HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:
Irwin B. Berch
Retired Director, Region IX
and
Fred L. Lofsvold
U. S. Food & Drug Administration
Burlingame, California
June 14, 1982

TAPE INDEX SHEET

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

DATE: June 14, 1982 PLACE: Burlingame, Calif. LENGTH: 128 Min.

INTERVIEWEE	INTERVIEWER
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FDA SERVICE DATES: FROM 1939 TO: 1980 RETIRED? Yes

TITLE: Director, Region IX, San Francisco, California
(If retired, title of last FDA position)

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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.

This is a recording in the series of FDA oral history interviews. We are interviewing today Mr. Irwin B. Berch, who retired from FDA as Regional Food and Drug Director at San Francisco, California. The recording is being made at his residence in [redacted], the date is June 14, 1982. Interviewer is Fred Lofsvold.

FLL: Mr. Berch would you sketch, briefly, your education, and your career in FDA, the various jobs you held and the particular times that you held them.

IBB: I attended the University of Washington, graduating in 1938 with a Degree in Chemistry and returned and did a year of graduate work in Organic Chemistry. Fortunately I had taken some specialized courses in Food Analysis as well as Biochemistry, so I felt that I had a fairly good background when I took the Civil Service Junior Chemist Examination in early 1939. I was given the option, when interviewed by Mr. Harvey who was then the Director of the Western Distict, of working either in the laboratory or in the field as a Food and Drug Inspector. In those days, I believe, we were called Junior Inspectors. An acquaintance of mine from the section of Seattle that I grew up in and who had attended the same school, Bob Silver, had gone to work as an inspector and he was also a chemistry graduate and he advised me, if given a choice, I should accept the Inspector position rather than the Chemist position in the laboratory. I believe his advice was

sound, although many years later when our chemists finally were given the proper instruments to do the research work that is so much needed, perhaps many years later, I might have made a different decision, but at the time the kind of work that the chemists were doing I had already done in my food analysis courses and I wanted to try something different.

I worked in Seattle from the Fall of 1939, one of the well known "class of '39" which was trained collectively in San Francisco, for the 11 western states. My recollection there, that stands out in addition to field training trips, was a survey of the almond industry. We all spent part of our time cracking almonds and classifying the rejects and I fell heir to the task of preparing a statistical summary of the results. As I recall, the decision from the survey was not to change the then existing standards which I believe are now called defect action levels, in part because there were other defects besides the insect damage.

I then went back to Seattle where I worked until I was transferred in 1941 and went to Los Angeles to continue in the next grade of an inspector, where I stayed until I entered the armed services about a year and a half later.

During the war I attended UCLA and took the aviation cadet course, became a meteorologist, stayed as part of the faculty at UCLA in the Graduate Physics Department. Later I was selected as a representative of the UCLA type of meteo-

rological training to go back to Chanute Field where all weather training was consolidated and remained there as commander of the unit until the end of the war.

On discharge from the service in early 1946, Mr. Harvey gave me the option of reporting anywhere in the Western District. I returned to Seattle for another year or two, transferring then to Portland, Oregan, in the substation which consisted of three inspectors and three analysts. Thereafter, in early 1955 I was transferred to Los Angeles where I became Chief Inspector of the Los Angeles District until 1962 when I became the Deputy District Director.

Thereafter in 1964, I was transferred to Philadelphia District as the District Director until late 1970. At that time the Philadelphia District was in the process of being converted into a regional headquarters. And for a short time before leaving Philadelphia, I served as both the District Director and the Regional Director until coming out to San Francisco where I served until my retirement in September of 1980.

FLL: Irv, is there anything in your early years as a working inspector that you would like to talk about?

IBB: Well, working in the Seattle Station, as it was then called, we did a lot of physical labor as the early trainees, loading and unloading cases of salmon and Fred you may well recall because we did some of that together.

FLL: Indeed I do.

IBB: We used to go out sampling salmon. If I recall correctly, in the lower floor they were stacked 14 cases high and the upper floor 12 cases high. And you had to first of all unload cases of salmon so that you could build steps so that you could climb to the top in order to open the cases. I believe we took two cans per case. The cases were 48/one pound talls, requiring opening 24 cases to obtain a case of samples. And I recall a team of two inspectors were expected to bring back about 25 cases of samples.

FLL: Per day.

IBB: For a day's work. And my earliest impression was that you didn't really need a college degree to do that and even then I felt we could of hired some sample collectors to good advantage. It kept me in pretty good shape, although the wooden cases and nail pullers left a lot of scars.

FLL: As I remember a case of 48, one pound talls actually added up to about 70 pounds when you had...

IBB: I think it was an average 62-1/2 pounds, but since I'm of rather short stature and weighed about 115 pounds at the time, it represented more than 1/2 of my body weight.

The Seattle District had a interesting array of work. There were a lot of fresh fruit and vegetable packers I got experience in. There were others, there were some sea food activities and one of the things that I got to do early on

that I found quite interesting is that they were developing the standards of identity for oysters, fresh shucked oysters. One of the problems, with oysters, is due to their solids content when put in contact with fresh water, they can absorb water and plump up, and it becomes a relatively easy task for unscrupulous merchants to water their oysters by allowing them to be in contact with fresh water too long. In order to ascertain correct drained weight and solids data for the standards, we had to put up authentic packs. And we went into the packing plant and performed, with reasonable speed, the washing, draining and packing of the oysters. We also had to count them and we put up pints, quarts and in some cases gallons. That wasn't so bad. The Pacific oyster is a rather large species, much larger than the eastern oyster. But then we went down to Olympia and packed the Olympia oysters, which are very tiny and about the size of a thumbnail. I can recall even today having put up packs of one gallon Olympia oysters that there are an average of about 985 Olympia oysters to the gallon, having counted many and averaged them. I found the work quite interesting.

Another thing that we were doing then which has since become a very active part of the government's activity, but no longer our agency's. We did some of the early work on illegal sale of dangerous drugs. There had been complaints, even in those days, about the illegal sale of "Bennies" as they were

most commonly called, or "Dexies". Originally our undercover work was done around the campuses because of the sales to college students. Having been a recent graduate I put on my old "W" sweater and was sent up and down the University District in Seattle to walk in off the street and see how many of them, how many of the druggists would be willing to sell me "Bennies" without a perscription. I met with some success in buying some and some failure but the thing that amazed me was that after about the fourth or fifth attempt, the druggist called me aside and said that he would be very happy to accommodate me but the word had gotten out that there was a federal inspector working up and down the street and he didn't dare to sell any "Bennies" to strangers, not knowing of course that I was the Federal Inspector. I still wonder how the word got out. That work has been combined now with the control of other narcotics by the Drug Enforcement Agency.

When I was transferred to Los Angeles one of my early tasks was to conduct a survey of the sanitary conditions in the candy industry. I had made one or two such inspections in Seattle but I was put on to this full time. I had several interesting facets that usually, of course, our work is concerned entirely with finding firms that were not in compliance with the law, developing the necessary evidence to establish that the law had indeed been violated and being able to sustain our position in court. The candy industry had complained

vigorously to our agency that we were only showing the bad side of the industry and that we had failed to compliment those who were obeying the law. One of my assignments was to find some truly sanitary firms and document with photographs, the methods whereby they did indeed put out a good clean product. Today we call this the good manufacturing practices of the candy industry. Interestingly enough I found several such firms in the Los Angeles area. I took photographs even of firms that were hand dipping chocolates, an operation which on the face of it seems to be very messy and that many people would think unsanitary. Actually it was conducted in a very sanitary manner and there were prompt and frequent hand washing operations, good practices to prevent the spread of any incipient infestation. I prepared a series of photographs which eventually made their way into some congressional hearings. On the other hand, I found instances where firms which on the face appeared to be modern, well constructed candy factories had serious and significant infestations. One of these ended up in a court case which received considerable attention on appeal, the Triangle Candy Case. This was a nearly new factory of cinder and cement block construction, in an older warehousing area, that had a significant rodent population surrounding the plant. The firm had been lax in allowing entry to the rodents, by carelessly leaving doors open, and inadequate periodic inspection to see if any rodents had

gotten into the plant. Also, storing empty cardboard containers in such a fashion that the rodents could nest in the area, out of sight from the periodic superficial cleaning that was going on. Walking through the plant, superficially, it appeared to be a modern clean plant but getting out the inspectors old aids, the flashlight and ultra-violet light and probing behind, it was pretty evident that the rodents had access not only to the packing material but had wandered out into various areas where food was being stored, some returned candy material that was being reused. As a result of that, after failure of the plant on first warning to clean up, we did bring criminal action and the case went to trial. Between the time I had made the inspection and the actual trial, I had been inducted into the armed services and came back in uniform to testify, factors that I think perhaps gave a little added weight to my testimony. The firm apparently had hired a rodent control operator who was not very well versed in his business because he had been the one who made the superficial inspections. When it went to trial, the ensuing questioning on the evidence, was the difference in observatons between that of the inspector and that of the pest control operator. An interesting side light on that, when I was put on the stand to be qualified as an expert in these matters, I had actually inspected only about 6 candy factories before inspecting the Triangle Candy Company. In discussion with the assistant U.S.

Attorney handling the case, I suggested to him that in questioning me he deal with my experience in the sanitary inspection of food manufacturing establishments, of which I had made between two and three hundred, and they never did on direct or cross examination divulge the fact that this was only about my seventh inspection of a candy manufacturer. Actually, in the kind of evidence needed to detect rodent droppings, rodent urine stains, and their documentation by collecting physical evidence and photographs, there is a great deal of similarity between all food firms. Candy firms are one of the industries that does reuse scrap materials, but not the only one. Macaroni plants have a similar problem, where any material that is reused must be very carefully protected from contamination and inspected before use.

Another interesting experience, in connection with the case, was that after I had presented my testimony the judge called me into chambers and remarked that his son was in a similar Air Corps unit and wondered if I had come across him son during my travels around the country. I hadn't. The Air Corps was a rather large unit.

FLL: Obviously it didn't hurt the government's case that he had that kind of personal interest.

IBB: Well, it was a jury case. And when the case went on up on appeal,the appellate court devoted a one sentence comment that the government evidence had amply established the exist-

ence of infestation in the plant.

FLL: Yes, the whole case on appeal revolved around the fact that we had failed to give them parts of our official samples on some of the counts. And I think two or three were dismissed for that reason.

IBB: I believe there was some question about how we had protected our sample while transporting it in the car and paper bags.

FLL: That question I believe was raised at trial but the appellate opinion, I don't think, even discusses that but goes directly to the question of failure to provide portions of the sample. I remember that after that case, there was a directive issued to those of us that were still in FDA to be more careful about the way we handled samples taken from bulk containers. Make sure our bags were kept clean and that we didn't let them rattle around in the back of the car for three days before we sent them to the laboratory.

And then after your service in World War II you returned to Seattle as one of the Senior Inspectors at the Seattle office still called Seattle Station.

IBB: Yes. While there I made some use of my military training. We had a firm that was selling an infra-red type lamp that was represented as being capable of producing desert air in your home, appropriately called the Desert Air Lamp. I installed one of those in my bedroom, together with meteoro-

logical instruments, in measuring temperature and humidity variations and obtained the results which I could of predicted at the outset, namely that the mere warming of air lowers the relative humidity and in accordance with the capacity of the air to absorb moisture. The lamp itself did nothing to add or subtract the moisture content in the air, and as a result of that was not capable of duplicating desert air conditions, certainly in an area such as Seattle. If they had started with a fairly dry air and then heated it even more, it perhaps might of approached desert qualities. I think we were successful in bringing action to restrict sale of the device which made representations for treatment of asthma and other pulmonary disorders.

Later when I transferred to Portland, one of the most vigorously promoted activities was a hair growing preparation promoted by a gentleman by the name of Brandenfels who proclaimed himself as the "Hair Farmer". He had a dilute sulfa solution which was being used to bathe the scalp and he represented that miraculous growth of hair would ensue. In fact he had built up the business so large, that the small town of St. Helens was awarded a new post office to handle the tremendous volume of mail which he had generated. When I went into the area to locate dissatisfied users, for possible use in trial, I encountered a great deal of hostility from the citizens until I learned that they had all thanked Mr. Brandenfels for

getting them a brand new post office. They didn't want the golden egg withdrawn.

We also had a lot of activity in that area from a firm called Nue-Ovo, promoted by a firm called Research Laboratories. This was an arthritis preparation that was sold nationwide and although that was the headquarters many inspectors throughout the country were engaged in working on that case. It actually was a series of cases because after some earlier victories the promoters changed their tactics, reorganized and started new companies.

During the course of those investigations, in which the government ultimately suceeded after some hard fought trials, I encountered one of the very few serious efforts on behalf of industry to try to get me to change sides. The promoter was a man of limited advanced education. He had a daughter who was just graduating from pharmacy school. He had suggested that as soon as his daughter graduated that he would put me through a quick two year law course and that upon my graduation he would turn the business over, as a partnership between his daughter and myself, and he figured that with my Food and Drug experience and the Law Degree and her pharmacy degree they could beat FDA without any trouble. Needless to say, since we were then in the very active late stages of bringing action against this firm, his efforts were in vain.

FLL: Then following your tour at Portland, you went to Los Angeles as Chief Inspector.

IBB: Yes. Los Angeles was very fortunate in having stationed in our office, an attorney from the General Counsel's office, Arthur Dickerman. And having on call the only medical officer outside of Washington, Ralph Weilerstein, who was stationed in San Francisco but who used to shuttle regularly down to Los Angeles to participate in the planning of investigations, as well as trial preparation for securing expert witnesses to support our cases.

We had many such activities which led to successful outcomes. An interesting one involved a hemorroid preparation that went to trial in Walla Walla, Washington. One of the more interesting aspects of that case, was during the course of the testimony of one of the dissatisfied users he remarked that not only had the product failed to give the desired relief and was quite painful in the process, but that some of the preparation had gotten off onto the toilet seat and had eaten the varnish off the toilet seat. This made quite an impression on the jury. In fact, at that point, for all intents and purposes the defense gave up and hardly bothered to cross examine any other witnesses.

FLL: Yes, I remember that case that was I think the product was called Amberin and the promoter made it by buying one gallon bottles of a well known lininent called Absorbine Junior. He bought the gallons for about four or five dollars and then put it up in four ounce bottles that he sold for ten

dollars a piece as a treatment for hemorroids. He was a man with no medical background. In fact he had served time in jail for assault and battery and for forgery, before he got into the medicine business.

IBB: Among the interesting promoters, we had one who was promoting the use of injections of a sulphur compound that was represented as being of value for a variety of run down conditions and some serious aliments. This promoter was making up his preparation in his sink, similar to an operation that I believe took place in Seattle many years ago.

FLL: Yes, Doug Hansen has described that one.

IBB: He has. Well, it broke out again in Los Angeles and the method was the same, flowers of sulphur dissolved in water in the sink in the hotel room, no sterilization, an injection.

Interesting thing in Los Angeles was that we'd get a lot of complaints about adverse effects from drugs and occasionally they would involve famous movie stars, usually actresses. When their names cropped up, there was a great to do in the inspection staff as to who was going to get to go out and interview the actress. I still remember Ola Bain, who was the senior member of the inspection staff, a kindly father-figure type, was generally sent out on assignments rather than some of our younger more excitable inspectors who tried very hard to get those assignments. I remember once, Marie Wilson who had starred in Ken Murray's Blackouts, had complained about

reactions from some injections given in the buttocks area, and we sent Ola Bain out to examine the evidence which she did not hesitate to display for the inspector's observation.

FLL: I remember when we were in training, here in San Francisco, one of Sally Rand's dancers at the Worlds Fair in '39 had a reaction to some cosmetic and Van Smart drew the assignment to go out and make the examination of the young lady.

IBB: We had other problems in the early investigation of the Relaxicisor device. This was a weight and measurement reduction passive exerciser attached to various motor control points of the body, with small electrical discharges being applied. We had done early work, this case continued until long after I left Los Angeles, but some of the early testimonials were given by movie actresses, many of whom did not want to be interviewed. We had considerable difficulty and had to work through many of their various agents and the studio representatives in order to even get in and talk to some of these people. This particular device...the promoter of it had, through connections still unknown to us, managed to get the article aboard on the first atomic submarine, as a means of giving an exercise program for a captive audience that could not get out to exercise. We even then had done the original investigation which disclosed that there might be a possible danger to health. Some years later we were able to

establish that the device was dangerous to health when used as directed and were able to take it off the market and enjoin the promoters.

FLL: We issued, as I remember, a public warning with posters in the post office warning people about the hazards.

IBB: Yes. We had many promotions that showed a great deal of ingenuity on the part of promoters. I always felt that those individuals had they devoted themselves to more legitimate entrepreneurship, could have really become quite well-to-do and we actually had an example of that.

This promotion was in the early years after World War II. German technology was held in high regard. This individual marketed a product, for "men over 40" category. He adopted the sponsor of the product as Konrad Adler which sounded a lot like Konrad Adenhauer the great German premier. The promotion was printed up in the typical German script, German type of printed letters too, and it proclaimed that out of postwar Germany this new scientific discovery had emerged. The promotions were sent by mail order from England and, of course, had a foreign stamp. They had learned that people are far more apt to examine more closely something coming from a foreign country. He claimed that out of post-war Germany a new discovery for the treatment of "male sexual weakness due to psychogenic causes". The product was a simple B-1 vitamin

preparation and it came in standard strength and super-strength. The standard consisted of 100 tablets in a vial, the super strength consisted of the identical product with 200 capsules in a bottle and you were directed to take twice the dosage. The bottles had, on their face, the picture of a very imposing gentleman with a bushy mustache curling up at the ends, looked every bit the part of a statesman. It claimed to have a money back offer personally guaranteed back by Konrad Adler himself. The money was rolling in, but we took action against the product. We first got an injunction and with the aid of the Post Office Department held up a lot of the money before orders could go out, and then we went to trial on a permanent seizure case because the tablets had come in from out of the state. During the course of the trial we had a lot of expert testimony on the limitations, and usefulness of vitamin B-1.

But the most interesting facet of the case and one which once again was a turning point. We were very curious as to who Konrad Adler was and we ascertained through the printer of the labels that they had sent out to Hollywood and purchased a stock photograph. Frank McKinlay, a very resourceful inspector, had traced this down and had a obtained a copy of the original photograph. It turned out to be a bit player in Hollywood who, along with others with distinguished appearances franchised out their photographs for endorsements. This

individual had appeared during recent weeks, on a T.V. late show protraying the part of a judge. By coincidence he died the week before we were presenting our case for trial. Frank testified to this, brought in the photograph and the judge was incensed. When the defense took the stand the judge asked if this product was, in fact, being guaranteed by a dead Hollywood actor who portrayed the part of judges on television? The defense literally folded at that point, although that was not really the material issue it was just a side issue in the misrepresentation. We brought criminal action and even got some jail sentences which were suspended. The individual who promoted this venture was an ex-convict, a very glib individual, a con man. Following our successful action against this and some earlier efforts in which he had been marketing methyl testosterone for the same purpose, he had turned to this innocuous preparation. This individual decided to give up his food and drug ventures and turning his attention to more legitimate operations founded and started a wax museum adjacent to the newly opened Disneyland. And reports we heard were that he had become a millionaire in a few short years, by turning his attention from food and drug quackery to more legitimate showmanship.

FLL: Do you remember his name?

IBB: I believe his name was Parkinson.

FLL: I remember some Parkinson cases earlier.

IBB: Yes, El-O-Pathic Pharmacy case, among others.

FLL: That's another precedent case.

IBB: Working with Dr. Weilerstein and Arthur Dickerman was a truly exhilirating experience. Although not required to, they both quite willingly and actively participated in the planning aspect of some of these investigations, with a view of course to getting the soundest case when we finished. It was a three cornered operation, the FDA investigations, the medical expertise and the legal expertise. I can remember also that when you prepared for trial with these two gentlemen, time meant nothing. We might work all day and all night.

They were each well versed in the problems and possibilities of the other two sides of the triangle. I'm sure that Dr. Weilerstein could have tried any Food and Drug in court. He was particularly adept with expert witnesses, drafting proposed affidavits in the kind of language that the individual himself used. I think it's the same kind of skills that are called for in presidential speech writers. The President knows what ideas he wants to convey and his writers have to put something in the appropriate style of the speaker. Arthur, in his pleadings and other court documents, made it very easy for the judges to draft their written decisions. Although the attorney is not supposed to draft them for the judge, Arthur certainly led them well along the path to produce the kinds of decisions that were the most helpful to us in future cases.

One case, I recall rather vividly of Arthur's, involved spray residues. Many years before, the agency had lost a case in the trial court, at the District Court level, which Arthur had strongly recommended be appealed. And for reasons beyond his control at the headquarters level, the decision was made not to appeal the case. Arthur knew that it was bad law, and should of been appealed. Some years later we brought a criminal case over in Arizona involving a similar type of offense, a much more difficult case because it was a criminal rather than a civil case, as the original one had been. He succeeded in persuading the court to adopt wording in the decision that in effect corrected and cured the agency's failure many years before to appeal a truly significant case involving spray residue tolerances.

FLL: I think that was the Bodine Produce case in Arizona. I believe that the earlier case was a case involving regulation setting a standard for canned peas. A judge in Maryland had permitted the claimant in that seizure case to attack the standard in the District Court, which Arthur strongly believed was an improper forum. When a similar attempt to attack the pesticide tolerance in Bodine was made he got the language put in the judge's decision that said flatly that once a standard had been established through the administrative process it could not be attacked in the District Court.

IBB: Yes, that issue was dealt within in the opinion, in the Bodine case.

FLL: Yes, very clearly.

IBB: And clearly put it to rest.

FLL: I remember one thing about Weilerstein, too, that always amazed me. No matter what kind of medical testimony you needed he always seemed to be able, in just a matter of hours, to find the proper medical witness.

IBB: Well, he maintained contact between trials with these individuals, kept in touch with them and was very successful in getting them to leave their practice for an appearance in court which proceedings sometimes were of a very uncertain nature due to the method in which the courts acted. And, of course, Arthur was very successful in his contacts with the U.S. Attorney's office, to get these medical witnesses put in out of order so that they could return to their offices. They knew that every effort would be made to accommodate their timing problems.

FLL: The really amazing thing to me was they did this throughout the entire Western District, the eleven western states. They knew everybody that they needed to know and they were totally trusted, I think, Arthur by the U.S. Attorney's and Ralph by the medical profession.

IBB: Another of the activities we had in those days, we did a lot of work on over-the-counter cases and a lot of them involving the illegal refilling of prescriptions. We had to get the cooperation of physicians to write prescriptions. We

of Eniwetok there had been some radioactive fallout on fishermen aboard their vessels but all of their tuna catch had been destroyed. Since this was the first such underwater blast close to shore and in a known fishing area, they decided that we would have to do better than that.

The military made available to us a detachment of 21 men and an officer from the Mercury test site. Since the operation was somewhat clandestine and much of it was classified, it was desirable that the public be kept unaware. These men were brought in, put under my command, outfitted with food and drug coveralls and dispersed. The canneries, of course, had been alerted and all of the larger canneries had survey instruments mounted at the top of the receiving chutes, as the fish come in and passed through and on down into the butchering line, with remote sensing devices that would set off alarms and stop the line if anything exceeded the predetermined level. In addition to that, at the smaller and other more remote areas, we monitored with portable instruments whenever these canneries were in operation. Very few industry people knew what was really going on. This was just another routine Food and Drug check as far as most of them were concerned. The interesting thing was we found one "hot" fish and one borderline fish. The hot fish was packed in dry ice and shipped back to Washington and experimental packs were put up to determine the extent of the radioactive contamination.

IBB: In Philadelphia, shortly after I had reported there, we had as you know a change in commissioners. The feeling was from the new commissioner that we had not given enough attention to the so-called ethical pharmaceutical manufacturers and I still don't know what that term means, since we had considerable reason to doubt that is was descriptive term.

We did a number of interesting things in Philadelphia over the years. I think some of them started with the early days in our intensified drug inspection program.

There are a lot of differing viewpoints on I.D.I.P., the Intensified Drug Inspecton Program. Not everyone was in favor of conducting it. And when it was decided that we would do it, not everyone had the same idea as to what we should do and how we should do it. There was however one decision made at a fairly high level, that the districts would be given far greater latitude than they had before in carrying out the program provided, of course, that we adhered to certain broad guidelines.

At Philadelphia we took them at their word and decided that we would indeed try out a lot of different techniques. Many of the field offices felt as we did, that qualified scientists should play a much more active part in the inspection and especially those parts of the inspection relating to their activities. For example, microbiologists helping to evaluate sterility problems. Our concern was that there was

lacking, in the industry, the proper management attitude towards quality assurance. At Philadelphia we had some useful experience with this concept. We had gone through a very time consuming effort in policing a successful injunction case against Philadelphia Laboratories. We had obtained an injunction against the firm because of serious infractions of the Good Manufacturing Practices Regulations. They produced many lots of drugs under these objectional conditions, had them in inventory, as well as some supplies that had been shipped. We had halted production by the firm and then had the problem of trying to decide, after we got them to make the in-plant corrections, what to do with all of the lots that were in storage. The firm suggested that in effect we station an inspector in the plant as a resident inspector, and provide him with an office. They made this request directly to the Commissioner who picked up the phone and said, "Why not?" and I said, "Well if you feel that way, why not."

FLL: This was Dr. Goddard?

IBB: Yes, this was Dr. Goddard. And we had a very highly qualified individual, Joe Phillips. Since he was working on this anyway, he went to work in the plant and we reviewed the complete history of every batch and we decided what could possibly be cleared if any of the work were duplicated, done over again, and whether the drug could be remanufactured. Some, we felt, with additional analyses we could rule out

some variables and these lots could be cleared. Another thing that we had to inform them of was the cost of the rechecking. Under the decree, of course, we were reimbursed for every hour of inspection or analytical time. We had to provide, in effect, what any good management consultant firm does, namely hard data, cost data. After going over with the firm everything that had to be done, they calculated what it would cost them to do it and we calculated what it would cost us to audit and verify this. They put the whole thing together and decided whether it was marketable, salvagable from a strictly financial standpoint or not. They did this for each and every lot. Some lots were simply destroyed because of cost, others were put through this process and we gradually worked through it.

We also pointed out to the firms that there were many management things that should have been done long before they got into the mess, how they could of headed this off. During these discussions, we pointed out all of these things. What the consequences are if you do something wrong financially, as well as legally, and what it costs to do something right. And we had in that experience, evolved some pretty good general principles. Oh, incidentially the firm, every Friday afternoon, had a separate top level decision whether or not to fold the firm immediately or to go for another week. They took all of these individual costs and went from week to week, finally

managing to liquidate this inventory. The net effect, they had two products that had NDA's and were trademarked products that were marketable. They finally took and sold those as assets to another firm and folded the rest of the operation, ultimately after they had salvaged what they could.

Well, when we went into this intensified drug inspection, one of the parts of the program that all the districts did, was to sit down with top management and tell them what we were going to do. Let them perform in the best way they could and then observe them to see if they could meet the requirements of the GMP's. We went beyond that and we suggested to the firms, every one of them, that they draw up some standard operating procedures from a managerial standpoint. How they would go about doing these, what kind of internal controls there would be, what their own internal standards were to to take care of these matters, how they would deal with expected emergencies and shortcomings, how they would back them up, and how they would go about meeting the GMP requirements. We then offered to review the material they drafted and offered constructive suggestions whether we thought it would or would not work in meeting their problems.

Well, of course, some of the larger firms do have operating procedures, that go part way along these lines. But what we did was pose certain questions to them. Supposing during the course of an activity one of your audit units or labora-

tory backups was inoperative, would you continue to operate, would you send things out, what would you do under circumstances like that? Well, these are the kinds of things which had, in the past, led to problems in the plant that should be covered with the operating procedures. We found an addition that we made during the course of our I.D.I.P. inspections. Many of the firms that pack under sterile conditions, or near sterile conditions, operate clean room type of operations under very carefully controlled conditions with change rooms, air locks, sensing units to detect the levels of possible contamination. But then during the course of one of these they had a telephone problem, telephone repairmen went right through their whole system. Nobody had any instruction of how to deal with the telephone man because they always assumed that he would be caught at the front door. Contaminated batches were produced and had to be destroyed. These are the kind of unexpected occurrences, outside service people come walking unannounced, do not understand what a clean room is, and just simply barge in. We found too that in this particular firm they didn't halt things soon enough and didn't limit the damage to ongoing production. As a result they had to destroy far more than they would of had to, and decontaminate again.

Well we pointed out as we continued in the program, these kinds of things, the kinds of situations that can and do

occur, perhaps not very often. Mostly who had the responsibility for doing certain kinds of things and what would happen if he's not there or if there is some change. During the course of our activities, at least 50% of the firms took us up on our offer and drew up some elaborate detailed procedures for their people. And even the balance of them made some improvements in their existing instructions.

In Philadelphia probably the most successful part of our I.D.I.P. program, 8 firms following our intensive inspection voluntarily decided to discontinue manufacture and to operate simply as distributors of products made by other firms, who could then bear the responsibility of meeting the manufacturing requirements. A number of the firms made some very significant and constructive changes. We did find, by remaining in the plant for protracted periods of time, that we were able to detect the kind of things that you are not likely to see during the limited inspection that we usually make. I think this telephone man walking through the system was one of those. We had been in the plant on and off for a period of 3 months before this ocurred and were not aware that the firm... this was one of the largest manufacturers in the country... that they did have some kind of vulnerability.

Another aspect of the problems on the quality assurance of drugs: the Good Manufacturing Practices had a lot of language that was open to interpretation. And one of the serious

problems that we had was to agree in advance how serious an infraction had to be, or how many moderate to serious infractions had to occur, before we would institute legal action.

FLL: You're speaking of a...

IBB: Guidelines for enforcement of the GMP's.

FLL: These are the regulations that resulted from the 1962 Kefauver-Harris Amendments.

IBB: That's right. That is written in the statute. The failure to manufacture drugs under conditions of good manufacturing practice, legally defined the drug as adulterated. Having gone through the drawn out administrative process of publishing proposals, getting comments and finally adopting these regulations, we were faced with the problem of enforcing them. There was a great diversity of opinion from headquarters and the field as to how this should be done.

I served for a time, on a committee, and we spent many months drawing up a system that was based on examples of what constituted significant deviations. One of the first arguments that came up, was about, "Is anything an insignificant deviation?", and we were of the opinion that is not true. If it were insignificant, then the regulation probably should be amended because it was only supposed to include by its definition those matters which are of significance. It's very hard, you know, standing off and looking at this, to draw up things in language that will cover all situations because

there are large firms and small firms and limited operations, even one man operations, producing prescription drugs. I think that has pretty much disappeared, since we have this requirement for double checking. But the costs of instituting systems, that really meet the GMP regulations, really rules out small firms because there is a certain size that you must attain in terms of volume of operations before you literally can afford to do the kind of things that the law contemplates. This was the basis for these 8 firms in the Philadelphia area to cease operations. We were able to convince them that their scale was not large enough to meet this requirement.

We had people from headquarters, myself, from the field, people with legal training, trying to set-up an example of classifying some very serious activities. If it happened only once that would be a basis, in terms on the effect of the nation's health. We did draft something and it was adopted at one time but not fully implemented because after a period of years we changed General Counsels. And it would seem every new General Counsel expresses some dissatisfaction over guidelines for enforcing the drug GMP regulations.

We did some other things in quality assurance in drugs, in Philadelphia, in those days. One of our Commissioners had come out with the statement that established the first absolute goal in terms of marketed prescription drugs and had approved the position that there should not be more than 1%

defective drugs, prescription drugs on the market. Well, without arguing the validity of that 1% figure, it seems that thereafter, the Philadelphia District was the only District that, in good faith, attempted to find out what the defect rate was and how to go about changing it. Our first step was to convince the commissioner that when he said 1% it was in terms of batches, 1% of the batches. We then compiled every bit of available data on every batch of our district's manufacturers, through a centralized sampling system that was in effect, supplemented by our own sampling, by any work that any other district had done in terms of any of our products that were being tested for whatever reason. We eliminated any duplicate analyses of the same batch, which sometimes ocurred through headquarters sampling.

At the beginning of the I.D.I.P. Program we determined that, in the Philadelphia District, there was about a 2.6% of the batches being marketed were defective for one reason or another. Some of the reasons were more serious than others. Some involved dissolution problems and others involved potency of serious drugs. At the end of the period we kept careful track. We had reduced the number of defective batches by 45% through our I.D.I.P. activities.

I believe we were the only district that compiled data of that kind. I think, in retrospect, there was a failure by the agency to adequately evaluate this program. A number of

people were happy to see it discontinued because of the very heavy drain on our personnel. On the other hand, I don't think they ever knew what the true benefits of the program were because it should have had a more extensive cost-benefit analysis when it was through.

We did one other thing in Philadelphia, that was unique, throughout the country. Some years before we had...in more recent years we have taken on the examination of drugs for the military and we have set up a profile system whereby we collect extensive data on every firm and it is used as a profile to determine whether or not they are acceptable bidders in government procurement.

At an earlier date, together with Les McMillin, at the request of the Deputy Commissioner I had developed a program for establishing the track record of drug manufacturers. It was literally the fore-runner of this later effort that we made. One of the questions that I had raised was that anytime that we had evaluated drug manufacturers, in a fashion, if we were going to do it in a meaningful quantitative fashion, and assign ratings of any kind, that we had better be sure that we ascertained the qualifications of the people who were doing the drug inspections. This was implicit in the I.D.I.P program, too. I was successful in persuading Commissioner Ley, although I had started it earlier with Commissioner Goddard, that the agency should adopt its own method of qualifying

people in the quality assurance field. I had pointed out that in the business world they had the Masters of Business Administration, the MBA program, that was very successful. In the health field they had the Master of Public Health degree program. The agency should have a Masters in Drug Quality Assurance Program. Our own training people had evaluated this request and decided that it just couldn't be done. However, we had at Philadelphia District a very competent science advisor, Dr. Murray Tuckerman, from Temple University. I brought the problem back to him to discuss it and he said, "Sure we are already doing it for the Environmental Health People." After I had outlined what we had in mind, he put together a proposal for a multi-disciplinary program involving the Schools of Pharmacy and Medicine, Business and Mathematics, to develop a program for a mathematical statisical quality assurance approach for the manufacture of pharmaceutical drugs.

I was allowed to put two people through a one year course and we allowed an industry applicant also to take the course. It was turned down originally on the basis that we would have an insufficient number of qualified people to enter the Masters level. Well, I had twenty qualified applicants, all of whom were ready to go. Two people completed this year-long course. One of them went on and was transferred to headquarters, at the EDRO (Executive Director of Regional Operations)

office, and set up a quality assurance unit within EDRO that has continued to function in this fashion. Unfortunately, for funding or other reasons they did not continue with additional courses, but had they done this I think we would have been better qualified to continue. I think if we would have at least one such individual from each of the Districts that had significant drug manufacturing, I think we would have had some significantly better performance and much more reliable profiles for what we were using today.

FLL: That was Cal Loucks?

IBB: Cal Loucks, yes. He holds...he's one of three people in the world that has a Masters in Pharmaceutical Quality Assurance.

FLL: The university did not continue the program?

IBB: No, not on their own.

FLL: Not on their own.

IBB: In evaluating the success of the I.D.I.P. Program, we felt that it was very successful in Philadelphia based on examining the output. After all the drugs themselves are what the patient consumes, not the good intentions or the bad intentions of the firm. Firms with poor intentions can sometimes still put out drugs with integrity.

A very interesting side-light on all of this: in our dealings with the drug manufacturers in the area I think we were somewhat more open than they were in other areas. We had

always tried to sell them on the idea that adherance to the Food and Drug requirements were just plain good business for the firm. I know that all of the major Quality Assurance Directors, some of whom are vice presidents in some of the drug firms, are graded and their salary is determined by their record or lack of a record in drug recalls. That I learned in our discussions from them. I also learned in our off-hand discussions of the magnitude of some of the errors that they themselves have found, before drugs left the plant, one of the most carefully guarded figures that QA people have in the industry.

It was very interesting that during the same period of time, the major drug firms in the Delaware Valley led the financial community in successful return on invested capitol. At that time the drug industry was one of the highest profit industries in the country and of all the drug manufacturers, those in the Delaware area led those in New York in the other significant areas. And that was at a time when we were devoting a great deal of effort and watching them rather closely. And I think they were aware of it, at the time. It would be interesting to get the comments of some years later, now. I know the firms were very apprehensive and I know that following our meetings with the firm there were many other meetings that the industry had themselves. But in this program we told them, frankly, we were out to observe them at their best and

we encouraged them to do their best and to try to remember because sooner or later we knew the program would end, and to try to adhere to it. We thought it made good sense to the company. We thought it was cheaper for them to comply, than to not comply and suffer the consequences and I still believe that.

Now, nationally I don't know. I think, Fred, you and I both know that this program was pursued in different districts with a differing degree of vigor. Some firms did not believe in it as strongly. After all in Philadelphia District we felt that the pharmaceutical manufacturing industry was our major FDC responsibility. Earlier on we were still actively engaged in OTC drug things. It took a lot of time, we had some very serious cases there. Examining all of our workload, this really was our most important workload, our most significant one. Certainly from a public health standpoint, although some years later the mushroom industry changed that around a little with their shortcomings in processing.

It's very hard for me to give a better evaluation of the program. I know it was a worthwhile program. I know in private conversations, with other directors, some were immensely relieved when they could divert their manpower back onto other programs. I did not agree with many of them, in this regard, because some of the programs that they turned their people back on were not as directly related to the health of the

public. They were significant but I think not as significant.

There was an immense amount of reporting to be done too. Time consuming efforts in doing this work. 'We did have very well qualified individuals carrying out the program in the area. We felt that our laboratory scientists got a great lift from going out into the plant and having people listen to their views, which I think is very important. And they contributed a great deal to the program but it was a very costly program, we can't deny that. And I could see in some districts where they had other competing work to do. It was not adequately evaluated by the agency when it was over. When it came time to evaluate it, there was really a new team at headquarters and they wanted to sweep it away. We did have other more pressing medical device work coming up that was important, so I think history will have to...

FLL: When did we officially stop the I.D.I.P. Program, do you remember?

IBB: It only ran for about a 2 year period, including all of the preliminary inspections that were made.

FLL: But I think it did, if nothing else, it provided a great training ground for on-the-job training of young investigators who were coming up. They had an opportunity to work not only with our experienced inspectors but with plant personnel and they gained a great deal of knowledge about drug manufacturing procedures.

From our conversations off the record, I understand that you don't want to talk about your San Francisco experience because it has been so recent, no opportunity yet to put it into perspective.

One of the things that we've been doing in these recordings, Irv, is to ask each of the persons we interviewed to talk about individuals, Commissioners and others who played the important role in the management of the agency over the years. Descriptions of their relations with such officials, what things that they noted that would give an idea of what kind of man each of these commissioners was, what his personality was, how he managed the agency, how he came across to you when you knew him and anything else that would shed light on the character of all the Commissioners you have seen. Could you start off some of the earlier Commissioners in your time and describe them?

IBB: Well, the first Commissioner that I met in person was Dr. Dunbar. Dr. Dunbar had come out to the west coast and I was Chief Inspector in Los Angeles, at the time. Dr. Dunbar is not a very tall individual, in fact not much taller than I am, and I still remember that he had addressed the group and then he came over and we met personally. He draped his arm around my shoulder and said, "You know, one thing I want you to remember. You don't have to be very tall to become Commissioner of this agency." And I guess I've always liked him

for that. I didn't have too much to do with him thereafter except through channels.

I do remember when Mr. Crawford came through on a similar visit. He was here, it was I believe on a Friday, and was going to be here over the weekend and we had been getting a lot of reports about injuries from Chloromycetin brand of chloramphenicol. He was around with a group of some of the district's leadership there. He surprised me and I think some of the others by openly informing us that the following Monday he was going to order the nationwide recall of Chloromycetin, that he'd be giving more information on that. Of course you understand that this is a matter that could and did have a very serious adverse effect on the price of this firm's stock. This is the kind of insiders information that generally is very closely guarded. I was greatly impressed with the fact that he trusted everybody in that room and I think he knew that we knew what these implications were, and yet he was perfectly willing to tell it. It is all within the family, of course, within Food and Drug. I thereafter viewed him with, I think, a great deal more respect than I perhaps would have otherwise because of this trust that he had in the people in the agency. I knew, of course, that he had played a very active role in the drafting of the law which had led to our recruitment. Because, Fred, as you know, you and I were the ones, that first big group, that were hired to enforce this

new act of 1938. So he was very directly involved in our coming with the agency. But even that fact and at other times I found those early Commissioners were very frank and open people and they trusted other Food and Druggers. It was something that I think I valued very highly, at the time.

I didn't know George Larrick very well before he came out to the west coast. But he also came out once and was in the office on a Friday. I don't know why, maybe L.A. was at the end of his trip, and for some reason he had some business in the area and had the weekend open, that he was free on a Saturday. In discussing matters with him, I learned that he was a gentleman farmer and was actually a real farmer on weekends, I believe in Virginia. And was very much interested in agricultural matters, generally.

In southern California the county fair is a tremendous operation, much larger than most state fairs, and has a wide variety of agricultural exhibits. And when I found that he was interested, I suggested and he promptly accepted an offer to go out and spend the day at the fair. And since I knew he wasn't from the area, I had a friend who had a convertible and I borrowed my friend's convertible and we put the top down and we spent the day in true California style driving out forty or fifty miles to the fair. We started early and spent a very lengthy day and I was really impressed with his knowledge of agricultural matters. We went through all the exhibits,

looked at all of them. Spent a very delightful day. I'm sure he enjoyed it, because on a number of occasions, thereafter, when the burdens of office became heavy he would come up to me and say, "I'd much rather be spending the day out at the L.A. County Fair." Other than that I didn't get to know him very well, excepting through our usual contact at conferences and the like. I found him to be a wonderful, delightful individual, off away from the job.

All the agency had a very marked change when the first outsider came in to be Commissioner. Outsider even though he came from the Public Health Service, which we later became a part of. When Jim Goddard came in to become Commissioner, it was a great shock to the agency. I don't know how it was at headquarters at the time. I'm sure it was even greater than it was to some of us out at the field, who were much more remote from it. Since his departure a lot of diverse views emerged on his outlook, his activities, his effectiveness. I found it a very interesting and challenging experience.

In those days all of our districts came together for planning conferences and each brought our plans together. I believe that was the first time I met him in connection with that or a similar conference, when he met with us. Both he and the public affairs officer, Ted Cron, had a somewhat different sense of humor than I think many of the Food and Drug people were accustomed to. And for some reason, I decided

in our planning conference, to adopt a little note of levity, I know those things get very dry. I had flashed on the screen before the Philadelphia presentation, I think, a humorous takeoff on Marat-Sade which was then playing on Broadway and quite popular. I knew that both he and Ted Cron were very much interested in the theatre, so I had made that slide. I found that they found it to be quite funny and I'm shocked to say that there were some district directors present that didn't even understand what it was all about. Also during the course of the presentation, besides the standard one, I had presented a different way of analyzing our activities by producing some drafts in terms of what I thought the effect would be of increased or decreased resources on different project. In other words what leverage was available to it, which he found an interesting concept. Following the conference he directed all of the participants to go back and revise their plans in accordance with the way that Philadelphia District had done. Well, knowing all of the work that had gone into these plans, I know that wasn't very popular. I can imagine what some of them thought of me, at the time, for having brought it up. But they didn't say too much.

One interesting thing was that during the course of this meeting, in which the Commissioner had sat with us, the entire time which was somewhat unusual for us. I guess Dr. Goddard decided that either he could trust me, or maybe I was one of

his kind of people, or something but he was sitting over at the side of the room while the conference was in progress. He called me over and he asked me very frankly to evaluate his performance and to tell me frankly if he was doing things right, with this group, which after all were a group of strangers to him. What I thought he might change or what I thought might be done differently. Well, to a fairly recently appointed District Director, this was quite a change to me to be asked for this kind of evaluation. I might say that later he didn't hesitate to pick up the phone and ask me similar questions. I'm happy to say, he did this with a number of others too, not limited to me. I know that he was much more direct in his activities in contacting individuals and cutting across agency lines to get the opinion of people who were closer to some of the problems at hand.

FLL: Of course he had elevated field managers to his direct supervision, at least in theory, which was a total change from what had existed for years before.

IBB: That's right. He had one individual, Harris Kenyon, as a liaison person to assist him in this task but he directed the field.

FLL: Actually he didn't even have that position until we urged him to establish it.

IBB: Well, that was kind of burdensome. He had some concepts that were totally different and he brought in some additional

people that looked at matters from completely different perspectives. I know he felt that the agency had become too inbred. Although he never expressed any objections to people rising from the bottom up to being commissioner, he did think that certain staff people ought to be brought in to broaden the perspective.

He brought in a planner to one of our planning meetings, that shared some of these views and really surprised a lot of the directors when he pursued such views as, frankly putting a dollar tag on a death and dealing with danger to health he said, "It all could be priced out death, injuries, suffering." And when he was faced with the ensuing consternation, he backed it up I think quite well by pointing out that this was going on every day in the courts of the land, where judgments, damages were being made, other kinds of things were being priced out on that basis. We had always held a view that you could never put a price on a death. He helped bring across, even though he was very unpopular, the concept of costs to benefits. I don't think the agency was in gear with the thinking of the times. I think we had fallen behind in a number of areas. And unpopular, though it was, I think it had some lasting effects. Especially today, without this kind of consideration, I think the agency would be lost. I don't think it could continue to function because of the very, very stiff competition for funds. I think it forced the agency to

do some better planning in a lot of different directions. Most of the agency people were very happy to see Ed Tuerck leave, I wasn't. I disagreed with him violently on many occasions but, nevertheless, I think it was kind of a healthy thing to bring in differing points of view.

Ted Cron was a master showman. I have heard the story repeated many times that President Johnson became jealous of Dr. Goddard, because Ted Cron had been so successful in getting Dr. Goddard's picture on the front page of a leading magazine and the President felt that he was being upstaged a little and I think there's some truth in it. I think some of Dr. Goddard's problems, later on, were a direct result of the fact that he had such a good press. Maybe not from the agency standpoint, I'm thinking about from the in the country in outside considerations.

I found Dr. Goddard very easy to get along with. I don't know why. We seem to think along similar lines. I knew even then that many, particularly the older old time food and drug people, were having extreme difficulty in following his reasoning in matters and agreeing with him, and just longed for his departure. I think history again will have to judge his effectiveness. I've met with him personally after his departure from the agency. We have discussed some of the reasons for some of the things that he did. They make good sense, when he tells them. He's frank to admit, that in retrospect,

he would do some things differently, not many,. He came to the agency with the understanding that he would not be there permanently, until his death or retirement, which was something new to Food and Drug. And I think he was just an example, of what was to follow for many years to come. Agency heads that will be around for 2 to 4 years, do what they can and move on, either willingly or unwillingly. And I think he helped break the ground and I think he helped prepare the agency for that point of view. Bringing in some of his own key staff, that would leave with him with others to follow. I think this is a practice that is more general among agencies.

Food and Drug had a long long history of people promoted entirely from within and I think it lacked some of this outlook. I always felt the agency was somewhat parochial in it's attitude in its earlier days and not well enough equipped to face the outside.

One of the early things that I had done both in Philadelphia and later when I came here to San Francisco, was to subscribe to other journals, such as Business Week. Early on we had subscribed to the Wall Street Journal. Other things, not strictly trade journals, to get a wider point of view. Following one visit, Dr. Goddard directed all of our districts to subscribe to the Wall Street Journal to find out what's going on and to try to understand the business community and its problems.

I think one of the greatest contributions he made was in trying to get the agency to open up more in its outlook. A lot of things that he did were unpopular. Still today, talking with a number of former directors, district and regional directors, they speak harshly of the Goddard times. But he fought an internal battle. I think he fought for us within the department. Because of his extensive public appearances he got some things done that others couldn't have done. But of course when an individual of a strong personality leaves, it's a great shock to an agency when he's replaced.

We went through a brief intermediary period, Dr. Ley. Through sources outside of the agency, I was aware that Dr. Ley was never to be kept on by the administration. I don't believe he knew it at the time.

I had been asked by some of these outside parties to make some recommendations and to comment on prospective candidates for the position of Commissioner, which I declined to do, since I knew I would be serving under them later on.

Thereafter came Dr. Edwards, I had very little contact with him, other than through our headquarters activities. By that time there was a considerable gulf between the Commissioner and the Field Management, the intervening units and the development of the intra-organization at headquarters and such. We were further removed from the Commissioners that followed.

FLL: When Goddard came in, it seemed to me that many of the whirlwind decisions, he made in his first few months in office, that did enable Ted Cron to publicize him so effectively, were really decisions that had been sitting around waiting to be made on subjects that had been staffed out and had not been implemented for a period of a year or two.

IBB: Well, I think that's undoubtly true. But one of the things that he understood, his responsibility in coming to the agency was to get some of these things moving. And certainly all of his decisions were based on staff work of other people, the head of all agencies operates in that fashion. Whether you can fault him for taking the credit for this, or how much credit he should get for getting things done that were floundering, and maybe would might not never come to light, that is a judgmental decision. It is true, but he did make a lot of decisions, particularly those relating to the drug area.

FLL: I was curious whether your impression was the same as mine, that there were these things waiting to be decided and he did in fact decide them.

IBB: Well, I didn't dwell too much on that. He told me that knowing he wasn't going to be there for an indefinite period of time, he had been counseled to get in and make decisions, even though they were hard decisions or not. To make them, just to go ahead and reach a decision and do it. He was greatly concerned about the length of time in the decision

making process. He and the Commissioners to follow, all had to grapple with the long time it takes to approve a new drug application. I don't think he radically changed that process, there were other decisions and regulations that he believed in.

FLL: Well he did make the decision, very fundamental decision in starting the DESI review. That had totally floundered and nothing was being done to handle that backlog of NDA's that antedated the 1962 Drug Amendments. I have always thought that one of the other things he did that was good was to institute management training for FDA managers.

IBB: Yes, he insisted that all of us go through the American Management Association training, which is an excellent course.

FLL: My recollection is that we had none of that theoretical management training prior to his coming.

IBB: That's correct. We had some limited courses, but nothing of any substance since then.

He very frankly wanted to shake up the agency and to get it going. He has a very high opinion of the people in the agency, as he's expressed it to me. He felt that they needed some stimulation.

FLL: Do you think that he had some fairly definite instructions to that end?

IBB: I believe so, yes. How high up they came from I don't know, but he was deliberately brought in from the outside.

After all we had a number of capable individuals who could have succeeded George Larrick, from within the agency. In the typical training, the men of considerable experience within the agency I'm sure could have run it in much the same manner that it had been run before. And I think the decision was reached for the agency to make some changes.

FLL: Do you think that any of those candidates could have done the things that were necessary at that particular time?

IBB: I don't think so. Because, one I have always felt that in order to operate successfully in headquarters, in Washington generally, you have to have clout and a constituency to back you up. The Food and Drug people did not have that. Dr. Goddard had at least the Public Health Service which is a rather powerful institution, backing him up fully. And having headed the Communicable Disease Center in Atlanta, he was a fairly high ranking Commissioned Officer in the Public Health Corps. He could call on a lot of people, had a lot of contacts and could operate sucessfully.

I don't think the existing Food and Drug people, although they may have known a few Congressmen in the committies that we worked with, they didn't have any constituency to back them up, to call upon. I think Dr. Goddard worked through the national meetings of the associations, and all, successfully to get some backing for some of the measures that he took. He was, I think, rather effective in testifying before Congress.

Some of our people have been successful and others of our best people have been noticeably ineffective in dealing with the Congress.

FLL: Which it probably depends on the chairman of the Congressional Committee, as much as it does on our representatives who are testifying.

IBB: That's true. In more recent times we had two Commissioners that came from the San Francisco area, that provided me with a somewhat interesting opportunity. Don Kennedy was a high ranking member of the Stanford faculty when he was appointed Commissioner. We jointly concluded, Dr. Kennedy, Bill Hill and I, that it would be advantageous for Dr. Kennedy to come into the Regional and District offices for a briefing prior to his being sworn in Rockville.

Dr. Kennedy came in and spent the day with us. We had a wide ranging open discussion on the agency and its role and the relationship of the field to headquarters, during which Dr. Kennedy brought up many of the anti-FDA comments that he had heard over the years, from his associates in academia. We gave him, I believe, some rational explanations of how the agency had dealt with some of the issues. I believe the discussion was very helpful. We tried to point out to him some of the pitfalls that the Commissioners were likely to face. Some of the political climate at headquarters and some of the

successes and failures of his predecessors. All in all it was a very frank and open discussion. He raised many questions and members of the staff who sat in provided, I believe, some very valid comments. Later on after he took office and I had occasions to meet with him formally at headquarters, he told me that he was amazed at how many of the predictions that we had made had come to pass, including some of the difficulties that he would be facing as well as some of the opportunities that he would have. He said that he found that it had been very desirable for a Commissioner to know what FDA life was like from the standpoint of people in the field and to understand that several of us had spent a lot of time in headquarters, either having been stationed there, as both Jim Nakada and Bill Hill had been, and as well as others had spent a lot of time on detail there.

Interestingly enough the experience was repeated when Dr. Goyan, who had headed the Pharmacy School at the University of California, was appointed to succeed him. We, in essence, gave a repeat performance and I found Dr. Goyan to be very open and appreciative of the opportunity to learn more about the agency.

I found that Dr. Goyan, being in the School of Pharmacy, had previous knowledge and contacts concerning the agency were somewhat more factual than Dr. Kennedy's. Dr. Kennedy had participated in a task force that dealt with EPA on pesticide

matters, and was fairly well versed on that aspect of it. But he had heard mainly a lot of the critical comments, far more so than Dr. Goyan had. Dr. Goyan was a great supporter of drug quality assurance and was well versed in our requirements and so it was considerably easier in dealing with him.

I did have a humorous experience... Preparing for Dr. Goyan's appointment, headquarters unit had prepared some detailed briefing books to be delivered to him so that he could review most of the pressing decision matters that were awaiting his attention in headquarters. To meet time deadlines, they had air freighted the material out and I arranged to meet the air freight shortly before midnight, out at the airport. When I arrived at a distant terminal, in the wee small hours, the plane was an hour or two late. The area was essentially deserted. I picked up the carton of material and placed it in my trunk and was slowly leaving the airport compound when I was pulled over to the curb with flashing lights. Two officers apprehended me and began questioning me. It turns out they were customs investigators and it soon became apparent that I had walked into the midst of a stakeout at the airport for pilferage from interstate packages coming in from overseas. Fortunately I had the bill of lading for the shipment with me and I pointed out that these packages were clearly marked as going to the next Food and Drug Commissioner. They seemed quite embarassed, all around.

Dr. Goyan, in his frequent visits back to San Francisco delivered a lot of papers out here, also expressed appreciation for the opportunity to get a briefing from the field point of view. And our relationships with both him and Dr. Kennedy were also excellent. I had a high opinion of both individuals and regret that they couldn't of stayed longer with the agency.

I do see Dr. Kennedy occasionally. He's gone on to become the President of Stanford University. He is highly regarded in his field and has taken the leadership in the question of the safety of gene-splicing operations. As you know, there was a first conference at Asilomar, early on, among the manufactures to determine the level of safety precautions that must be taken. He has continued these discussions from the safety standpoint, on into the commercial aspects of University researchers, being closely tied in with what everybody believes will be the next multi-million dollar corporations in the drug field.

FLL: Irv, I really appreciate your taking the time for this interview. The information that you've provided, much of it has not appeared in previous interviews and I'm certain will be a valuable contribution to the project. Thank you very much.

IBB: Thank You.