

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Charles A. Herrmann, Retired Director
New York District

and

Fred L. Lofsvold
Flushing, New York

July 11, 1978

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Fred L. Lofsvold, who is currently the Food and Drug Administration Regional Director at Denver, Colorado.

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

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

DATE: 7/11/78 PLACE: Flushing, New York LENGTH: 54 minutes

INTERVIEWEE

INTERVIEWER

NAME: Charles A. Herrmann NAME: Fred L. Lofsvold

ADDRESS: [REDACTED] ADDRESS: U.S. Food & Drug Administration
[REDACTED] Denver, Colorado

FDA SERVICE DATES: FROM 1920 TO 1966 RETIRED? Yes

TITLE: Director, New York District
(If retired, title of last FDA position)

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L. - This is an interview with Charles A. Herrmann [REDACTED]
[REDACTED] Mr. Herrmann retired in 1966 as Director of the New York District. The date is July 11, 1978. My name is Fred Lofsvold. Charlie, would you start by sketching your career with FDA.

H. - Well, I started with FDA as a junior chemist in 1920. I had taken the civil service examination in 1918, before my graduation from Marquette University, and it was an unassembled examination, just filing an application. Then I was drafted in World War I and I went in the army for six months and came out and forgot all about the civil service application. Then in 1920, I got a notice from the Civil Service Commission asking me if I was still interested in the job as junior chemist. There was an opening in New York at \$1,440 per annum as junior chemist for the Food and Drug Administration, which at that time, was under the Department of Agriculture, the Bureau of Chemistry of the Department of Agriculture, which had responsibility for enforcing the Food and Drugs Act. I debated about coming to New York, and my father said, "Why don't you try it". Jobs were scarce after the war, so I came to New York to try it. He said, "You don't have to stay there the rest

of your life", but I'm pretty well along in staying here.

I reported for duty at the New York Station, which was then located in the Appraisers' Stores Building at 641 Washington Street, which was at the corner of Christopher and Washington, near the waterfront.

The Food and Drug quarters were on the 10th floor, and they were handy to the examination of import products because the appraisers had some of the merchandise brought into the appraiser stores for examination, and we would go down to the floor from Food and Drug to examine the merchandise while the packages were opened by Treasury Department.

I reported to the chief of the New York station, as I say, on April 13, 1920. At that time, I should say something about the structure of the Food and Drug Administration, or actually, it was then the Bureau of Chemistry. The organization was that their headquarters in Washington was staffed by a relatively small staff consisting of a Chief of Food Division, Chief of Drugs Division, an Import Division. Dr. Taylor was in charge of the Import Division; I think Dr. Elliott was - Food Division; maybe it was Dr. White. Mr. Murray was in the Drug Division--those are some of the names that come up at the time. Now,

the operations were left largely to the three districts, the Eastern District, headquartered in New York; the Central District, headquartered in Chicago; and the Western District, headquartered in San Francisco. All of these districts were directly connected with the station, occupied common quarters, and used the same files and clerical staff. The Eastern District chief at the time, was Ben Hart, who shortly thereafter, went to the Western District, I believe, and was replaced by W. R. M. Wharton, who reported to the Eastern District from St. Louis station where he had been chief. He became the Eastern District chief, and my service under the Eastern District was entirely under him. His staff of Eastern District people consisted of Frank Wollard chief inspector, Cleon Orestes Dodge chief chemist, and Harold B. Mead, who was handling our cases and issuing instructions, and did most of the actual paper shuffling. The Eastern District occupied two rooms on the same floor, the 10th floor of the appraisers store, with the New York station. One for the chief and one for the assistants. The New York station consisted of chief Harry W. Redfield, assistant chief Joseph Cummings, and of the chemists, I think there were about a dozen chemists, but such

names as I recall, as Joe Cummings, chief chemist, Dr. Howard, chief drug chemist. Joe was food chemist, Dr. Hubbard was drug chemist. Walter Kirby, Elizabeth Greenberg, Katz. Those are some of the names. Dr. Parsons was bacteriologist; he was an M.D., but he did the bacteriological work and he was concerned mostly with the sanitation and oyster work, and bacterial problems. Instead of sending it to microbiology in Washington, he handled that work in New York district, and travelled from there to Baltimore and Philadelphia when the oyster season was on, etc. I was assigned a desk--a table in the laboratory, and immediately after being introduced to the other chemists--was put to work. My first sample that I examined was a sample of cloves to determine the percentage of stems. There was a limit of percentage of stems allowed, because of the fraud of substituting excessive stems for cloves; because the stems are worthless, flavorwise.

My second sample was a sample of filberts, and the examination consisted of taking a hammer, cracking a hundred nuts, and splitting them open with a scalpel, to determine whether they were moldy or wormy. There were limits, we had no tolerances as such, but there were working limits for detentions. The main

interest, of course, of New York district in those years, was import samples, and New York was the largest port. The ships would come in from foreign ports, loaded with the crops that were due to be seasonally shipped, filberts came in by the boatload, or a good portion of a boat, unloaded on the dock, and our import inspector brought samples to the laboratory, taken from individual bags, with a trier usually, to be sure that the bad rejects were not concentrated in certain bags. They took samples from different portions of the stack as it was unloaded from the ship on to the pier. They put the individual samples in paper sacks, identified with the entry numbers, and the laboratory chemists and technician--well we had no technicians, as such, in those days--but the chemists cracked the nuts and examined them. And then, if the percentage of rejects exceeded the working limit, the shipment was detained--held up--and not allowed entry into the United States. The importer had an opportunity to appeal the decision and ask for a re-examination if he thought that he was being unfairly dealt with. The re-examination was granted and the final action was taken on the basis of the re-examination results. The emphasis of enforcement in those days was largely from the

economic and aesthetic standpoint. Economic in preventing fraud, such as excessive stems in cloves, substitution of cheaper materials for the genuine, such as salad oil for expensive olive oil; peanut oil, sesame oil, cottonseed oil, were mixed with the olive oil and palmed off as genuine olive oil at higher prices. And the laboratory was charged with detecting those and taking action accordingly. In the line of drugs, the U. S. P. 10 was in force then, I believe, and National Formulary 5 and there, the official drugs listed, consisted largely of leaves and herbs such as stramonium leaves, digitalis leaves, henbane leaves, which had alkaloidal content, and measurable therapeutic effect, which the doctors used at that time in the form of elixirs or tinctures, and which the druggists largely prepared themselves, from fluid extracts and tinctures furnished them by the drug houses that manufactured them, or manufactured their own--fabricated their own elixirs and tinctures in the pharmacy. The U.S.P. furnished the standards by which these drugs were judged at time of entry, and the problem was to prevent substitution or worthless drugs from coming into the country. This was done in the laboratory, first by the identification of the plant by the pharmacognosist who had

botanical training for that purpose, and then by the chemist who determined the compliance with U.S.P. standards, such as the percentage of alkaloid, the percentage of ash, and other constituents specified in the standard.

If the product failed to comply, it was refused entry and, in that way, the drugs sold to the pharmacists or dispensed by the doctor, were assured to be of full potency and strength.

Getting back to foods, the emphasis was, as I said, on economic and aesthetic violations. The economic violations were fraud, substitution of cheaper materials for the genuine, excessive foreign material; and the aesthetic violations consisted mostly of determining spoilage, mold, decomposition, worminess, worm contamination, rodent contamination, and since these harvests were imported from other primitive countries, they took quite a bit of attention, because the standards in those countries, the sanitary standards, were far below what they are in this country. And what was considered acceptable in some producing country, was far from acceptable in this country. The same applied to warehouse inspections after the imported product had been stored. Going into bakeries to see if there were rodents, whether the

storage space was rodent accessible; some of the buildings were in disrepair; they were in neighborhoods adjacent to railroad tracks, or someplace where rodents were prevalent, and they had easy access to the food materials if the stores or bakeries, or food plants did not take proper precaution. Another favorite method of contamination was flies. To allow flies in the factories, without screens on the windows and have the place swarming with flies; to allow the discarded material to accumulate, and the garbage to generate fruit flies or house flies, and contaminate the food.

- L. - Charlie, in those days in the 1920's, we were working under the old 1906 Food and Drugs Act, which did not have authority for us to inspect a factory. I gather, from what you say, we did make factory inspections at that time.
- H. - Well, let me correct the record there. Not as such, not as we understand it at the present time, but the inspectors, I believe, did visit places to examine the structure and note conditions which might contribute to adulteration. If the owner refused permission to go in, the inspector had no choice but simply to leave. But if he did leave, the implication was that the firm had something to hide, and

so we did get away with some of the inspections which we had no strict legal authority to perform.

L. - Charlie, it seems to me that I remember one of the big problems that FDA faced in the 1920's, was pollution in the growing area for oysters in Chesapeake Bay, that resulted in some illnesses. Do you remember something about that?

H. - Yes I do. I alluded briefly to Dr. Parsons, who was in charge of the bacteriological examinations in those times, and I think they had a typhoid epidemic from pollution and the....I seem to recall that the trouble occurred from sewage pollution in some areas, and there was a problem of, first of all, determining whether the waters were polluted or not, and secondly, of enforcing or preventing the oyster men from fishing those waters. And the authority was divided, as I recall, between the states and the federal government, and it was very difficult to ascertain or determine whose the responsibility was for this or that enforcement work, and enforcement was very difficult at that time, in that field; but we did work at it. I think it was in Baltimore district. I am not too familiar with just exactly what the problem was.....but I do remember something about taking oysters and putting them on floats to purify them,

and in that way, insure that if they had been contaminated, they would clean themselves after leaving them on the floats for a certain length of time; and I think that was one of the determining factors in eliminating the epidemic.

L. - During the period that you were talking about when you were examining drugs in the New York laboratory, did you have any notable experiences?

H. - Yes indeed. There's one that stands out in my mind. I examined a sample of stramonium leaves, I believe it was, and found it deficient in alkaloid. Well, detention was issued and the importer appealed and wanted a re-examination; and as a basis for appeal, he had a report from a commercial laboratory, Seil, Putt, and Rusby, which showed that the alkaloid content was up to U.S.P. standards. The Doctor Seil was a former Food and Drug chemist, and so was Dr. Putt and Dr. Rusby, of course was the outstanding expert on crude drugs. They had this commercial firm and they did work for importers. So, as a result of the appeal, the chief of the district, or station, ordered a re-sampling and a sealing of the samples for joint examination. This was done and the sample that was appealed was kept until Dr. Seil had time to come up for a joint examination, at which time we opened the

seal and took out the sample, ground it through the mill for rough grind, and then quartered it down to maybe a hundred grams or something like that, and then started working on that to put that through the fine mill to comply with the U.S.P. provision that the sample must pass through a hundred mesh sieve. Well, that's a kind of a tedious operation, because the mill will take most of the leaf material and reduce it, but the stems are stubborn and will not grind that fine; and you wind up with a small amount of stems and a mortar and a pestle to make them go through the hundred mesh sieve. I was working on the final grinding with the mortar and pestle and Dr. Seil said, "Oh the hell with that; that takes too long. That doesn't have any effect on the results anyhow. There are so few there, throw them in and mix them with the others." So I did, and we proceeded with the examination chemically, according to the U.S.P. instructions, and we came out, safe to say, right on the button of what I had originally reported, a shortage in alkaloid.

Well, Dr. Seil left, somewhat chagrined, and the next thing I knew, I was summoned in the front office to explain why I didn't follow the U.S.P. procedure in the re-examination. He had said that I had not

followed strictly, the U.S.P. provisions. Well that resulted in another examination of the final detention, but it taught me a lesson--never to vary one iota from instructions, and not to fall for somebody else's suggestion of that nature.

- L. - Do you have any other stories that illustrate the kind of analytical work that you did at that time?
- H. - Well, one experience comes to mind, and that is an import sample of sardines that was examined and had excessive lead. In those days, the cans were soldered and sometimes the lead solder contaminated the contents of the can. So imported sardines were examined for lead. This particular shipment was examined and found to contain excessive lead; and was exported--required to be exported. Sometime later, another shipment came in and was sampled and, again, found high in lead; and on re-examining the shipment itself, it was noted that some of the cases that had been marked by the inspector on the dock in the first shipment, were coming in the second time. So it was really a re-entry of the original shipment, and when that was discovered, why the importer had no leg to stand on and the sardines were exported for good.
- L. - Up to now, you told us about your experiences as a bench chemist in the laboratory; but my recollection

is that most of your career was spent in administrative and management in FDA. How long did you work in the lab?

H. - I believe it was about six years, when I was transferred to the Eastern District office because of the need for additional help there. I was put into the Eastern District office as the project director, or a project clerk would have been a more apropos title, since it was my duty to write project plans for the six stations that comprised the Eastern District: Baltimore, Boston, Buffalo, New York, Philadelphia and Savannah at that time, later moved to Atlanta. As I say, my job was to write the project plans which were formulated as a result of district conferences, planning conferences in the spring. The fiscal year always ran until June 30, my job was allocating percentages of time and funds to different projects as necessary in the different districts, because the needs were so different in the territories served by these districts. The Atlanta district, for example, had problems that Boston never had. For example, the citrus crop, and Boston had the sardine canning; and both of them were problems that involved Food and Drug enforcement. The sardines had possible lead in them from the can, or they were packed at the wrong

time and were belly blown and unacceptable for that reason; and, in the case of the Atlanta District, for example, the maturity of the oranges was a factor in marketing the fruit. New York problems were mostly concerned with imports, although we had some drug plants developing and wound up eventually with most of the principal drug plants in New York territory, like Merck and Co., Geigy, Hoffman-LaRoche, etc. In addition, it was my duty to write project reports covering the activities of the stations in the district for the year, after the year ended (the fiscal year ended). Besides doing that work, I also helped with the summaries and recommendations, so called, which were reports from the stations recommending as to disposition of official samples--whether to put them in permanent abeyance because of a lack of evidence or other factors, or whether there was evidence there to warrant prosecution. In the case of prosecution recommendations, they were then forwarded to Washington to be evaluated by interstate division and forwarded to general counsel's office for prosecution procedures.

I started that work around 1926, or thereabouts, I believe, and I gradually had more and more responsibility of the district office, and it was affected

to some extent by the fact that we had difficulty in uniformity of enforcement. Cleon Dodge got interested in a project which he was going to develop, namely a universal index. This universal index was to encompass all the sources of enforcement policy and standards into one index: the U.S.P., the N.F., the Food and Drug Decisions, the Service and Regulatory Announcements, all tolerances, etc. And by that reference, the enforcement could be uniform if that index were kept up and circulated among the stations; it would facilitate a uniformity of enforcement. Well, the first step in that project of Dodge's was to get the stations to do part of the listings, and then he would take and edit those and supplement it, and it was such a monumental task to get all those standards listed. Mind you, this was not a reference to the U.S.P., but it was just a U.S.P. figure. And if there was a change in the U.S.P. from 10 to 11, and the figures were changed, the index would have to be amended throughout. It was a preconcept of what later was used as the Commerce Clearing House records, for which Food and Drug subscribed. (I don't know, do they still?).

L. - Yes.

H. - There the indexing was done centrally by somebody else, and purchased by the Food and Drug Administration, and then the problem became as to where to get some conscientious person to make those changes when they come out, so you're sure you're up to date.

But that's aside from the point.

Since Dodge became more and more tied up and I think he had the final draft of the A's done in a year's time or so, and Mr. Campbell, who was then head of the Food and Drug Administration said, after all that time and all that money and we are through with the A's, forget about it, and cancelled the project.

But as a result of that, I had been assigned more and more responsibility and Mead had left the district office. I don't know whether he retired or was transferred. I think Dodge was transferred out into the New York district, and I became assistant district chief to Mr. Wharton where I served until I succeeded him in 1948. At that time, there was a reorganization of the structure of the Food and Drug Administration, and instead of having the three districts held responsible for the enforcement work, the three districts were abolished and each station was made responsible for the work in its own territory, and to report directly to Washington. This meant a

large increase in the staff in Washington but it eliminated what had grown to be a sort of habit on the part of the three districts--well I won't say that it was a habit of three districts--what had developed in the Food and Drug Administration as a result of Washington reaching out more and more into the business of the three districts and not letting them make decisions of their own, but requiring them to refer more and more matters to Washington for approval than was originally intended. As a result of that, what was really happening was that the three districts were transmittal bureaus and really contributed very little to the enforcement work because they would receive a request from a station and they had no responsibility for answering it, but they referred it to Washington, got the answer back from Washington and reported to the district or to the station. So, it cleared that and abolished the three districts. Well, Mr. Wharton retired at that time, in 1948; Mr. Clark, of Central District, became Director of Planning and Appraisal in Washington; Mr. Harvey became Director of Litigation, and Mr. Rayfield, of the Eastern District, became head of field operations.

After I took over as Director of the New York

District, there were problems that came up within the drug field through the development of the sulfa drugs and that was an innovation which obviated the precise diagnosis of the location of trouble in the human body, depending upon a therapeutic agent to go to the source of the trouble and alleviate it. For example, in the case of pneumonia at that time, there were several different types, and in order...the treatment for different types entailed different...the different types of pneumonia required treatment by different antitoxins; and one wasn't effective for the other types, as I recall it. Whereas the sulfa drugs would treat all types with equal efficiency. Well the sulfa drugs were not too long on the market, they were very expensive to manufacture, especially sulfanilamide. Anyway, Merck and Company finally succeeded in developing sulfanilamide, which was an effective agent for a number of viral diseases, including pneumonia. The sulfanilamide was on the market at a considerable price...at a fairly high price, naturally, because of its scarcity, and shortly after it came on the market I had a call from Mr. John T. Connor, who was at that time, general counsel for Merck and he said he had an important matter to discuss, could he come up to see me. We made an

appointment and he came up to the office on Varick Street and told me that a druggist in New York or suburbs had been offered genuine sulfanilamide at a greatly reduced figure, by a salesman for a rival company, and was assured that there were unlimited quantities available. Merck and Company, naturally was alarmed, saying it was either stolen goods or it was a fake product. I agreed and we got together on a plan to root this thing out and find out what it's all about. Naturally, we were concerned about violation of the Food and Drugs Act, because if it was a fake product, we didn't want it on the market. So we were protecting the consumers and had a legitimate reason for joining Merck in ferreting out the source. The plan provided that I would get one of our inspectors from another district, who was not known in this area, to handle the investigation. And I got Luther Johnke from Philadelphia to come up to New York and we consulted together and laid out the plan. He contacted the druggist that had tipped off Merck and was put in touch with the salesman who made the offer. Johnke posed as a wholesale druggist from Philadelphia, who was interested in buying a considerable quantity. So the salesman put him in touch with another party whom he was to meet in a

diner in Jersey. Johnke went into the diner for a cup of coffee at 10:00 at night, as agreed, and this other party came into the diner and identified himself with a pre-arranged signal, and the two of them walked out and into the visitor's car. There they haggled over price and quantity and Johnke was assured that the stuff was genuine and he said, "Oh hell, I'm not going to spend money for something that hasn't been tested; I'm not taking your word for it". "All right", he said, "I'll give you a limited amount--you can have it tested, and if it's all right, why we'll close the deal on the larger amount". "Fair enough", so Johnke got a small sample, brought it back to New York, and turned it over to Merck, for testing. Well the test proved that it was the genuine article, so he made arrangements for the purchase of a larger quantity which cost \$600.00. Well the New York district had no such sample money in it's treasury, and Merck agreed to furnish the \$600.00 cash to make the large purchase. With the \$600.00, Johnke again met the unknown supplier at the diner. They went out of the diner and into a car and the unknown person drove around to lose Johnke and confuse him, and stopped at a certain corner in front of a pharmacy which was closed for the night, but had a

staircase running outside to the second floor on the outside. The man left Johnke in the car and went up the staircase. He returned in a few minutes with a package which he gave to Johnke. After looking at the tablets Johnke paid him the \$600.00 and the man drove to the railroad station where Johnke caught the train to New York. At Penn Station, Johnke noticed a man with a briefcase who seemed to be following him. He wanted to lose him before he reported to the Merck people, who had hired a room in a Pennsylvania hotel opposite the Penn station. And so he wandered through the subway entrances and exits around Herald Square and lost the guy with the briefcase, got up to the room of the Merck people, and told them what had happened. The next day Johnke and some of our New York inspectors went back to try to pick up the location where he had picked up the sample in front of the drugstore. They succeeded in doing so, and confronted the pharmacist in the drugstore, or the owner of the drugstore rather, because the owner was not a pharmacist. He was the son of a pharmacist who had died and was running the drugstore with a licensed pharmacist that dispensed drugs. This owner lived upstairs over the store. Johnke identified him as the man he had met in the diner and

who sold him the sulfanilamide, and we initiated a prosecution case. We were successful in the prosecution, but the person prosecuted never revealed who the Merck employee was that stole the sulfanilamide out of the plant.

L. - Many years later, Johnke told me that story when I was in Philadelphia, and he ended up by saying, "And John Connor, the lawyer that I worked with is now the president of Merck & Company".

H. - You know...I can add that John Connor is now, I believe, chairman of the board of Allied Chemical.

L. - Do you have any other of these kinds of cops and robbers adventures with food products?

H. - Well, there comes to mind a story about oleomargarine when the sale of colored oleomargarine was made legal. We had known that there was on the market a brand of butter which consisted of oleomargarine, colored oleomargarine; and we tried to trace the source and finally got wind of trucks that made the delivery and followed them, which led us to a plant. We sent a crew over to make a factory inspection and we spent a couple of hours turning the place inside out and found nothing. And we were about to leave when they came out on the sidewalk and Jerry Martell, who was with them,

one of their crew, started pacing the sidewalk in front of the building and said to the others, "I think, from the layout, I think there must be a room under the sidewalk--an extension of the building". So we went back in and tried again and had difficulty finding an entrance; but finally, behind some packing cases, some file cases that looked permanent, they found that one swung out and led to a door and there was complete equipment in there for printing oleomargarine, coloring it, and butter cartons and everything else.

We put an end to that particular source of butter.

End of tape.