

HISTORY OF THE  
U. S. FOOD AND DRUG ADMINISTRATION

Interview between

William V. Eisenberg

Retired Assistant Director,

Division of Microbiology

and

Robert G. Porter

U. S. Food & Drug Administration

Bethesda, Maryland

July 25, 1984

## 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.



Food and Drug Administration  
Room 500 U.S. Customhouse  
721 19th Street  
Denver, Colorado 80202  
303-837-4915

TAPE INDEX SHEETCASSETTE NUMBER(S) 1, 2, and 3GENERAL TOPIC OF INTERVIEW: History of the Food and Drug AdministrationDATE: July 25, 1984 PLACE: Bethesda, Maryland LENGTH: 150 MinINTERVIEWEEINTERVIEWERNAME: William V. EisenbergNAME: Robert G. PorterADDRESS: [REDACTED]ADDRESS: U. S. Food & Drug Admin.[REDACTED]  
Denver, ColoradoFDA SERVICE DATES: FROM 1937 TO: 1980 RETIRED? YesTITLE: Asst. Director, Division of Microbiology

(If retired, title of last FDA position)

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.
--------------	-------------	----------------------	-------------

SUBJECT

1	A	0	1	Eisenberg's Education - Hired by FDA
		4	2	Early Work in Microanalytical Division
		10	4	Development of Microscopic Methods for Detection of Filth in Foods
		23	8	B. J. Howard
		30	11	End of Tape 1-A
	B	0	11	B. J. Howard (continued)
		1	12	Identification of Indices of Filth Including Field Studies
		6	14	Mold Count in Tomato Products and Indices of Insect and Rodent Contamination
		12	16	Filth in Spices
		18	18	Cooperation with District Field Offices
		27	21	Development of Evidence for Use in Court
		30	22	End of Tape 1
2	A	0	22	Development of Evidence (continued)
		13	26	Expert Witness for the Government
		22	28	Filth in Spices
		27	30	World War II - Effect on Food Industry
		30	31	End of Tape 2-A
	B	0	31	Ballistics Method for Drug Identification

TAPE INDEX SHEET - PAGE 2

CASS. NO.	SIDE NO.	EST. MIN. ON TAPE	PAGE NO.	SUBJECT
2	B	3	32	Microscopic Identification of Drugs
		9	34	Decomposition in Raspberries and Strawberries - Mold Count - Processing Conditions and Procedures
		22	38	International Food Standards Program - Committee on Food Hygiene - Codex Alimentarius - Codes of Hygienic Practice
		30	40	End of Tape 2
3	A	0	40	International Food Standards Program (continued)
		9	43	Post Retirement Activities - Quality Control in the Food Industry
		12	44	Macroscopic Methods of Food Analysis
		13	44	Manual of Macroanalytical Procedures (AOAC)
		19	46	Identification of Food and Drug Ingredients by Microscopic, Histological and Crystallographic Methods
		22	47	Identifying Ingredients in Quack Drugs
		23	47	"Powder X" Case
		29	49	Court Testimony
		30	50	End of Interview

STATEMENT OF GIFT

I, William V. Eisenberg, hereby give to the United States of America for inclusion in the collections of the National Library of Medicine and for administration therein by the authorities thereof, the magnetic tape recording of the interview held on July 25, 1984, between Robert G. Porzer and myself, together with the final edited transcript made from this recording. It is my understanding that a copy of the final edited transcript is to be deposited in the library of the Emory University as well as in the National Library of Medicine.

I hereby dedicate to the public my literary rights to this recording and its transcript, so that they may be freely examined, listened to, cited, quoted, or reproduced in whole or in part, subject to such restrictions as the Library may impose to insure their proper protection and preservation.

Sept 16, 1985  
Date

William V Eisenberg  
Donor

Accepted:

\_\_\_\_\_  
Date

\_\_\_\_\_  
Chief, History of Medicine Division  
National Library of Medicine  
Bethesda, Maryland

BP: This is a recording of an interview with William V. Eisenberg, made on July 25, 1984. Bill Eisenberg retired from the Food and Drug Administration in 1980 when he was Assistant Director of the Division of Microbiology. The recording is being made at his home in [REDACTED] [REDACTED]. My name is Bob Porter.

Bill, would you start us out with a thumbnail sketch of your education and career so that anybody who listens to this tape will know who you are.

WE: I received a Bachelor of Arts Degree with a Major in Chemistry and Biology in 1934 from Brooklyn College in the City of New York. I received a Master of Arts Degree, with a major in Botany and Plant Pathology in 1942 from George Washington University in Washington, D.C. I've also taken graduate courses in Plant Physiology at Catholic University and Botany and Chemistry at the U.S. Department of Agriculture Graduate School.

BP: OK. Now, tell me some about how you got started in FDA, who hired you, and when and what kind of things were going on at that time.

WE: I was working in the U.S. Department of Agriculture, of which the Food and Drug Administration was a part. I was working as a scientific aide in the Bureau of Plant Industry of the Department of Agriculture, when I transferred in

December of 1937 to the Food and Drug Administration, which was an agency as part of the U.S. Department of Agriculture at that time. I was hired by Mr. B. J. Howard as part of a team that was hired, at that time, as a result of the passage of the FD&C law (the 1938 Act which involved a radical change in the sanitary requirements in the production of food). A group of four were hired at that time; the mission of that group was to implement and develop scientific methods for enforcement of that section of the law dealing with the sanitary production of food.

BP: OK. Just go on through your career briefly and then we will go back and pick up the highlights.

WE: The four of us who were hired at that time were given a six month training course. During the period of this course the different talents of the group, to a large extent, were shown. My own particular aptitude, because of the background I had in both chemistry and biology, leaned towards methods involving chemical microscopy, as well as histological microscopy. Some of the early work I did, at that time, involved detection of adulterated food, substitution of cheaper ingredients into foods which could be detected by microscopic methods involving both chemical microscopy as well as histological microscopy. In this way we could not only determine the ingredients of foods that were part of the genuine form-

ulation of the food, but we could also pick up very minute quantities of substitute ingredients (usually cheaper ingredients that were formulated with the food as an economic cheat). This type of technique was particularly applicable both to foods and also to drugs, because it involved not only optical microscopy, but it involved applications such as the use of polarized light and the principles of microscopic crystallography.

I also was involved in the development of methods for the detection of filth in foods, which were the basis for enforcement of the 1938 law which required that foods be produced in a sanitary manner. It defined adulteration as food produced under conditions whereby they may be contaminated, so that action could be taken not only on the basis of objective analysis of the food showing the incorporation of filth indices, such as insect fragments, rodent hairs, and molds, but could form the basis of action against the food where the food had been produced under unsanitary conditions. This involved Section 402(a)4 of the Food, Drug and Cosmetic Act.

BP: You mentioned four of you whose talents were identified. Was there a conscious effort to take each one of you and make him an expert? In other words, you became an expert on this, Kenton Harris became an expert on that, etc. Was there a sort of a policy of developing experts in that way, or was this



more a matter of chance?

WE: It was a matter of chance in the sense that certain people, because of their backgrounds, and because of their aptitudes, showed an expertise and a talent for certain aspects of the work. For example, with my background in biology, I showed a preference for the mold count work and for the work dealing with the decomposition of foods. I did quite a bit of work in the entomological area, but Kenton Harris, for example, who had a degree in entomology and majored in entomology, specialized in that aspect of the work for the most part.

Helsel, who had a major in biology as well as chemistry also tended to prefer mold count work, but again, we were expected to be knowledgeable and skilled in all types of the so-called microanalytical work involving the examination of foods, to determine whether they were in compliance with respect to the sanitary safeguard sections of the Law 402(a)3 and 402(a)4. All of the four who were hired at that time to implement those sections of the law were skilled microscopists and skilled in biological sciences.

I had quite a background in chemistry in addition to my involvement in the biological aspects of the work. The detection of ingredients involving chemical microscopy was a technique that I utilized. I was one of the four that spec-

ialized, to some extent, in the area of chemical microscopy and microscopic crystallography, where we could determine not only biological components of food, but also chemical components of foods in the form of pure chemicals, as well as the chemical components of drugs. This also included botanical ingredients of drugs where ingredients could be detected by histological structures and diagnostic characters of drugs derived from plant and animal products, where the ingredients were in the form of organized biological cellular components, as opposed to synthetic components, such as the crystalline drugs.

BP: Bill, when you first started and went into this kind of work, was there a body of methods which you could apply, or were you developing your own methods for the most part as problems arose?

WE: There was some background of methods in the drug area. The histology of drug components in the form of botanical and animal products had been established to a large degree at that time. Optical crystallography and microscopic crystallography for the detection of synthetic and crystalline drug components had been established to some degree in the pharmaceutical sciences. We had adapted techniques which had been used, for example, in mineralogy, and in methods for the determination of crystal ingredients in ores and in mineral products. There

was not a large body of knowledge in that area involving the determination of food and drug ingredients by chemical microscopy and by optical-crystallographic techniques. Most of that was developed in the Microanalytical Division where we were working.

Now, in the area of the determination of filth by microscopic indices, such as insect fragments, rodent hairs, and other microscopic features which could be used quantitatively to reflect the type of raw materials and also the incorporation through insanitary conditions into the food; this was a new science and prior to our hiring of the four people who came in at that time in 1937, some techniques had been developed by Dr. Howard and Mr. Wildman, but the large body of methodology was developed from that period onward.

BP: Was Food and Drug, particularly your group in Food and Drug, at the forefront of the development of these methods, or was industry doing much at that time? Was Food and Drug really the place where this all started?

WE: Yes, there was very little work being done by industry. Some of the large food manufacturers supported the work in the sense that they participated in the annual meetings where this type of methodology was reported. These were the annual meetings of the Association of Official Analytical Chemists. Occasionally they acted as collaborators in studies, but in 1937

and 1938 when we were beginning, industry participation was at a minimum. It grew in later years, but was never really a major part of the development. Today, industry and even to some extent, the Universities are participating a little more actively. The vast body of methodology was developed essentially in the Microanalytical Division, which it was called at that time. It later became part of the Division of Microbiology. At that time all of the methods were literally developed in the Microanalytical Division. The field laboratories participated to some extent and in later years, participated much more. At the present time there is a great deal of cooperation between the central laboratory in Washington, the Microanalytical Branch, and the field laboratories.

The Microanalytical Division, which later became a branch of the Division of Microbiology, was at the forefront of publishing and developing this vast body of knowledge, which became a chapter in the AOAC in about 1945 and also was incorporated into a number of methods manuals. This was largely triggered by the people in the Microanalytical Branch. Today the Microanalytical Branch is still the "spark plug" for the development of microscopic methods, but we're getting a much greater participation by the field laboratories in the development of methodology. Industry today is playing a greater part in developing methods.

BP: Bill, is this a good time for me to ask you to tell us about B. J. Howard; what kind of a man was he, what kind of man was he to work for, what were some of the things he did, or any anecdotes. As you know, with this kind of a history, things that are in the files of the Food and Drug Administration can be retrieved, so we're looking for the kinds of things that maybe did not end up in an official file somewhere - a more personal look at the man.

WE: My recollections of B. J. are that he was a very meticulous worker, and the work was really part of his life. He not only lived the work during the hours he was at the laboratory, but he lived it even at home. Even his vacations were really part of his work; in other words, he lived his work 24 hours a day, 365 days a year. As I indicated, he was a very meticulous worker and it was this type of ability that was needed in the type of work he was involved in. Microscopy as applied to food and drug work, required the ability to perceive very minute differences between the various substances that go into foods and drugs, differences which would allow a person to identify deviations and identify changes that might occur during the processing. It was this ability to perceive these minute differences between the substances that comprised a food or a drug, the multitude of ingredients, which provided the basis for determination as to whether the product was

normal, or whether changes had occurred which might affect the quality of the product.

BP: Was he hard to work for?

WE: No, B. J. was not one who looked over your shoulder as you worked. He would give you a problem and let you approach it and develop it in your own manner. He only judged you on the finished product. He went over your finished piece of work quite meticulously and called you down on any shortcomings. Then again, he was a very kindly and fatherly type of person and would point out your shortcomings in a very constructive way, which would enable you to rework the parts of the project that needed reworking, and he gave you sufficient time to do a first rate job.

B. J. was so meticulous in his approach to a problem that he wanted you to look into every aspect of it. Sometimes he was a little perturbed if you completed the project too quickly. One of his favorite expressions after you finished a project would be, "Have you checked this other aspect of it?" Or, "Could you look into this collateral matter?" He especially wanted you not to hurry back, for example, if you were out on a field project. I would sometimes call in and tell him that I thought we had completed the assignment. He invariably would say, "Well, do you think you might stay a little longer and check out some other aspects of the work?"

He never wanted you to do things in a hurry. It was a research type of approach to a problem, and to some extent it seemed like an endless technique. I was the type of person who felt that the project deserved all the attention that it merited, but we had to call a halt at some point, because other things were waiting to be done. B. J. was sometimes, I thought, somewhat too research minded, in the sense that he wanted you to develop and to look into so many aspects of a problem that it could turn into an almost endless task. So to that extent, the person who worked under B.J. had to pace himself and had to rely on his own judgement in many cases as to the input that a regulatory problem warranted. He would let you evaluate the problem as to its relative importance and rely on your own judgement to a great extent to indicate that you had exhausted at least the project from the public standpoint of practical approach to it and that the end product was useful and could at least solve the immediate problem that was involved.

BP: What was B. J. Howard's relationship with his peers in the organization and with the Commissioner? How was he perceived by people like that, so far as you remember? Was he highly respected?

WE: At the time I joined the Microanalytical Branch, B. J. was approaching the end of his career. Actually, I worked

with him during the last five years of his tenure with FDA. He was a very well respected man. He was considered the "Dean of Workers" in the field in which he was an expert; the area of the microscopy of foods. He was an excellent photographer, especially in photomicrography (taking pictures through the microscope).

B. J. Howard had an assistant by the name of George L. Keenan. Keenan, at the time, specialized in the area which I eventually took over...the area of optical crystallography and chemical microscopy. As a chemical microscopists, George L. Keenan worked with a number of the chemists in the Food and Drug Administration, especially chemists in the Division of Foods; also chemists in the Drug Division. B. J. had relegated almost all of that work to Mr. Keenan, although in some of the early years of Mr. Howard's career, he had also done quite a bit of work in that area. Eventually most of his work was limited to problems in food and to mold count work in the area of decomposition of foods and also the work involving insect fragments. He directed his efforts to the detection of insect infested foods and to studies relative to the incorporation of insect infested foods into milled products and into pureed products, where visible insect contamination and damage was hidden and obscured by processing steps that resulted in insect fragments which could only be detected by microscopic



methods requiring the extraction of these indices of contamination and identifying them at suitable magnification. As I indicated earlier, Howard's expertise lay in the ability to observe and identify minute differences between food ingredients and between changes that might occur in specific ingredients from attack by biological agents of disease or deterioration.

One of the skills that was required in the identification of filth indices, such as insect fragments, rodent hairs, and molds, involved the ability to distinguish between these indices of contamination and the minute particles of finely ground or milled foods. This essentially was based on the histological and anatomical differences between the food ingredients and the contaminants in the form of insect fragments, rodent hairs, molds, and other types of arthropods or animal substances left from adulteration by these agents.

BP: I just want to go into the way you worked. Did you spend all your time in the laboratory working on samples that came in, or did you on occasion go out and have personal experience in the industry...in the field?

WE: Almost all of the Microanalysts in the Division were required to do field work involving factory studies and field studies to identify the sources of adulteration. In order to be able to interpret and evaluate the findings that could be

disclosed by microscopic methods, one had to go into production and processing areas and into the factory at the origin of the sources of these contaminations, to observe the entomological and the biological habitats and conditions relative to the life cycles of insects and the habits of animals involved in the contamination of foods, to study the plant conditions and routes of contamination that might be involved in the introduction of contaminants, and then to see how these contaminants would be changed by their handling and the processing conditions. This permitted the analytical findings in the finished product to be interpreted and to be evaluated with respect to the conditions under which the food was handled, and the conditions involved in the introduction of these contaminants.

All of our work involved considerable studies of the types of contamination and the agents of contamination, as shown by studies and investigations of field conditions, crop conditions and factory conditions with respect to sanitation. This body of information could then be developed and synthesized so that the objective findings in the finished product could be interpreted in terms of such conditions. We would then be able to determine whether the conditions under which the product was prepared met the sanitary standards, or whether the conditions were involved as an adulteration under the

Section of the Law, 402(a)4.

BP: Would you describe for me one of your early trips...a trip you can still remember rather well, where you went, what you did, what you were trying to find out, and maybe something in general about these field trips in regard to your career.

WE: Well, some of the other studies involved further development of field conditions involving decomposition in tomato products. This was bringing up to date the body of knowledge that B. J. Howard had developed earlier, in fact going back to 1906 when he was working on his "mold-count" method for tomato products.

BP: Does it go back that far?

WE: Oh, yes. It goes back to 1906. That is the beginning of the law, the beginning of the Food, Drug and Cosmetic Law. I believe it goes to that fall, though some of the early work was published in 1911 in the Yearbook of Agriculture. But B. J. Howard, I am sure, was working prior to that in developing the basic information and experimental data which lead up to that publication in 1911.

Some of the early studies that I undertook related to mold-count data for determining the amount of decomposed tomatoes, i.e., rotten tomatoes, going into tomato juice, or tomato puree, or tomato catsup. This involved studies where we went out into the field to determine crop conditions and

the types of diseases and decomposition that occurred during the growing and harvesting of the crops. We studied not only the particular tomato fruit diseases that had affected a crop; we also studied other types of deterioration due to insects, e.g. the tomato fruit worm that might affect the harvested tomatoes.

We were involved with drosophila, house flies and other types of insects that infested the crops. We'd follow the crop into the plant, determine the handling of the product, and the storage of the product prior to its processing. We would do quantitative evaluations of the contaminants in the form of decay, or in the form of insect damage to the crop, and then we would collect samples of the finished products where we would correlate the objective laboratory findings with the conditions of the raw material, both as it was delivered to the processing plant, and also with the manner in which the plant had been able to prepare and clean the product prior to its incorporation into finished product. I did quite a few of these studies in the early days.

BP: In what areas of the United States?

WE: Well, initially I worked in the Buffalo District area of New York State, Pennsylvania to some extent, and also did some work in a number of New Jersey plants. Later I did some work in the mid-west - in Indiana, Ohio, and Michigan plants. Of

course, as the years went by I also visited many plants in California. Also, a number of plants in Oregon and Utah.

Almost all of these studies involved investigations of crop conditions and conditions in the processing plants with respect to various sources of contamination and the correlation of these sources and types of contamination, both qualitatively and quantitatively, with the findings revealed by objective microscopic methods of analysis of the finished products.

In the area of insect fragments and rodent hairs, I remember undertaking several studies of spices, involving again deterioration and contamination of spices as handled by spice grinders (the manufacturers of ground spices). To a large extent, of course, this involved spices that were imported into the United States in semi-finished form. These were dried spices that had been semi-processed to some extent overseas and were imported into the United States.

Again, this involved evaluation of the raw material with respect to damage caused by insects, molds, rodents and other biological agents of deterioration. It involved studies of factory conditions in spice grinding in spice manufacturing plants. Finished products were collected in the form of ground spices or prepared whole spices and analyzed by suitable laboratory methods relative to defects, such as insects,

rodents, molds and other biological agents. The analytical data were correlated with the quality of the product, as well as the processing conditions under which the spices were manufactured as revealed by the factory inspections and investigations.

The Microanalytical Branch and the Microanalytical Division, as it was early designated, was probably one of the few Divisions in Food and Drug whose laboratory personnel was required to do considerable field work because of the unique relationship between factory conditions and its interpretation by this new microscopic methodology. The findings, of course, could be somewhat difficult to interpret because of the ubiquitous nature of contaminants in the form of insect fragments, and rodent hairs. Because of the ubiquitous nature of these types of natural contaminants, one had to develop a body of interpretive data. One had to develop a microanalytical profile of the product relative to types of contaminants commonly

involved in the processing of such a product, so that the quantitative and qualitative data which the method could elicit, might be interpreted. This could only be done by investigations involving field work where the products involved could be followed from their production in the growing area, to the transportation, to the processing plant for studies of processing conditions and manufacture of the products into its final

form; and then to the development of a method which could be applied to the final product form and generate quantitative findings for evaluating background data which the field and factory studies provided.

BP: Bill, in doing this kind of work, did the District offices play any part in it and if so, how did you work with the District offices?

WE: In every investigation the central laboratory in Washington, for the most part, attempted to get the particular District where the food was produced involved in the work. Not only did we want the District to become involved in the work because they were close to the scene, but we also wanted personnel from that District to cooperate fully in the studies; i.e., become expert in the methodology involved, and also in its interpretation. District personnel had an advantage in being on the scene from the standpoint of following up on incidents of adulteration. It was certainly a reasonable concept to have the local or regional laboratory, who was close to the manufacturing scene, know from first-hand knowledge what was involved. They could be in a better position to make recommendations on improvements and recommendations for compliance. Then again, the central laboratory only had a limited number of personnel, so from the standpoint of good management, it was very desirable to have the District laboratories

involved in this work. We did build up a group of skilled Microanalysts in practically all of the District laboratories.

BP: Would these District Analysts then go right out with you and work together with you so you were investigating conditions and you were teaching as well?

WE: Yes, in most cases, we generally took laboratory people along with us, however in many instances, inspectors accompanied us where the District felt that the particular problem was best handled from the Washington laboratory. In such cases, the Inspector was a part of the team that was involved in the investigation and developed a forensic appreciation of combining the inspectional and laboratory findings.

The Inspector also developed into an expert in the area of food sanitation, from the standpoint of identifying problems in the field, and in the factory, which he felt merited follow-up by the laboratory. This could be handled strictly on a local basis where the Regional or District laboratory was expert in the methodology and in its interpretation; or at least the Inspector could identify the problems which could be handled by the District laboratory on an objective basis. If experts were necessary for interpretation, the data could then be referred to Washington. In almost all cases, the District laboratories were involved either from an inspectional stand-



point or from the laboratory standpoint or both.

BP: Was this a close and cooperative sort of relationship that you had?

WE: Oh, yes. I particularly felt that we could only approach these problems through cooperation and sharing of information, because as I mentioned, the District Laboratory was close to the scene and could provide us with information in a much more economical manner than we could approach it from Washington. They could keep us up to date on changing conditions, being close to the problem. The Inspector was usually out in these areas of investigation on an annual basis, so this close cooperation was very important from the standpoint of enforcement.

BP: Once the problem was solved, they remained, then, to apply the methodology in enforcing the law, so they had to know how to do that.

WE: That's correct. The District Laboratories, of course, applied on a routine basis the information and the techniques we developed where background data were sufficient to develop a regulatory program or project in a particular field. The District Laboratories were equipped, both from an inspectional and an analytical standpoint, with the methodology and the skills to handle these problems as they arose. They could then handle them in a more or less routine manner.

BP: Bill, there's one thing I'd like you to talk about before we get too far and find that we are all through here. I know you have testified as an expert in many, many cases around the country, and I wondered if some of them stand out in your memory as being particularly interesting, and if so, tell us about it...not only the technical fact, but personalities ...things that went on behind the scene. Anything of that kind.

WE: Well, some of the interesting cases involved the mold count method; the application of the mold count method to enforcement and removal of products from the market that were made from decomposed fruit. The decomposed fruit, as I indicated earlier from our field factory investigations, could arise either from diseased crops that were harvested and were not properly handled in the preparation of the finished product or they could arise from the storage of these products under conditions which resulted in excessive amounts of decay and decomposition developing in the materials, and again, not being properly prepared for processing into a wholesome finished product.

As with all microanalytical methods, some body of data had to be developed which would enable us to establish a level of compliance; that is, criteria which indicated that the amount of defects from decomposition was excessive or was at

least within the level of acceptable manufacturing practices.

Developing these criteria involved, as I indicated, considerable studies, and the interpretation was not always so sharply and clearly defined that one could conclude that specific mold counts reflected sharply defined amounts of decomposition.

B. J. Howard, in his early studies, was aware that the variation involved in the methodology and the variation involved in interpretation of mold counts did not lend itself to sharply defined limits. Because of the variation involved in both the methodology and in the data correlating poor manufacturing conditions and defects with the indices of contamination, there was some degree of controversy between producers and the enforcement agency that resulted in a legal contest where the government was confronted with upholding its case on the basis of the scientific evidence and possibly inspectional evidence that was involved in the court case.

The interpretation of laboratory findings that were involved in court actions, presented the expert with the need to define to the court, or to a jury, that the mold counts of the product that was marketed, represented and demonstrated production of a product that contained an excessive amount of decomposed or rotten tomato fruit, or similarly in cases involving other fruits because the mold count was applicable not

only to tomato products, but to a large number of fruit and vegetable products. At any rate, the Analyst and the Expert had to demonstrate to the court and to the jury that the mold count reflected excessive amounts of decomposition, reflected unreasonable practices by the processor, due to the incorporation of fruit that should have been eliminated (decayed fruit or decomposed fruit or vegetable material that should have been eliminated in the handling of the product and in the processing of the product).

In most cases, it was difficult to interpret or evaluate the range and number of mold counts for a product in terms of a specific amount of decomposition. In most cases, because of the nature of the contaminant and the variation due to variable amounts of mold filaments contributed by different species of molds, the best that the Analyst could do, on the basis of his investigations and his knowledge of background data, would be to evaluate the mold count as excessive from the standpoint of industry practice, and that it meant at least a certain amount of decomposed material and very probably represented more than that. The interpretation was in terms of the minimum amount of decomposition reflected by the counts, and that minimum amount was excessive in terms of industry performance.

At any rate, because of these variations in the mold

count studies, one could say that some of these courtroom scenes portrayed different opinions by people who had done studies in this area. Government experts in many cases were confronted by industry analysts and industry experts, and also to some extent by information in this area that was developed by University people who had experience in some aspects of the work. However, very few of the non-government experts had devoted the time to develop the full array of information which the government required in developing its regulatory program. Many scientific principles were involved in the interpretation of mold count methods in enforcement work. It involved the science of mycology, plant pathology, and microscopy. Some aspects of these sciences had been developed by others and very few had the complete body of information that was needed to develop a practical enforcement program. The government was unique in this sense: Their background information and their complete understanding of the problem from the amount of studies that had been done in the area provided a comprehensive industry profile. In most cases, the government was in a position to develop a very complete and understandable position before the court, so that the government prevailed in most cases. In some of the few cases where the government had problems, it usually involved aspects of the studies related to the safety of a food in which possibly

excess mold had been incorporated. This aspect of the safety of the product occasionally became an issue, and some courts felt that since safety had not been raised as an issue in the case, that the government's position did not rest on very strong grounds. Although the law did not require showing harm from a product and the law was explicit in declaring a food part to be adulterated if it contained decomposed material, the Food and Drug Administration did recognize that the showing of decomposed material had to be presented in a manner which demonstrated that the amount of decomposed material was present in excessive amounts. The fact that a tolerance existed was a showing that the government was not unreasonable, in that it did not expect the manufacturer to accomplish the impossible, but that the law required processing to be done in a manner which would require a reasonable performance with respect to removal of objectionable material from the product. In other words, in many cases, the government was trying to reflect what the homemaker would expect or what the homemaker would accomplish if the material was being prepared in the home. At any rate, because of these different aspects of the problem, the issue of whether a manufacturer had been performing in a reasonable manner, occasionally became an issue and resulted in a court case. In most cases, the government's scientific basis was upheld. Scientific validity of

the method was upheld. The few cases that the government lost usually represented a question of whether the mold counts or the level of performance by the manufacturer was actually in excess of what the government felt was a reasonable performance, or whether it was not.

BP: Bill, I know that you took part in a number of such cases. I don't want you to be unduly modest; we want this to show exactly what happened. What was your capacity in cases that were brought of this kind, where there was a contest?

WE: My involvement with these cases included analysis of the products, so that I could testify from my own involvement as to the results that I obtained from examination of the samples, and then it involved my evaluation of these results in terms of the background data that I had developed from studies that I had conducted, both in the field and in the processing plant. I would testify as an expert and give my opinion as to what these results actually meant in terms of the conditions they reflected.

In some cases, it involved quantitative evaluation of the raw materials; in some cases, the mold might reflect the unsanitary conditions in the plant, so that our expertise sometimes went a little beyond the analytical results of the field because of our ability to distinguish, in some cases, different species...at least grouping of certain species of fungal

tomato rots in terms of their incorporation into the product. Because of the fact that some fungal rots incorporated more mold filaments than others, we were able to go a little beyond the interpretation of the routine analyst in ascribing the objective findings to conditions in the plant and to the amount of various types of tomato fruit rots that were involved in the case.

BP: Could you distinguish...I think you said, but I'm not sure...could you distinguish between the kind of rot that occurred...the kind of filaments that occurred from molds that contaminated the plants, as contrasted with those which grew in the tomatoes themselves?

WE: Yes, we were able at least to distinguish one type of mold that was involved in plant conditions. This mold had the common name of "machinery mold" and it was identified scientifically as a species of *Geotrichum candidum* Link. Link is the author of that species. So, we could readily distinguish that type of mold which would come from unclean machinery and unclean food contact surfaces in the plant from the fungal rots and the fungal tomato rots that were due to field conditions. Also field rots and storage rots. Also among the field and storage rots we could group certain species based on the type of filaments. This type of grouping would give us some idea as to the probable amounts of rots that would



contribute to a given mold count. Certain rots would affect the mold count to a greater degree than others. As an example, anthracnose rot would give you a higher count for a given amount of decay than soft rot caused by the bread mold, *Rhizopus nigricans*. The ability to group some of these species would enable us to interpret the mold counts to some extent, in terms of general amounts of decomposition that might be involved.

All these questions generally came up in the court cases and involved differences of opinion by some of the industry scientists and the government scientists. Industry scientists, of course, had a certain partiality in their view of the problem, and the government scientists, of course, were motivated by their mission in requiring industry to do a reasonably good job in preparing food for the public. We certainly didn't have a "police attitude" towards the industry and as scientists we were motivated primarily by the data and the information that we developed as a result of our studies and our investigations.

BP: How about a "war story" or two? Actual cases where something interesting happened.

WE: Well, I do recall an investigation of some of the spice plants that had arisen during the war, to supply certain products which were not available because of transportation dif-

ficulties from abroad and embargo by war conditions.

In South Carolina, I recall, a paprika industry had been developed to supply this spice which had formerly been obtained largely from Yugoslavia and Spain. This area of South Carolina had decided to grow this sweet variety of red pepper, which was the source of the paprika. We visited one plant in our factory studies where I observed some war prisoners who were screening one of the ground products, and on closer observation I noticed that the product had become completely infested with this insect. I believe it might have been the cigarette beetle, or a similar type of storage beetle. These were German war prisoners who were sifting out the insects and trying apparently to salvage a product which had become thoroughly infested. I informed the management that although the size of the screen was probably sufficient to screen out most of the beetles, that not only were parts of the beetles going through the screen, but all the excreta from the larva was moving through the screen, and the product that resulted was certainly not fit for human consumption. We convinced the management that this type of reconditioning, by just trying to remove the so-called whole beetles and larvae of the contaminant, was not a proper way of preparing the product. Not only that, but I informed him that the government methods could quickly determine that the source of the product was a highly

infested material, because the microscopic methods would pick up not only the insect excreta, but also insect fragments which would sift through the screen.

BP: I recall seeing something like that in southern Colorado. A man who had a small business, was going out and collecting wild mushrooms and drying them. I came upon him screening out insects that might have originally been in the mushrooms. His position was that the insects were always present and it was normal procedure to screen them out.

WE: Well, you go back far enough, of course, under starvation conditions people would be eating many things, like maggot infested meat, and what have you, and survived. But I don't believe that conditions even during the war were that bad or that practices of this sort had to be resorted to.

I do remember one thing about the effect of the war on the food supplies and food products relative to the Food and Drug sanitation requirements, i.e.

In the industry, we recognized that there was a shortage of personnel in the processing plants that were involved in preparing the raw material for production, say in tomato catsup, and other types of tomato products which were going to not only to the Armed Forces, but to the public as well. We did have at that time a tolerance requirement for tomato juice, tomato puree, and tomato catsup and the government did

relax those requirements. Although they didn't publish the higher figures which they used, they did relax the tolerances which had been publicly announced years before, and were somewhat more lenient in permitting amounts of decomposed material and amounts of tomato rot to go into these comminuted products. After the war, of course, when labor was more plentiful, but the published tolerances that had been announced as trade announcements, were reinstated. Not only were they reinstated but there were additional studies updating the evaluation of industry performance. The Food and Drug Administration amended the tolerances to require better performance, based on improvements in the industry. To this day, of course, the FDA is involved in reevaluating their tolerances and criteria of industry performance in order to update these requirements in terms of industry and technological improvements.

BP: I would like to ask you about the ballistics method applied to drugs. Give me some background of how the idea originated and how you developed it, and in the end, what it accomplished.

WE: The ballistic method of identifying a drug as to its identity and its source of manufacture was developed because of the requirement to prove the interstate movement of an illegal drug. Let's say if a drug was picked up by the

Inspector in, say New Jersey, and if it could be shown that the drug was manufactured in Pennsylvania, then interstate movement would be proven and the jurisdiction of the government established.

Now, the microscopic examination of drugs with which the Branch was involved for many, many years, lent itself very nicely to this type of analysis. For one thing, in establishing a manufacturing source as a particular place, there was a need to show that the equipment used in the production of a particular drug...say the punches in the dies used in producing a particular tablet, would wear and have very characteristic microscopic markings, based on the wearing and the scoring that would arise from the use of that particular punch.

Another aspect in identifying the manufacturing source was the formulation of the drug. Each manufacturer usually had a master formulation sheet, which included all the ingredients that would go into a particular drug product. These would include not only active ingredients, but usually an array of three, four, or five or more excipients, as they're called in the industry. These are processing aids which permit the incorporation, for practical purposes, of the active ingredients with the other ingredients, such as starch, talc, magnesium stearate, and other ingredients which enabled the mixing and the formation of granulations amenable

to molding by the dies used in punching out the product. By obtaining a copy of the formulation, a copy of the formula used in preparing the product, as well as obtaining authentic samples of the tablets produced by a particular machine, the microscopist then could analyze the finished product in terms of identifying the mixture of ingredients by microscopic crystallographic procedures. He could examine the tablet microscopically for score marks, which were characteristic of that particular machine on which the drug was punched out. By establishing these diagnostic features involving the score marks and the ingredient formulation, one could then identify the particular drug as having come from this establishment. The likelihood of a drug having similar score marks and a similar formulation coming from another factory was very slight. So by developing methods based on maintaining an authentic collection of tablets produced by different drug manufacturers, as well as formulation data, one could then analyze a drug, and by referring to reference samples conclude that the drug based on its similarity to the reference sample must have been manufactured in a specific plant, i.e., the same factory in which the reference sample was manufactured.

BP: Would the courts accept that as evidence of interstate commerce?

WE: In all the cases that we tried, I don't recall one in

which that evidence did not hold up in establishing the interstate movement. Now occasionally, of course, other collateral evidence was developed also, possibly by shipments, but in all cases this type of evidence was either supportive of other evidence, or else it was utilized in itself as the only evidence in establishing the interstate movement of the drug.

BP: We use the term "ballistics" to describe the method of checking the scoring, etc. Is that because of...

WE: It's similar to the rifling marks of a bullet going through and the scoring that would be shown.

BP: Where you identify the gun because of the...

WE: Because of the particular score marks that a gun would produce on the bullet, in a similar manner the machine would inscribe score marks on the tablet.

BP: Bill, maybe because of my years in Chicago, I remember that you did some interesting and very worthwhile work on black raspberries in Western Michigan. I'm sure there are some things you could tell us about that investigation.

WE: The work in Michigan was largely sparked by regulatory actions against processors of raspberries, black raspberries and processors of strawberries, against whom action had been taken because of decomposition. That is, the incorporation of fungal rots affecting the fruit which were going into frozen processed products. I recall that Congressman Claire Hoffman

was very much involved because of his constituents in Michigan having had some unhappy experiences from a regulatory standpoint. Congressman Hoffman put the pressure on the Food and Drug Administration for us to engage in at least some educational work among the processors, and also to do some studies to develop a better understanding of the problems from the processor's standpoint as well as from the enforcement standpoint.

The Processors were somewhat concerned by the fact that for black raspberries, red raspberries, and strawberries, the government had not promulgated any mold count tolerances or trade announcements indicating what level of performance we expected them to meet, with respect to the presence of decomposed fruit material going into the product. The Food and Drug Administration felt we probably should do a study which would incorporate both of these aspects. That is, some recommendations in educational work to indicate to the processors, at least, the types of conditions which were generally involved in the production of violative products and possibly developing some quantitative guidelines which they could utilize themselves for inspecting and for analyzing their product. As a result of this, we met with industry groups during the course of the processing season and did a study involving crop conditions, transportation of the crop, picking



of the crop, movement of the fruit to the processing plant, and the handling of the fruit at the processing plant. All of these field and factory studies involved quantitative evaluations of the fruit in terms of decomposition; it involved evaluation of the processing conditions and the practices in the plant in handling the fruit, and collections of the finished product and analysis by mold count. Through the course of the investigations, we spoke to both the farmers and to the processors, and demonstrated to them the types of fruit that were involved in excessive amounts of decomposed material. We evaluated the deliveries from the growers, in terms of the quality that we felt could be handled in a normal manner, and those where we felt special precautions had to be taken to eliminate the decomposed material. We analyzed hundreds of samples and then wrote a complete report, including recommendations to both the growers and the processors as to conditions which would meet Food and Drug requirements. We also established in the report a mold count level, which we told the processors that they could meet if they adhered to the recommendations which we had included in our report.

BP: Do you think it accomplished anything?

WE: Oh yes. The processors were very pleased, to the extent that at least they had some objective measurement now on which they could evaluate their finished product. They had certain-

ly some understanding of the quality of the fruit as delivered to the Processors, and the type of handling that they should adhere to if they expected to meet the quantitative mold count figure, which we had given them as representing the limit at least, of good performance.

BP: As I recall, one of the important elements of all of this was to teach them to handle the fruit expeditiously from the time it was picked to the time it was actually packed. Didn't they change their practices in regard to not holding fruit overnight and running the factory until all fruit picked that day was processed, and things of that nature?

WE: We recommended not only practices of that sort, involved in the storage of the food, but we also recommended prompt picking of the fruit, especially during certain rainy parts of the season. During hot, humid conditions, of course, picking of the fruit was very important. Prompt picking of the fruit was very important because we recognized, and they did too, that decay did occur in the field as well as after picking and during storage for undue periods of time under improper storage conditions. Our recommendations went not only to the processors from the time of delivery, but it went back to their control of picking conditions as well. In other words, the processors had to coordinate their work with the growers to be sure that the crop was handled expeditiously and in a

proper manner, such as scheduling deliveries, etc.

BP: Did we later, in subsequent years, find a lower incidence of bad fruit?

WE: There's no doubt of it. After our survey and the issuance of our report, conditions of the industry improved greatly and there was little, if any, regulatory action after our investigation and after our study was distributed.

BP: I'm sure that's true, because I inspected those areas in subsequent years. I wasn't there at the time you did the initial work. We found conditions, I would say, generally quite good.

WE: We extended these studies not only to parts of Michigan, but we did additional studies in other parts of the country where black raspberries and strawberries are grown, such as Washington State; also in New York State.

BP: Bill, how about some of the other aspects of your work that we haven't covered yet this morning?

WE: Well, during my latter years with the FDA, beginning in about the year of 1966, I was involved with the International Food Standards Program. As the U.S. Delegate to the Committee on Food Hygiene of the Codex Alimentarius. This involved the drafting of codes of hygienic practice; also review of codes of technological practice, which incorporated many of the concepts of food processing and food technology with which the

Microanalytical Division and the Microanalytical Branch had been involved. It involved almost all of the concepts of good manufacturing practice; the preparation of wholesome products fit for human consumption, relative to the quality of the raw materials, the proper handling of raw materials, the quality control involved in processing conditions, and the production of a clean and wholesome finished product. Now of course, in the Codex Alimentarius, we were concerned with this aspect from an international standpoint and we had the benefit of knowledge in this area that was presented by delegates from dozens of other countries. The Food and Drug Administration approach to clean food was appreciated by many of the countries involved in the drafting of codes of hygienic practice. A number of countries did not feel they could afford to apply the extremely rigid sanitary standards that the U.S. applied, and in many cases the regulatory criteria that FDA applied to domestic products were only given lip service by the foreign producers. They recognized that if food was to be shipped to the United States, it would have to meet these sanitary requirements and these regulatory action levels that the U.S. had established. But many felt that their industries were not equipped to apply these rigid requirements to their products for domestic consumption. However, the drafting of these Codes of Hygienic Practice had a very salutary effect on many

of the developing countries, and at least from an educational standpoint, was quite beneficial. It at least gave them a goal that they could look to for improvements in their own industry.

In my work with the Codex Alimentarius, and as the U.S. Delegate to the Committee on Food Hygiene, I did have occasion to visit processing plants in a number of countries overseas, and I had occasion to provide technical assistance to many of the developing countries. This technical assistance involved visits to processing plants, visits to organizations in the foreign countries involved in the export of food to the U.S., I made them aware of the Food and Drug requirements. In my visit to the plants, I was able to point out deficiencies in the handling of food that would result in problems. I traveled abroad to provide technical assistance to developing countries and to other countries involved in exportation of food to the United States. My visits to these foreign countries enabled personal contact with manufacturers, making them aware of our requirements. The reports to the foreign countries made available not only recommendations on handling of food to meet our requirements, but also the methodology involved which we applied at the entry points in the United States. The availability of such methodology would provide them with methods which they could apply to the products prior

to shipment to the United States.

The work of the Codex Alimentarius, and especially the Committee on Food Hygiene, had a great influence and was very beneficial in making many of these countries aware of the strict food and drug requirements, especially with respect to the sections of the Law, 402(a)3 and 402(a)4, relative to the sanitary safeguards in the production and handling of food. There's no doubt about it, the U.S. has been in the forefront of food sanitation from the standpoint of filth and esthetic considerations. Although almost all of the foreign countries do have some section of the law dealing with filth and decomposition, very few have implemented it to the level that the U.S. has applied, not only in the development of methods and in inspectional oversight of food production, but also to the extent of vigorously enforcing the sections of law dealing with the wholesomeness and some of the cleanliness and purity aspects involved in the handling of food. Although some of these requirements seem to lean to esthetic considerations, the overlap of esthetic considerations with aspects that may contribute to a health hazard are quite evident. Many of the deficiencies that one may consider minor deviations are frequently a source of more serious violations, when some hazardous elements are a part of the problem.

As I indicated earlier, in the contacts made with repre-

representatives from many foreign countries during our meetings of the Codex Committee on Food Hygiene, very few countries other than the United States and Canada are applying the body of scientific knowledge developed by the Microanalytical Division, and the body of microanalytical scientific methodology. Very few are applying this body of knowledge to the control of food production in their own countries for domestic consumption. All of these countries are aware of these methods because of publicity and dissemination by the FDA, and are obviously required to apply it from a practical standpoint in the export of food to the United States. From our experience, at least from my experience, very little of this application has gone to control of food products within their own countries, that is, food products prepared for domestic consumption. In fact, in some cases, we have a two-tier system, where the principles and the requirements are adhered to very closely for food going for export to the United States, whereas a different set of controls and requirements may be applied to domestic consumption.

Possibly, as improvements in food technology and processing technology occurs, some of these countries may begin applying the techniques and the methodology and processing attributes, which relate to the elimination of contaminants of the types I have discussed in my earlier comments. At this

stage of application in food production throughout the world, the United States and Canada are probably the two countries that are at the forefront in this area of quality control. Certainly the feeling of FDA has been... My feeling has been that application of microanalytical principles involved in preventing the incorporation of filth and decomposition in foods has been a tremendous benefit, not only in assuring a clean food supply, but I think it has been a tremendous benefit, possibly indirectly, in preventing more hazardous conditions which may contribute to a potential for harm, or potential for poor safety standards in the production of these food products.

BP: You have been retired since 1980 and yet I know you are still active and interested in the kind of things the Food and Drug Administration does, and you've actually done a number of things in relation to that. Why don't you just talk about your post-retirement days a little more.

WE: Since retiring in January of 1980, I have been doing a certain amount of consulting work with industry. Trying to be helpful to industry in problems encompassing my expertise, which has usually been in the microanalytical area. I have done a little writing. In most cases the consulting has involving drafting of recommendations for industry quality control measures. I've developed protocols, which include



essentially a sanitary code of performance by the industry, which would aid in meeting FDA requirements.

I have also been involved with studies in cooperation with FDA. One firm sponsored a thorough study throughout the processing season involving the mold count of tomato catsup. This was a study which simulated, to a large extent, the type of investigations that I carried on while I was working with FDA. It involved the complete study of field and factory conditions, evaluation of the source of contaminants in the final product and correlating that with the analytical findings in the finished product. All of these data and reports were made available to FDA. The study was actually one part of a national survey that the FDA itself was conducting. I am sure that the study I supervised, although in only one of the plants that FDA had inspected and investigated as part of their study, did lend some additional information because of the fact that the data that I presented represented information throughout the season, whereas the survey FDA conducted on a national basis spot-checked the problem across the country.

Another aspect of the consulting work that I've been doing, involved the preparation and update of a manual of methods for FDA, and this work dealt with the drafting of so-called macroscopic methods, i.e., methods involving the

direct examination of food products visually or with low powered magnification. It involved compiling all of the methods that FDA utilizes in the field of filth and decomposition in foods, other than the microscopic methods which are published in the Methods of Analysis of the AOAC. The manual included not only all of the macroscopic methods of analysis, but we amplified that by including field methods of this type, which are used by the inspectors. It also included a number of chapters dealing with the principles on which these methods are based, the apparatus and reagents used for the methods and special techniques involved in macroscopic methods. It discussed the relationship of these macroscopic methods to the microscopic methods of the AOAC and how they could be used in combination for dealing with problems related to filth and decomposition.

BP: That has not yet been published?

WE: Yes, the galley proof of the final book of methods, the final manual, has been transmitted to FDA and is ready for publication and very likely will be published sometime this fall. (Note; September 1985: The AOAC has published the Manual of Macroanalytical Procedures, which is now available by purchase order.)

BP: Did you do this under contract with FDA?

WE: Yes, it was done under contract and I provided the tech-

nical expertise that was involved in most of the writing of the book.

BP: I am sure Bill, that along the way, there are some things that we didn't cover, is there anything else that you would like to add to this interview?

WE: Yes, there is one aspect of the microanalytical work that I was involved with that probably resulted in more appearances in court than any other. This was the application of the technique of identifying food and drug ingredients based on the histological and the chemical microscopic and crystallographic features of substances, which enabled me to identify these ingredients specifically.

In the area of food, of course, this involved for example, adulteration of black pepper with buckwheat hulls. The cheapening of cocoa powder with different types of starches, or the incorporation of spurious species as sage, for example. The official sage is made from a species identified as *salvia officianalis*. Occasionally other species, such as California sage made from a species other than the official species, would be substituted for another genera. For example, Mexican sage could be made from species of *poliomintha* or *Lippia*, which didn't have the delicate and aromatic properties of the official sage.

That was one aspect of identification where ingredients

in foods had been substituted. In many other cases, it involved the identification of ingredients in quack drugs, which were marketed or promoted as cures for various types of diseases. These identities generally were necessary as a basis for the pharmacologist to express an opinion that these substances were valueless in the treatment of certain diseases, whether it was cancer or what have you. All cases involving quack medicines required that the particular quack medicine be identified specifically as to its ingredients before the expert pharmacologist or medical expert could offer an opinion as to the value of those ingredients and the value of that product in the treatment of a certain disease. At one period in my career I was involved in the examination of so many of these products, that I was in court practically once a month.

BP: Is that right?

WE: For a year or more I was in Court where I had to offer testimony as to the ingredients of a particular drug as a basis for the medical opinion.

BP: Were you involved in that Powder X case in Minneapolis?

WE: Oh, yes.

BP: That was when I first met you, I think.

WE: That was a case involving a powdered mineral that was made from volcanic ash, which I identified, and the particular powder was being promoted as a cure for some type of cancer.

BP: I think ulcers.

WE: Ulcers? Yes.

BP: I collected the authentic sample you examined by going up in the mountains where the original raw material came from and hacking out a piece of rock right off the cliff.

WE: The rock had a local name of "maternity rock" as I recall. Perhaps local folklore was involved in attributing some medicinal properties to that type of rock, known locally as "maternity rock".

BP: As I remember the story, the promoter used to take his vacations up near Rosita, Colorado, and there was an old woman up there who had conceived the idea that this rock was good for medicinal purposes and used it initially for animals.

Then gradually people attributed all sorts of values to it.

The promoter heard of this, so he had a local man blast out a whole freight car load of this rock and ship it to

Minneapolis. Then he ground it and put it in small one or two ounce containers. It was basically pumice stone.

WE: Yes, basically a pumice stone. Volcanic ash and pumice stone are chemically essentially similar materials.

BP: It doesn't seem like a very good treatment for ulcers.

WE: I recall my identification was that it was essentially pumice or volcanic ash. We also had a chemical analysis of the product which coincided with the chemistry of that type of mineral.

BP: How many times did you testify during your career with Food and Drug?

WE: I would certainly estimate it to be in the 100s.

BP: It seemed to me that you were always there.

WE: It is interesting to think that some people, at least some people in the laboratory and even some of the Inspectors, have gone through a large part of their career without ever appearing in court, certainly in the early days and especially in the those early days involving microanalytical aspects. When I use the term microanalytical aspects, I am talking about the microscopic identification involving ingredients of foods, with respect to substitutions and identity and also to contaminants of foods that could be determined by microscopic means. Microscopic methodology was particularly applicable to many of the Food and Drug problems of the 1940's and 1950's that ended up in court, and for that reason, not only I, but our Division and Branch were probably involved in more court cases than any of the other Divisions of the FDA.

BP: I am sure that is right. I have seen you testify and you were a very effective witness, too.

WE: Well, thank you. Experience, I am sure, played a good part.

BP: Well, Bill, shall we call a halt to this for now?

WE: Well, for the time being I can't think of anything additional.

BP: I'll have it transcribed and send it to you for editing and at that time you can certainly add any thoughts or entire narratives if you are so inclined that you feel should be part of it, or if you have any very special pertinent papers you'd like to have us attach as an appendix, or anything of that nature, you can give some thought to that.

WE: I certainly will.

BP: In the meantime I want to thank you very much for your interview this morning and this will be the end of the tape.

WE: Thank you.