the procedures that they were going to use and in pretty good detail and had to observe those that were promulgated, in detail. In other words, you have to give due notice and you have to provide opportunities for hearings on about every matter. They had a series of cases that tightened up the rules under which agencies had been operating. These probably would have put constraints on the way Bill operated, as well as giving impetus to the way that Peter Hutt wanted to operate, or perhaps they gave him the ideas. That's one of the ways in which the agency got into the...so deeply into the regulation making situation. Of course, as I said previously, Congress started mandating regulations right and left in the laws that they passed. So really the agency had no choice except that they aided and abetted, particularly in the device area. We had no options in the matter. The regulations that we did promulgate I think in many cases went beyond those that were necessary or those that were required.

Porter: Choose kind of a...

Brandenburg: The Freedom of Informations Regulations promulgated by FDA, I think, put unnecessary burdens on the agency. There has been some relaxation by the courts in the interpretation of the requirements of the Freedom of Information portion of Title 5. That is the Administrative Procedures Act

and Freedom of Information law is merely an addendum to that. So, I think we could have started with much less stringent requirements being placed upon the agency, than those that Peter Hutt wrote.

Porter: So, we had both internal and external forces that led us in that direction?

Brandenburg: Exactly. Peter was a great believer in having the regulations spell out everything. I think if there hadn't been some internal objections that there would have been more regulations that tied the hands of the agency than he finally wound up with. He did a pretty good job while he was at it, you'll have to admit. The regulations process is a grinding one, as you know. He wanted to have a regulation that would tell everyone just exactly what they had to do. I mean in every aspect of the agency's operation.

Porter: Which seems to me tends to put obligations on the agency, that certainly the way the act was written, were really industry obligations.

Brandenburg: Exactly, but don't forget Mr. Hutt came from industry and went right back to industry.

Porter: Yes, I know.

Brandenburg: These regulations work to his benefit now. Not casting any aspersions on his intent, but I am sure that unconsciously the thoughts were there. The intent. Since he had operated on the other side of the fence from an FDA not constrained by these regulations and felt that they should be.

Porter: Right.

Brandenburg: This was his opinion as an attorney and when he became General Counsel he exercised his prerogatives.

Porter: Yes.

Brandenburg: Perhaps feeling that he was made General Counsel because of them. Be that as it may, I am not going to...I can delve into his inter psyche.

Porter: No, we have to assume that he thought what he was doing was...

Brandenburg: Oh, I am sure he did. As I say, he was in tune with the times. Now I don't think he would be. I don't think that he could operate in the way in which he did, under present circumstances. Of course he was followed by, I forget the guy's name, but he was from the University of Virginia and Peter had been down there working with him on various matters for a couple of years, I know. Maybe ever since he came in. So there was very little difference between Peter and perhaps his next couple of successors.

The General Counsel now, Tom Scarlett isn't it, yes.

Porter: I don't even know.

Brandenburg: I believe it is Tom who was one of the people who came into General Counsel while Peter was there, as I recall, and Tom is a very bright guy. I think that they know what they are doing in the General Counsel's Office, but I think they have gotten somewhat of the viewpoint now, from

what I have been able to determine and observe, that General Counsel's Office really should be in charge. There is no place for...really for decision making on enforcement matters by laymen.

Porter: Yes.

Brandenburg: Now this, of course, is the way that Federal Trade Commission has traditionally operated. I think it is a mistake.

Porter: Everything is a legal decision and not an administrative decision.

Brandenburg: In so far as compliance matters are concerned. Whereas, Bill Goodrich felt that there should be a very strict division. He did not want his people to be making decisions that involved direction of the field force. He wanted his people to be making legal decisions, and giving legal advice, and not directing the field. He wanted the decisions on compliance to be made by the Commissioner of the Food and Drug Administration, essentially.

Porter: Right.

Brandenburg: Peter had started eroding that while he was there, in my opinion.

Porter: Well, this was aided and abetted by the fact that the Commissioners change every couple of years and it was natural for a new man as Commissioner to depend more on the General Counsel.

Brandenburg: A new man and a strong man. When you had a General Counsel who had more tenure than the Commissioner, had been here there longer and knew more about the agency, who else should make the compliance decisions? This is what had started occurring. The Commissioner, when there was a question, when his General Counsel was opposed to the course that was being proposed by the men that he inherited when he arrived, the Commissioner usually took the General Counsel's advice. So, as an example, when Sam Fine sometimes would make a recommendation that Peter Hutt didn't like, Mr. Hutt usually prevailed. Of course this was not true when Goodrich was there because of his seniority and the length of time that he had been there and his personal philosophy.

Bob, I don't know that I have much more to add to this.

Porter: It has been very good.

Brandenburg: There are all kinds of people that we could talk about, but basically I think I have touched on most of the more important cases. Of course I can't remember them all. Unlike a lot of other people, I took no papers with me from Food and Drug.

Porter: Yes.

Brandenburg: I have to depend on my recollection. Where I did make diaries, I threw them away. Destroyed them.

Porter: Well, I think you have given us a real good story here, today. I certainly appreciate you taking the time and

thought to do it. If you have any kind of closing thoughts that you might want to put on the tape, we have a few minutes. These tapes end up in all sorts of ways. You would be surprised to know that when Larry Warden, I finished the interview with him and we still had 10 minutes on the tape, he sat down and...

Brandenburg: ...played the piano.

Porter: He played the organ. So his tape ends with an organ concert.

Brandenburg: Well, that is wonderful. Larry is a particular old friend of mine, as you may know.

Bob, I am distressed by what I have read in the newspapers, I hear very little from former FDA'ers, but it appears to me that the Food and Drug Administration has abrogated the past. They seem to be intent on rediscovering the wheel. Now the wheel, I didn't know it had been lost, but they are doing it. I noticed in the paper recently that we are going to pass regulations that will force people to report, with respect to new drugs, any adverse reactions. I thought we had done that maybe 20-30 years ago.

Porter: Yes.

Brandenburg: These things bother me. The counterfeiting of drugs is another area where people make look-a-likes and there were court actions being brought and apparently the Food and Drug Administration didn't even enter into the matter, it was

the Federal Trade Commission. As far as I remember there was a Section of the Act saying that one drug shall not assume the appearance of another, you know and so on.

In many other fields it appears there has been a great lessening of basic compliance. Now, advisory opinions are fine, but we have been through this a number of times in the history of the Food and Drug Administration where we adopted a policy in certain areas of giving advice or where the courts forced us out of an enforcement situation. Under all of these circumstances we found that when we did reenter the arena with enforcement activities that industry had regressed so far that it was very painful. If you recall the Phelps Dodge Decision, that kept the Food and Drug Administration out of warehouses for several years. When that decision was reversed, by Congress, we went back into the warehouses and we made seizures, thousands upon thousands of them, in warehouses throughout the United States.

That sort of previous experience should tell us something, but it doesn't appear to be. We have an outfit that I am reliably informed is doing very little compliance work, enforcement work. As I say sooner or later this laissez faire policy will reverberate to the disadvantage of both the agency and of the industry that is involved. Why should it be necessary for us to go out and seize all of the flour in country, as an example, which we almost did following the Phelps Dodge

Decision. I can anticipate that if the present policies are continued that we will have some very bad horror stories concerning, as an example, antibiotics wherein lapses of manufacturing technique and a lack of strict observance to adequate testing will put some products on the market that will cause widespread injury. This is just a forecast, but I think unfortunately that it is one that we can anticipate in the future.

Porter: You know Bob, we'd talked about this in some other interviews, especially the group interviews and I've discussed it with Harvey Young. If you go clear back to 1906 and sort of graph-out the regulatory stance of the Food and Drug Administration, you tend to get kind of a sine curve. This isn't the first time that we have gone into a period where the compliance actions were not as important and then we have moved up again and I suspect, maybe you and I won't see it, but I suspect that curve will sometime move up again. It might be triggered by...

Brandenburg: I think it will move up and for that very reason, Bob, I think it will be triggered by some incident but it seems a shame that it has to be. I don't think an incident should be required to jostle the memory of people about what has occurred previously. Unfortunately, as I say, the wheel needs to be reinvented every once in a while and they are in the process of doing so right now.

Porter: I used an introductory statement in the transcripts of these interviews in which, I don't quite put it in those terms, but one of the reasons that these interviews were started was (Fred Lofsvold and I pretty much became concerned) that past experience was literally being lost. In an agency that has grown like FDA, there are so many young people who literally don't know what has happened in the past. If our interviews are read and if they serve no other purpose than to maybe prevent a little bit of this remaking of the wheel they will be worthwhile. We are hopeful that they will play some part, not only as background material for articles that will be read, but they are going to be available to new employees and to new Commissioners for that matter. If they can take the time to read them, hopefully it will prevent a little bit of that. These interviews are not really intended for entertainment, although some of them are entertaining, but it was one of our goals, when we started out to do this thing, to maintain some continuity, to let the younger people know what kinds of things this agency did, what kind of people it had in it and how it used to operate and what made it an agency that most of us that are your age and mine were very proud to be in.

Brandenburg: I think it is a laudable program, Bob, and I hope that is has some success.

Porter: Well, thank you Bob, and I certainly appreciate this interview and the time you have taken. This is the end of the tape.