HISTORY OF THE U. S. FOOD AND DRUG ADMINISTRATION

Walter A. Ernst, Retired
Planning Officer

Interview between:

and

Robert G. Porter

Tucson, Arizona

March 20, 1979



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

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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

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.

- P. This is a recording of an interview with Walter

 A. Ernst. My name is Bob Porter. The date is

 March 20, 1979 and the recording is being made at

 Walter's home

 Walter, what

 year did you retire from the Food and Drug

 Administration?
- E. I retired at the end of 1963.
- P. 1963...I wonder if you'd start out by giving us just a litle thumbnail sketch of your career in Food and Drug.
- E. My career started out by my being assigned to the New York Station where I reported for duty on November 1st, 1929. At that time the area was known as the Eastern District and I was given a desk in the inspector's room where we were located in the old Custom House. I was more or less trained by Charlie O'Neil, who was one of the old timers in that area. My work there was fairly limited for I remained in New York only until April 1930, when I was sent to the Baltimore Station. While in Baltimore I became quite familiar with the extensive work of the Station involving sea foods and pesticides on fruits, and of course general inspection work in the area. One of the things that is most vivid in my mind is the fact

that we traveled throughout the country via public transportation; Baltimore District had one car for the entire station. In the mountains of West Virginia and that area I found it quite difficult because of the fact that the trains probably ran only once a day or something like that, so it was quite difficult. But then it became necessary for me to buy a car so I could get around. Traveling at that time, they paid three cents a mile for mileage.

- P. So you used your own car.
- E.- ... Used my own car.

In July of 1931, I was transferred to the Chicago District (Chicago Station at the time) where I remained until February of 1958, when I was transferred to Washington, D.C. to the Bureau of Program Planning and Appraisal. While in the Chicago District, many changes came over the Food and Drug Administration because of the passage of the new Food, Drug, and Cosmetic Act including coverage of devices, which were quite numerous at the time.

Now going back to my original stint in New York, I recall that they had two fairly important projects underway there. One was the investiga-

with tea seed oil. And the other was the checking of spray residues on apples because they had just received a complaint from the British Government that they were finding excessive spray residues over there, arsenic of lead on their apples, the Albemarle Pippins, which were being shipped from Virginia to Britain. Of course there's a follow up on that one. When I was sent to Baltimore Station, I was assigned the job of collecting numerous apple samples through the Almemarle Pippin section, as well as other fruit growing sections in the Baltimore Station.

- P. Did you meet with a lot of trouble with the growers like it was kind of traditional, it seemed like later at least?
- the time we collected samples from their warehouses, but once they began harvesting the fruit, and we began sampling the fruit that was being shipped out, then they were not too cooperative. As a matter of fact some of the packing plants tried to hold off shipping the fruit until we had left the areas. But, we found it necessary to just stay with them until they did ship. We

were fortunate in the West Virginia area and the Virginia area to secure the cooperation of the Fruit Inspection Service, where they made sure that we had checked the fruit before they certified it or graded them. Of course this initial work brought on through the British discovery of the arsenic on the apples rapidly extended out throughout the entire United States, so that when I was transferred to the Michigan area or to the Chicago Station area we immediately were engulfed in the checking of apple samples, and small fruit samples which had been subject to spraying.

- P. It was all lead arsenate in those days wasn't it?
- E. At that time it was arsenate of lead. And then it wasn't long before they got some of the more sophisticated residues which they had to contend with.
- P. Did you do any work on the Ginger Jake case?
- E. Very little, very little work on that. But that was one of the big projects as I recall there when I was in Chicago.
- P. Yes, I think Sam Alfend gave me quite a bit about the Ginger Jake case. He was involved in the analytical problem.

- E. Billy Ford who was at Cincinnati Station was one of the principal investigators at that time.
- P. Do you remember any other sort of cases that we still think about that occurred back in those days that you were involved in? And also, weren't you involved in the Youngstown flood investigation?
- E. Well, that was Cincinnati District area. We had the Ohio Valley flood during January 1937 which engulfed quite a few of the towns along there including of course, Cincinnati. Charlie Curry and I were sent down from the Chicago District to assist Cincinnati there and we were sent to Portsmouth, Ohio and branched out up and down the river from there. That proved to be an interesting assignment in that we secured the help of the local law enforcement officials in the condemnation or salvaging of all the food and drug products that had been subjected to the flood waters. Practically all destructions were voluntary actions under our direction.
- P. Walter, was that some of the early flood work the Food and Drug did. You didn't have much in the way of precedent then did you?
- E. As far as I know we had no real precedent before that time. That was the biggest flood that they

had.

- P. What year was that? Do you remember?
- E. In early 1937 as I recall.
- P. No, it must have been earlier than that.
- E. Gee, I don't remember.
- P. Okay.
- E. I can check the dates of it, I have it here, January 1937.
- P. That's all right.
- E. We, in Chicago, it was brought to our attention that fish, both white fish and herring and tullibees were heavily infested with cysts and of consequence--we checked, naturally, all the imports of white fish from Canada. And we were having a lot of trouble with the tullibees from the Warroad, Minnesota area and the herring from the Lake Superior area. We would have to meet the express each morning that the fish were shipped into the Chicago fish market there and that meant we had to be out there before 6:00 in the morning to sample the lots while they were still in the possession of the express company so that we could have them examined and the results back and stop the sale of these fish.
- P. Was that a health problem or more just a problem

of aesthetics?

- E. Well, at that time they were just considered aesthetic because the fish was either treated, cooked, or smoked and consequently there's no, as far as I know, there's no danger of worm infestation of a human.
- P. Didn't that early work cause the Canadian government to instigate an inspection service of their own and certfied the fish? Wasn't that when that started?
- E. That's right. That started it because there were a lot of complaints because of the fact that so many of the shipments were rejected.
- P. Knowing fish dealers, did you have any interesting experiences with some of those Chicago fish dealers? Almost any experience with a fish dealer is interesting.
- E. Yes, --it was difficult to believe the stories they would tell you, so consequently you had to check for yourself all of the fish around the place to see where they had them stored. Because they would never tell you when they got them in, particularly if they were received in shipments other than the usual, routine morning express shipments that we had a chance to check. I recall

one time--one of the fish dealers who did not appreciate my efforts went into the freezer with me to check on the fish he had in there and while we were in there the handle broke off the door and we were locked in this freezer. But, fortunately he had a strong voice and with a lot of pounding on the door, and a lot of yelling, somebody finally opened the door and let us out. But that was kind of a close call.

- P. That's frightening. I've been in freezers when somebody outside turned the lights out thinking no one was in there.
- E. But this was really--particularly scarey, knowing that this fella didn't appreciate my presence ... hard to tell what might have happened. But they were all the time finding ways and means of getting by. Naturally, the dealers did not appreciate our efforts.
- P. Doug Hansen, when I talked to him, told me about a lot of shenanigans that went on up in the Northwest in regard to salmon where the dealers would try to substitute salmon. And they even got involved in a situation where the Army Quartermaster was buying on the basis of samples shipped to them by the dealer rather than collected

- by a Government agent. And of course you can imagine what was going on there.
- E. Oh, yes.
- P. How about some of the people. Who was in charge of Chicago when you went there? Was J.O. Clarke in charge at that time?
- E. I believe Harry Garrett was the Chief of the station and J. O. Clarke was Chief of the District.

 Walt Simmons was Chief Inspector. And we had a total of seven inspectors at the time when I was assigned to Chicago. And at that time I was loaned out that first summer, I was loaned out to St. Louis District to assist them in their apple survey work.
- P. They had most of Illinois didn't they?
- E. Yes, and they had fewer inspectors.
- P. Later on in regard to the fruit work in Chicago you did some very interesting and important work on the canning of fruit. It seems to me you were involved in some pretty interesting campaigns.
- E. Well, with the factory inspection section of the revised law, we had an opportunity to do more work on the fruit processing. I recall at one time we were making or I was making an inspection of Gerber Products Baby Food operations and they were

canning peaches. They did peel the peaches but they used the whole peach in the puree of the fruit and in checking the raw material they were using, I pitted a number of peaches and found that they were getting an appreciable number of wormy peaches included. So it ws necessary to shut down the operation of the plant until they could set up procedures for splitting and pitting all the peaches and sorting out any worm infested or decomposed peaches. We attempted to bring a prosecution case against them based on the factory inspection evidence, but we had insufficient experience in bringing that type of case in to the courts. And even though we had this evidence of the insect contamination, both in the finished product and in the raw material they were using, the government did not prevail in this case against the Gerber Products Company. But, the incident did cause Gerber Products to enhance their controls, factory controls, checking on their materials, and of course the inspection of the raw materials and finer operations in the plant. Now as far as the small fruits were concerned, we did a lot of work on the mold in strawberries, raspberries, and back raspberries

- and so forth processed up there. So that meant almost constant checking of the various packers there because if the fruits had an opportunity to stand any length of time in the hot weather they molded very rapidly, particularly if they were over ripe.
- P. Didn't you or weren't you involved in some work over there in Michigan that in effect changed the whole industries' way of handling fruit at that time?
- E. Yes, because of the attention that we had been giving them, the industry found out that it was necessary to pack the fruit as soon as it came in and in other words keep the operation going day and night, particularly at night, in order to use up all the fruit before it had an opportunity to spoil.
- P. Previously fruit that came in the evening was held over night.
- E. That's right, they held it up until the next day and then they would operate. As a result of that, many times the fruit they held over night, particularly if it was a damp and hot weather, it would mold.
- P. See by the time I came along and started doing some of that work, it was just sort of standard operating procedure to do that.

E. - Well, as a matter of act, during those formative years we found it necessary to check rather closely with these packers because they still were a bit lax in checking the quality of the fruit they were packing. It meant inspections all hours at night. In the cherry canning industry they would run three shifts a day, so they would close down at noon for clean-up and at midnight for clean-up, otherwise they operated right around the clock. So at times it was necessary to make the inspections all hours of the day.

And as far as the pesticide investigations, during our earlier period there, we were unable to have too good a contol over the packers. They were reluctant to clean the fruit before shipment. And I can remember in one case we had attempted innumerous times to trail truckloads from this one packer out of the state. But had been unsuccessful, so they finally assigned me to a job of checking I started checking at 8:00 in the morning and kept on throughout the day until 9:00 A.M. the following day when the trucker came through and we were able to sample his apples at that time.

- P. Was this at the state line?
- E. At state line patrol. After the new law was passed

in 1938, most of my work took a radical change because of the vastness of the coverage that was granted under law, including devices and drugs, not formerly covered by us. One of the largest areas of attention was given to Dinshaw P. Ghadiali who was distributing a Spectro Chrome machine, a colored light device used to treat everything known to man as far as diseases are concerned. I recall that -- Milwaukee had a large organization for distributing these devices and they had some very enthusiastic operators there. When I first started investigating their activities in the Milwaukee area I found that he (Dinshaw) had been so active that he had induced the Chief of Police and the State's Attorney to each purchase one of these machines for self-treatment. Of course they did not want to be mentioned once they found out that it was a fake.

- P. Walter, he had these groups of people, they weren't just people who he sold the machines to, but it was almost like a religious sort of thing.
- E. It was a religious group and they were conscientious followers of him. They had prescribed a diet that the people would follow and it was a sect, really a sect. Trying to recall the name of

the ringleader there in Milwaukee...Kurt Bader and he was not too far distant from the old country I believe and he was a real enthusiastic. And he had a lot of followers there and there were a tremendous number of machines sold up there. At the time I was making my investigations they had a lot of secret meetings. But our biggest project first was to sample—get documentary samples of the shipments made into Milwaukee. And these shipments were subsequently seized and I found that some of these people were so fanatical that they would cause you to wonder why you had attempted to try to separate them from a machine.

- P. Now this was a very expensive machine too, wasn't it?
- E. It was \$450 or something like that.
- P. Which was a lot of money then.
- E. They had one machine he put out for \$1,000, but I don't recall that anyone in Milwaukee had one of those machines. But I know it was available if they wanted it.
- P. And all it did was shine various colors of light?
- E. That's all. They had these sliding glass slides on the front of it and you had the six basic colors and then they would--six basic colors they used and

then they would make variations by sliding back and forth either single or double or whatever they desired to treat the conditions.

- P. And it was almost good for anything wasn't it?
- E. Everything. Even supposed to regrow amputated parts of the body. He also had an effective group promoting the sale in Detroit. But the Milwaukee ones were staunchest and Milwaukee tended to supply parts to other parts of the country once Dinshaw found it was impossible to ship the machines interstate. I know one time I was sent up to Milwaukee to attempt to locate or determine their method of distribution up there. And after several days' surveillance I found one of the interested workers up there had a autoload of parts and he left for St. Louis. I had followed him across the state line at night. On the way he left just before dark. He stopped at a small town and went to a movie while I had to wait for him to come out again. So it was about midnight before he crossed the Wisconsin-Illinois state line. I stopped him at the line there, but he refused to allow me permission to check his car. Consequently, I was unable to do anything about checking what he had in it. And so we notified St. Louis District that

this party, who was known to the St. Louis District was passing on through, but I don't know that they ever were able to accomplish any checking of the shipment. But, we were certain that they had parts they were starting to make in Milwaukee for these lamps.

- P. Did you ever infiltrate any of their secret meetings?
- E. We frequently would set up a microphone in the meeting room and listen to their meetings. And that was one way we were able to pick up information on their activities and intended ideas of promotion of the equipment. But I never did actually get in the meetings themselves because they were strictly closed and ---
- P. They knew each other.
- E. They knew each other. The meetings were always attended by people who were well known in their group.
- P. Didn't he go to jail for awhile?
- E. Yes, we first got an injunction against him and promptly, temporarily stopped the shipments but later on he shipped more and they eventually prosecuted him and he had to serve time.
- P. Which made him a martyr to his people.

- E. Yes, he was a martyr and Bob Stanfil of the

 Philadelphia District was one of the most active

 participants in the investigation of these

 activities since his factory was located in the

 Philadelphia District at Malaga, New Jersey.
- P. Are there some other interesting cases you'd like to talk about?
- E. Well, as I said this era opened up a whole new field for us. And I remember making an inspection of Keefer Laboratories that was operated by Don Keefer. He had an abortifacient which he called Utragel. And it was being sold around. We collected samples of the product and finally obtained an injunction against the manufacture and distribution of the product and it was a fairly extensive court case in which we had to secure witnesses to testify of their experiences with the product.
- P. Was it just ineffective or was it harmful?
- E. It was harmful and dangerous to the health of the individual. It was a very difficult investigation to make because of the fact that the doctors were not cooperative in that at that time it was illegal to perform abortions and any doctors that had utilized the product generally refused to admit

- ever having used it on the patient.
- P. Was it used by what we would think of as legitimate doctors?
- E. No, well some of them were legitimate, most of them were not. Most of them were not M.D.'s. cases they were just individuals who had used it with no medical background. About this same time the Koche "cancer cure" was being promoted throughout the country. It was Koch Laboratories in the Detroit area. And this meant the investigation and collection of a lot of shipments. My experience in that area was fairly limited outside of collection of samples of which shipments were made to doctors, M.D.'s. And then after the injunction, the prosecution involved inspections of the laboratories where they were manufacturing glioxalide. So we were assigned the task of checking on the envolvement of the glioxalide that they were preparing which was supposed to have some mysterious characteristics.
- P. What was it Walter? Do you remember?
- E. The glioxalide was a form of oxide that was difficult to check because anytime they tried to make a test, it disappeared, it would dissipate. It was not stable. So actually as far as we could

tell it was a fictitious product as far as treating a patient was concerned.

Another interesting field that opened up in that era were spielers and lecturers selling drugs and vitamins and other preparations for the cure of many conditions and diseases. Now this opened up a new field for us in that we began to make tape recordings of the spiels from these various individuals. I recall in one instance I was sent to Detroit with one of the other inspectors to assist me. We set up a radio on the inspector, who was listening to the spiel, and we set a tape recorder in an adjoining building for recording the spiel. Everything was all set up and appeared to be working fine when we set it up but when the time came for the recording of the spiel, the message didn't come across. So we had to take our equipment over to Wayne Technical Institute there and have them check our radio. After we had it back in working condition, and we returned to listen to the next spiel they put on, and made our recording which ended up in the seizure action against the product that was being offered as of therapeutic value. In addition to the spielers we were able to cover the promoters of health foods and similar

products by having them visit your home. And I recall at one time George Fowler, who was Resident Inspector in Milwaukee at the time, invited one of these spielers to come to his home. And we set up the recording devise. In that case we did not use a radio, we just used the microphone and tape and recorded the entire proceedings. And of course Mr. Fowler proceeded to order or buy a sample of the product. And this sample resulted in a court action in the District Court in Milwaukee in which the judge permitted us to enter into evidence the tape which was made at that time.

- P. Do you remember what the product was?
- E. The fellow's name was Shearon. The product he was selling at the time was Elemin, a vitamin preparation. But, to my knowledge that was the first case in which the Government was able to present as evidence tape recordings made at such an occasion.
- P. That's interesting.
- E. Incidentially I still have that court exhibit which was turned back to me after the case was terminated.
- P. On a tape recorder, or was it live?
- E. No tape recording.
- P. The big tape, not a cassette.

- E. The big tape, yes.
- P. Walter, I'd like you to use some of the time this morning to talk about how the management information system for the field forces of the Food and Drug Administration evolved during the time you were in service. And I'm asking you particularly because I know that you were in charge of the system for 5 years during the time you were in Washington. How did we first start keeping track of time and number of operations and things like that as far as you recall?
- E. To the best of my recollections, with the passage of the new Food, Drug, and Cosmetic Act in 1938, Washington deemed it necessary to keep track of our operations so that they would be in a position to supply Congress with suitable information on their activities. And as a result of that they devised a large sheet involving an appreciable number of operations and they set up a project code for various products that were involved. And this sheet was filled out daily. And the end of the month it was turned in and submitted to Washington.
- P. When I came in we filled a big sheet like that and as I recall it was called Form O and then it was revised and it became Form P.

- E. I remember Form O.
- P. And it had columns where you could record whether it was an inspection or a sample collection and under the project which would indicate what product was involved and some place you put down the amount of time you spent on it.
- E. Time.
- P. I thought we kept the information in our diary and just made those things out at the end of the month.
- E. Well, they were supposed to be kept up daily and submitted at the end of the month. But you could very well keep it in your dairy and report it at one time if you wished. It was set up so it could be kept up daily.
- P. Do you know what happened to those when they went to Washington?
- E. No, I'm sure someone had the job of collecting the data from them in order that they would be in a position to submit to the budget the information on the various activities of the Food and Drug Administration.
- P. Well, then we moved into a revised system called the T and P; time and production system. Is that the next step?
- E. Yes, they had the T and P card which was revised so

- it would cover these same operations on a daily basis.
- P. Do you know anything about who devised that? Did J.O. Clarke have quite a bit to do with that when he was in charge of the planning section in Washington?
- E. Yes, I'm sure that J.O. with the help of Glenm Underwood did appreciable amounts of work in setting that up.
- P. And that was a card, a mark sensing card.
- E. Mark sensing card, that's right.
- P. Well, it wasn't first though. First it was the same system but you just put it down on a piece of paper. We had little pads 8 x 5, or something, paper. And then it went to Washington.
- E. That's right actually it was set up so that it would have to be manually taken off the card---
- P. In Washington---
- E. And then they got the mark sensing developed for the tabulators, then they were able to put it through the tabulators by use of the mark sensing card. And that of course then was the beginning of our computerization of the operation. Well, when I arrived in Washington...
- P. That was in 19--

- E. 1958, Dr. Underwood was contemplating changing over to the computer system and he assigned me -- that was one of the first tasks he assigned me there to assist the computer section of HEW to set up a system whereby information could be accurately secured from these cards. And it took a material amount of time to acquaint this personnel with our system of reporting and setting up a program which would detect errors and elminate any cards that might be improperly filled out.
- P. Now that was still on the old IBM tabulator before the computer that you're talking about.
- E. Yes, that was on the--and then it was converted from that system which required a continuation of the operations that they had been working on before.
- P. And you were the man that really worked with the computer programmer to get that thing going. Correct me if I'm wrong, but I have, as I recall, and I must have learned this from you at some time, the first HEW computer was actually ordered for Food and Drug, but by the time it was delivered and installed HEW actually decided to take it over. Is that right? Or is that your recollection.
- E. Well, I don't know, but yes, it was supposed to be

- obtained for Public Health and Food and Drug. And before we got going on it, why HEW had become so involved in it that the Public Health had taken it over completely. And they were just assigning us time on it.
- P. But, really Food and Drug work in a sense justified the money spent on a computer, but by the time the thing got going we found ourselves just being allowed a little piece of time on it. And that was an RCA computer at first?
- E. Yes, I think the first one was.
- P. And that was the first one HEW ever had?
- E. Yes.
- P. And as I recall, you worked with a programmer that was furnished by RCA who--and eventually when he finished the job he left and went to Florida or someplace.
- E. Yes, that's right.
- P. And we had to deal with him by telephone because they really didn't have a competent programmer yet in the Department.
- E. That's right and actually we had to call him back on several occasions to help us out with these problems because the report they originally put on the tabulator would take sometimes more than one

- day to run all the information on. And once they got the computers going, why if they would give us two hours and we would have a complete report out.
- P. Food and Drug had probably the best system of that kind of any Government agency I've heard. And certainly I don't know of any others that--
- E. Well, the information gleaned or obtained from the records submitted by the field is probably the most detailed of any that was being obtained at the time and covered a vast area of information which was a big help to Food and Drug in planning their field operations as well as their budget applications.
- P. Justifying budgets. But at that time the individual Districts didn't have any ability to process data. It all went in by mail to Washington and processed.
- E. That's right. When I left they were still mailing the information in.
- P. You might be interested that Food and Drug is now involved in replacing the IBM data entry equipment by mini-computers in each District. And the mini-computer will feed data into the centralized computer, but in the mean time the Districts can manipulate, so to speak, maybe that's not the right word but they can collate and develop any

- information themselves, locally. It's a pretty sophisticated system.
- E. Yes, I imagine so. Yes, it was quite a step from the manual collection of information to the computerized--speeded up their operation and simplified the matters for those seeking information.
- P. Well, you know after we got fully on the computer and didn't--about the time you retired, we still had quite a large number of statistical clerks taking data off of the cards and punching it on paper tape and doing that kind of thing. But we were able to eliminate all those jobs when we got fully on the computer.
- E. Course as you recall, a terrific amount of information gleaned from the computer reports appeared in our annual report to the field so that the field knew exactly what they had done in each program and the work that had accomplished. And of course it was instrumental in setting up our program plans too for the field for the coming years.
- P. Now what were those program plans, Walter?
- E. Well, based on our budgetary committments the work was planned for the field both in number of inspections and time they'd spent on the various

- activities to be sure that the fields were propertly covered.
- P. And uniformly covered--
- E. Uniformly, yes, as uniformly as possible. Because of the distribution of personnel in the field it was not always, we were not always able to accomplish the goals that we had set out for us, but did a good job of approximating it.
- P. Thank you, Walter.
- E. I forgot to mention the many investigations of injuries which presented themselves under the 1938 Food, Drug and Cosmetic Act. I investigated many cases of injury involving the Roux Lash and Brow Dye and the drug chloramphenacol and others. Of course we were involved in many drug recalls too.