HISTORY OF THE

U. S. FOOD AND DRUG ADMINISTRATION

Interview between:

Einar T. Wulfsberg

Retired, FDA

and

Robert G. Porter

Aurora, Colorado

June 17, 1982

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. 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 & HUMAN SERVICES

Public Health Service

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TAPE INDEX SHEET

CASSETTE NUMBERS 1 and 2

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

DATE: June 17, 1982 PLACE: Aurora, Colorado LENGTH: 97 Min.

INTERVIEWEE	INTERVIEWER
NAME: Einar T. Wulfsberg	NAME: Robert G. Porter
	U. S. Food & Drug Admin.
[redacted]	Denver, Colorado

FDA SERVICE DATES: From 1939 To 1967 Retired? Yes

TITLE: Food & Drug Officer, Division of Case Control
(if retired, title of last FDA position)

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Porter: This is a recording in the series regarding the history of the U.S. Food and Drug Administration. Being interviewed today is Einar T. Wulfsberg. Einar retired in November of 1967 after having held a number of important positions in Food and Drug Administration. The interview is being held at my home in Aurora, Colorado, the date is June 17, 1982. My name is Bob Porter.

Porter: Einar, I would like to have you start the recording, if you would, by giving us a thumbnail sketch of your career in the Food and Drug Administration.

Wulfsberg: After leaving college my first job was teaching high school math and science in a small town, in eastern Montana. From there I went to work as a bench chemist for the Water Department of U.S. Engineers on the Fort Peck dam. Our function was to make chemical analysis of construction materials in accordance with the federal system of standards. From the War Department of U.S. Engineers, I went to the Bureau of Reclamation in Denver, Colorado, again as a bench chemist examining cement, steel and other construction materials for that bureau. In 1938, I accepted a position with Food and Drug Administration which was upstairs on the fifth floor of the Old Custom House in the same building in which I was working for the Bureau of Reclamation. From there, a group of us, about 25 I believe were gathered in San Francisco for 3 months training as inspectors and chemists. I was reassigned to Denver.

Porter: Einar, I thought you were in the class of '39, it's almost a famous group that you were a part of, it's always referred to as the class of '39. Did you come in...?

Wulfsberg: Yes, I came in with that group. I may be off a year there.

Porter: Okay.

Wulfsberg: That would be about September 1939, when we went out to San Francisco and we returned shortly before Christmas to our assigned station. I worked for Mr. Vincent out of the Denver District until Pearl Harbor, at which time being a reserve officer I was immediately called into the Army and the Chemical Corps. I packed up my wife and family and went to Edgewood Arsenal and subsequently to the Huntsville Arsenal in Alabama.

I returned from military service to the Denver District and not long thereafter was assigned as a resident inspector at Salt Lake City, Utah. There I had the good fortune to have as my assistants Del Dean and later Bob Porter.

When the Korean incident erupted I was back in the military service again from 1951-53. Returning from that service to Denver, I was transferred to the Kansas City District under Samuel Alfend. From there I went to Bureau of Program Planning and Appraisal in Washington under Shelbey Grey. In about 1959 when the Food Additive Amendment was made effective, an office was created in the Office of the Commissioner to handle

this function under Arthur Checchi. I think the first two brought in there were Fred Cassidy and myself to assist Checchi. Checchi, not long thereafter, went with his brother's consulting business overtown in Washington. I took his position together with Fred Cassidy, Allen Spire and later a number of others handling the food additives workload. The Food Additive Amendment which became Section 409 of the FD&C Act, probably is a result of the apprehension that was popularly felt for chemicals in foods. After the war years, the period of the 50's and 60's rapidly escalated chemical research. And from that came substances which the industry proposed to use in food. This resulted in an extension of the popular antipathy toward chemicals and the Food Additive Amendment came about to provide that any new food chemical would have to be made the subject of a petition demonstrating its safety and uses before a regulation could be written describing safe usages. Under the Food Additive Amendment certain substances were described as exempt from the definition of food additives and this included a group which we called prior sanctions. These were substances for which the Food and Drug Administration had concluded, after review, that they were safe to use in foods during the years prior to this amendment. These were then excused from the Food Additives Amendment and we titled them as prior sanctions. Mostly they occurred in the form of copies of written letters addressed to

industrial firms throughout the United States and there was a great deal of interest in these because it exempted them from the tedious process of preparing a food additive petition.

Porter: Einar, was this the GRAS list, or is that something else?

Wulfsberg: Something else. These prior sanctions then, in the form of letters, were resurrected by all of the parties whom they benefited. Many times they brought them in and asked to have them recorded, confirmed, so that we would know about them or we would search our own files and find them on references that they made. This was a fairly substantial activity and I remember that I created a system of file cards, 10x12 in tub files, in which I recorded everything that came across anybodys desk which was in the form of a prior sanction, that is a commitment on the part of the Food and Drug that they had no objection to the use of the certain substance in a certain food process.

Porter: This would be a guy who would come in and say here is a letter that Food and Drug wrote me 10 years ago that said I could use a certain chemical in my product?

Wulfsberg: Yes.

Porter: And he would say I just want you, in effect, to remind you that this letter was issued.

Wulfsberg: Yes. Or they'd write in by mail, we would answer their letter the same way. Now, this prior sanction was

applicable not only to the man who held it, but to all persons engaged in similar aspect of food processing, so that it had wide application once the thing had been established.

Then the other group of food chemicals that were exempted from the definition of food additives, were those which were "generally recognized as safe". These had to be recognized as safe by the scientists in the Food and Drug Administration, as well as generally considered safe by other qualified scientists wherever they might be. Now, the FDA scientific groups in anticipation of the effective date of the act prepared a list of substances which they felt were qualified for this exemption, "generally recognized as safe". This fairly voluminous list circulated through the Food and Drug Administration, addressed by mail to scientific men throughout the United States, who strangely enough had very little comment to make on it. This was published as a proposal and became part of the definitions attendent to the Food Additives Amendment.

Porter: And this is the one that was well known by its acronym, in the GRAS list?

Wulfsberg: GRAS list, white list. Yes. It was never added to very much, it more or less stayed there. Of course in the preface to that, Larrick made the statement that, "There may be other substances and the list was not intended to be all inclusive or exclusive."

I'd like to make a few comments on this "generally, recognized as safe." I am a dedicated disciple of a man by the name of Paracelsus.

Porter: You want to spell that.

Wulfsberg: Paracelsus. He was a "physician", in the year about 1530 and a German. His position was that there is nothing safe and there is nothing poison. It is all a function of the amount. Freely translated from a publication, extracted by the National Library of Medicine from a document published in Cologne I translated Paracelsus's statement and it says as follows, from German to English: "What is there that is not poison, all things are poison and nothing is without poison. The dosage alone determines that a thing is not poison." In the "generally recognized as safe" list, we included such things as sodium hydroxide, hydrochloric acid, acetic acid, which we regulated under the Hazardeous Substances Labeling Act. These could only be sold with the skull and crossbones, yet here they appear in the generally recognized as safe list. Which is a bit of an anomaly. Actually in my mind the definition should, in a more cumbersome way have been: "substances for which there is general recognition of the safe conditions of use," because the substances themselves are obviously not safe.

Porter: Okay.

Wulfsberg: With the advent then of the Food Additive Amendment...I think it was fully in effect about January 1, 1959. The industry people came in in great numbers to discuss their own particular problems or to somehow or another enhance their understanding of the whole program. I think that in the first year that I was in that office there were probably 300 people came in in groups or alone, attorneys, chemists, administrators from the industry to discuss their own particular problems or general understanding of the Act. So, it made for a very busy place.

Porter: Well, you had a small group of people.

Wulfsberg: Yes.

Porter: I would presume, at least on some of these, more than one of you would sit in, or did you individually handle these interviews?

Wulfsberg: No you're correct. I had 8 professionals and a clerical staff of six and a couple of administrative people. Well, I wouldn't mind naming these chaps that worked with me there, there was Fred Cassidy and Allen Spiher there the longest, then Russel White, Robert Brigham, Pamela Ikari, William Randolph and Leonard Louie. The workload was divided in that Allen Spiher handled all of the food additives that were related to animal feeds. Fred Cassidy and I handled most of the industry interviews. There was a tremendous amount of correspondence to reply and I had a good secretarial staff.

Porter: Einar, now there were a lot of these questions that came up during the conferences that must of required a scientific opinion or decision before you could reply, is that right?

Wulfsberg: That is correct

Porter: You then in turn had many, many meetings with scientists, and possibly others, but mostly scientists in Food Division.

Wulfsberg: That's true. I neglected to say that many of the meetings were done over in the Bureau of Science, other than my own office. The moment they wanted to present any kind of data or discuss the scientific aspects of it, it involved people over in there particularly Arnold Lehman and his group in pharmacology.

Porter: In pharmacology.

Wulfsberg: In pharmacology. Many of them that had strictly scientific problems went directly to the Bureau of Science to discuss their problems. We had enough business of our own so that was no problem with us.

If a substance then fell within the definition of food additives the proponent had to prepare a petition, the rules are laid out in detail in the regulation. This included all the elements that must be included in the petition, the format in which it must be set up and so forth. When the petitions came in, five copies, we assigned a serial number for control

and routed the copies primarily to the scientific divisions for their review of the safety aspects of the thing. The law, I believe, provided that petition processing should be completed in 90 days, though the Commissioner on his own and the secretary on his own volition could extend that period not to exceed 180 days.

But this was never really observed, the clock could be started again, just simply by asking the proponent for additional safety data. This would set the clock back to zero and you could continue this process indefinitely. Actually, I don't believe that any petition was processed in 90 or 180 days. Some of them took years until they fully satisfied the scientific people that all of the requirements of safety had been reviewed and research had been done, and all this sort of thing. This would finally then result in clearance from scientific divisions, the preparation of a regulation and publication in the Federal Register. Ultimately there was publication in the code of federal regulations.

Porter: Well, now if you had a conflict, in-house conflict, and you must of had differences of opinion and so on, who in FDA ultimately resolved those? Would this be Kirk, based on your recommendation or...

Wulfsberg: No regulation went to print without Kirk, obviously. We were a processing agency, we didn't come into much in the way of differences of opinion among the scientific

people. When Kirk would get them signed off, particularly by Arnold Lehman, that was it. Without clear cut commitment on their part he would hold the thing up.

Porter: I recall in an interview we did with a group of pharmacologists 2 or 3 years ago. They were talking on the same subject and I think the comment was made that they did not recall a single instance when they had come to a conclusion that Kirk over-ruled them.

Wulfsberg: I think that would be correct. We sometimes chafed under the length of time that it took them to make up their mind.

Porter: You took some of the static...

Wulfsberg: Well, the industry of course was constantly after us coming and saying well how are we doing and that sort of a thing. We would have to try and give them an honest answer, and maybe if necessary refer them to scientific divisions and let them sit down and thrash it out with them as to what they didn't like about the thing and what they were dissatisfied with. The net result of it was, a tremendous amount of work was done and the code of federal regulations began to get thicker and thicker in the section devoted to food additives.

I held the food additive office for a period of a few years. At which time, by more or less mutual agreement, I had a falling out with J. Kenneth Kirk I think he was about as anxious to dispose of me as I was to leave. I was assigned to

the Division of Case Control under Malcolm Stevens and actually worked for Chester Hubble in processing pesticide cases coming in from the field, proposing legal action in one form or another. I was there through one reorganization which resulted in Stevens being promoted to a position of Assistant Commissioner for Regulation and the case processing function came under Allan Rayfield as Director of the Bureau of Regulatory Compliance.

Along about October of 1964, I was relieved from my duties in pesticide case processing. As it occurred, Mr. Rayfield called me into his office and handed me a note from J. Kenneth Kirk indicating that in conversations with Kirk I had expressed some ideas that were out of conformance with administration doctrine. One was that I had expressed an opinion that the zero tolerance was an unscientific concept. Well, as a matter of fact that had been expressed by Larrick in June of the same year and he had been struggling with how to administer a law with a zero tolerance concept in it. Also Rayfield brought up from this memorandum from Kirk that I had some difficulty with my conscience in processing certain cases. I didn't feel that that was a problem. I made a hand written memorandum immediately at the conclusion of the interview. Rayfield advised me he was going to discuss with Mr. Yakowitz and Mr. Hubble my reassignment to some other work. Later I discussed with Hubble what problems I had with my

work as far as he was concerned, and he said he didn't know anything about the matter. The decision had been made, of course, without reference to Mr. Hubble or Mr. Yakowitz. Ultimately then when Dr. Goddard came in and brought Ed Turk in for program planning and budgeting system, I was transferred to that office as one of the staff people. Our function up there was to project work plans for the FDA in terms of broad spheres of activity. I can remember at the time one of the great thrusts was salmonella and a great deal of emphasis had to be placed on bacteriological contamination of foods. My function there was a staff function and we energetically and diligently prepared these projections as part of what was called the 5-year plan. But I was somewhat disillusioned with that work because nothing ever came of it. We would complete one five year projection and as far as I was concerned drop it in the waste basket and start on the next five years. So, though I can't say I did not enjoy the work, I could see nothing coming of it, and we worked very hard with good people.

I'd like to go back, a little bit, to a circumstance surrounding my release from case processing in pesticides. I mentioned in October of '64 I was called into Rayfield's office and he advised that he had a memorandum from Kirk indicating that I had some ideas that were unacceptable. Actually, this happened in that some couple of weeks before I stopped

into Kirk's office in the course of delivering certain papers regarding a case under consideration. He asked me to sit down and discuss how things were going, things that I was thinking about and all this sort of a thing. Well, it was out of that conversation that this note went to Rayfield, suggesting that possibly my release should be considered.

Porter: This would indicate that you and Kirk had a philosophical difference about certain matters...reading between the lines.

Wulfsberg: I think that's true, yes. That probably...some of these will illustrate a little bit about of how it came about. I mentioned that he asked me if I had trouble with the concept of the zero tolerance, and I said yes, I didn't believe in it and I realized that Mr. Larrick, several months before, had publicly expressed his concern about the zero tolerance. Larrick at that time didn't really know how to handle it. The thing that had really happened was that during the late 50's and the early 60's the science of analytical chemistry had made tremendous strides and this resulted in the idea of zero being almost incompatible with science because the tiniest amounts could be detected. Previously the Food and Drug Administration had been able to say none was there with a method that was now relatively crude. But now all this has changed because of the teriffic breakthrough in the science of analytical chemistry. One of Larrick's suggestions was that

they should freeze the analytical method for these determinations. Obviously this would be scientific nonsense. He had been given bad advice.

Porter: I believe I have heard that opinion attributed to Billy Goodrich.

Wulfsberg: That could well be. He was not a scientific man.

Porter: I believe somewhere, someone has mentioned that.

Wulfsberg: Yes. This however was several months before my conversation with Kirk, so as far as I was concerned I was in reasonable concord with the thinking in the Commissioner's office.

There was another incident that Rayfield made reference to. I had handled a seizure recommendation from the field, calling for the seizure of parsley. And if I recall properly it had a fifth of a part per million of parathion, well the tolerance on most fruits and vegetables for parathion, I believe was a part per million. No tolerance had been provided for parathion on parsley. I told Kirk I had problems with seizing this because I didn't eat parsley and I didn't think very many ate parsley, and it was used as a decorative thing on salads and the amount there was relatively trivial. The problem was that as the law was being interpreted, "if there is no tolerance for a pesticide on an agricultural product, the tolerance is zero". This gets you into an anomaly from time to time, and I have some other examples of it.

Kirk explained to me that the consumption aspect was not a factor and the purpose of that seizure was to impress the producers as to their abuse of the pesticides.

Well, there is another incident somewhat similar to that of which Rayfield reminded me. That was a detention of black pepper at the Los Angeles District because the black pepper had .5 part per million of DDT. There was no tolerance for DDT on black pepper in the regulations. The District had concluded that the tolerance was zero. When the importer complained that this was unfair in view of the seven part per million tolerance on general run of fruits and vegetables, he was advised to consult later at the Washington level. Well, all of this correspondence came in then, with this detention case. I discussed it with Hubble and told them that in view of the small consumption of pepper and the tolerances on fruits and vegetables which we eat in quantity, this seemed to be an unreasonable detention. Actually what happened was that Hubble agreed and I called Howard Ballinger in Los Angeles and the pepper was released. But it didn't do me any good, personally, to have taken this position on it, which was actually in sympathy with the importers. The whole body of facts to me indicated that the detention was ill advised. It appeared to me that the regulations could be more appropriately interpreted for the guidance of the Districts in situations like this.

Well, there was one other incident to which Rayfield made reference, and that was that a Dr. Chapman had come in from Canada Food and Drug Directorate. He had a problem with respect to heptachlor in dehydrated beet pulp that was apparently being fed to animals and the milk was being shipped to U.S. or else the pulp was being shippped and the dairy animals were fed in this country. One of his concerns was how you deal with very small amounts of pesticides, for which there are no regulations and supposedly then a zero tolerance. Well, I mentioned to him that I had been quite impressed with the manner in which the Federal Radiation Council had handled the subject of strontium 90 in milk. After that Nevada test explosion there was quit a bit of interest in this, because of fall out and animals eating grass.

Porter: I remember.

Wulfsberg: So, the Federal Radiation Council set up to monitor this thing all over the country. The analytical methods were entirely adequate for strontium 90. Well, the Federal Radiation Council was then an arm of the Public Health Service and there was never particularly much love between Public Health Service and Food and Drug Administation. They published monthly reports, and in the first part of this monthly report they said there is strontium 90 in milk but in amounts which are of no significance to health, but they didn't say that they were zero or anything like that. After this discussion I

said that they had taken this position, clearly advising the public that there was strontium 90, and of course the toxicologists consider strontium 90 a highly toxic substance. So, I said that I would send him a copy of the most recent Federal Radiation Commission's monthly report and he could see their philosophy outlined in the front page. Well, he acknowledged receipt in a letter. I simply sent him a transmittal. I was criticized because I had not run the transmittal letter through the administration. I made a mistake there. Actually, we were handling hundreds of letters, going directly to the industry all over the country and none of them cleared the commissioner's office because they just wanted no part of that voluminus correspondence with respect to food additives. Anyway, that was brought up by Rayfield as one of the things where my ideas were somewhat non conformist.

Another problem that the Food and Drug had, it involved the seizure of alfalfa hay containing DDT. The seizure of the hay was made in the hands of dairymen, they could not find a way to allow that hay, slightly contaminated with DDT, to be diverted to horse feed. I expressed an opinion that there must be some way to be able to divert this to a non-food animal, rather than to destroy it. The result of the memorandum, Kirk to Rayfield, was of course, that I was relieved. Rayfield made some remarks about the type of explanations that I was giving to the field districts in connection with the

processing of seizures and he thought that these remarks were unnecessary. However, in a prior staff meeting he had asked us to be as informative as possible so that the districts would become familiar with Washington thinking. I agreed that I would discuss this with Mr. Hubble and endeavor to become better advised as to the form of explanation appropriate in the letters to the districts. Rayfield concluded this discussion by saying that it was appropriate for me to work out the matter of these explanations with Hubble, but that he would ask Mr. Yakowitz to give consideration to my reassignment.

Porter: During the time that you were handling pesticide matters, were there any cases that you were involved in that you think might be particularly interesting.

I think of one I know of, but not to much about, where we seized spinach, as I recall in southern Colorado. It finally ended up in a lawsuit which the government lost. Is that an incident that is worth talking about?

Wulfsberg: Well, I think that we could mention it. This is the case of Mizokami Brothers at Fort Garland, Colorado. They were big spinach producers and at a particular season of the year their spinach would dominate the market because of the climate. As I recall, Food and Drug seized a carload of that spinach, in New York, and subsequently Mizokami brought suit against the Food and Drug Administration for, I believe, 2.5

million dollars for damage suffered when the seizure broke the price of spinach in the New York market.

Porter: Excuse me, Food and Drug seized it because of excessive spray residue?

Wulfsberg: Right. Excessive pesticide residue. Mizokami brought suit and I was then assigned to the Department of Justice in their efforts to prepare a defense. We did a great deal of research on the cars of spinach coming in to the New York market, I went to the Department of Agriculture to follow the pricing as it moved from day-to-day, because they had records of all of this sort of thing. Actually, it was impossible for the seizure of the spinach to have affected the price structure because the price structure broke in advance of the seizure. It broke sharply in the New York markets for reasons other than our interest in sampling this spinach.

Porter: Was he claiming that all of this spinach, not just this car, but because of the seizure of the car he had to sell all of his spinach cheap? Is that the idea?

Wulfsberg: Correct. In otherwords the market broke and stayed down for a long time and he had to sell his spinach as it matured. So, he then had to play a market with much reduced prices than he would have liked to. I thought our case was persuasive, convincing without a doubt, but apparently the Court of Claims decided that they would give him his money and the Food and Drug Administration lost that judgement. I think

it was a very erroneous decision on the part of the Court of Claims, but once they made up their minds there was nobody going to tell them otherwise.

Porter: No, that is it. Any other specific cases? In fact even going back to food additives, if you like. I am interested not only in the procedures, and what we did in house but examples of things that happened that might have some particular interest or have some value as precedent.

Wulfsberg: I don't think there was anything very dramatic that happened over there in food additives. The industry was determined to adapt themselves to the amendment. At their request, I made speeches around the country to different kinds of groups, as best I could with respect to the Food Additives Amendment. I can't recall anything that you would say is dramatic in the handling of food additives.

Of course, after I left, Frank McFarland came in and I think he continued the work and did a good job of it. It was a subject of a great deal of interest but I don't believe there was much commotion attended to it.

In November 1967 I ended my career with the Food and Drug Administration under the age 55-thirty year service provision.

I worked over town then as a free lance consultant. My principal client was the American Paper Institute. I had other clients, one of them was Charles Fistere, an attorney, and I did handle one petition for Freeport Gulf Sulphur, that

was a modified form of Kaolin for the use in the paper industry.

Porter: You had dealings with FDA then in person or by telephone quite often, I would guess.

Wulfsberg: Yes, not often, but there were times. During the time that I was retained by the American Paper Institute, the big flap came up of PCB's in recycled paper board, or grey-board, from which cereal boxes and things of that kind are made. That incident was time consuming for all concerned.

The National Cash Register Company under contract with one of the paper companies had developed a self copying carbon paper which included polyclorinated biphenyls, PCB, as a vehicle for the dye on one half of the system. Actually I understood that it was a form of microsized gelatin capsuls, containing the dye which when broken by the force of a pencil or a pen would interact with the other surface and produce color. Clorinated hydrocarbons are considered very bad. Paper from these self-copying systems went in to the waste paper system and finally wound up in recycled paper board. With the methods now available, or then available, they could detect it. The question was, did it get in to the food? Well, we did some experimentations at Hazelton Laboratories, to try indicate how it might get in to cereals and things without any conclusive results. The Food and Drug Administration could find recycled paper, greyboard as we called it, and detect polyclorinated

biphenyl but, never to my memory did they ever find and act against a food because of contamination with polyclorinated biphenyl from the package in which it traveled. It caused a great deal of commotion and pain in the industry and they agreed with Food and Drug, somehow, on some level, that would more or less be acceptable, an informal sort of thing. They had to tool up a tremendous amount of equipment and chemists in order to satisfy their customers with a chemical report that they were below this agreed upon level and this cost them a great amount of money. Even though they might know that their run was well under control, they still had to have the chemists running the analysis and provide it to the buyer of the paper because they were scared of what was going to happen to them. That was the most dramatic thing that happened during the work that I did for American Paper Institute.

Porter: Einar, I'd like to ask you to go back in your career, you just gave us a short sketch of it, and talk about incidents, personalities, those that you think would be of interest, whatever you'd like. If you want to kind of think about some things like that.

Wulfsberg: Well, I think I told you once before that to me the most interesting legal cases that the Food and Drug had were Marmola, Lexington Mill and the Bodine Lettuce Company decisions. The history of these cases in which the Food and Drug had been involved, was compiled by Vincent Kleinfeld with

the first couple of volumes by Kleinfeld and Charles Wesley Dunn and then later by Kleinfeld and his collegue Kaplan. These I think are excellent references to the early day litigations of the Food and Drug Administration bound in hard back volumes. But as I mentioned, there are three cases that particularly interested me.

Porter: Now were you personally involved in these cases?

Wulfsberg: No, I wasn't involved in any of them. Just that I came upon them by studying these reviews of cases.

As far as personalities are concerned, I don't have anything very exciting. I worked for Wendell Vincent, at the Denver District. My relations with Vincent were essentially professional at all times. I understood that he had some drinking buddies, but I was never one of them. I was pretty much a family man, went home after work, never stayed around afterwards. I had no problem of my respect for Wendell Vincent. He was a hard working man, I think he understood his job well, he had some problems other than that.

I worked for Samuel Alfend in Kansas City. Sam was a very dedicated food and drugger, a hard working man who expected hard work from everybody that worked for him. Sam was a bachelor and I think his principal hobby was mountain climbing and he used to go to Colorado for his vacations and climb these 14,000 foot peaks out here. Sam is one of those who is still living among our retiring years.

Porter: He still belongs to the Colorado Mountain Club. The last I heard, which is maybe a year ago, he still did do some mountain climbing, but he's getting up in years now.

Wulfsberg: He certainly is, that's remarkable.

Porter: Incidently, I interviewed him in this series so that we'd have a record of his recollections.

Wulfsberg: I worked in Washington for Shelbey Grey. Shelbey Grey was very much a gentleman in his dealings with you and I didn't have any problems with Shelbey Grey. Of course he had his problems. It was a devastating blow to his sensibilities when he was replaced by General Delmore, who returned from the military service. As I mentioned earlier, Kirk and I had some philosophical differences and ultimately after a few years in the Foods Additives Office, I suggested that we consider separating, which was quite agreeable, I'm sure to him.

Winton Rankin was in my car pool, from out in north Arlington, with Doc Osbourn, James Cribett and Ramon Davilla.

Porter: There must of been some interesting conversations in that car pool?

Wulfsberg: Well, it was back and forth every day, but you see our conversations were pretty much on the light side. We never discussed anything that occurred in the Commissioner's office. Now Winton Rankin, of course, is responsible for that posture. Winton was more or less considered as not having any

close friends in Food and Drug Administration, socializing buddies and the like. There was a reason for this, for which I am perfectly sympathetic. Winton was, as I am sure he knew, being groomed for the position of Commissioner. He did not want to make any close friends among the people whom he would then be administering. I think that the scenario that was generally agreed upon was, that when Larrick retired, John L. Harvey would step in to the office for a sufficient length of time to establish his name as being Commissioner of Food and Drug and then he would immediately step out and Winton Rankin would succeed to that position.

Porter: That is what we all thought, anyway, didn't we? Those of us down in the ranks sort of assumed that was the scenario.

Wulfsberg: That is the way that we looked on it. Of course, things happened otherwise. I don't think Kirk really aspired to the position of Commissioner of Food and Drugs. But I think he did aspire to the position of Deputy Commissioner of Food and Drug in a comparable position to John L. Harvey.

I never had much close contact with Allan Rayfield. From the point of view of an inspector in the field, Allan Rayfield was kind of a man to be feared.

Porter: Right.

Wulfsberg: He was not a warm sort of person, as concerned those of us who were way out in the boonies.

Porter: I would say, I at least both feared and hated him. Just to be frank with you. In those days. Now I have changed my opinion drastically. I did after I got to Washington and worked with him and I hold him in very high regard now, but that wasn't true back in the years when I was in the field.

Wulfsberg: As far as the incidents in my career, just briefly, I'll mention of course the Pure Food Case in which a firm that made inexpensive imitation jellies shipped a batch, distributed it through the Rocky Mountain west. In Nampa, Idaho I think it first showed up that the children who ate jam and jelly sandwiches prepared with this imitation grape jelly became violently ill and threw-up all over the place. So, of course, we had to find out what was happening and there was a recall and the incident stopped very quickly. The fortunate thing about it, the toxic substance was fluorine and it was in a sufficient concentration that upon eating one of these jam and jelly sandwiches a child would immediately vomit, which was of course the best thing that happened. None of them were seriously injured other than the discomfort of nausea. But the goods were recalled and then we had to find out what had happened and we got samples of it. Sam Fine, of course, immediately found a high load of fluorine in it. And I was assigned to go down to Pure Food Manufacturing Company and find out how the fluorine got in the jelly. Apparently there was only one batch, they made it in big kettles.

Porter: Yes, Well I've been in that plant.

Wulfsberg: So, I searched that premises from top to bottom. I found a 1/2 pound of sodium fluoride colored blue that they scattered along the edges of walls to get rodents to pick it up, and wipe it into their mouths, but no way that that could have caused it. Finally Sam Fine who kept at this thing, he said, "now there are three things in there in fairly good amounts that I think don't belong in jelly, magnesium, silicon and fluorine." I went and grabbed a Merck Index of chemical substances, the big blue book, and sat down and started thumbing through that thing to find out what had magnesium, fluorine and silicon in it. And, of course, there's a compound in there of magnesium silico fluoride which had 6 molecules of fluorine in it so it's pretty heavily loaded. Well, I kept reading the fine print underneath there to find out what the dickens this stuff was used for. One of the uses was as a hardner for concrete floors and so I started calling building supply companys, "do any of you have some magnesium silico fluoride?"

Wulfsberg: As I mentioned, I started calling building supplies and I found one of them had it. Well, I went down there and found out that crystals were cubes, reasonably resembling sugar. I brought a sample into Sam Fine and he told me right out this is it, as soon as he had worked with it a little bit. Next question was how did the compound get into the jelly.

Well, I started inquiring about where they got their sugar and they told me among other things that they bought slip-bag sugar. This means that when a bag is damaged by a fork-lift or in handling, the warehouse puts a slip-bag over it and ties it up. This becomes sugar that is sold at a slightly reduced price because the bag had been cut. Then I talked to the warehouse operator out there and asked them if they had ever had any contractor in there using magnesium silico fluoride, a concrete hardner. "Oh yes." Was there any left over? "Yes, there was 1/2 a bag left over." What became of that? "I don't know it just disappeared." So, at that point we pretty well figured we had the answer, that this had been slipped bagged by an employee who thought it was sugar, because the crystals are cubes resembling sugar. So, that pretty well answered the question but it was very interesting exercise.

Porter: Yes.

Wulfsberg: If we have the time, I'd like to discuss a few concepts that to me have been rather interesting.

I mentioned that as a disciple of Paracelsus I would not agree that anything was safe or that anything was poison. In connection with that, I researched some old Webster's International Unabridged Dictionaries and found that there had been a change in the way they handled it. In a dictionary from 1957, in defining the word "poison" they said, "an agent which

introduced especially in a small amount, into an organism may chemically produce injurious or deadly affect. Morphine is a deadly poison. The poison or the venom of a snake are two examples." But at the same time Torald Sollman probably the Dean of Pharmacologists of his time said that "morphine as an analgesic, is highly effective in the suppression and of the appreciation of pain." In other words, the question is, is morphine a deadly poison or is it one of God's blessings to men in great pain?

Porter: Yes.

Wulfsberg: Now, later the dictionary did not identify anything as poison, per se, they got away from that because of the fact that you have to ordinarily have a highly toxic substance and an "amount" which becomes part of the organism and causes injury to health. But the amount is critical, in the case of morphine one amount is used to relieve pain, another amount will cause death. The Food and Drug law has some problems with this whole concept of poison. It's not the fault of the Food and Drug Administration but legislation is a peculiar sort of a thing in which many people up there on the hill tried to get their own concepts into it. They may not be very well educated scientifically. So, you have to take with the law, in my opinion, what you get and work with it as best you can.

Now, as one example I think Larrick was opposed to the Delaney Amendment, but the Food and Drug had to take it and

they have had to live with it all these years even though I think reputable scientiest everywhere say that it does not make sense from the scientific point of view. To get rid of it, is not easy once it gets into the law and I think the Food and Drug Administration has had their problems kind of working around this Delaney clause all during these years. It's not difficult to find scientific people who would say that this clause is not a good part of the law.

In the Food and Drug Act, of course, you've got some of the same sort of problems. In 408 pesticide section, we have any "poisonous or deleterious" chemical, or any pesticide chemical and so forth. Now the term poisonous is used there. I would rather see any "pesticide chemical", if that's what they want. To identify them as poisons is not accurate, but legislatively it gets into these sort of things. This section continued, "shall be deemed unsafe for the purpose of Clause 2 of Section 402(a), unless a tolerance for such pesticide chemical has been prescribed by the Secretary." This is where the zero tolerance thing comes in, which has also been very controversial and very difficult for Food and Drug Administration. Back in Section 406 you use the same term, "Any poisonous or deleterious substance added to any food" etc., actually you could just simply use the term "any substance added to any food which may cause injury." We will take action against canned soup with too much salt in it, but salt is not considered as being a toxic chemical, a poison.

Porter: Right.

Wulfsberg: But in some amount it becomes poisonous. I used to keep records of incidents in which death had been caused by common chemicals. There were seven babies died in a hospital in Binghamton, New York because a technician mistook salt for the sugar in making up the baby formula and the babies can't taste the difference, so seven of them died. So salt then, per se, is a toxic substance, it is lethal. You don't have to go too long in the papers until you see a "gin duel", and there was one in the Denver Post not long ago, in which a couple of guys decided to see who could drink the most gin and both of the participants were dead at the end of the incident. So, ethanol is a lethal substance and you can find incidents like that of common substances which are poisonous if the amount is proper. So, I don't like to see these terms in the Act as they are used, but I know the Food and Drug Administration has had to live with them.

The zero tolerance thing comes about in pesticides, and I gave two incidents of where it doesn't work out. Some of the decisions pop up like that touch of parathion on parsley and then the touch of DDT on black pepper. These are not consistent with scientific common sense. They were each an ad hoc decision made at the time. I don't have solutions for some of these problems, I'm just saying how they interested me.

Porter: Yes.

Wulfsberg: Another thing that I was interested in was the concept of tolerances and I wrote a discussion. You can have a copy of it, unpublished. It is a bit verbose, but I went into the subject of tolerances rather extensively. There are many kinds of tolerances. The simple ones you'd think of are in food standards, good, better and best. Eggs that are large, medium and small or fresh or double A and so forth. These simply are designed to try give the consumer the value that he wants for his money. Then in the pesticide amendment, the text of the law that reads says that the presence of a certain pesticide in foods is considered poisonous or deleterious unless there's been a tolerance precribed. This is a difficult thing. Many scientists have commented on this, that certain substances in exceedingly small amounts should be disregarded even though they are pesticides, disregarded because they are of no interest to health. Then there's a difference between what I call a chemical tolerance and a toxicological tolerance. To me, in the area of poisonous and deleterious substances no tolerance is actually necessary to enable FDA to act. FDA has done this over and over again, taken action against foods that were contaminated with something. Simple things, like I remember cinnammon red hots, they had too much cinnamic aldehyde and they burned kid's mouths. There was no tolerance for cinnamic aldehyde in "red hots". But we took take action against the "red hots" by simply proving by the

chemist that the amount was there and by the pharmacologists that the amount may be dangerous to health. (In this case people were actually hurt.) That's all you need to have. A tolerance does this in one package. The chemist testifies as to the identity of the substance and the amount. Then already pre determined in the tolerance is the testimony of the pharmacologists that the amount (over tolerance) may be injurious to health. So, with a tolerance you save the testimony of the pharmacologist in a court case if you want to proceed against something. You need to have the chemist there to tell how much. It's a time saving device that is actually unnecessary as far as Food and Drug Administration taking action. However, we can take action against any food that has pesticide or any other substance in it as long as you have a chemist to advise the amount and a pharmacologist that says that this amount may be injurious to health. Kirk was a great believer in tolerances, he thought every regulation would be better with tolerance. I don't think so. Now the concept of a "chemical" tolerance comes about that people are very afraid of having too much chemicals in their foods. This is despite the fact that all food is 100% chemical. And this has probably been promoted some by Ralph Nader's group, others that can get a tremendous uproar going over chemicals in food. We must have the least amount. The great desire of people to have natural foods now days is the same thing. Well, the

people over in scientific divisions had some problem there, because there's another phrasing there in the food additive section that says, "If in the judgment of the Secretary, a tolerance limitation is required, in order to assure that the proposed use of the additive will be safe, the Secretary shall not fix the tolerance at a level higher than he finds reasonably required to accomplish the physical effect." Now, if you just kind of forget about the word "safe" up there, then you come down to setting the tolerance at the amount that's required to accomplish the technical effect. Okay, then a man uses more than that amount, to me there's no provision in the law that says that it's an offense unless the amount may be injurious to health. The only authority we have is back in 301k, which says you can not ship an adulterated or misbranded article in interstate commerce.

Porter: Yes. That's 301a.

Wulfsberg: 301a. And that has a definition under adulterated food, a food shall be deemed to be adulterated if it bears or contains any poisonious or deleterious substance, which may render it injurious to health. There's nothing that says there that if a food additive is used in excess of what is required to accomplish the technical effect, the thing is then injurious to health. Pharmacology and chemistry people had problems with that at times. For example there is a substance polysorbate 65 which is an emulsifier used in cakes, ice cream

and products of that kind. Polysorbate has a food additive tolerance of .10% in ice cream and other frozen desserts, but 0.146% in cake mixes. This additive is essentially non-toxic in any reasonable quanitity. These tolerances, in accord with the Food Additive Amendment, are based on data showing that they are the quantities reasonably required to accomplish the technical effect.

Porter: You're reading now from a report of some kind?

Wulfsberg: Yes, I'm reading from a report from Fitzhugh and Ramsey discussing the problem that they had if there were a violation of these tolerances. There's no way that a pharmacologist could say that this is adulterated in a manner that's injurious to health, no way at all. So, this is what I call kind of a chemical tolerance, because it does not involve pharmacology and I don't think there are provisions in the Food and Drug Administration for bringing action against this sort of thing. 301a just doesn't cover it, because it requires adulteration and adulteration is described as having a health aspect. Now, they suggest to work themselves around this sort of thing they proceed by citation to anybody who violates the provision for polysorbate 65, which is essentially almost innocuous as far as an emulsifier is concerned. Or you might ask the question, what temptation is there for a man to use more than what's necessary? To me there's none, because he's throwing away his money, and may ruin his

product. But he could be violating a Food and Drug regulation. I don't know what the answer to this is, but this kind of illustrates what I call a chemical tolerance. It might be possible to limit the emulsifier by a food standard. Violation would be a misbranding. Now, in the language of the regular, toxicological tolerances, for instance, there was a lot of hue and cry against DDT. Back some years ago, they wanted to ban the stuff. And it almost has been banned, I guess. There are some exceptions where no other pesticide will do the trick and they can get an order of some kind permitting its use.

Porter: In EPA's regulation?

Wulfsberg: Well, I imagine that's where it went over there. Anyway, when this excitement arose the Food and Drug Administration, of course, responded and tried to discourgage the uses of DDT. At one point, back about 1968, I was then away from Food and Drug Administration the Commissioner proposed in the Federal Register to reduce the tolerances on DDT, as a kind of a way of beginning to phase it out. To me this was very interesting because if the tolerance cleaves between that which may be injurious to health and that which is safe, and he reduces the tolerances, he's setting it at a lower than safe level which is not what a tolerance is suppose to be. Tolerance is suppose to divide between that which is may be injurious to health and that which is not. So, you can't manipulate a tolerance unless you have new scientific evidence

as to the toxicology, or new scientific evidence as to the amount being consumed by the public. But just to arbitrarily mandate that the tolerance should be lower in order to discourage the use of it, I don't think the law provides for it.

Porter: Well, in the part of the amendment that gives the Commissioner the authority to set tolerances, does it have that concept in it that that's the point of division, or is that something that one would infer from what is said there? I'm asking, I don't know, I haven't looked at these things for...

Wulfsberg: Yes, well basic to the concept to the tolerance, to me is that above tolerance it must be deemed to be unsafe, below that it can be tolerated. I feel that the tolerance contains a two-fold package and that pharmacological considerations are built into the tolerance. And rather than having the pharmacologists appear and testify the tolerance takes care of it, because he already testified in the creation of the tolerance. I was out of Food and Drug and I protested by letter to the Hearing Committee.

Porter: Oh did you?

Wulfsberg: Yes, two letters. I don't know if anything came of it. One of the letters was written in 68', one of the letters in 70' and I agreed that DDT should be banned, I agreed that the Commissioner's purpose was entirely benevolent, I just simply said I didn't feel there was any provision in the Food and Drug Act for manipulating a tolerance.

We got into the same sort of thing, a little bit, in PCB's in paperboard. FDA had a level that was considered acceptable, but it hadn't been promulgated as a tolerance. But then the Commissioner came out with a Federal Register proposal that as soon as the industry could do better, he was going to lower it. In other words a tolerance represented what the industry could do under the best available state-of-the-art manufacturing conditions. At that point it was no longer cleaving between that which must be deemed to be unsafe and that which could be considered safe. So, I objected to that, because there is no provision in the law for manipulating a tolerance in that way because if X is a point which divides between the two, the only way he can lower it is that he finds out that the substance is more toxic than first believed to be. Then you must lower the tolerance. That was not a consideration at all, it's just that they thought the industry could do better or make it better, meet a tighter standard and so on.

On the subject of filth, of course, we had some unofficial tolerances, they are not published as tolerances in the Federal Register. But the industry knows that's what they are.

Porter: They published some of them, at least in the standards, which makes them part of the regulation.

Wulfsberg: Possibly, yes. And these are really indications of the capability of the industry. For instance, we say that

you can have not more than so many mouse pellets in so much wheat.

Porter: Yes.

Wulfsberg: Well, that's a case again then. The health consideration is really not there. Then way back when they found the method for detecting worm fragments in comminuted tomato products they simply worked with the industry to some extent to drop this down until they got within the capability of a well run tomato factory. Now all this is in the area of filth, not poisonous or deleterious substances.

Porter: Yes.

Wulfsberg: Of course the law provides that you can't have any filth in food. Well, this is a little bit of an anomaly you might say because there is no such thing as filth free food in the absolute sense. So that had the same effect as a tolerance, Food and Drug will go to court on those things which are persuasively filthy and they'll make the cases stand, even though you can not go to the Code of Federal Regulations for the tolerance. You can't find a worm fragment tolerance for comminuted tomato products. It's interesting to me the interplay of all sorts of ideas revolving around this sort of a thing, a zero tolerance. The National Academy of Science has considered the problem. They wrote a rather substantial document on zero tolerances and concluded that the concept was scientifically unacceptable. Of course the Congress didn't

realize the impending progress in analytical chemistry back in the days when they were passing Food and Drug legislation.

From the little incidents I've given you, you see how sometimes the Food and Drug has to kind of work around these things. For example, I think we proposed a seizure or two of sodium benzoate in pickles at one time or another that were substantially over the tolerance of 1/10%. Pharmacologists wouldn't touch it, insufficient toxicity to the stuff.

In connection with the subject of pesticides, food additives and that sort of a thing, I was much impressed when the Food and Drug Administration undertook what they called the Market Basket Survey.

Porter: Yes.

Wulfsberg: The purpose of that was to examine a representative food basket and with these modern sensitive methods to come up with an idea of how much is there of clorinated hydrocarbons, parathion type compounds, and other things even the heavy metals. To me that was very sound because if you want to keep kind of an oversight on what the public is getting in the way of compounds that are considered highly toxic, that appeared to me to be the best way to do it. By funneling in all of these results from the different laboratories around the country to make a picture out of this sort of thing. This is one of the things that they did which I thought really was good.

Porter: That program still exists you know and continues and has been broadened in the terms of the things they look for.

Wulfsberg: Yes.

Porter: They monitor radio activity in foods through that program too, I believe.

Wulfsberg: Probably so.

Porter: I even think it's even been made broader than that. Then again I've been away from it too long and I don't know exactly what they look for.

Wulfsberg: That's good. The law, Section 406, was the original Pesticide Amendment, until back in the 50's when they decided they had to overhaul this thing, come out with a brand new one, which is very voluminous. Section 406 is very interesting to me in establishing a pesticide tolerance. That section has to do with poisonous and deleterious substances in general. It provides that the Commissioner or the Secretary in determining the quantity of such added substance to be tolerated in or on different article of foods, shall take into consideration the extent to which the use of this substance is required. He shall also consider the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. In other words, in setting a tolerance for something, you should know all of what is impacting on the consumer day by day right now and that's the Market Basket.

Porter: Yes.

Wulfsberg: As Section 405 provides, "The Secretary shall give consideration to the other ways in which the consumer may be affected by the same pesticide chemical, or by other related substances that are poisonous or deleterious." So in the case of DDT, a clorinated hydrocarbon, you take into consideration the amount of DDT, but also the amount of all other clorinated hydrocarbons that are impacting on the consumer as disclosed by the Market Basket. That is why I think Section 406 is consistent. The whole concept of toxicity.

Another of the concepts that I got into, sometime or another, probably back when I was with Shelbey Grey's group was the concept the measure of accomplishment.

Porter: Oh yes sure, I was involved in that a lot.

Wulfsberg: Traditionally in the Food and Drug Administration the measure of accomplishment for the Districts, District Chiefs, and the Inspectors and etc., was the number of citations, seizures, prosecutions and injunctions that originated from that District. I was under the impression that this was not a good index of accomplishment. Now, if the number of violations were infinite or exceedingly large compared to your capability, then you could use it. But as your work is effective and induces compliance in the industry, you rapidly come to a point of diminishing returns and we'd already experienced that. I kept figures during the period of 1954 to 1963. During that time our total input in man-years, for field work

went from 179 man-years to 651 man-years. But during that time, the number of seizures approved was fairly constant but in seizures per man-year we went from five to less than one.

Porter: Yes.

Wolfsberg: In other words, then as a measure of accomplishment, you have reached the point of diminishing returns here even in this period. I kept thinking there must be another way to do this. Well, if you could develop a measure of compliance or index of compliance and the target would be 100% you could never reach that so you were safe and you would not reach a point of diminishing returns. So if you had some way of saying that some particular industry segment had a compliance of 60% then you say, next year we hope to improve this by so much, and we want to budget so much manpower and dollars to raise it to 70%, or something like that. Well, you could keep this up of course and I don't think you'd ever reach 100%. But depending on how the industries complied you could direct your manpower, conclusively I think, and persuasively at those which had the lowest index of compliance. Well, we did some work along these lines. I think one time we had a wheat campaign in which the reports of the wheat cleanliness were reported on data cards.

Porter: That's right.

Wulfsberg: Then we could get an idea of the level of compliance of the grain shipping and handling industry, in

determining, do we need to put more manpower on this or don't we?

Porter: Yes.

Wulfsberg: Accomplishment is measured not by how many wheat carloads you seize or prosecutions, but you try to determine which Districts have acceptably clean wheat. At the time the only one that was somewhat interested in this, was Morris Yakowitz. I even got as far with it one time as making a staff speech, for the assembled Food and Drug. Do you remember we occasionally had them?

Porter: Yes.

Wulfsberg: I had a prepared speech suggesting that some consideration should be given to finding some positive way of measuring accomplishment. Of course, I don't think the District Directors particularly cared for it, because it's difficult to reward an inspector for finding a plant NAI, in compliance.

Porter: Yes.

Wulfsberg: It is much more interesting for the inspector to be able to find and develop a violation that results in a seizure prosecution or injunction. And that traditional feather in the cap of the District Chief, would have to take second place with this sort of a thing. Of course, you could probably run the two programs concurrently for awhile until you found out some way of trying to measure compliance.

Porter: You see in bringing this up more to the present... You have an entirely different philosophy of enforcement now that leans much harder on education and voluntary methods. Consequently, the numbers of legal actions have dropped even more drastically in the last years since those figures that you stated.

Wulfsberg: Yes.

Porter: Since, those figures have dropped, it's been even much more drastic, and of course the organizations has become bigger too. So that kind of thing is really no measure at all, I mean no one even thinks about that to measure accomplishment anymore.

Wulfsberg: Don't you agree with me, that during my time there was quite an amount of rivalary between the districts?

Porter: Oh yes, in fact when I came into Washington, into a job that was at least I think I had it probably in parts some of the same responsibilities that you had.

Wulfsberg: Right.

Porter: Oh yes, I worked on that a long time and I remember digging out some of your old work and redoing it too. We struggled with that, and the main reason we did struggle with it is that it had been pointed to with pride over a period of years and suddenly we had to reverse direction in a way because we couldn't keep up. If we kept pointing to that. It would not be with pride anymore. The legal actions were going

down. So we had to think of other ways to try to go at it and other ways to collect data. But even when you try to collect data not on the basis of legal actions but on some sort of compliance guide, there are so many variables and the whole thing can be thrown into confusion by merely a change of inspection instructions.

For instance, Food and Drug is doing very little about insanitation, very little. Part of that's because it isn't needed nearly as badly needed. Industry in general and education of people who work in the industries is such that the standards are higher, although there are many back sliders, I'm sure. But the fact is, that it's not only the condition of the industry but a change in philosophy of Food and Drug or change of instructions, change in approach, change in training of inspectors all those things can impact on your figures and they don't have a damn thing to do really with whatever this theoretical compliance state of the industry might be.

Wulfsberg: Well, that may be true, but I am not fully persuaded.

Porter: It's too complicated a thing to measure, I think.

Wulfsberg: Well, that of course is true in most government activity.

Porter: Right.

Wulfsberg: And in non government activities you just look at the balance sheet and you know whether that organization is effective or not.

Porter: That's right.

Wulfsberg: But the government doesn't have anything there that can be measured.

Porter: We don't produce widgets.

Wulfsberg: We don't produce widgets.

Porter: That's right.

Wulfsberg: Well, anyway I struggled with that idea a certain amount. It's interesting to hear your remarks that the whole concept of accomplishment by seizures, prosecutions and injunctions went down the drain, but quick.

Porter: Had to.

Wulfsberg: Here you were reaching the point of diminishing returns.

Porter: Yes.

Wulfsberg: Back in late 50's and 60's.

Porter: It would of had to go if there would have been no change in philosophy, but the change in philosophy accelerated that.

Wulfsberg: Yes.

Porter: Einar, Before we do finish this tape I would like you to have the opportunity to talk about some of the people you knew, in maybe more detail then you did awhile ago or give

some anecdotes, or whatever you'd like to say. Are there any people you'd like to say a little more about than you've already have?

Wulfsberg: Well, I would like to say a little about Arnold Lehman. I had a professional relationship with Arnold but also a friendly relationship in as much as he was a neighbor of mine, he lived not a far distance from our home. I always had a tremendous respect for Arnold Lehman. I think that he was aggressive in producing papers and publications, of which, I believe there's quite an assemblage that many of them were published in the what we called the AFDOUS, the Association of Food and Drug Officials.

Porter: Yes.

Wulfsberg: These enjoyed large circulation and publications concerning food additives, such as this one here, "Toxicological reasons why certain chemicals cannot be permitted in food."

Porter: Was that an AFDOUS publication?

Wulfsberg: That was an AFDOUS, yes. Also when we would, in Food Additives, get petitions, processed petitions, with AJL on them, I had it made and could go ahead with preparing a Federal Register Proposal. So, after Arnold Lehman retired, I used to call on him at fairly regular intervals and we would talk about all sort of things and have a great time. He was not in very good health after he retired, but we had a lot of fun kicking things around.

I also, of course, had the privilege in Food Additives of becoming acquainted with the attorneys around Washington who became involved in this thing. I was particularly impressed by guys like H. Thomas Austern, Vincent Kleinfeld, Ed Brown Williams, Mike Markel, Kenny Mulford from Dupont, Charles Fistere from the American Dairy Association, and many others. These were men of stature around Washington and with whom it was an experience to have the opportunity to make a contact.

Porter: Yes.

Wulfsberg: I think that is about all Bob.

Porter: Okay.

Well, Einar, I really appreciate you taking the time and this was an interesting interview. Thank you very much.