

HISTORY OF THE FOOD AND DRUG ADMINISTRATION

**Interview between:
Morris Yakowitz, Retired
Director, Division of Case Guidance
and
Robert G. Porter
Tucson, Arizona
April 19, 1979**

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter, who retired from the U. S. Food and Drug Administration in 1977.

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

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



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1 & 2

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

DATE: 4/19/79 PLACE: Tucson, Arizona LENGTH: (Tape #1 - 39 Min)

INTERVIEWEE

INTERVIEWER

NAME: Morris Yakowitz

NAME: Robert G. Porter

ADDRESS: [REDACTED]

ADDRESS: U.S. Food & Drug Administration

Denver, Colorado

FDA SERVICE DATES: FROM 1937 TO 1966 RETIRED? Yes

TITLE: Director, Division of Case Guidance
(If retired, title of last FDA position)

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Attachment: Previously recorded statement by Mr. Yakowitz covering highlights of his career. Among subjects discussed were Elgar O. Eaton, drug chemist, the 1938 FD&C Act, Elixir of Sulfanilimide investigation, Dr. Henry Welch, Abbott large volume parenterals recall, and the Allerjoy Case.

P. - The date is April 19, 1979. This recording is being made in [REDACTED] at the home of Morris Yakowitz. Morris was employed by Food and Drug Administration in 1931 as an analyst in San Francisco and he finished his career and retired in 1966. Is that correct?

Y. - That's correct.

P. - What was your title at the time you retired?

Y. - I've forgotten. It was the head of one of the divisions that had to do with regulatory matters. I've forgotten the exact title of the division.

P. - It doesn't make any difference, but it was in DRM or one of those.

Y. - Yes, I came to Washington in 1948 to work in the administrative offices of FDA at the Washington Headquarters.

P. - First I want to thank you for the tape recording that you've already furnished me Morris with the history of your career and with a number of interesting comments about cases and events during that period. But right now I understand you're interested in a current matter, or that you're involved in a matter. It would be interesting to all of us.

Y. - Perhaps so. From about 1948 to 1966, I was working

at the Washington Headquarters of FDA, usually in an administrative capacity. During much of that time I was responsible for signing out letters to the drug industry responding to inquiries that the drug industry might make of FDA. Thus, in about 1954 the Ciba Geige Company sent a letter to FDA asking if FDA would agree to the over-the-counter sale of a product known as Vioform, intended for treating dysentery. After consulting with the Bureau of Medicine physicians, I signed out a letter to the company stating that we would agree to the over-the-counter sale of the drug at that time. However, our medical officers became concerned over the possibility that Vioform may cause adverse effects, and at their request in 1960 I signed out a new letter to Ciba recommended that Vioform no longer be sold over-the-counter but that it be restricted to sales by prescription only. The firm agreed to this and from 1961 on Vioform was not available in the United States except on prescription. The picture in Japan was quite different. There the product was allowed to be sold over-the-counter and during the period 1960 to 1970 many cases of a condition known as SMON occurred. SMON

is the acronym for sub-acute myelo-optic neuropathy a paralytic condition which manifested itself by paralysis of the legs and injury to the optic nerves. During the period 1960 to 1970 there occurred perhaps up to 10,000 cases of SMON of varying severity in Japan. I should add, that for a long time no one was able to identify the cause of the SMON condition. But in about 1970 some physicians noted that some of the SMON patients had a sediment in the urine which, upon examination, turned out to be crystals of Vioform. This led to the theory that Vioform had caused the SMON tragedy in Japan.

From about September 1970 on, the Japanese Government forbid the further sale of Vioform in their country and SMON cases stopped appearing. The drug has not been sold in the U.S. since 1971, even though it may be legally be sold ~~perhaps without~~ **on** prescription. The fact is that the company decided not to sell it anymore in the U.S. And as I've indicated they could no longer sell it legally in Japan. I must add that the patients who suffered from the condition had banded together in Japan to sue the various drug companies that sold the Vioform

in Japan. However, a number of the drug companies involved in the sale of the Vioform have refused to admit that the drug has been responsible for the SMON condition and they say other possibilities such as perhaps a viral infection may explain the SMON condition. Thus, a question is still in the minds of some physicians as to whether or not Vioform actually causes the SMON condition.

The lawyers representing the SMON plaintiffs learned of the exchange of correspondence between FDA and Ciba back in 1954 and 1960 and came to me to ask for some further explanation of the content of the letters. I was able to direct them to Dr. Dennis J. McGrath in Washington, who had been a member of the Bureau of Medicine at the time we wrote the 1954 and 1960 letters to Ciba. The lawyers were able to get from Dr. McGrath the background information regarding FDA's medical concern over the possibility of adverse effects from Vioform.

Dr. McGrath and I have been invited to attend a meeting in Japan to consider the general subject (which we held in Kyoto, Japan) under the title of the "Kyoto International Conference Against Drug Induced Sufferings". The topic of the SMON condition

attributed to Vioform will be discussed. However, my role in the meeting will not be to discuss SMON at all but, merely to talk about the support that the World Health Organization has given to drug control in Latin America. It's a general topic and as I've indicated is not directly connected with the SMON situation.

P. - Why don't you tell us something about what you did in the World Health Organization where you were active after your retirement from Food and Drug and some experience with--what drug firm

Y. - Smith, Kline and French. Very well.

P. - I think that would be interesting.

Y. - Very good. When I retired from FDA in August of 1966, for a while I was unemployed, but in the latter part of 1966, I was invited by the drug firm of Smith, Kline, and French of Philadelphia, Pennsylvania to join them as advisor on drug control matters. I worked with Smith, Kline, and French from September of 1966 to the end of 1967. At that time I joined the American Regional Office of the World Health Organization with sub-head-quarters at Washington, D.C. I worked for the American regional office of WHO from 1968 until August of 1975, at

which time I retired and now am completely retired from the drug field.

While I worked with the World Health Organization my job was to visit the Latin American countries to inspect their drug control agencies and to make recommendations for improving their procedures and their organization. This was a very interesting field and although it's difficult to say that a great deal of positive results occurred, I nevertheless feel that some ideas that were brought by me from FDA to the Latin American governments were very helpful to them.

P. - Did you go to almost all of the countries in South America?

Y. - Yes I did. I visited the capitols of almost all of the South American countries including Mexico and down to Argentina and Chile. In general they suffer from lack of funds. That was their big problem. Salaries of the government officials in Latin America are generally low. Many men are unable to maintain a family on the basis of a government salary and therefore, they either avoid working for the government, or if they do work for the government, they take a second and even a third job in order to eke out a

sufficient income.

P. - They couldn't attract people with the right education then either?

Y. - Well, in some cases they do, but generally speaking most of the analysts are women, a fact which speaks for itself because the women apparently are content with the lower salaries. And that is why, in my opinion, most of the analysts in the Latin American Food and Drug Administrations are feminine.

P. - It's almost like it is here in this country that the women get paid less than the men, don't they?

Y. - Probably. Or at least they are content to accept a lower salary than the men. I think that's perhaps the explanation.

P. - Down there that's true. I'm not sure that's true in this country.

Y. - I don't know. It's very interesting to make the comparison, but I'm sure it would show that in general the salaries for either men or women of the people who work for the Latin American governments are quite low.

P. - Tell me, let's go back to your days in Food and Drug a little bit. Which Commissioners did you know personally the best?

Y. - Well, I first met Dr. Dunbar as the Commissioner. He was succeeded by Charles Crawford. I knew Mr. Crawford. He was succeeded by Larrick and then he was succeeded, as I've indicated in the other tape, by Dr. Goddard.

P. - Are there any sort of personal things that happened in regard to Dr. Dunbar that you remember? While you're thinking of that I can tell you a story of my own that I always think of in regard to Dunbar. About the time he, or just before he became Commissioner, I had sampled some peanut butter up in Idaho Falls, Idaho. And the only thing wrong with it was--and we seized it for short weight. The U.S. Attorney up there and this was during the war and the U.S. Attorney hadn't gotten the word that when you had a seized material to dispose of during the war, if it had fat in it, well, you saw to it that the fat was recovered, because as you may recall, housewives were saving their fat and selling it for a penny a pound back to the butchers so that it would go back into national defense channels. So this peanut butter was destroyed. Just at the time this was picked up by the United Press, this story, Dr. Dunbar was made Commissioner. And some reporters actually

caught him on the train between New York and Washington and asked him about this. . The article that appeared around the country from United Press sources was that Dr. Dunbar had said he guessed his agent out there in Idaho had goofed. Well, I was his agent out there. I had never met him. I was a young Inspector at that time. Later he and Larrick made a trip and you might recall that--well you were in the Army at that time--but Mary Vee will recall that I think the summer after Dunbar became Commissioner, he and Larrick made a trip all the way across the country. It just happened that they weekended in Salt Lake so that they spent the whole day there when normally they might not have spent that long. When they arrived and they got off the train, everybody traveled by train pretty much in those days, the first thing Dunbar said when he was introduced to me is he said, "I'm glad to meet you. The first thing I want to say to you is that I want to apologize for the way I was quoted by the United Press about the peanut butter matter. He said I was misquoted. I did not say that. I would never say that about one of my men, whether I knew him or not." Now he had that on his mind about me and he had never met me

before.

Y. - That's typical of Dr. Dunbar. He was a very gentlemanly type.

P. - I thought maybe you'd had some experiences that--

Mary Vee - Mentioning that you worked for WHO. I was thinking that Mr. Larrick was the consultant for them ahead of you.

Y. - That's true, after he retired from FDA.

Mary Vee - That should be put in.

P. - What was that? I didn't quite hear---

Y. - When Commissioner Larrick retired from FDA at the end of 1965, he was given a temporary assignment by the World Health Organization to visit Latin America. This I think occurred about in the middle of 1966. And he turned in a very interesting report concerning the countries that he visited such as Uruguay.

P. - That's all right, the lady we hear in the background is Mary Vee, who's also a Food and Drug employee.

Y. - And then to finish what I said about Commissioner Larrick, he visited Brazil, Argentina, Uruguay and perhaps other Latin American countries. And he turned a very interesting report regarding their Food and Drug testing organizations as they existed at that time. His report was very helpful to me when I

assumed a position with the WHO.

P. - Did he make any recommendations?

Y. - No, he really described what he saw and let it go at that. The problem is--if you write a report that is quite critical, it gets back to the governments and they of course feel quite upset by it . So in a sense - anybody who writes a report regarding another country must exercise a degree of carefulness so that he doesn't overly offend the country that acted as his host when he visited the country.

P. - So then you followed Larrick then in that or a similar job?

Y. - In that sense. But Larrick's appointment was a temporary one, for perhaps about a month and a half. Mine was a permanent appointment and as I indicated I worked for the American regional office of WHO for about 8 years.

Going back to Dr. Dunbar. It's hard for me to think of specific instances but I assure you that everyone revered him as a gentle leader who was very firm in his decisions, but very pleasant in the way he carried out his ideas and the way he made sure that his directives were carried out.

P. - The only thing that might be considered critical of

him that I ever heard was--it had nothing to do with him as a person--I guess everybody liked him. But that when the war started and all the agencies were increasing in size so much, I had heard the story that Dunbar had said that he didn't want Food and

Drug to grow enormously during the war and be cut back later on. And so we tackled the job we had to do with a lot less money and people we might have had otherwise. And then when the war was over I think everybody got cut back including us. I don't know that's just one of those things you hear.

Y. - There may be some truth to that. He was a very careful spender of his own money according to reputation and perhaps that carried over into his spending of the government money. However this is a point in which if Dr. Dunbar was alive and Commissioner now, he might be highly acclaimed for his careful expenditures.

P. - Right. The budget certainly has changed since those years.

Y. - Oh my. As I've indicated earlier this citizen's committee report of about 1955 recommended a 15% increase per year and that's the way it went for at

least 10 years or longer. So that FDA's budget increased greatly from 1955 up to the present time.

P. - Well, then did you know Crawford very well?

Y. - Not very well. He was Commissioner when I was in Washington and I worked in his unit as--In fact for a number of years letter writers such as myself signed themselves out as Assistant to the Commissioner. It was a glorified title, but it did indicate that we were at least fairly close to the Commissioner. Crawford was another of the gentle but very positive types. And as I've indicated in the other tape, when he ran into a budget cut in about 1954, the need to save money by dismissing employees so hurt him, he felt that it showed poor leadership on his part. Nobody could talk him out of that idea. And as a result, he retired. He somehow felt that he had been disgraced by what had happened. A false feeling but nevertheless one that he couldn't shake off.

P. - He didn't live too long after he retired, do you think he might have already been sick and that was something to do with his decision?

Y. - Possibly. It's even possible that he became sick because of his mental perturbation. That's not impossible.

P. - No.

Y. - It is true he lived only for another two or three years after he retired.

P. - How about George Larrick? You must have known him pretty well.

Y. - Very well, yes. George was a very practical minded man. He took into account all of the factors that any reasonable person would in making his decisions and in making his appointments. Unfortunately, he ran into all the troubles that I referred to in the earlier tape of the--He was Comissioner when the Welch affair became bad publicity. He was Commis-sioner when the physician in FDA appeared before a Congressional Committee and criticized the Dr. Jerry Holland who had been appointed as the head of the Bureau of Medicine by Larrick. Larrick had the ut-most faith in Holland and it hurt him when his own people later on claimed that Holland had been a friend of the industry rather than a free and independent member of the Food and Drug Administra-tion.

P. - He had a lot of faith in Welch too, didn't he? At least up until pretty late in the day and maybe always. I don't know that.

- Y. - Well, at the end he was forced to demand as it were, that Welch get out. Welch would have had to resign in any event, but I'm confident that Larrick felt we could no longer stand the bad publicity that was coming out of the Welch investigation. And I'm sure that he invited Henry to leave.
- P. - From a scientific standpoint I guess Welch was probably eminently qualified.
- Y. - Welch was regarded as one of the best scientists that FDA ever had and one of the best administrators that FDA had. His only trouble was that he became apparently friendly with the heads of big drug companies and their incomes were much greater than his. And he perhaps felt that he should be rewarded at the same rate as the presidents of the drug companies. At least that was the feeling that many people expressed at the time. But concerning his capability and his actions, really as a member of the FDA, there was no criticism.
- P. - I guess one of the most traumatic aftermaths of that was the investigation of every Food and Drug employee by a group appointed by the Secretary.
- Y. - It was an attempt to win back public confidence in the integrity of FDA following the bad publicity

about Welch.

P. - I don't know whether it had more effect in winning back public confidence or in hurting morale of the Food and Drug Administration.

Y. - Those were sad times for Larrick because at the same time he suffered from physical ailments that kept him out of the office for long periods and this of course was not helpful at all in the dealing with the bad publicity that emanated from the Welch and the Holland and the Abbott cases.

P. - How about Harvey? You must have known Harvey just about as well as anybody ever knew him.

Y. - Harvey was an interesting personality. He was a very capable person. He was a very capable speaker and he loved to speak. And in fact FDA used him frequently as a principal speaker at banquets and other occasions of that kind because they knew that he had something interesting for the audience to listen to.

P. - Can I tell you kind of a funny story? I think it's funny.

Y. - Go right ahead.

P. - Last summer I went out and interviewed J. Edward Kimlel. Kimlel's about 90 years old now.

Y. - Yes, we hear from him at Christmas time.

P. - Incidentally he looks very well for a man his age. So we were talking like you and I are talking, and I asked him about different people. There might be nothing behind this because he is getting old enough that sometimes for a moment it would slip a little. So when I came around I said well now how about John L. Harvey, because he was describing some of the Commissioners and so on. And he said, "Oh, Harvey was an Inspector". And that's all he said. And I waited for him to say some more. He didn't say anything.

Y. - That's strange.

P. - And in my own way, suspicious way, I guess, I wondered if maybe he and Harvey hadn't gotten along too well or he was jealous of Harvey or, you know, you can attribute all kinds of things that might not be true at all to that kind of a thing.

Y. - Well, perhaps I can make a comment that possibly bears on what you've just said. Wendell Vincent was head of the Western District for a number of years. I've forgotten the year in which he was removed from that position and appointed as head of the Denver District. In order to make room for him at the head of the Denver District, they had to move Kimlel away. Kimlel was the head of the Denver District up until

that time. They moved Kimlel to San Francisco where they gave him a kind of a semi-flunky job. He was not head of anything, but sort of third assistant to District Chief. Now, Harvey was the--after Vincent was displaced as head of the Western District, Harvey had been appointed as head of the District and he was the one who had moved Vincent to Denver and had moved Kimlel from Denver to San Francisco to the District Headquarters. It may well be that Kimlel resented being forced out of the position that he loved, and you know, could shed some honor on him as head of the Denver District to assume a really lower ranking position at San Francisco.

P. - But then he did become actually deputy to Harvey eventually. At least that's what--

Y. - For only a short time.

P. - Is that right?

Y. - When they broke up the Districts in 1948, and moved Harvey to Washington, they also moved Kimlel to Washington and gave him some minor position he resented and didn't like and he retired as soon as he could.

P. - I got that impression too. he made some remark that would indicate that he was not at all happy with

what--

Y. - Very unhappy. He didn't like living in Washington.

He didn't like what they gave him to do. He felt that they were making work for him. I remember that part very well.

P. - Well, it might be then that there was some resentment there, that even after all these years he still feels. Almost everybody I've asked about Harvey says--not everything is great about him, but you know generally speaking you get good comments about Harvey.

Y. - Well, the thing about Jack Harvey and I think most people will agree with me, was something like this: if you were his friend, he was your friend. He was a very loyal person. But if you became a critic of him, no matter how good you were, he might resent that and it might have rebounded against you.

P. - A pretty human sort of--

Y. - Oh sure Harvey was as human as they come.

By the way, coming back to Kimlel, my recollection is that he had a degree in chiropractic and was even licensed to practice chiropractic. Of course he never did practice it, but he could have done it if he wanted to.

P. - I had forgotten that, but I remember having heard that at some time in my life.

Y. - And then remember the interesting story of--what was the name of the Chemist at Denver who had an M.D. degree and was licensed--

P. - That was Chernoff.

Y. - Chernoff, he never practiced medicine, but he could have.

P. - Chernoff is still alive. He's in his nineties.

Y. - Where does he live? Do you know?

P. - In Denver. I haven't been to see him, but I know he's there.

Y. - If you ever run into him, give him my best.

P. - Okay.

Y. - He was a peppery little fellow.

P. - Oh yes. Mildred worked for him.

Y. - Oh did you?

Mildred - I worked for him, yes. When I worked at Denver he was Chief Chemist.

Y. - He was very knowledgeable wasn't he?

Mildred - Yes.

P. - We have reservations about him so--

Y. - Really

P. - Yes. I knew him in two ways. He also played the

violin in the Denver Symphony. I had a brother-in-law in the Denver Symphony and so the story around my family was that as a Chemist he was a good violinist and--

Y. - And as a violinist he was a good chemist.

P. - Well, I guess he was a pretty good violinist, but yes, we did say that sometimes. But I think he resented the fact that he didn't go farther in Food and Drug.

Y. - I'm sure you're right. He was Chief Chemist and that was as high as he ever got.

P. - And another man in Denver in those days was--good chemist was Mr. Feldstein. Remember him?

Y. - I met him once in this famous Diaplex for diabetes case.

P. - There was a true gentleman.

Y. - He was a real gentleman. I remember that, yes.

P. - How about Wendell Vincent? Do you want to talk about some of his troubles?

Y. - Well, I really didn't know them very well. I came to San Francisco in the middle of 1931 and I think Vincent was pretty much removed from his position as head of the District in about perhaps 1935. I don't know what year it was.

- P. - I don't either because he was already in Denver when I came along.
- Y. - Really had very little contact with him. My contacts were with Mr. Eaton, who was my immediate boss. We formed a sort of a small unit in the drug laboratory and only ventured out once in awhile to talk to the rest of the organization. Really and truly.
- P. - When I was there George Smith was the Chief Inspector. I understand George Smith is alive.
- Y. - His wife died. We received a note from him about a year ago.
- P. - Oh well then you know better than I.
- Y. - She had passed away, yes. Smith has an interesting story connected with him. It was said that he--they had to urge him to cash his paychecks. Apparently he had so much money that he didn't bother to deposit the paychecks.
- P. - Oh, is that right?
- Y. - That's what they said. Ask him, now George you've got checks running for six months, get them in because you're ruining our bookkeeping. A very lucky FDA employee.
- P. - He must have been good on the stockmarket or something.

Y. - Something, yes.

P. - Maybe he inherited it. I didn't know him too well.

I worked for him just for those few months. And then I went to Denver. And I never really saw him again.

P. - Well, who were some of the unsung heroes of Food and Drug. You know, we talk about bigshots, but maybe you know some stories--some work that was done. I was going to ask your wife about some of the things she did too. I bet she did some things that--

Y. - Well, the one that I would mention is Lewis McRoberts, who was a Chemist at the San Francisco lab. He was one of the best Chemists that FDA ever had. He was a very thorough, a very careful person and you could trust him with practically any type of examination that was in the chemistry books. Mac's problem was that he was self-effacing and he never, not in my opinion, received the reward he should have had as a member of FDA. He was never promoted as rapidly as his true capabilities warranted. Other people with much lesser qualifications would be jumped over him. But he never complained. Probably if he had complained they would have paid some attention to him. But he was really one of the best Chemists they've ever had.

P. - Do you remember, you might say, precedent setting methodology or anything of that nature?

Y. - Yes, I can think of it. In the determination of Vitamin B₁ which for some reason became a major problem in about the early 1930's. McRoberts was the one Chemist who could be depended upon to run the tests, come up with the right results, and practically everyone else had tried the methods that were proposed by the Vitamin Division ran into trouble, but not McRoberts. He ironed out all the little details that were necessary to be performed and came up always with the best results. As a result the Vitamin Division would send their test methods to McRoberts for trying out rather than to anybody else--

P. - I don't know if that was a good idea or not.

Y. - Well, they got back some good results in the end. Yes they might end up with a method--

P. - That an ordinary guy couldn't run.

Y. - Quite possible, quite possible. But he reminds me in a way of George Daughters. George was in a sense the opposite of McRoberts. He didn't hide his light under a bushel. For a long time he was a Chief Inspector here and Chief Inspector there. And

finally they appointed him as Chief of a District. It came about after a speech he made at the Washington Headquarters when he was describing the work of the Inspectors before a selected audience. And he said now in training a man, here's what you do. And he went through all of the steps. He said always be very careful when you're dealing with him. Be very kind with him because you never can tell when he'll become your District Chief over you. Dunbar was the Commissioner. He got the idea and as soon as they could they appointed Daughters as Chief of one of the--

P. - I don't remember, but he was Chief in Chicago when I was there. But I think he'd been Chief somewhere else first.

Y. - Yes, perhaps Denver or St. Louis or New Orleans. No it couldn't have been New Orleans.

Mildred - Was it Baltimore?

Y. - Yes, I'm pretty sure you're right.

P. - Baltimore, I believe yes. Now let's see we just finished talking about George Daughters and the fact that he first was made Director in Baltimore and then Denver and then eventually Detroit.

Y. - Right.

P. - You know I knew George well and I'm sorry I didn't--
Mildred - Baltimore and then Chicago and then Detroit.

P. - Oh that's right; Baltimore, Chicago and Detroit.

Y. - Let me add a little more about Daughters.

P. - Okay.

Y. - As I traveled through Latin America visiting the various Food and Drug testing laboratories, on occasion I would encounter one or more Chemists and Inspectors from these Latin American Food and Drug Administration who had come to the United States for training in Food and Drug Administration. And those who had been assigned to Detroit invariably glowed with pleasure and pride as they told me how they'd been received by George Daughters. What a great man he was. They were all terribly impressed by him. They would mention other Districts they'd been to and just pass over casually who they had dealt with. But when they came to Detroit and told about how Daughters would glad-hand them and bring them into his family, they positively glowed with pleasure. It made me feel good.

P. - He was quite a character, George.

Y. - He sure was.

P. - Before he came to Chicago I had never met him despite

the fact that we had both worked in Western District and so on. Because of all the stories I was afraid that here was a man that I wouldn't get along with, because of the things I had heard about him. Well, quite the reverse was true. We just got along famously. I never enjoyed working for anybody more than George.

Y. - Well, he was an odd one though in some respects.

P. - Now George had the fault that you mentioned about Harvey, but do I think well, at least certainly had that to a very great degree. If you were one of George's boys, --

Y. - You couldn't do wrong. And if you weren't you couldn't do right.

P. - That's right. In Chicago I was kind of one of his boys and...

Y. - It wasn't difficult to deal with him, but if he became upset with you, you were in trouble with him.

P. - And sometimes for no good reason you know. I always, for instance, as much as I liked George, I always resented the way he treated Jimmy Herring because Herring was his assistant in Chicago. And you knew Herring?

Y. - He worked for me, died while he was in the Division.

P. - Well, then you knew him well. He was an extremely knowledgeable and conscientious person, but kind of an old maid in the sense that he, you know, had to be just sort of just--

Y. - He didn't sparkle. He wasn't spontaneous.

P. - No and the kind of a person George Daughters was was just so opposite, you know, that I didn't think George ever made an effort to realize that he didn't--well you know how you do when you have people working for you, they're all different kinds and you kind of make the best of each. They're all different and you do the best you can with them. And he didn't do that with Jimmy at all. And of course I knew and liked them both.

Y. - You know there's an interesting little story about Herring that I might bring in at this time. He became ill while he was working in one of the divisions that I was connected with. And he finally died of the condition. I can't think of it. It had something to do with muscle---

P. - Oh, myastheniasgravis.

Y. - An interesting thing about Herring is that he diagnosed his own problem long before the physicians did. But he would never volunteer to them what he

thought his symptoms were leading to. They were progressive. His eyelids started drooping and he couldn't open up the eye.

P. - I think he already had that in Chicago.

Y. - Is that so?

P. - Because later after I knew what, you know, what was wrong with him, I recall that he would sit at his desk and you'd think he was almost half a sleep. You didn't know he was working because his eyelids were drooping. I'm sure that those first symptoms were occurring them.

Y. - But I'm sure the story is correct. He would never volunteer this supposition that it was myasthenias-gravis to any of the attending physicians. And it was only later in the day that they tumbled to what he had. But of course the condition is progressive and there isn't a tremendous lot they can do.

P. - There's now some drug that's very promising for that kind--

Y. - They had him out at the clinic in Bethesda National Institutes of Health, but it didn't help very much.

P. - Well, now let's see I interrupted you--

Y. - Yes, what were we going to talk about?

P. - We were talking about Daughters and then there was

somebody else you were going to say something about.

Y. - Oh yes, Gordon Wood. As I recall Gordon was appointed to FDA at San Francisco just about the same time as myself. And we became pretty good friends. About a year after, no when he was going through his probationary period he was involved in an automobile accident with an FDA car. And just because of that they were going to release him at the end of the probationary period. That is I think the people at the District level thought--well, the guy causes problems, we don't want him. But Grant Morton, who was Chief of the San Francisco District, defended for Gordon Wood so vigorously that Harvey decided to keep him on. But Wood was almost dismissed at the end of the probationary period because of the automobile accident.

P. - There was a time in my life when I would have wished that that had happened. I went through a period with Gordon was pretty critical of me and I was unhappy with him. Later we got to be friends again and I had a good interview with him last winter.

Y. - Well, he would get very--He would act too rapidly I think in some situations.

P. - He made judgments--He and Rayfield that was one thing

they had in common, they both could make judgments based on very little evidence about personnel at least. I had a little problem in Denver that Gordon jumped on and made far too much of it. As I look back now I think because I did so many different things in my career and I can look back on it now. I do think that at the time when I was young, I couldn't judge him, but now I do feel that he did not--

Y. - He acted too rapidly.

P. - But Gordon looks very well. He looks just fine. He looks vigorous and I think he's happy.

Y. - Good for him. Going back to his ability to make rapid decisions, I remember that at one of the District Chief's meetings, he was adamantly opposed to FDA's getting into the field of acting against physicians and pharmacists who sold amphetamines illegally. He said that's none of FDA's business. That's for the narcotics people to get after. It doesn't fit into FDA's pattern of operations at all. The very next year lo and behold he's come back arguing exactly the opposite. This was an important thing in the Los Angeles District. "By God we needed more men for this type of activity." I couldn't help

but laugh in his face over his sudden change of attitude.

P. - Well, in his interview with me he was telling about some of those cases and it was obvious that he got personally involved--

Y. - That's what happened.

P. - Became very enthusiastic--

Y. - But when the early days of that type of activity, he was against it. That was not the kind--

P. - You could understand it you know. Most of us really who were trained in a traditional way were against that initially.

Y. - That's right. I think that's so. And it became a separate part of FDA and of course it branched off into the, whatever it's called, DEA or whatever the name of it is. Los Angeles had many interesting cases of that type. There was I remember, involving and M.D. who sold prescriptions for amphetamines and also sold amphetamines directly. His name was Dr. Fakahanie and all of his clients called him Dr. Fake because he wasn't a doctor. He wasn't really a good doctor at all and they knew it but they went to him in order to get amphetamines and barbiturates. And old Gordon was not on his trail, I remember.

P. - He described that case.

Y. - Dr. Fakahanie?

P. - As I remember particularly that we had some problems with spelling in that transcription.

Y. - Yes, his name was a very peculiar one. If you called him old Dr. Fake, that would have been good enough. Yes, there were some interesting episodes but with the passage of years it sort of all gets dulled in the mind.

P. - Yes, it does.

Y. - Hard to recall all of it.

P. - Particularly because you have other interests and it just really fades in the background. In some people, it's very interesting, this work I'm doing. Some people look forward to this interview as an opportunity to say all kinds of things they wanted to say.

Y. - Any critical people?

P. - Not very many, no. I find that there's a great reluctance to be critical. I try to get them to be critical because we want the truth to come out at this late date.

Y. - What is truth? In dealing with people you can't be their friend for 30 years and then say they were a

bunch of--

P. - I know it. But you know everything wasn't good about all these people and some of their traits might just as well be recorded; makes them more human. But you don't get much of that. A few people have, but Mr. Boudreaux is an example. You knew Boudreaux pretty well?

Y. - Fairly well. Now you see he was at a distance. I knew him largely by reputation, Bob. But, I knew him.

P. - Now he's--I don't mean that he's been critical of people. He has not been critical of people, but he wants to get on the record the things he knew and the things he experienced. And after he knew I was coming to interview him, he sat down and he wrote an article on the history of Food and Drug enforcement in New Orleans, and an article of the history of the seafood inspection. And furnished me with those. We gave me quite a few pictures. After the interview he wanted some insertions, some additions. He's very interested in this you know. And gee, he's been away from it a long time too. But he's maintained his interest and of course he still visits the office there probably more than they would want him to. But

he keeps up his interest.

Y. - He must be getting up in years by now.

P. - Yes, he's in his eighties now. He told me, I've forgotten. He's either 83 or 87. I think 83.

P. - Well Morris, if there aren't any other things that maybe you'd like to talk about why, I think we'll just close off this tape. I want to thank you very much for your help today.

ATTACHMENT - PRE-RECORDED STATEMENT BY MORRIS YAKOWITZ

My name is Morris Yakowitz. I was employed by the Food and Drug Administration from July, 1931 until August 1966. When I entered the Food and Drug Administration it was divided geographically into three districts, namely the Eastern District, the Central District, and the Western District. The Western District contained four stations with headquarters at Seattle, San Francisco, Los Angeles and Denver. The Western District at that time was headed by Mr. Wendell Vincent and his assistant was John L. Harvey.

I entered at the San Francisco station which was headed by Mr. Grant Morton. I was assigned to work in the drug laboratory headed by Mr. Elgar O. Eaton. Mr. Eaton was the only drug chemist in the district at that time and I was his only assistant for a number of years. We did the drug analysis for the four stations. In short, we were regarded as the district drug laboratory.

The San Francisco station headquarters and the Western District headquarters were located in the old Appraiser's Building at the corner of Sansome and Washington Streets, in San Francisco. This building was made of brick and the walls were at least three feet thick, although the building itself was only three stories high.

I'd learned a great deal while working with Mr. Eaton. He had a very pragmatic turn of mind as illustrated by the

following story. At that time ether was the usual anesthetic material and there were two large manufacturers, namely the Merck Company and the Squibb Company. We tested many samples of ether made by Merck and by Squibb to determine whether they complied with the Pharmacopoeia standards. One of the standards involved evaporating 50cc of the ether and weighing the residue. The Pharmacopoeia required that not more than 1 milligram of residue be present in 50cc of the ether. On one occasion we had a great deal of reserve sample left over after we had tested a batch of the Squibb ether. Mr. Eaton decided to evaporate down the reserve sample and lo and behold, he found about 3 or 4ccs of a thick, viscous liquid which further testing proved to be ethylene glycol. It so happens that ethylene glycol is fairly volatile at steam bath temperatures and that is why we had never found any of the residue when we had evaporated 50cc of ether in performing the Pharmacopoeia test. The Squibb firm was notified of our findings and were much chagrined. It turned out that during their secret process of manufacturing high quality ether; they bubbled the ether vapor through a bath of ethylene glycol and had not realized that they were picking up a small amount of the ethylene glycol which then remained present in the finished ether. Needless to say, they quickly modified their method

of producing ether for anesthesia.

In about 1932, Mr. Eaton was called upon to testify in an important case involving fluid extract of Jamaica Ginger. This material contained a high percentage of alcohol but also contained so much extract of the Jamaica Ginger that it could hardly be swallowed even by a hardened alcoholic. One vendor of the Fluid Extract of Jamaica Ginger substituted a material called tricresyl phosphate for much of the ginger extractives so that the finished product, although it looked and smelled like Fluid Extract of Jamaica Ginger, could be swallowed without much difficulty by a person who wanted the alcohol effect. Unfortunately, the tricresyl phosphate turned out to be very toxic and caused paralysis, and soon there was a veritable epidemic up and down skid row, of a condition that came to be called Ginger Jake Paralysis. In the prosecution case brought by FDA against the vendors of this fake Jamaica Ginger extract, Mr Eaton testified that he made the product in the manner required by the Pharmacopoeia and examined the residue after evaporating off the alcohol and that it differed greatly from the residue that he got when he evaporated the spurious fluid extract of Jamaica Ginger. The vendors were found guilty of violating the Federal Food and Drugs Act, but appealed to the next higher court, namely the Federal Appellate Court. The judges

decided that Mr. Eaton had performed the correct operations in making the comparison between the fluid extract of Jamaica Ginger which he had prepared under the Pharmacopoeia directions and the spurious product marketed by the convicted vendors.

From time to time Mr. Eaton or I had to testify in a court case involving alleged misbranding of a drug product. These cases were brought under what was called the Sherley Admendment, which stated that a drug shall be deemed to be misbranded if its labeling contained any statement which is false and fraudulent. The background of the Sherley Amendment is interesting and is as follows. The wording of the original 1906 Food and Drugs Act stated that a product should be deemed misbranded if its labeling contained any false statement. However, in a court case that went up to the Supreme Court, the majority decision written by Justice Oliver Wendell Holmes stated that that provision of the Act applied only to statements of composition, and did not relate to statements of therapeutic value.

Following the Supreme Court decision, Congress attempted to correct the situation by passing the Sherley Amendment, but as already noted, it contained a joker which required that the Government prove that the therapeutic

claims in the labeling were not only false but that the vendor operated in a fraudulent manner. A 1936 court case at Denver illustrates the problem. FDA was taking action against the vendor of a product called Diaplex, for diabetes. This product was nothing more nor less than a weed called salt bush which grows wild in the Denver area. The vendor claimed that by making a tea, the user would have a treatment for diabetes. In the ensuing court case held before a jury, the vendor testified in his own behalf and it soon became apparent that although he was ignorant of medical matters, he actually did believe that his product was a treatment for diabetes. As a result, we lost the case. I remember coming out of the court house after the case was over and encountering one of the jurors on the street outside the front door of the building. He recognized me as one of the persons who had testified for the Government and came up to me and said, "Look, we jurymen are not crazy, we agree that the product is no good for diabetes, but it was obvious that the ignoramus who sells the stuff believes that it is a treatment and therefore, the Government failed to prove fraud in his case."

This situation was corrected when Congress enacted the Federal Food, Drug, and Cosmetic Act in 1938. The new law required only that the Government prove that the

thereapeutic claims in the labeling were false, and this would be enough to obtain a conviction.

In about 1932 there appeared a book entitled, One Hundred Million Guinea Pigs, written by persons involved in the publishing of the Consumer's Union magazine. They claimed that the Food and Drug's Act of 1906 was weak and that the Food and Drug Administration as weak-kneed in enforcing the law. At that time FDA was part of the Department of Agriculture which had Henry Wallace as the secretary and a gentlemen named Rexford Guy Tugwell as the assistant secretary. Mr. Tugwell induced the people at the head of FDA to write a new proposed law which he had introduced in Congress, where it was promptly dubbed the "Tugwell Bill". Congress played around with the so called "Tugwell Bill" for four years and during that time all that happened was that various portions of the bill were cut out and weak portions were substituted for the stronger portions. As an example, the original proposed bill as prepared by FDA would have given FDA control over advertising in newspapers and over the radio etc., generally over such products as foods, drugs, and cosmetics. However, in about 1936 Congress enacted the Wheeler Lea Amendment to the Federal Trade Commission Act which gave the Federal Trade Commission jurisdiction over advertising directed to the

public concerning foods, drugs, and cosmetics. This portion of the proposed FDA bill was therefore eliminated.

Congress finally enacted the new Food, Drug, and Cosmetic Act in 1938, following the elixir of sulfanilamide tragedy. Sulfanilamide became widely used as a general treatment for infection in about 1935. At the beginning it was available only in solid dosage form such as pills and capsules because alcoholic solutions and acidified water solutions were unstable. The Massengill firm located at Bristol, Tennessee asked its chemist to find a solvent in which sulfanilamide would be both soluble and stable. The chemist came up with a solvent named diethylene glycol. Unfortunately he failed to take into account the fact that this solvent was definitely toxic and when Massengill's Elixir of Sulfanilamide was put on the market, it promptly caused at least a hundred deaths. The principal symptom that could be easily recognized by the attending physician was anuria. The resulting publicity induced Congress to take up the dormant Food, Drug, and Cosmetic Act and enact it into laws after altering the section which defined the term "new drug" and require that the sponsor of a new drug not market the product until it had proven the safety of the product and had obtained marketing permission from FDA.

When I entered the Food and Drug Administration in 1931, the Commissioner was Walter G. Campbell, who had risen from the ranks of inspectors to become the Commissioner. He was succeeded in about 1952 by Dr. Paul Dunbar, who had been his (Campbell's) assistant. Dunbar retired in about 1953 and was succeeded by Charles Crawford, who had been Dunbar's assistant. Crawford ran into a peculiar difficulty. A canner of foods in upper New York State came to FDA and asked if FDA would object if the firm sold cans of small beets carved from large beets. FDA considered the matter and provided the opinion that this was inherently illegal because the small carved beets would resemble baby beets which was a premium product which commanded a better price than large beets. The food canner appealed to his Congressman, a Mr. Tabor, from upstate New York. Congressman Tabor expressed great indignation and said that FDA was acting in a very arbitrary manner. Unfortunately for FDA, Mr. Tabor was head of the House Appropriations Committee, and succeeded single-handedly in reducing FDA's budget for the coming year by about a half a million dollars. This required Commissioner Crawford to run a reduction in force which led to the dismissal of about 50 FDA employees. This experience so aggravated Mr. Crawford that he resigned his position as Commissioner in about 1956.

Crawford's successor, as Commissioner, was George P. Larrick, who had risen through the ranks of inspector within FDA. Larrick induced the Secretary of the HEW Department to establish a citizen's committee to examine FDA and to make recommendations concerning its future. This committee turned in a report, which among other things, recommended that FDA's budget be increased about 15% per year for an indefinite period. FDA's budget problems were thus resolved, but new problems presented themselves. One of the problems involved Dr. Henry Welch, a microbiologist of note, who headed FDA's division of antibiotics, the certification arm of FDA in the field of antibiotics. It was learned that Dr. Welch would write editorials for one of the medical journals and that the operators of the journal would then sell reprints of the editorials to various drug companies who were involved in the making of antibiotics. The companies paid the medical journal on the basis of how many reprints they obtained and Henry Welch received a royalty based on this transaction. It turned out that the companies that purchased the reprints would do nothing with them but would eventually destroy the reprints. When this became a matter of public knowledge there were many critics of FDA who claimed that the whole procedure was nothing but a stratagem for passing money from the antibiotic drug companies

to the pockets of Dr. Welch. As a result of the bad publicity, Welch had to resign. His actions were later thoroughly investigated by a Federal Grand Jury, but no indictments were ever returned.

In about 1957, Commissioner Larrick employed Dr. Jerry Holland as Director of the Bureau of Medicine. Holland remained with FDA for several years and then left to join the American Home Products Company, one of the large drug manufacturing establishments. After Holland's departure, one of the physicians in the Bureau of Medicine testified before a Congressional Committee to the effect that while Holland had been with FDA he had encouraged all of the staff to favor industry in their decisions and that Dr. Holland had been very partial to industry in his own personal decision making.

Dr. Joseph Sadusk became Director of the Bureau of Medicine in about 1961 and remained until he joined the Parke-Davis firm in about 1964. Like his predecessor, Dr. Holland, Dr. Sadusk was criticized by one of the Congressional Committees for supposed favoritism towards the drug industry.

In 1964 Abbott Laboratories had a misbranding problem that caused bad publicity for FDA. Abbott manufactures large volume parenteral solutions such as litre flasks of 5%

dextrose solutions and physiologic salt solution etc. Each batch consists of approximately 10,000 flasks and labels are fed into the machine from packet of 500 labels each. On two occasions in the spring of 1964, a batch of 500 wrong labels was fed into the machine so that two batches of the Abbott parenteral solutions emerged from the factory with 500 misbranded bottles. For each of the batches a pharmacist who noted the disparity between the label on the flask and the label on the shipping carton notified Abbott and they promptly notified FDA so that FDA could work with Abbott in rounding up the misbranded product.

FDA required Abbott to notify all physicians and other users of large volume parenterals so that Abbott was forced to spend over a quarter of a million dollars in Western Union telegrams to notify the persons who would be interested in the fact of the misbranding. Later on, FDA decided that Abbott had been punished severely enough by having to spend a quarter of million dollars for the Western Union telegrams, and therefore decided not to prosecute the firm. One of the Congressional Committees held hearings regarding the Abbott matter and roundly criticized FDA for its decision not to prosecute Abbott.

The Allerjoy prosecution case held in Kansas City in about 1962 also created bad publicity for FDA. Allerjoy was

a concoction that resembled milk. It was intended for use by infants who were allergic to cow's milk. Unfortunately many batches of Allerjoy contained too little protein to be useful and a number of infants became ill with a condition called hypoproteinemia when they were fed only the Allerjoy. FDA decided to prosecute the vendor of Allerjoy and in preparing for the case arranged to record the statements made by two women who were hired by the Allerjoy Company to stand in a super market and extoll the merits of Allerjoy as a substitute for cow's milk for infants. For this purpose FDA sent a young inspector and a young female clerk into the store with a radio transmitter. They talked to the two women representing the Allerjoy Company and the voices and conversation were broadcast to a receiver and tape recorder in a car outside on the parking lot of the super market. As it turned out, the two women said nothing that was really of any interest to FDA and FDA did not use the recording in the trial. However, the existence of the recording became known during the testimony of one of the FDA inspectors and the attorney for the Abbott defendant promptly used the recording to divert the attention of the jurors from the real facts of the case. It so happened that FDA had sent seven people as a group to make this recording. The inspector and clerk who entered the store and five other inspectors who

were in a car outside in the parking lot where they picked up the radio transmission and monitored the tape recording of the conversation that was being held inside the super market. The Allerjoy attorney referred to the actions of this group of FDA employees as a "safari". He claimed that there was an invasion of the rights of the defendent and of the two women who had acted as the Allerjoy representatives in the super market and he was entirely successful in diverting the attention of the jurors. The jurors returned a not guilty verdict almost immediately after the trial was over.

There was further adverse publicity on the national scale. The Allerjoy attorney happened to be an ex--governor of one of the Southern states and he had a friend in Congress, a Senator Long from Missouri, who headed up a sub-committee which held hearings on the Allerjoy matter. Nothing actually came of Senator Long's investigation of the Allerjoy case, but as I've indicated before, the publicity was very harmful to FDA.

When Commissioner Larrick retired from FDA in the end of 1965, the officials at the head of the HEW Department appointed a Dr. James L. Goddard from outside of FDA to be the new Commissioner. Undoubtedly their decision to no longer promote from within FDA was based on the long series of

adverse pieces of publicity regarding FDA actions during the period about 1955-1965.