HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

James Nakada, Retired

Assistant Director, Region IX

and

Fred L. Lofsvold

U. S. Food & Drug Administration

Burlingame, California

June 16, 1982

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold, and Ronald T. Ottes, retired employees of the U. S. Food and Drug Administration. The interviews are being held with F.D.A. employees, both active and retired, 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

Food and Drug Administration
Room 500 U.S. Customhouse
721 19th Street
Denver, Colorado 80202
303-837-4915

TAPE INDEX SHEET

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

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

DATE: June 16, 1982 PLACE: Burlingame, California LENGTH: 194 Min.

INTERVIEWEE	INTERVIEWER
NAME: James Nakada	NAME: Fred L. Lofsvold
ADDRESS:	ADDRESS: U. S. Food & Drug Admin.
Burlingame, California	Denver, Colorado

FDA SERVICE DATES: FROM 1951 TO: 1982 RETIRED? Yes

TITLE: Assistant Regional Director For Compliance, Region IX
(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
1	A	0	1	Nakada's Education, Early Experience
		9	4	Thalidomide Episode
		21	9	Drugs - Good Manufacturing Practices Regulations
		23	10	Drugs - Training of Investigators
		25	11	Drugs - GMP Violations
	B	0	13	Abbott Laboratories Recall - Large Volume Parenterals
		8	16	Fountain Hearings
		29	25	Reorganization of 1964
2	A	0	26	" " "
		4	26	Equal Employment Opportunity
		5	28	Philadelphia Laboratories Episode
		10	30	Intensive Drug Inspection Program, IDIP
		26	37	Canned Mushrooms - Botulism
	B	0	40	" " "
		3	41	Personnel Problems in Philadelphia District
		19	47	Dallas District, Experience In
		22	48	Frog Legs, Importation of
		28	50	Federal State Relations in Dallas District
3	A	0	51	Relations With Mexico - "CONOCALPE"
		5	53	Small Business Activities
		10	55	Federal State Relations
		12	56	Aflatoxins
		15	57	Illegal Drugs - Nevada
		16	57	Intraocular Implants

TAPE INDEX SHEET

James Nakada Interview

Cass. No.	Side No.	Est. Min. On Tape	Page No.	Subject
3	A	20	59	Raw Milk
		22	60	Color-Therm Case
		24	61	Pure Food Corp. - Canned Tomatoes
		25	62	Pesticide Residues
		28	64	Watered Tomatoes
	B	0	65	" "
		3	66	Pepsi Cola Case
		5	67	Viobin - Wheat Germ Oil
		8	69	George P. Larrick, Commissioner
		16	72	John L. Harvey, Deputy Commissioner
		18	73	James Goddard, Commissioner
		24	75	Government Wide Quality Assurrance Program, GQUAP
4	A	0	76	" " " " " "
		1	76	Charles Edwards, Commissioner
		5	78	Donald Kennedy, Commissioner
		13	82	Concluding Remarks
		14	82	End of Interview

This is a recording in the FDA oral history project. The recording today is with Mr. James Nakada at his residence in Burlingame, California. The date is June 16, 1982. Interviewer is Fred Lofsvold.

FLL: Mr. Nakada would you briefly sketch your education, how you came to FDA and the various positions you held with the Agency.

JN: I was born October 18, 1926 in Los Angeles, California. My early education was in California until World War II broke out at which time I was put into a concentration camp because of my ethnic background. I completed my high school education in Oak Park, Illinois and went to the University of Illinois. I enlisted into the Army and was in the service for several years during which time I did attend the University of Illinois in electrical engineering and the Pennsylvania State University in electrical engineering. After the service I returned to the University of Illinois and received my Bachelor of Arts Degree in Psychology. I also completed pre-med during that time and was not fortunate enough to get into medical school. I attended graduate school at the University of Southern California in 1949-1950. I did not receive my Masters Degree, although I did all of the course requirements for that degree.

I worked as a social worker for Los Angeles County in 1950-51, following which I was employed by the FDA in April of

1951. I worked for the agency in Los Angeles for approximately 6 months and in October, 1951 I was RIF'd or removed from the agency because of a cut in appropriations. At the time the expression, I was "taborized" was used. I worked for the Navy as an inspector for 3 1/2 years in Los Angeles, and the San Fernando Valley area. Initially I did work in the inspection and purchase of pharmaceuticals. Later I was involved in the inspection and purchase of aircraft, submarine and other parts for the military. Upon increased appropriations for FDA in 1955 I was reemployed and had been in continuous service from then until my retirement January 8, 1982.

My reemployment by FDA was at Los Angeles and I worked there as an inspector from 1955 to 1960. During that time the principal areas that I worked included the tomato canning industry, pesticide industry, drug industry, medical devices and food products. I was transferred to St. Louis District in 1960 with my promotion to GS-11.

While in St. Louis I worked on a number of different cases including the Pepsi Cola prosecution, the Viobin seizures and a number of other legal actions. While at St. Louis I also did what probably was one of the first food additive inspections in the field. This was a large chemical manufacturer. During this era we were told to get as much food additive time in as possible and my chief inspector suggested that since the firm had many food additive petitions I conduct an

inspection. The inspection lasted several months which was a precedent at the time. It was interesting, and I believe it included about 16 or 17 different facilities. When I asked for a review of the data upon which they submitted their food additive petitions the firm delayed that portion of the inspection for several months. They used excuses such as, it's in a remote area; it's difficult to get to, finally when I went out there I found a brand new animal facility. I had reason to question whether or not they had in fact done real animal research when they submitted their petition, but they did have animal facilities by the time I arrived. My report went to Washington, and no one really wanted to review it because they had not encountered such a thing before. Of course, since then we have encountered firms that have had their petitions questioned in terms of the authenticity of the data. This inspection took place in 1961.

In 1961 I was instructed to transfer to headquarters in a two year management trainee program. I was probably one of the few in FDA who received a written request with a time frame of two years. Since I had basically not wanted to go to headquarters, I was told that I had no choice, that I had to go. While at headquarters I served as a Food and Drug Officer in the Bureau of Field Administration. The early part of that training involved reviewing food reports and medicated feed reports and color additive reports, things that I had been

somewhat familiar with but was certainly not my area of expertise. At that time in the Bureau of Field Administration most of the technical areas were managed by people who were laboratory people, chemists, microbiologists and so forth.

People who were inspectors basically did not get involved in those areas. If you wonder why I'm raising or bringing this issue up, it was that in the summer of 1962, when I returned from a vacation, I was immediately told to monitor the Thalidomide project. This particular project had previously been handled by chemists and it was very puzzling to me that upon return from a vacation I should suddenly be thrown into this project. It eventually involved the recall of Thalidomide totally, the investigation of Richardson Merrell and related firms, and the subsequent development of data which led to regulations on new drugs, on clinical research, on investigations, and a whole new area for FDA investigators, good manufacturing practices.

My involvement in the thalidomide episode was to monitor the entire project in terms of recall, the accountability, keeping track of all the deformed infants, and to report regularly to the Bureau Director, Mr. Rayfield and to Mr. Harvey, Deputy Commissioner and Mr. Larrick, the Commissioner and in fact a number of my reports went to Secretary Celebrezze. I worked with Mr. Rankin personally since he was the primary liaison between BFA and the commissioner, this included pre-

paring most of the press releases that were issued. I issued most of the assignments that went to the field, received most of the information and kept track of all of the data that was accumulated. The press regularly tried to get in touch with me during that time and I steadfastly refused to talk to them.

The investigation of Richardson Merrell was made to determine whether or not they withheld information, whether or not they falsified information; and what the circumstances were as to why FDA did not receive the information on deformities in Europe and the USA in a timely manner. This necessitated my review of new drug applications, including a review of Richardson Merrell's portion in German, which I had to translate in order to determine whether or not there was any problem. It involved working with Dr. Kelsey at the time to validate certain things and to verify that some of the data that she was testifying on was in fact accurate. It meant to keep track of the multitude of information that was coming from the field involving accountability. The reason for much of the lack of good data on accountability was that up to this point the agency really did not require the accountability of drugs or other products. Thus to find a base was very difficult. Not only that, there were at least four other firms involved in the distribution of thalidomide during this time. With the total of five firms distributing the product it was very difficult to determine total accountability. Some of the

drugs were found months after the recalls were completed and this was in part due to perhaps poor information but also because there was no base line from which accountability as to how much went out, how much was returned, or how much was consumed, could be determined.

Later on I was deposed in conjunction with one of the infants who was deformed, to verify that I was involved in the recall, to verify that FDA had conducted an investigation into the matter and had determined that the infant's family did in fact receive the thalidomide. I was involved in the monitoring the coordination and in a sense the directing the activity involving thalidomide. Do you want anymore information?

FLL: At that time, if I recall correctly, we did not have a requirement that any firm submit their plans for new drug investigations and it was a direct result of this that led to the passage of the 62' Amendments and FDA established what now we refer to as the IND procedure.

JN: That's correct. Well, this is the next phase that I was going to get involved in because our GMP's and everything really evolved from the Thalidomide disaster.

I served at headquarters for approximately 3 1/2 years after which I was promoted to the Chief Inspector at Philadelphia. This was from August of 1966 until January 1974. In 1974 I was transferred to the Dallas District as the Station Chief or District Director or whatever the position was

called. Basically, I was involved in the management of the Investigations Branch and the Compliance Branch at Dallas. I served for two years in Dallas after which I was transferred to San Francisco to the Regional office and served as the Assistant Regional Director for Compliance from February 1976 until my retirement January 8, 1982.

The field involvement in the thalidomide episode was tremendous in terms of the recall and accountability. Investigators, at the time called inspectors, contacted doctors, patients, pharmacies, hospitals, and went any place where there was a potential for the drug to be found. They followed up many times in some instances to determine that the drug was no longer available. The investigators also followed up on all infants who were known to have deformities at the time to determine whether or not there was a relationship between the Thalidomide and the deformity. In many cases there was no apparent relationship. This type of information was coordinated at headquarters and I kept most of the records.

The field was also involved in the inspection of all of the firms involved in Thalidomide distribution to determine whether or not they had knowledge of problems before they were reported to FDA headquarters. There was some indication that there were delays but at the time there was no requirement as to how soon such problems had to be reported to headquarters. Thus, none of the firms ended up with legal sanctions involv-

ing Thalidomide. The investigations did uncover other problems and one of them involved MER-29 for which Richardson Merrell was eventually prosecuted.

FLL: As I remember our knowledge of distribution was so sketchy that we actually went to the Bureau of Vital Statistics in the states trying to locate records of birth of abnormal children and follow back from that end just to see if we could find some distribution that we hadn't found from our vists to manufacturers.

JN: That is correct. In fact the field really has to be commended and they did not get the recognition that they deserved because they went to great lengths to determine whether or not there was some relationship between abnormal births and the drug. At the time there was no requirement that the firms keep good records on distribution of investigational drugs. Many firms had very sketchy information. The field investigators followed up on almost every possible lead whether it be a nursing home, a pharmacy, a prison, hospital, teaching institution, or doctors. They visited many pediatricians and obstetricians to determine whether or not they might have been recipients of the drug. In fact it was during this time that it was determined that many doctors gave the drug to other doctors who were not investigators and those doctors in turn gave other doctors the drug and thus the distribution pattern really became very, very large and difficult to follow up.

FLL: In retrospect it's hard to remember that our control over the distribution of experimental drugs was so loose, as they were at that time.

JN: That is correct, and yet they were considered the most stringent of almost any country in the world.

FLL: That's right.

JN: The Thalidomide episode really resulted in national and international awareness of the potential problems related to experimental drugs. I was somewhat involved in the review and write up of regulations involving the clinical portion of experimental drugs, I was involved in the writing of the portion of good manufacturing practices which evolved from the Kefauver-Harris Drug Amendments of 1962. I was involved generally in the entire change in direction of the agency with regard to new drugs, experimental drugs, food additives, pesticides and other chemicals over which our agency had regulation. William J. Conway who is now Assistant Regional Director for Compliance in Philadelphia and I were much involved in the writing of the Good Manufacturing Practice Regulations. We were told at the time we don't have any such regulations and were asked what we thought should be required? We worked with Julius Hauser and several other people in the Bureau of Drugs and frankly sat down and worked on all the things we could think of involving what we considered good manufacturing practices. We were very happy that many of what

we thought were good ideas ended up in the regulations. The pharmaceutical industry was somewhat ambivalent about it - some thought that it didn't go far enough and others felt that it was going too far. Generally it was felt that we did reach a happy medium in terms of what the regulations should require. The early hearings on the regulations did not create the controversy that subsequent rewrites have involved. The industry was given an opportunity to question, to add or dispute some of our proposed regulations. But in reality other than clarification, they did not have too much to say about the regulations. Even the new ones are really a refinement of the regulations that we did in a hurry in 1962.

The regulations resulted in an entirely new approach to inspection and enforcement in the pharmaceutical industry. This necessitated training investigators and monitoring their activities to determine that guideline and levels for legal action of the pharmaceutical industry. This also includes the writing of reports, of the pharmaceutical industry and in fact the research industry. I was involved in the drug schools from 1963 through 1966 in the outline and preparation of the curriculum and teaching good manufacturing practices, investigation and research inspections.

FLL: That would include basic drug school that was conducted at the University of Rhode Island and also the advanced drug school that we had both at headquarters and at Pittsburgh?

JN: I taught at the University of Rhode Island as well as at headquarters in the inspection of drug manufacturing and at headquarters and University of Pittsburgh for the advanced drug courses, which involved clinical investigations. The involvement regarding good manufacturing practices required that we review all of the inspections that were done during this era to gain national uniformity since this was an entirely new area and to monitor flagrant violators to see that either corrections were made or perhaps legal action was pursued. During this era one particular firm, E. R. Squibb & Sons, New York had many violations involving good manufacturing practices. Even though they were aware of the requirements, they got involved in penicillin cross contamination of their product and this was probably the first of the big firms involved in legal actions.

FLL: That was at the old Brooklyn plant?

JN: And it also ended up at the new plant at New Brunswick. They then realized they had to have separate facilities. This was one of the firms that I monitored very closely to see that they either corrected or that they were proceeded against. The firm was subsequently prosecuted.

FLL: That problem, which other firms also had, involved airborne penicillin dust that was carried through the plant and contaminated other products during their manufacturing.

JN: That is correct, or inadequate cleaning or improper

maintenance of equipment. For instance the Fitz Mills in some of the plants were not cleaned, the skirts were not changed, and thus there would be contamination from one lot to another.

FLL: These were the mills that ground materials?

JN: That is correct. The pharmaceutical firms generally realized that they had to have total isolation for their penicillin products. During my headquarters stay which I had hoped would only last two years, I did endeavor many times to return to the field since I felt that my expertise was in field management and not in directing headquarters technical activities. I was involved in the early assignments to investigate all firms involved in pharmaceutical research. It was during this time that it was determined that many of them had the same problems that Richardson Merrell had in terms of their research of investigational drugs. Many of the problems encountered were subsequently incorporated into the regulations that were amended a number of times to reflect changes and corrections by the pharamaceutical industry.

The advanced drug school also was geared to try to determine that firms were adhering to the regulations and if they were not, to document the problems so that subsequent legal action could be considered. My area of involvement during this era was primarily in new drugs, investigation of new drugs, antibiotics, veterinary drug products, and to a

lesser extent the proprietary and prescription drugs that were not regarded as new drugs. For clarification of...the agency had a policy that certain drugs that were prescription drugs did not have to fall under the purview of the new drug requirements. Among those drugs were those that were on the market prior to 1938 and were prescription drugs and certain drugs that were on the market prior to 1962 which were not regarded as new drugs. The agency has since established a policy that almost any prescription drug must go through the new drug procedures before they can be marketed.

It is rather...I think, unfortunate that during the emerging Abbott Laboratory problem involving large volume parenterals, Mr. Conway who was in charge of prescription drugs was on vacation and I was filling in for him when the problem broke. When Mr. Conway returned from vacation we were so involved in the recall problems that I was told to stay with it. The Abbott Labs problem was really a problem of failure to comply with good manufacturing practices. However, the firm was not prosecuted at that time for those particular problems.

FLL: Was this the first time that we had a problem with Abbott's large volume parenterals?

JN: There had been isolated episodes, but it was the first major problem and it really started out as a problem involving one lot of bulk solutions in which 500 labels of another

product were inserted into the system. The field involvement showed that it was not isolated to that one batch. There were many different products that had mislabeled bottles. The firm ultimately was requested to recall all of their bulk solutions. I was involved in many of the discussions with the firm and with the Commissioner, Deputy Commissioner and Mr. Rayfield, involving the particular problem. I was directly involved and responsible for the wording of the Abbott recall telegram which started out "Do not use any Abbott large volume bulk parenteral solutions until you have first checked the label to see that it corresponds with the cap etc." The firm wanted a less obtuse version. In that particular meeting I remember Dr. Ruskin and possibly Dr. Weinstein...sat in on it and they initially felt that if you get distilled water instead of saline its not such a serious problem. In my...perhaps unfortunate way, I questioned their evaluations since there was in some cases dextrose, 5%, that was labeled as distilled water, and there were several isotonic solutions that were labeled as dextrose. I remember posing the question to one of the doctors "What would happen if you had a diabetic who was to receive distilled water and instead got 5% dextrose?" They agreed that would be an alarming situation. I asked, "What would happen to a woman who was supposed to receive dextrose and instead got the isotonic solution?" I cited several other examples and that's when the doctors

agreed that it was a very serious situation and they affirmed that all of the bulk solutions had to be recalled until the problem was clarified.

In other recalls I usually evaluated what I considered to be the problem and also discussed it at lengths with the doctors. If I disagreed, I would question their own evaluation and cited examples that might be extreme. For instance, in most of the deliberations at that time they felt that any normal healthy male receiving a mixed up drug might not really be hurt. However, I remember in one case involving penicillin and Diabinase, I said, "What happens if a penicillin sensitive diabetic receives penicillin instead of Diabinase?" And they agreed that that was a very serious problem. This concept of a lay person challenging a doctor has since been changed so that the agency now has an institutionalized evaluation of which lay people are not really given an opportunity to question the deliberations of the physicians. My own personal opinion is that I think it is unfortunate because you can evaluate problems in many different ways.

Getting back to the Abbott problems...the evolution of the recall which started with one lot ended up to where all of their bulk solutions were recalled and again the field was much involved in following up on the distribution. At this point there was a requirement for certain records to be maintained for distribution. However, again there was subdistri-

bution and sub-subdistribution and it was the investigators who were able to pursue and follow-up to determine the availability. I can recall that in some cases the investigators pursued distribution within a major institution to the operating rooms and actually finding that the solutions were being used in the operating rooms and where they had to be terminated right in the middle of an operation. I don't feel that the investigators received the credit they deserved for all of the work that they did. It also pointed out some of the major weaknesses of the GMP regulations which were subsequently corrected.

It also pointed out that a major pharamaceutical firm was having GMP problems. In the past it was felt that it was the small firms that have the problems and that the big firms do not. My own view is that the size, the dollar volume, the reputation, the membership in a national organization is not the criteria for compliance but rather the attitude of management that determines the compliance of the firm. The proposed Abbott prosecution which I was involved in...much of the background to me was very unfortunate...I disagreed with the decision not to prosecute the firm. However, I did not disagree publicly or in subsequent hearings.

The Abbott episode ultimately led to the Fountain Hearings in 1964-65. While I was involved in the management of the recall, the inspections, and investigations, I was not

involved in the hearings initially. The reason being, the records at the time showed that I was a manager and not a person making decisions, not shown as a link in the particular process. In fact one of Fountain's investigators, Mr. Donald Gray, talked to me at length and then said that I would not be called up because I was not directly involved. The hearing, as related by Mr. Gray, did not fit together at all, there were too many missing links that they could never really come to grips with and so they had to pursue their investigation further. At some point after the hearing appeared to be almost over Mr. Morris Yakowitz came to me and said that since I was involved in the case obviously there were things that were not in the record that had to made clear. I did not wish to get involved, however under pressure and direction from Mr. Yakowitz, I then completed certain documents - namely affidavits and memos to tie in the relationship between Mr. Harvey, Mr. Larrick, Mr. Rayfield, Cliff Shane, Jerry Bressler, John Guill and others, which until then were not really clear. As soon as they went into the record and I wonder if Mr. Gray or the Fountain Committee were not advised because it was a matter of days after I prepared the documents that he was at my desk insisting that I come clear. I indicated at the time that I answered all of his questions to the best of my ability and perhaps he did not ask some of the right questions. He agreed that that was probably correct. That resulted in my

appearing before the Fountain Committee, but not at my request. It was not at all voluntary. In fact, I asked for instructions from Mr. Rankin's assistant to be guided as to what I should or should not say at the hearings. I was told that I would receive no instructions and that I should say that which I felt I should. I also asked if I should not be represented by General Counsel. The answer was no, I would receive no legal support in the hearing. I feel that the hearings were unfortunate. It would have been very easy to have denied knowing anything. However, I saw that Mr. Shane and Mr. Bressler in Chicago basically were put into a position where their testimony made no sense at all. After mulling the idea at some length I decided that...I had to at least clarify the records. With Mr. Yakowitz insistence that I do so, I did prepare the documents. I did have rough records from which I dictated the particular memorandums. I feel that the Fountain Committee also put me in a very unfortunate position in that at the beginning of the hearing they said that I could not refuse to answer any question, that I could not stand on the Fifth Amendment, and that anything I did not discuss openly would be in contempt of Congress. With no legal counsel to advise me as to what my rights were or what I could or could not say I felt that it was a very unfortunate situation.

Also in the second hearing that I was involved in... there were five of us from the agency. I appeared to be the

adversary in the hearing...I tried to answer the questions the committee presented to me as best I could. I had no specific knowledge that Mr. Harvey in any way intervened on behalf of the agency for Abbott Labs or his brother who was then Vice President of Abbott Labs. The questions that the Fountain Committee presented left the inference that I had such knowledge. I felt very badly that when Mr. Harvey retired, that he said I was honest but I was wrong in my assessment. And really it was in a sense the Fountain Committee that put the words in my mouth rather than that which I actually said. Mr. Harvey actually absented himself from many of the decisions involving the earlier Abbott recall, stating that there could be conflict of interest and thus Mr. Larrick was the person that I went to to discuss and get approval for the recall. Mr. Harvey's involvement was somewhat later when we were involved in more and more lots of the products being recalled and the feeling was at that point that it was redundant and perhaps there was no longer any need to continue the recall effort. I think this was blown out of proportion by the Fountain Committee and it ultimately resulted in embarassment to Mr. Harvey, to Mr. Rayfield, to Mr. John Guill and to Mr. Frank Clark. In retrospect, perhaps I did the right thing, perhaps I did the wrong thing. I certainly did not enhance my career by doing what I did. I knew it at the time; however, in retrospect I have no regrets for having made the decisions and doing what I did.

FLL: At the time of this testimony, that would of been while you were at Philadelphia?

JN: No, I was at headquarters. This was all at headquarters.

FLL: About what year, 1963?

JN: 1965, I believe. I went to Philadelphia in 1966 and Mr. Rayfield had retired in...I think in early '66 or late '65 and the hearing took place in the fall, I believe in '65.

FLL: These were of course the culmination of a whole string of hearings that we had about that time. First with Senator Kefauver and then with Sentator Humphrey and then with the Fountain Committee, all of which were critical of FDA management.

JN: That is correct. I think it was unfortunate that it went the way it did and I really feel badly that I had to get involved in it the way I did but such is life. It does happen and I was at the wrong place at the wrong time involved in the wrong projects and got stuck with it, and subsequently Mr. Yakowitz's insistence that I set the records straight.

FLL: Was Yakowitz's instruction his own idea or was that from the Commissioner's office, do you think?

JN: I didn't ask him that question. All I know is he came to me and he said to me, "Nakada, you've got to write to set the thing straight" because he says all of this makes no sense, the Fountain Committee is upset because they can't tie the loose ends together...I would say he ordered me to...to pre-

pare the documents. I told him at the time I did not want to. He may not recall that. This was a very...very difficult time.

FLL: The discrepancies were...the testimony of the field people versus the testimony of the headquarters people?

JN: Yes, essentially that...actually the controversy in the testimony, one involved whether or not Mr. Harvey had directed the recall not be pursued, which really was a minor point. The greater discrepancies occurred when Mr. Rayfield ordered Jerry Bressler and his investigators out of the Abbott plant in the middle of their inspection. Again I was in the wrong place at the wrong time in that I was sitting in the room when Mr. Rayfield was talking to the Chicago district, and I believe he was talking to Mr. Guill ordering the inspection terminated. I saw Mr. Shane's memo on the subject later since he had prepared such a document. At the time I agreed that what he said was factually correct.

Later on when...involving Mr. Harvey and Mr. Rayfield, Mr. Rayfield denied that he had made a call to Frank Clark who was then Acting Bureau Director to terminate all future recalls with the firm. At the time other mix ups and problems were being encountered at Abbott. I felt it was my responsibility to bring them to the attention of the Bureau Director, who at the time was Acting Director Mr. Clark. I was in his office when he called Mr. Rayfield, who I believe was on

leave or on duty in Mississippi or Alabama. Mr. Clark's secretary, during the course of the Fountain Hearings, signed an affidavit stating that she placed the call and the telephone company verified that that call was made on that date from Washington. It pretty much supported my position and when both Mr. Rayfield and Mr. Clark denied that such a call was made and then denied having any knowledge of it, I think that's where their credibility was questioned. It really was not over the major portion of the recall. As you know the recall had pretty much had wound down when additional problems came up but the firm had already been told to recall everything so it really was no great thing. I did not attach any great significance to it although I did keep notes on it. And it was really in both of their denials of the occurrence that created a problem rather than the problem itself.

FLL: What was Rayfield's reason for calling Bressler...or calling Chicago to stop the investigation?

JN: I don't recall the facts but I had a feeling that the firm may have talked to Mr. Rayfield and questioned...perhaps that there was harassment in the inspection, the inspection had already been going on for some time. Bressler, I think thought that they had finally come to a point to where they had found something, and whether it was a coincidental or what I don't know but I was there at the time that the instructions were issued to terminate the inspection. And again it could

have been handled differently. Such as...if you've completed enough of your work lets not pursue it any further, rather than that which transpired.

FLL: You and I knowing Allen Rayfield and his style, he was not the man to give subordinates reasons for things, he just issued orders. He expected them to be carried out.

JN: And if you remember in the early part of the testimony it was Shane and Bressler's word against Mr. Rayfield's, and at that point, Mr. Rayfield's position was affirmed, that he did not order them out of the plant, they decided to terminate the inspection. I felt that it was unfortunate that the two men were being...so called thrown to the wolves, with no support. What would you have done?

FLL: That's quite a hard question to answer unless you're there. You have to make those difficult decisions at the time from whatever you know.

JN: I could never understand my relationship in headquarters to people such as Mr. Rayfield and Mr. Harvey and Mr. Larrick, since I was a GS-13 at the time and at least three or four levels below them in management, and yet I was on a regular basis told to go meet with them. This in a sense violates most management principles.

FLL: It's not too surprising though, Jim...considering that these people that you're referring to, had grown up in a small agency where it was not unusual for the Commissioner to go

directly to the person who had the information, rather then going through formal channels. And I think that that was their style and they had done it for so many years that they continued to do it even after the agency had become larger and it was no longer a practical way to manage.

JN: It could be. There were times when I felt very badly because I had a supervisor, and he had a supervisor, and he had a supervisor. All below Mr. Rayfield, and yet Mr. Rayfield would circumvent them and come directly to me and leave them in the dark. I know this happened in Thalidomide when he would come directly to me or Mr. Rankin would come directly to me for information. And certainly in the Abbott episode where I did not deal with the three levels between me and Mr. Rayfield.

FLL: I observed it, during a 30 day detail there in 1965 in one of the units that was ostensibly reviewing case work ...it happened all the time. This was after that reorganization where Rayfield was given responsibility for both field supervision and the enforcement activities and I remember in cases involving over the counter drug sales, his regular practice was to go directly to Les Baukin who was the individual reviewing the file and bypassing all of the people who supervised Les in the process. I think that it was more of a problem of management, probably than any other thing.

JN: This I agree. It was a problem in management and I felt

at the time things were happening and that I really ought not to be there. My boss, or his boss or his boss should be the one discussing a recall or problem, and yet I got involved time and time again.

FLL: At least if you were there, they ought to have been there with you.

JN: Yes. Anyway the Abbott hearings were a very traumatic part of my life in terms of FDA and the activities involved. I was subsequently selected as Chief Inspector in Philadelphia.....

FLL: And was glad to leave no doubt.

JN: ....in 1966 and I was very happy to leave headquarters. I felt that I'd put in an extra year and a half at headquarters under extreme pressure and that returning to the field was a blessing. However short lived.

FLL: While you were there, there was another event that I think was significant to FDA and its future, an internal event, the reorganization of 1964, I believe it took effect about January of 65' when the bureau structure was revised and top managers were reassigned...you were there at the time I believe.

JN: Yes, I was there at the time and being quite a lowly person on the totem pole, it was strictly my opinion and observation but I really wondered about the rationale of the reorganization. Since the two big enforcement arms namely the Field

Operations and Enforcement Operations were put into one unit and yet a unit called Education and Voluntary Compliance had the same stature as that part of the agency along with the Bureau of Science, and people in headquarters generally and I certainly felt that the agency's enforcement and scientific efforts were being submerged, for whatever reason at that time. I felt very badly, personally, that people such as Mr. Malcolm Stephens and Mr. Robert Roe were I would say demoted in that reorganization and that Mr. Goldhammer was basically demoted and put into a staff position. I felt that the enforcement guts of the agency were basically reduced, that the scientific portion was split so that the unified actions of the past certainly were not going to be pursued in the same fashion. It is difficult to assess whether that is correct or not. Certainly statistically the enforcement actions of the agency were not the same as they were at that time and, of course, the scientific stature has been questioned time and time again, whereas I believe in the 50's and early 60's the agency was looked up to as one of the best scientific agencies in the government if not the country.

FLL: And in some areas, pesticide methodology and so on, they were world leaders.

JN: That is correct, and if you recall in pharmacology with Dr. Lehman, FDA was considered the last word in pharmacology and I don't think that's true today.

FLL: Do you think that that reorganization...bringing voluntary compliance to a high level and the other things that happened might have been the result of outside presssures, the Citizens Committee reports, the criticisms by the Kefauver and Humphrey committees?

JN: Maybe so. I did not talk to Mr. Harvey about it but I understand that he was the principal author of that reorganization. There certainly were a lot of pressures from many different places to try to change direction of the agency. I believe that there was a Citizens Committee report indicating that FDA was too much in enforcement, a police agency and they had, "matured" to the point where they now should pursue other ways of gaining compliance with the law. Being basically an enforcer of the law myself, I had some difficulty accepting some of the changes that did take place.

FLL: Now, after you left Washington behind, and went to Philadelphia were there some events there that you would want to comment on?

JN: I would say there are probably several events. The first probably was the Philadelphia Labs injunction and problems. Normally this might not be the subject for discussion but in a sense it contributed to what we later considered to be the IDIP or in depth inspections of pharmaceutical firms. Also, I want to highlight the episodes involving Lacy Ward, from my perspective, the IDIP inspections, the mushroom recalls and several other unrelated things.

For instance, at one point I had essentially 1/3 of all the women investigators in the country at Philadelphia. This was long before women's lib and the push for equal rights was being pursued. When I arrived in Philadelphia there was one woman investigator and I think the agency sort of looked to tokenism at that time, each district should have at least one woman investigator and that was about as far as they pushed. During my duty in Philadelphia the recruiting efforts were in the direction of women and blacks and I recruited a fair number of both. I frequently hired more women than men and I think there were facetious remarks such as "Nakada's Harem" something like that. I'm very happy to say that the first woman Chief Inspector is one that I hired, trained and helped along in her career and there are now, I believe, 4 or 5 supervisory investigators who were recruited and trained by me or my staff at Philadelphia. I feel that my pursuit in that area has been very good, although I received absolutely no credit or recognition.

The Philadelphia Labs episode really pointed to the fact that a small firm that did not adhere to even the basics of good manufacturing practice could get into real hot water... that mishaps could be life threatening to people and that correction had to be effected if the firm was to be allowed to continue. When I arrived in Philadelphia the district was in the middle of the pursuit of getting the firm corrected. Joe

Phillips was the primary monitor and he did an excellent job in getting the firm straightened out. The message that the firm finally received was that they should only produce as many products as they could properly manufacture. I believe when they were taken over by another firm they reduced their total number to about 10 or 12 drugs, which is an amount a firm that size could probably properly manufacture.

FLL: How many had they been making before?

JN: I'm only guessing but I would think about 100 to 150. You were there at the time they were in the midst of their hey day when they manufactured practically everything that was saleable with virtually no controls. The experience of the Philadelphia Labs episode wherein the investigators were involved in the review of batch records, in the review of analytical records and of the controls of drugs from beginning to end, really was the beginning of what we ended up doing as IDIP inspections.

The support from top management in that Mr. Berch did not set guidelines in terms of times in and out of plants in one day but rather to pursue problems to their logical conclusion can help measurably to effect corrections such as at Philadelphia Labs. I guess you want to have me discuss a little bit of IDIP at this point?

FLL: I think it would be well to put something into the record about the evolution of that program.

JN: Philadelphia Labs was probably one of the first firms involved in leading to the IDIP concept. When Commissioner Goddard came on board we were in the midst of many drug hearings and there were questions regarding the state of the pharmaceutical industry. I believe one of his early statements was that he would do everything in his power to get the pharmaceutical industry straightened out and producing drugs that the public would have confidence in. To that end he...I believe called in a number of bureau and field people to explore different ways to effect correction and quality assurance of drugs. The military at the time had their zero defects concept in place, which appeared to be fine but really did not work too well. The firms were more interested in getting plaques and recognition, rather than pursuing drug quality. When Mr. Berch returned from a conference and said that there was a new program, and that we should pursue it with enthusiasm, we of course asked headquarters for instructions and directions. When the concept of IDIP started we asked headquarters at what point do you terminate, at what point do you consider that a firm is in compliance? Is it based on statistics? Is it based on non-violative GMP findings? Is it based on total correction of everything? What is it? In the entire time that IDIPs were going on we really did not receive directions from headquarters as to how to pursue the problems. Thus, each district went its own way. I think it was very

unfortunate. At Philadelphia we sort of took the philosophy that IDIPs would continue in firms until we felt the firm should be taken to court, or until the firm in our mind was essentially in totally compliance with the GMP's. We were fortunate in that one of our supervisors had gone to school and received a Masters in pharmaceutical sciences and his speciality was in statistics. Thus we approached GMP statistically as well as from inspectional viewpoint. We set up a sampling program for drugs to try to determine if that would be the best way or whether the inspection route would be, the two went pretty much parallel and surprisingly consistent. In other words firms that statistically could produce legal drugs also could comply with GMP's. This was not accepted at headquarters, to my knowledge, even after the program ended. We had to set priorities as to how we would inspect our firms since we had too many firms to inspect in the first 6 months or a year. We set them up according to the size of firms, the patient impact, the significance of the drugs and their legal history, i.e. the kind of problems they had. Of course, we had a major problem in having sufficiently qualified investigators to do the inspections. We thus embarked on a program to train investigators and we had Joe Phillips using his concepts at Philadelphia Labs to train investigators. We also called on several of the large pharmaceutical manufacturers to give us assistance in this area. We called on General

Electric and their clean lab used by the space industry to provide training to us. We provided training to...I don't remember how many investigators but to more than half of the districts in the country. They came to Philadelphia for training and we hoped that they left with some of the flavor of Philadelphia's approach to IDIP. This was done not because we felt that we were the leaders, but we'd asked headquarters for guidance in training, as well as in IDIPs and there was a vacuum. I do not know if you recall that particular vacuum in that we received virtually nothing from headquarters.

FLL: I was in Denver by then where we had only one pharmaceutical firm, Cutter Laboratory in Salt Lake City, so it wasn't much of a problem for us. But, I think at that time that was fairly typical because in early Goddard regime...his idea was to totally decentralize the field and that included just about all forms of advice and guidance from headquarters.

JN: That could very well be and that could be why we did not get any guidance that we were hoping for.

FLL: Another thing probably was that they didn't have any better ideas than you did.

JN: I would say my experience in lecturing at Rhode Island and headquarters in drug manufacturing, certainly helped in that I was able to provide a lot of information that maybe some of the other districts did not. But the fact that more than half of the districts sent personnel to Philadelphia to

learn what we were doing, I felt was a tribute to what the district was doing at the time.

In terms of selection of firms, we started out using certain criteria and weighing factors and started out in the inspection of firms. We told them that our goal was either to get them in compliance or to take them to court. We sought their cooperation. Most firms did but there were few that did not. I would say that in Philadelphia we pretty much adhered to the philosophy from beginning to the end. We took a number of firms to court and, we encouraged a number of firms to go out of business. The biggest such firm was National Drug. The firm is a member of the Pharmaceutical Manufacturers Association, and is a large firm, they are still in existence but as a manufacturing facility in Philadelphia they closed their doors.

FLL: That was a part of the Richardson Merrell complex?

JN: Yes. There were other small firms that also went out of business, because they could not comply. We basically did not approach the firms because they were large or small or PMA firms or members of NAPM, but rather their track record and what their systems were and how they pursued and complied, what management's attitude was - these were just a number of things that we used as criteria, rather than because they were quote "reputable" or "not reputable". We had some large firms for several years in the inspection program. We had

some small firms for several years. Someone might ask, well why did you go this long? Since headquarters did not tell us what was sufficient, we felt that we had to inspect them sufficiently so that we had adequate samples and documentation to pursue legal action and then to submit them to headquarters. If headquarters turned us down because of insufficiency, then we would pursue the inspections further. If they felt that our findings were irrelevant, then we might terminate the inspections. In some cases they would say that we should pursue the legal actions, in which case we did. The firms that chose to go out of business, did so strictly based on their discussions with us, with the district management, rather than anything from headquarters. I'm sure they were in consultation with headquarters to determine whether or not their violations were sufficient that they should pursue other areas of endeavor, but none the less there were firms that chose to cease operating. I feel that...certainly in Philadelphia the program was generally sucessful. We did not take all the legal actions that we might have been able to. We certainly took quite a number of them. We certainly encouraged the voluntary compliance route wherever we could. For instance, we held workshops with each firm before we started the IDIP inspection and that was almost unheard of, in the past with FDA. I am not sure that we are doing it today. We had regular meetings with top management. We issued the...what we used to

call a FD483, the FD2275 now, on a regular basis.

FLL: The report...

JN: The report of findings. And this could lead to a conference with top management each time one of those issued. We certainly had open dialogue with firms. When we found violations we requested immediate correction. We took actions such as recommending suspending certification privileges on antibiotic firms during the course of this IDIP program. This was another area that was used to bring firms into compliance and not to take legal action, but to find an administrative remedy to effect correction. One of the firms involved in this was Wyeth Labs. They were producing, I believe, about 20 to 25% of all the penicillin produced in the United States at the one plant. FDA suspended antibiotic certification because they could not comply with the antibiotic certification requirements and the GMPs. The firm very quickly got themselves in to compliance in that area. But the impact was tremendous. Thus, not all actions were formal, legal action. We also, in an unrelated area, took a seizure action against SKF in that era. Some of the people said that the IDIP program was primarily to pick on the little guys and to put them out of business. I think in Philadelphia the big firms felt that the action was taken without regard to the size of the firms. We pursued corrections or legal actions regardless of the size of firms.

FLL: What year did we actually start the progam?

JN: '68.

FLL: '67...'68.

JN: '67, '68 that was the era.

FLL: And it lasted for how long?

JN: About 2 to 2 1/2 years. In some districts it only lasted for a few months, but in Philadelphia I think at the time we had over 100 firms. When I came to Philadelphia we only had about 4 or 5 drug inspectors, so we had to train quite a number of them. I believe during that time I was able to transfer in enough investigators so we had about 20 of them doing the inspections. We did a lot of in-house training as well. I would not say that the firms were all staying in compliance as I believe that Philadelphia district has pursued legal action against several firms since then. I think perhaps one of the fallouts was that the concept of indepth inspections - be they pharmaceutical or food firms or device firms - was firmly established in Philadelphia and I think it is being so pursued today. They are still taking quite significant legal actions in other areas and it is based on knowing what to do, how to develop evidence, how to do enough to say a firm is in compliance or not, or pursue some other remedy. I feel that IDIP wasn't just a program that started and ended and everybody forgot about it. The concept stayed on and there are people today who were involved in the IDIP program and are

still carrying on many of the principles of IDIP.

FLL: During your stay in Philadelphia you had problems not only with drugs. I remember that there were some mushrooms, at one time, that had practically the entire field force of the Food and Drug Administration involved.

JN: Yes. The mushroom episodes continue to this day. But certainly had its greatest impact during the time I was there. As an amusing side episode to this, in 1967 or '68 I hired a woman investigator, the one who is now Chief Inspector. When we were starting up the IDIP program she was new and thus was not involved in the drug program. FDA has traditionally started their investigators in sanitation and filth work. Headquarters, Bureau of Foods, wanted to run a survey of the mushroom industry in Pennsylvania and we had no one available to send except this new recruit. She accompanied the headquarters person to the firms and even with her newness she was told to write all of the reports. It was her work that provided the information which led subsequently to our real understanding of what the total mushroom industry was. We felt very good that a neophyte investigator could get the facts sufficient to pursue two years later.

Later we had the low acid can food regulations, which really preceded the mushroom episode. This was as a result I believe of the smoked fish problems in New York, where there were concerns about the pH, temperature, the length of time,

the conditions of manufacture of products that inherently could have "bot" spores, and where under anaerobic conditions, could develop into the toxins. I cannot recall what really precipitated the mushroom episode but it did get started. It resulted in our having to inspect all firms in Philadelphia. And again we had to call on the low acid can food inspectors from all over the country, because I think we had about 3/4 of all the mushroom firms in the country in our district. We had 3 or 4 people who could do the inspections. Again, we had to provide a quick crash course on inspections and this resulted in not one or two but many firms having to recall their canned mushroom products. They plainly could not comply with HACCP (Hazard Analysis and Critical Control Point) and low acid concepts and they could not give the public assurance that their products would not contain "bot" toxins. In fact, a number of firms' products did contain the toxins. Why there weren't more fatalities is difficult to understand. Getting back to the low acid program, I guess the Bon Vivant soup case along with the smoked fish episode created a milieu for pursuit of HACCP and low acid inspections.

FLL: It convinced FDA that there ought to be an investigation of the canning of low acid foods because we didn't really know the answers yet.

JN: Let me relate one particular episode, to show the interest of the investigators - whether you pursue a food firm, a

drug firm, in this case a mushroom firm. There was one firm that had questionable practices and was very reluctant to recall and they would move their product out of the plant by night when our investigators weren't there. Our investigators were sufficiently alert to pursue and follow. We used some over-the-counter, OTC, techniques.

In this plant we had investigators observing on double shifts to see where mushrooms were shipped. We followed their trucks through eastern Pennsylvania by a number of different routes. We were able to effect mass seizures of whole warehouses full of mushrooms. As a result of these many efforts the district, the investigators were given a Commissioner's Special Citation for which I was very pleased. I was able to get cash awards for many of the investigators at the time. I felt that there was concern from headquarters, but I don't think we had very good support. Certainly to pursue the type of legal actions that we felt should have followed. I felt that if the regulations were to really have teeth we expected firms to comply, especially for health hazard problems. We did not get headquarters to share our views. In my own personal opinion some of the subsequent problems involving mushrooms directly relates to our not taking action at that time.

FLL: Failure to drive home the importance of the regulations?

JN: That is correct. You don't have to prosecute all the firms or take legal action. But if you show them that you

mean business, and that if the worst violators were prosecuted they would know that we are serious. We did take injunction action against some firms. Being somewhat enforcement minded I felt that those who really did not comply should have been stopped.

In this work, I feel, we enhanced our relationships with the local agencies, that is the state and cities and counties. During the mushroom recalls, we called on them to help us. They were able to mesh their recall efforts with ours so that the data reported was included with FDA's not duplicated. This involved a lot of coordination between the various state agencies, the cities, the counties and FDA to be sure that the information was obtained and reported in exactly the same way. I know this has been done since by other districts and regions. I think the mushroom crisis was one of the first times that it was done. It was not done during Bon Vivant, which created a lot of additional problems because of the way things were reported. The mushroom problems validated the need for technical training and the ability to understand what goes on in the canning industry, both from the investigators viewpoint and the supervisors viewpoint. The agency had tended to train people technically but not their bosses and it created a problem. This was true in the pharmaceutical field. It was true in the low acid canned food field and I think to some extent it's true in the device field today. The subordinates in some

cases know more than their supervisors who must accept what they have reported. I think it put the agency in some embarassing situations.

One of the most tragic events in Philadelphia that took place during my assignment there involved Lacey B. Ward. He filed a discrimination case against the agency, against the director, myself and others. He also included all people who managed or supervised him from the day he started with FDA, years before my arrival. I felt that I took the brunt of the abuse. When I first arrived in Philadelphia, he had turned in his resignation and then withdrew it. He said he didn't know what he was planning to do, but he wanted to leave his options open. I had several lengthy discussions with him to pursue what his goals were, what his aspirations were, and really did not get very definitive information from him. Prior to my arrival at Philadelphia, I talked with people in the personnel office at headquarters who indicated that I probably had the agency's number one personnel problem in Philadelphia, in Lacey B. Ward. I was mindful of the problem and yet I considered that it could be managed.

When Lacey Ward was up to have his federal driver's license renewed, it was determined that he had falsified his documents with regard to his arrest record, his traffic ticket record, and his accident record. This was verified by the State of Pennsylvania and when he was advised of this he asked

if we were going to fire him, or what we going to do. We indicated that we had set the record straight but that he ought not to be doing things such as this in the future.

In my opinion the thing that led up to his decision to pursue the discrimination action was multifold. During the late 60's with the activities of blacks, not only in Philadelphia but other parts of the country, he was quite active and it appeared to be a time when action could be pursued. Also during the late 60's when the IDIP program was being geared up, I selected a number of people for GS-12 Drug Investigators. However, during that time I did not select a single person from Philadelphia, because it was my understanding that the policy was that for a GS-12 position one needed multi-district experience. Thus people in Philadelphia whose entire career was spent there did not have the depth of experience that was desired. A number of other investigators at Philadelphia, who were at the GS-11 level, considered whether they would file some type of action against me and chose not to do so. I can remember one heated meeting in which they were comparing their qualifications and experience with some of the people that I had selected for GS-12 Drug Investigators. Nonetheless, I held to my position and most of these people none of whom were Black chose to transfer to other districts such as New York, Buffalo, Chicago...and to headquarters where they could also be promoted to a GS-12. Mr. Ward during this

time decided that he was going to get his GS-12 at Philadelphia because that was the only place he would live. Prior to his decision to file a case, I had a discussion with him regarding his career. He indicated that he still had not made up his mind but wanted to pursue a number of different areas. I thus arranged for a detail at headquarters for several weeks so that he could see what the headquarters experience was. When he returned, he indicated that he did not wish to be assigned to headquarters but wanted his GS-12 at Philadelphia. When that did not come forth, he filed his action. Mr. Sam Hoston, a Black at headquarters HEW, who investigated or was part of the investigating team at Philadelphia, felt that any Black filing a discrimination case must have a case, or he would not have filed, regardless of the facts. The investigation took place concurrently with the IDIP inspections. The findings as I received them, were that there was discrimination based on the transfer policy over which I had no control, that there was discrimination, otherwise they would not have filed a case, and that there would not have been a number of employees involved in filing a case. Under the EEO program and instructions, the instructions required a filing of discrimination case in close proximity to the activity and that a time, place, episode and person must be named and designated for pursuit of the investigation. These were lacking. For instance Mr. Ward stated that "discrimination took place

from the first day he arrived in Food and Drug", and he cited as an example when a trained investigator took him out on his first sampling assignment, he indicated that a particular market was a place where he could buy...I think it was mustard greens. Mr. Ward felt that it was discriminatory for anybody to infer that he would eat mustard greens. In Mr. Ward's discrimination statement he also indicated that he was discriminated on a continuing basis from then, until the time the case was filed. He included past Chief Inspectors, past District Directors and past investigators and inspectors in his case. I asked for specifics on a number of occasions and they did not come forth. FDA finally agreed to settle the case if Mr. Ward could be reassigned, perhaps outside of Inspection Branch. Among the possibilities were to be made a Food and Drug Officer, another was to be sent to a resident post in Newark district and a third would be take a position as a specialist in the Special Programs Branch. This was not to indicate that he merited the GS-12 or promotion but merely to find a way to settle a case. Mr. Ward refused to take the assignment in Newark, which would of been across the river from his home, but still within commuting distance. He wished primarily to take the position as the specialist in consumer product safety. He was thus assigned to that particular position. And subsequently attained his GS-13, GS-14 and finally District Director of Philadelphia for CPSC. However, it is my

understanding that CPSC fired him for submitting false vouchers to the agency. While it was unfortunate, it did not surprise me because he was not in pursuit of objectivity and truth during the time he was there. However, the agency, I feel, felt that it was totally my responsibility that he filed a case and this action went the way it did.

I know in two recent interviews with Mr. Ottes of EDRO, he basically started the interviews for future positions by saying let's discuss the discrimination case at Philadelphia. I feel it was very unfortunate because he did not have all the facts, and an interview from a management position generally does not start with that type of a questioning.

FLL: In the settlement of the Ward case, was the position in product safety after product safety had been removed from FDA?

JN: No, remember, it was a special program. While it was a special program he was still in FDA.

FLL: And subsequently he did transfer with the program when it went to the Consumer Product Safety Commission.

JN: That is correct.

FLL: I wasn't clear on that.

JN: The records of Philadelphia indicate that Mr. Ward either threatened or filed a discrimination case in pursuit of his promotion to GS-9 and to GS-11. In talking to people from CPSC after his transfer to that agency, it was my understanding that he also threatened similar action in his pursuit of

the other promotions. It is my understanding that for the District Director position he told them in advance that if he did not get it he would file a discrimination case.

While at Philadelphia, in addition to the large number of women that were recruited as investigators and technicians, we also recruited a number of Blacks and others in complying with the spirit of EEO. In fact there was one Black woman who was a dishwasher in the laboratory, Mrs. Nichols, who wanted to try out as a technician, she was encouraged to pursue her education so that she could meet the requirements, which she did. She ended up being an excellent technician and I understand she is now an investigator. During the course of her training, she took driver training using semi-trucks, since at the time it was required. We received word that she finished number one in her class.

Also during my time in Philadelphia, many of the people received special awards, citations, promotions and recognition for individual efforts in most of the significant areas of endeavor in Philadelphia. The Commissioner Citation was only one of the many recognitions given to the district. I am also very glad that a number of my people have passed me up through the years and have been promoted to positions higher than myself, either in headquarters or in the field. Others have pursued their careers in industry and again many of them have done very well.

I feel that with the ups and downs in Philadelphia, that overall I have to have a warm feeling for the people there, certainly for the friends there, for the pursuit of excellence at the district, in pursuit of consumer protection.

FLL: When you finished at Philadelphia, your assignment there, you went on to Dallas?

JN: That is correct. And the assignment at Dallas was... peculiar at best, in that I did not wish to leave Philadelphia in the position of Chief Inspector. I was willing to...end my career at Philadelphia.

Mr. White at Dallas called me and said there is going to be an opening in Dallas and if I wanted to pursue my career, I should file for the vacancy announcement so that I could be considered for the Dallas position. I debated hard and long and discussed it with my wife and family, and initially chose not to consider the position at Dallas. Upon subsequent calls, I gave it further thought, in fact I talked to Ron Ottes regarding the matter and he again brought up the matter of the discrimination and suggested that maybe it would be in the best interest of FDA if I left Philadelphia and applied for the Dallas position, especially if I wanted to consider my career. I, thus, reluctantly applied for Dallas and was selected, on a lateral transfer. I was told that if all worked out at the end of a year, there would be a potential for a promotion to GS-15 in that position, since it qualified for such.

My arrival at Dallas was to a new position created as a result of the reorganization of the region. It was a position which was called both Dallas Section and Dallas District. And it consisted of an Investigations Branch, clerical staff and Compliance Branch and staff. It did not include the laboratory or the regional administrative staff. However, the total number of people I supervised exceeded both Houston and New Orleans combined.

In the two years that I was in Dallas, I did not receive a promotion and the position remained confused as a District and Section. During my stay at Dallas, I did organize the groups so that technical competence could be upgraded. I provided special training for investigators and technicians, and instituted a program of rotating people for Compliance training. I emphasized the need for objectivity and if violations were found, that cases should be developed as they warranted.

Among the significant cases that were developed and subsequently adjudicated in Dallas, included the "Frog Legs Caper". This involved coordination with many other districts and regions, and resulted in a conspiracy conviction. Essentially this involved the following. Frog legs were imported from India to New York. In New York they were analyzed and found to be salmonella contaminated. The importer agreed to reexport the frog legs through Brownsville, Texas into Mexico. They were not to be reentered into the United States unless

they were reconditioned and relabeled. New York District first advised us that the frog legs, to their knowledge, were not all being sent to Mexico but were being diverted to other parts of the country. They thought that since they could not handle it, they asked Dallas to pursue the matter. About the same time Houston Section was created out of Dallas District, and normally Brownsville would be handled by Houston Section. However, since this was started at Dallas, it was decided to continue at Dallas. We were able to follow-up on the shipments and subsequently made seizure actions in a number of different districts of salmonella contaminated frog legs which should have gone to Mexico but did not. We developed the conspiracy case showing that the person in Mexico did in fact reship some of the products in interstate commerce in the United States without the benefit of reconditioning or relabeling. As an interesting side light, the individual who was subsequently prosecuted, was a personal friend of the judge, and we attempted to have the judge disqualified because of his relationship with the defendant. The judge refused, but the judge did find him guilty, on all counts. This case is noteworthy because some short time after the case was finally completed, the instructions from headquarters were that no future conspiracy cases were to be considered without first having approval of Mr. Hile and the General Counsel, so that they could pursue the matter from beginning to end. This case is

noteworthy because the entire case was developed, handled and executed through the Dallas District.

Another case that's noteworthy, involves a warehouse in Dallas District, which was involved in injunction, prosecution and seizure actions and continued to be violative. In an inspection it was determined that it continued to be violative and that we thus wished to file a contempt of injunction case against the firm. We missed the 30-day deadline because we submitted our case to headquarters 2 days before the deadline. The instructions from headquarters were subsequently changed so that if the case did not process through headquarters by the 30th day, it would not be considered. We reinspected the firm, since headquarters had turned it down and were ready to file a case when the decision was made to let it drop when the firm agreed to go out of business.

I would say that in Dallas the significant things were not the cases developed but were the federal/state relations developed there with New Mexico, Oklahoma and Texas, with FDA investigator training in the technical areas. This was especially in pharmaceutical production which was increasing in the district, and low acid canned food inspections and in other technical areas. I provided technical lectures to the University of Texas, School of Pharmacy at Austin, Texas, in good pharmaceutical manufacturing practices, in legal aspects and in technical areas not previously covered by this university.

I was involved in the creation and support for CONOCALPE, for an organization which had as it's objective to facilitate cooperation between the United States and the Mexican government with regard to importation of products to the United States, to open communications, to provide training, especially in the technical areas, such as laboratory analysis, and to enable the officials in Mexico to better understand the ways of operations of FDA in the United States. I attended a number of the meetings that were held in Dallas, in which the mutual pursuits of the two countries were discussed. Initially the program was set up to enable Mexican produce to come to the United States, meeting the pesticide tolerances established in the United States, and to avoid the illegal or misuse of pesticides. There had been problems with Mexican strawberries and peppers and other products wherein produce bearing residues of pesticides legal in Mexico but illegal in the United States or not registered in the United States were being detained. The Mexican government wanted to pursue the capability of testing their own produce and not rely solely on pre-harvest intervals for a determination of their legality. We conferred with them in the setting up of their laboratories, and we provided training in analytical methods. We also set up a quality assurance program so that they could check to determine that they were finding the same residue as our laboratories.

We were also involved in the certification of shellfish growing areas in Mexico, so that they could ship their raw and frozen shellfish to the United States in compliance with the National ShellFish Certification Program.

FLL: Were you also involved in that work after you left Dallas and came to San Francisco?

JN: Actually, it was going on in Dallas but it finally came to a culmination where it was certified after I reached San Francisco.

FLL: After your stay in Dallas you were transferred here to San Francisco where you finished your career?

JN: That is correct. I left Dallas in early 1976 and worked in the San Francisco regional office until January of 82'. Again, this was not at my choosing, I had reconciled my differences with management at Dallas, and felt that I was well on my way to completing my career in Dallas. In Region IX Mr. Berch lost his Assistant Regional Director for Compliance and he asked if I would consider a lateral transfer to San Francisco, since California was my home base and that there was great need for a person to fill this position. I subsequently learned that my departure from Dallas also enabled the Dallas region to rectify some of it's reorganization problems, in that my vacating the position in Dallas enabled the region to reassign Mr. Anderson as District Director over the laboratory, compliance, and inspection, and Mr. Ken Hansen, transferred to Seattle as the District Director.

FLL: In other words they reverted to the more standard sort of organization with two districts and Houston Section rather than trying to run a regionally supervised operation?

JN: That is correct. It eliminated the Regional Director of Investigations and the Regional Laboratory Director, both GS-15s, with my leaving the district. I did not question Mr. Berch but I wonder if perhaps headquarters didn't consider that I should transfer to San Francisco, to eliminate that potential problem.

FLL: Plus the fact that they needed somebody with your talents out here.

JN: Well, maybe. In San Francisco my position required not only reviewing the compliance activity of the two districts but also to manage the specialists, i.e. the radiological health people, milk programs, the shellfish programs, food service programs, the veterinarian and several other programs. It also involved liaison with the states to a greater extent, and to be the principal liaison involving state contracts. State contracts were a significant item in Region IX, especially with California, since they had developed the capabilities of doing equivalent inspections very early in the contract program.

In recent years perhaps the most significant thing that I was involved in was in the creation and management of the small business activities. The Device Amendments of 1978,

called for the creation of small business assistance to small device manufacturers. Headquarters created the position fairly early and decided that there had to be some field activity as well. Headquarters made the decision to initially start a pilot program of four small business assistants units. Region IX was selected for one of them since they had the largest medical device inventory in the United States. In Region IX we operated somewhat differently in that the small business representative was assigned to the assistant regional director for compliance and not directly to the regional director and his immediate office. Also, we opened our office in a resident post where space was readily available and would be at no additional cost to the agency. The position was announced and created in a matter that provided for maximum flexibility, but still meeting the objectives of the program. We were able to do substantially more of the areas contemplated than most of the rest of the country. For instance at no time did our representative fall below 25% of the total activities and in most cases he was approaching the 50% level for the entire field. We were told by the Headquarters Bureau of Medical Devices and the Small Business people that Region IX carried much of the load for the agency in the field. This past year the Commissioner's office evaluated the program and decided that it would be expanded to most of the other regions and they are now in the process of filling and starting up the programs.

I feel that through whatever direction I gave the person that I selected, who was excellent, helped to put the program into a positive perspective and with a maximum effort to suceed.

In terms of other areas of pursuit, among my responsibilities in federal state relations was to have close liaison with the state agencies. In one state, in particular, Hawaii, the district at the time I arrived had recommended dropping the state contract. This would thus necessitate the FDA taking on total responsibility in doing all of the inspections in Hawaii. I felt that for cost reasons and to upgrade the activities of the state that we should not permit the total program to drop. We did drop the sanitation portion of their contract, but continued their interstate travel carriers program. Also through efforts of dialogue and correspondence and communication we kept the communication channels open for other areas.

One of the areas that we worked very closely with the state of Hawaii, was in the shellfish program. This was a new experimental program where-in all the shellfish were grown in aquicultural facilities on land, in a totally controlled environment. None of the shellfish in other states are cultivated in this manner and thus there were many special problems that were created. Hawaii had no experience in regulations or understanding of our regulations and it took considerable effort to get them to understand where we are and why. The state had

subsequently gotten their regulations approved and FDA had certified their capability of putting on the program that they have. The Hawaii Department of Agriculture had had little or no communication with FDA for a number of years. Through my efforts they are now working closer with FDA. Specifically in recent months they have had problems of pesticide in their milk. It required a close working relationship to work out the problems.

With California in which the two districts have communications it involved an entire different type of relationship with the state since I had to represent the agency as a whole and not just each of the individual districts. Their contracts with us had been excellent and they had done considerable work including enforcement work in support of our activities.

In the food and agriculture area aflatoxins has been a major problem and we've had to deal with Arizona and with California to see that the public is protected from milk contaminated with alfatoxin.

FLL: Is that principally in the cotton seed meal?

JN: Yes. Arizona's was entirely in cotton seed, and California's was mostly in cotton seed. Arizona has a very active program in monitoring it. But in both states it took considerable liaison and learning and holding hands to affect correction.

FLL: Do you want to talk about the drug problems in Nevada, the legalization of laetrile and some of those other preparations?

JN: Nevada had legalized many of the drugs that we consider as illegal and we've had to remind the state that their firms are still responsible for good manufacturing practices. It was made very abundantly clear that shipping their products in interstate commerce would be a violation of our law. To this end the state has been monitoring the activities of the firms in their state with regard to these activities. There is still considerable work to be done in this area, especially since we have had considerable difficulty with the U.S. Attorney's office in Nevada. Altough not entirely their doings, nonetheless it has taken considerable dialogue between FDA and the state in these illegal drug areas. It's been very unfortunate in that one of the cases in Nevada, in Las Vegas involved a clinic where DMSO, laetrile and gerovital were given. The region and the district tried to pursue legal actions in these areas and were consistently turned down by headquarters. I feel that it was very unfortunate that it had gone the way it did, but perhaps something will happen in the future.

One area that I've been involved in the region was to monitor the various legal activities, and one that involved the plastic lenses...

FLL: The intraocular implants?

JN: There are two different episodes, one involving intraocular lenses and the other involving soft contact lenses. The first one I want to refer to is on the soft contact lenses. There was a firm in San Francisco District that was illegally dispensing the soft contact lenses under the guise of being custom manufacturers. FDA headquarters initially pursued the matter through the Bureau of Drugs, but subsequently transferred it to the Bureau of Medical Devices. The firm was eventually told that their IND would be suspended and that they should recall their blanks and contact lenses. The State of California determined that the firm continued to dispense the product and did not recall their blanks. This was brought to the attention of San Francisco District who then pursued the recall matter and did bring it to a successful conclusion. The intraocular lenses again involved the State of California as well as FDA. It was pursued through the courts and was eventually completed, sucessfully. It did not have the same element of the problems between the state and the FDA District but rather with Headquarters and FDA.

FLL: That situation as I recall involved a physician who was implanting these lenses and who was getting a high rate of injuries from the operations.

JN: That's correct. From the burrs on the lenses themselves.

JN: One of the ongoing problems that involved the State of California and the two FDA Districts, is the distribution of

raw milk. Raw milk which is not covered under the Interstate Milk Shippers program is a responsibility of the two respective districts. Los Angeles District has one of the largest producers and distributors of raw milk in the United States, namely, Altadena Dairy and they on a regular basis have had salmonelia contaminated raw milk. They have even shipped some in interstate commerce to Nevada and to Hawaii. The State of California has suspended their operations whenever they have encountered the contaminated raw milk. In recent months the firm has attempted to change the state law so that the state agency would not have the authority and responsibility to pursue the salmonelia contamination problems. The two districts while aware of the problems and while attempting to follow-up on the violations, have not been successful to date and to my knowledge not developed any legal action against the firm.

FLL: Raw milk is legal under the state laws?

JN: Yes, it is legal in California under the state laws. It is legal in Nevada under the state laws. It is legal to ship it in inter-state commerce provided it is not contaminated. The IMS program which is the Interstate Milk Shippers program covers only pasteurized milk. Since raw milk is not pasteurized it falls under the general provisions of the FD&C Act. This had been a problem, certainly in the six plus years that I've been involved in California but I understand that it occurred even prior to my time.

FLL: When you were talking about the early part of your career, when you were an Operating Investigator, you described the Monsanto Case at St. Louis, but I don't believe you mentioned any other experiences, were there some other things in that period that you would like to talk about?

JN: Yes. The first one I would like to discuss is the Color-Therm case which is an off-shoot of the case in the Seattle District, namely a lamp with the number of different colored slides, that rotate and are supposed to cure all diseases. When I was given the assignment I was told to be very cautious because I would likely to be thrown out and if at all possible we would attempt to take seizure action. The firm was sufficiently astute that they attempted to keep the products in their home. They tried to keep all their parts unassembled so that there were no assembled lamps. And they kept their literature in a different location. However, through my efforts we were able to seize the lamps, the components and the literature, and the individual planned to contest the entire matter, except that he ended up in prison on another matter and the whole seizure action went by default.

FLL: Was this in Los Angeles?

JN: Yes.

FLL: About what year?

JN: About 1957-58.

FLL: It's probable other legal actions that have been brought against this device?

JN: Yes. And theres a very famous case in Oregon, I believe, where we made seisure in a person's home and it was considered legal. I believe it is subsequently be considered illegal to seize a product in a person's home.

FLL: I think that case is the one that involves Dinshah Ghadiali's spectrochrome. It was a similar device. The case was US vs. Olsen, and strangely enough that question was not raised in the Appellate Court, about the seizing of the article in the home...

JN: That's true, correct.

FLL: Presently it would be. But I think Color-Therm was involved in a precedent-setting legal action in one of the Mid-west states Nebraska or somewhere there. There was a question about locally prepared directions and claims for the article which had been shipped to interstate commerce.

JN: That's correct and this case preceded the Leland Kodel case regarding accompanying literature. And also until the medical device amendment was passed, the agency was very reluctant to seize components. I guess through my ignorance I proceeded to sample the components and we affected seizure actions.

FLL: We lost a case on components of a device I believe in Detroit about that time.

JN: Yes. Another significant case in Los Angeles involved a firm called Pure Food Corporation. This firm manufactured

canned tomato products. Their operation was questionable, at best. When I was given the tomato project in Los Angeles, the first thing I was told was I was the low man on the totem pole and it's a project that never leads to anything, that we have not taken a legal action of tomato products in L.A. for years, but it was mine to pursue. Pure Foods Corporation manufactured products at or below the tolerances for mold that we set for various tomato products. They had a particularly wet fall season and their tomato products were especially bad. They were a very uncooperative firm and it took tremendous effort to collect factory samples, to document shipments and to get samples. Nevertheless, I was able to, and there were at least 10 carload seizures of their tomato products. The FDA finally filed and obtained an injunction against the firm and the firm went out of business. I guess I set a record in Los Angeles on seizing tomato products and having violative inspections that no one else in the district has equalled since. I did receive the cooperation of many of the districts who collected samples for me.

In Los Angeles probably the most significant area that I worked on was the pesticide project, which I monitored for about 3 years. I trained practically every inspector who was hired from '57 to '60 on how to investigate pesticide violators, to collect samples, to report shipments, to interrogate people and generally to see that our law was adhered to.

There were quite a number of seizure actions taken during the era in which I was monitor. I would say that one of the funniest episodes that I encountered was...I was doing an inspection with another senior investigator and the proprietor did not initially see me. When the other investigator started to question him in regards to his pesticide practices the proprietor said that he did not speak English. Since he was of Japanese origin I proceeded to conduct the inspection in Japanese, at which point the individual quickly reverted to English and the inspection was pursued to its conclusion. I did the same thing several times with my very poor Spanish, to people who claimed they did not speak English. I found that by speaking their language they usually quickly spoke English so that we could complete the inspections.

While at Los Angeles on the pesticide project, I used to regularly attend the entomology meetings of southern California and to visit the University of California at Riverside, where they did the experimentation on pesticides. At the time that I started the program, the university was generally setting their own pre-harvest intervals based on their own empirical data, in making their recommendations to farmers, suggesting they ignore the USDA and FDA requirements. During the course of one of these meetings, in which problems arose where the farmers used the state recommended intervals but not the federal and their products were in violation the university

was putting itself in a position of possibly causing the violation of the farmers. At that point the university decided that they would no longer issue their own books with their own recommendations. They might not necessarily follow the USDA or FDA recommendations, but they would not officially sanction recommendations outside the official requirements.

In St. Louis, I was only there one year, and in that one years time there were some rather interesting cases that developed. One of them involved watering of tomatoes. This is something that FDA has suspected of a number of firms for many years but to prove this was difficult. I was given an assignment to inspect the tomato canneries in Arkansas. One specific firm, Kelly Canning Company, was thought to be adding water to their whole tomatoes, rather than tomato juice. Our assignment was to determine whether this was in fact true or not. I had a neophyte inspector with me, who had never been in a tomato cannery and in fact had not done such inspections of other products. With appropriate instructions and coaching we made the inspection and we proved that they were in fact adding water to the tomatoes and we determined where the water was being added. The firm, knowing that we knew of this, chose to not ship the lots in question in interstate commerce. We knew where they were being stored and we had other investigators whenever they were in the area, check to determine the status of the lot. The firm, after some time, felt that it

was safe to ship those tomatoes and they shipped them to Missouri a matter of about 50 miles away from their plant, we were fortunate in that an investigator was in the area about the time this occurred. He collected samples in Missouri. The firm in Missouri, upon our sampling, chose to refuse acceptance and shipped the tomatoes back to Arkansas and we seized the goods in Arkansas. The firm did not contest that seizure action. We may have one of the few watering of tomato product legal actions on record.

FLL: How were they adding the water?

JN: They were using a hose to wash down the facilities and while they were not washing the floors, they were putting the hose in the tank where the tomatoes were being held.

FLL: Prior to dropping into the cans.

JN: They were not aware that we were watching that particular operation. The way we really uncovered it was when we first arrived at the place, we noticed that their peeled tomatoes were in a holding bin and there was not much juice there. But as the evening went on, the tomato juice kept rising in the tank and we were trying to find out where all of this juice was coming from.

FLL: Somebody put the hose in...

JN: Actually, the way we determined the tomatoes were actually watered was that we collected samples of the tomatoes when we first arrived there. We collected them when they were

watching us to show the change in the solids. Then we collected them after there was so much water there. The firm did not contest the seizure action, and it was for adulterating with water.

Another interesting case that I pursued was a product used as an arthritic remedy. This again was one of these assignments that usually leads to no place and I was given the assignment just to do something. The individual was known to be uncooperative. And the agency had really not been successful in stopping his operation. His office was his home. And after many attempts to locate the individual I did finally get him at his home, I got him out of bed, and he permitted the conduct of the inspection in his pajamas, unshaven, unbathed and generally uncooperative. He refused the formula. I made an inspection of the firm that made the product and they also refused the formula. But by observing their practices I was able to get most of the active ingredients that went into it. Even though he refused shipment information, I was able to determine that they shipped across the state line from Missouri to Illinois. I drove through the state following up on leads and I was able to pick up samples. The firm was subsequently enjoined and put out of business.

The Pepsi Cola prosecution was an unusual one in that Pepsi Cola being a very large corporation was generally uncooperative. We had the highest incidence of complaints of

foreign material in their bottled products of any firm in the St. Louis District. It was mostly foreign objects such as cigarette butts, candy wrappers, and other nondescript filth. When I was given the assignment I was told that better inspectors than I had been to the plant many times and had never been able to develop a case, such that we could take legal action. I was given the assignment and told to take along again some new inspectors. My assignment was to determine if we could find out where and why the problems were occurring and that I was not limited to one day inspections as others had been. I conducted the inspection covering two and three different shifts and we determined that their electric eye and their inspectors both did not check all of the bottles as they were supposed to be doing. Their sodium hydroxide or caustic soda equipment was not functioning all the time and thus their bottles were not being cleaned. Their magic eye did not reject bottles that contained foreign material. We then went in to Illinois and candled many, many bottles and found bottles in interstate commerce with foreign objects. We collected samples which we used in our case. When the case was being developed, every effort was made by the firms attorney to quash it. This occurred under the Kennedy administration and the case did go forward and once it was filed the firm pled guilty to the violations.

Another case of significance was the Viobin Corporation

case. This firm manufactured wheat germ oil and defatted wheat germ by an extraction process. They also sold lots of their wheat germ to major cereal firms throughout the country. The firm also processed animal byproducts into powdered products, such as thyroid powder and various granular products. I took a new inspector on this assignment, and again I was told that the firm is never in violation. We found that the firm's warehouse was overrun with rodents and we collected a number of samples. We reported shipments. In order to conserve time, because we knew the products would be utilized in a matter of days, while taking our sample back to the district lab for analysis the new inspector typed the collection reports as we traveled, so that by the time we got back to the district office all the sample collection reports were completed, the samples were identified and the laboratory was able to analyze the samples. We effected seizure actions in many places in the country.

FLL: Jim, one of the things we have been doing in these interviews, is asking the person interviewed for his or her opinion on the Commissioners and other individuals that held leadership positions in FDA. We have asked under what circumstances did you know them, what did you observe that gave a clue as to their personality, their management style or the way they operated. Could you do that with some of the top managers that you encountered during your career?

JN: Most of my contacts with Mr. Larrick were official and I feel that each of the contacts were contacts I should never have made, because my boss or his boss or his boss or somebody else should have done the contacts. I was given the instructions to go see Mr. Larrick or talk to Mr. Larrick about something, which I did. And I found him to be a very down-to-earth practical man, very humble, not using his position or title and basically being very honest and forthright and not giving evasive answers. He generally gave me an answer that I could react to. I did appreciate that, very much that I had this particular encounter with him. An unusual episode involving him and me, occurred the day that President Kennedy was shot. I was on my way up to his office to see him on a recall matter and I was unaware that Kennedy had been shot. As I was getting into the elevator to see him, he stepped in and said he was on his way up to see Secretary Celebrezze because of the President's death and they had to determine how it would effect HEW and the FDA. It was just a simple statement on his part, but he was so excited and he had to let somebody know and I guess I was the first person to bump into him. To me it his the nature to be a very personable person who was willing to talk to anybody.

FLL: You were around there when he was getting a lot of criticism from various congressional committees for the way the agency was being operated. Do you think much of that was warranted?

JN: Some of it may have been. I didn't think most of it was, however, in light of what has happened since he left as Commissioner and the criticism the agency has received by Congress, the press and others, I don't think the criticism of him is nearly as severe as some of his successors.

FLL: Another thing about his time in office, I wasn't in headquarters enough to really judge it, but there always seemed, from a field perspective, that his immediate subordinates were engaged in so much in-fighting over turf that it couldn't help but affect the operations of the agency. Did you observe that while you were there?

JN: I did not observe it as anything between Mr. Larrick and his subordinates, but I certainly felt it and heard it in the relationship between the former Bureau of Enforcement and Bureau of Field Administration. Whether it was Mr. Larrick or Mr. Harvey or the two bureau directors who were responsible, I couldn't say. But I know that there was a lot of hard feelings between those two bureaus.

FLL: That's what I was getting at was that...it was between the subordinates. And I wondered, was there something that either Larrick or Harvey could have done to...

JN: Well, it's only my personal opinion...but the reorganization of 1964 basically affirmed the position that they took, which I thought was very unfortunate in retrospect in that Mr. Stephens who was head of the Bureau of Enforcement really got

the short end of the stick in that particular thing. And I didn't think it was justified, even though I was not in his bureau, I was in the Bureau of Field Administration. I could remember the "Pink Sheet" referring to the fact that the BFA would be dancing in the streets over the reorganization and in fact we all felt very badly that the reorganization was set up the way it was, into the BRC (Bureau of Regulatory Compliance). We at the working level felt the conflict. I don't know that we would necessarily put blame on any particular individuals. You know both Mr. Stephens and Mr. Rayfield and you know their quite different personalities.

FLL: Probably given those personalities, the clash was almost inevitable.

JN: Yes, if anything I think that the Commissioner and Deputy Commissioner did a good job in keeping the two men effective, even in the face of their differences and they were both very effective in my estimation. I thought that Mr. Stephen's organization in the way it was set up was far better than anything that has happened since then. He had the regulatory management, the advisory opinions, and case control, and those were related and yet they were significantly different units. I think they operated very efficiently at that time. Maybe in todays' climate they might not.

FLL: For their time they were superior type organizations. I would agree with that.

JN: I probably had more contacts with Mr. Harvey than with Mr. Larrick. I had nothing but respect for him. I won't say that I always agreed with him but he always had a reason and he always gave a reason for why he would do something or not do something. I took in many recall requests to Mr. Harvey, and he would discuss them openly and if he chose to disagree, he would say so and would give reasons for his decisios.

I felt very badly that his career and mine ended up the way they did. I certainly did not have any ill feelings towards him. I'm not sure he did anything wrong. All I can say is that there were a series of circumstances and things did not look right in a certain way and I know that Congressman Fountain drew certain conclusions, which he's entitled to do and whether their right conclusions, I'm not sure.

FLL: Did you ever observe anything of the relationships between Harvey and Larrick, as to how they worked together?

JN: I saw them together on a number of occasions but I would say generally that Mr. Larrick let Mr. Harvey take the lead in almost any of their discussions.

FLL: The day to day operations?

JN: The day to day operations.

FLL: Which really was Harvey's responsibility.

JN: As far as I can see they were generally Harvey's responsibility. I would say that people expected that I would perhaps dislike Mr. Harvey and I would say no, I did not agree

with him on all things, but then you never agree with the person and all of his actions and I really had nothing but respect for him.

FLL: Of the people that were in headquarters, at that time, do you think that there were any of them qualified to succeed Larrick as Commissioner, given the kind of climate that existed at that time?

JN: Yes. In addition to Mr. Harvey who certainly wanted to be Commissioner, I would say that Winton Rankin was fully qualified and I think he would have been a very able Commissioner. I think that Malcolm Stephens would have been a very able Commissioner. I think that Mr. Goodrich could have been a very good Commissioner. I'm not sure of Mr. Kirk but then a lot of people had very strong feelings, pro and con, about Mr. Kirk. I would say of the individuals I named all could have been excellent Commissioners. In comparing them to Herb Ley or Gere Goyan, I would say that they would have stacked up... as good, if not better.

FLL: Certainly had they come instead of Dr. Goddard we would have been spared some trouble. But on the other hand would probably not have done some things that we have done since then. Did you have much contact with Goddard?

JN: Some, I probably had more contact with Kennedy and Edwards than I did with Goddard. My relationships with Goddard were limited but he seemed to be flamboyant, he shot

from the hip. I think he had no trouble making decisions, whether we agreed or disagreed. I think he may have sensed the political climate too quickly and in some cases wrong, but nonetheless as Commissioner he was entitled to that type of action. I would say I had fond regards for him. I know that most FDA'ers did not but I think for the limited time that he was Commissioner, and under very difficult circumstances, he did well. He was also the first non-career Commissioner. He had difficulty getting information, as any outsider would and all of our subsequent Commissioners have experienced the problem of communication with career people, just as the President has. But I think that in spite of that he was able to get a number of things done. I did not necessarily agree with his concept of decentraliztion but it was pursued by President Carter also. I think Nixon to some extent tried some of the decentralization processes. I'm not sure that a career person could have shaken up the agency the way Goddard did. Not to in any way diminish the capabilities of Mr. Rankin, I think he had shaken up people but I'm not sure he could have shaken up the agency the way Goddard did.

FLL: Well, I think that's probably true because any career person would have had old relationships with people that would be his subordinates now and those would have been difficult to work through. You mentioned that you had seen Edwards when he was Commissioner.

N: Yes. One particular episode which is rather unusual, from my point of view. When Paul Hile was the EDRO, before it was called the EDRO, one of the things that he considered pursuing was what is now the GWQAP program, mainly the inspection of drug facilities making drugs for the Federal Government by FDA rather than by the Department of Defense. Since I had worked in the Department of Defense and had specifically done inspections and purchasing of pharmaceuticals, I had direct experience in the activity. For instance I signed out many DD-250's which our investigators are just now doing. Going back to the era when I was at headquarters and really as a fallout from the Thalidomide episode and our increase in recalls, the Department of Defense found it very critical that they have some communication with FDA; until then there had been very little communication. Fred Garfield, took the leadership in establishing a liaison with the Department of Defense, and Bill Conway and I became the working part of that relationship. We used to have regular meetings, in either Washington or Philadelphia or New York, with the Department of Defense personnel in discussing mutual problems. We invited them and they did attend our drug training sessions, both basic and advanced. There was an evolving relationship with the Department of Defense. Then GAO suggested that there was duplication of effort, Paul Hile, knowing of my past experience both in the Department of Defense in both Philadelphia

and in New York, asked if I would pursue a program of the feasibility of FDA doing inspections for the Department of Defense. I was able to get Joe Phillips of Philadelphia to work with me, and for several months we worked setting up procedures for doing military inspections. When the final report was written and given to Mr. Hile, he called for a meeting with Dr. Edwards to discuss the program. In the particular meeting in which there were perhaps a dozen individuals, I sat at the opposite end of the table from Dr. Edwards. After Mr. Hile's initial statements, most of the conversation took place between Dr. Edwards and myself, talking across the table and I tried to acquiesce to Mr. Hile, but Dr. Edwards insisted that he talk directly to me on the matter. I felt that Dr. Edwards wanted specific direct information as quickly as possible. Maybe that's an unfair view of my contacts with him. I would say that in my other observations he tended to be impatient.

A rather amusing episode took place after I moved from Dallas, I was at a bank opening an account and one of the tellers, when he found out that I worked for FDA asked if I knew a Charlie Edwards. It seemed that he used to date Dr. Edwards' daughter in the Chicago area. His views of Dr. Edwards and mine were almost alike. He said that as a father, he was much like he was as the Commissioner.

FLL: Did you have any contacts with his successor...Dr. Schmidt?

JN: I had almost no contact with Dr. Schmidt.

FLL: I don't know that he ever visited the field, I don't remember ever meeting him outside Washington.

JN: I think I met him twice. Once at Houston at the AFDO meeting. Remember that?

FLL: Yes.

JN: It was held at Houston and all of you had a meeting in one of the rooms afterwards and then one other time. But I found that he was the most difficult person to speak to of any of them, including Dr. Edwards. I found that I could speak to Dr. Edwards in his abrupt way easier than I could talk to Dr. Schmidt.

I had no trouble in my dealings with Herb Ley, both in the bureau and as the Commissioner. It was unfortunate that he was Commissioner at the time that he was.

FLL: He was in a position sort of as a caretaker really.

JN: He ended up being in that position and while he had the authority, he really wasn't given the authority that he needed. He was hamstrung time and time again. Both from the department and from the agency itself. I thought that FDA did not give Dr. Ley a fair chance.

I'm surprised you haven't asked about Allan Rayfield.

FLL: I didn't know whether you wanted to talk about Allan. You also have not talked about Don Kennedy and I think you saw quite a bit of him out here.

JN: Yes. I met Don Kennedy before he was sworn in as Commissioner, when he came to San Francisco for indoctrination. I'm not sure initially that he appreciated some of my abruptness. For instance, he asked what I felt the morale of the people in the field versus the headquarters was, since he had heard that there was quite a strong feeling about the two. I'm not sure he appreciated the comments that came out of that particular discussion. But I had nothing but real respect and really affection for Dr. Kennedy. He was very personable, very exuberant, very enthusiastic. He wasn't always thorough on all his facts but he generally could grasp them very quickly and could assess them. If he has a similarity to Goddard it is that without too many facts they are both able to make very quick decisions and generally good decisions. Of course, he's a very personable person. He was a very personal type of Commissioner in that he wanted to meet people, he liked the hearings that he held, he did not have to direct the hearings but he did, many, many times even though they were long and exhausting. He intended to leave a positive image of himself in the agency and I think he did just that, in the short time that he was Commissioner. That's my own opinion but he also made the agency as visible or more visible than it ever was. He became a household word, and the agency certainly did. Although I'm disappointed in todays paper, out of Washington, because of an article in which they refer to FDA as the Federal Drug Administration.

FLL: Oh no.

JN: Dr. Kennedy, I think is presently in a position that he most likes being in, talking to students. I was on the Stanford campus just a month ago, and it appears that the students have nothing but affection for him. They said he is a taskmaster and he is hardnosed. When he wants something done, he expects it will be done forthwith. On the other hand he is very personable, and he talks to people. He appears to be trying to change the image of Stanford, and I think he is going to succeed in that pursuit. He is a person in pursuit of excellence. I think he sought that for FDA. I think he felt a little frustrated that he did not quite achieve it. Again these are all my own personal opinions of my observations of him.

FLL: I think he was perhaps the one Commissioner that I most thoroughly enjoyed as a man.

JN: Yes.

FLL: He was fun to be with.

JN: Very definitely. All the time you are with him, you did not feel nervous, you did not feel that...you know there's a man who's there and your down here. He could get down to your level very quickly. He is a man with very diverse interests and imagination. He was a very good Commissioner, he was an excellent one. If I had to rate them all he would be number one of the non-career Commissioners.

FLL: I think Dr. Goyan perhaps suffered from the same problems that Dr. Ley did.

JN: He did.

FLL: He was frustrated by the national administration and the Secretary's office, inhibited from doing some of the things that he would of liked to have done.

JN: He also was not the personable charismatic person that Kennedy was.

FLL: No. Kennedy was a hard act to follow.

JN: That's just it. To me Goyan at another time could have been quite a different person. But following Kennedy it just was as difficult as it could possibly be. Goyan also does not have the feel for picking things up quickly and then making a quick decision on it. I don't know how Dr. Hayes is at that, but I felt that only Goddard and Kennedy really had that feel. Edwards was very analytical and he just would not make decisions very quickly, Schmidt did not either, in my estimation.

FLL: That may have been one of the problems about Dr. Schmidt's regime.

JN: Yes, decisions were just sort of postponed and you know we will "take it under advisement" type of decision.

Kennedy gave the field a lot of support that I would say Ley, Edwards, Schmidt, Goyan and Hayes have not given.

FLL: Well, part of it I suspect was because he got to know the field, the others that you mentioned really had limited,

if any contacts, with the people in the field.

JN: But he made an effort and the others did not.

FLL: Right.

JN: That's the difference. I am not sure he was any less busy than the others. I think he was more busy. I think he made a comment on how many hearings he had to attend in the first 6 months he was Commissioner and it was really astronomical. I think he said he was up with the leaders of those having to testify and not just another one, certainly out of proportion to his appropriation.

FLL: He did have one advantage, however, that being appointed in a Democratic administration when the Democrats controlled both houses of Congress, he did not get the kind of hostility that Republican appointees got from some of those committees.

JN: That's true. Goddard was appointed under Johnson and served two years under Johnson.

FLL: Right.

JN: Goyan, served his first year and a half under Carter, so it was really only at the end of his tenure that he was told to resign. I did not feel that he really got things going the way he could have. He could have made certain decisions that he did not do. We do not always like the decisions, but you know the lack of a decision is sometimes worse than one that you don't like.

FLL: Right.

JN: That you can live with.

FLL: At least you know where you're going.

JN: Very definitely. I felt that Edwards knew where he was going. But I'm not sure that I felt that Schmidt knew where he was going. And that's maybe unfair to Schmidt to say that but...again my own feeling about Dr. Schmidt.

FLL: Jim, is there anything else that you'd like to put in the record?

JN: Through the years I am not sorry that I made some of the decisions that I made, that perhaps I could have used a different approach. In some cases it is unfortunate that I was at the wrong place at the wrong time. Generally, I would say that I feel and hope that I contributed something to the agency and to the U.S. public during my career.

FLL: Well, thank you very much for taking your time to sit through an interview like this. I appreciate the things you told us and they do add considerably to the record and clarify some things that to me at least had been quite puzzling. Thank you very much.