Roe, Slocum, Garfield

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Meeting for the purpose of discussing the history of FDA science with retired FDA scientists, Rockville, Maryland, June 29, 1978.

Attending:
Robert S. Roe
Glenn G. Slocum
Fredrick Garfield
William V. Eisenberg
James Harvey Young
Richard MacFadyen
Terrance Gough
Wallace Janssen
Elizabeth Kelly
Nancy Ross
Fred Lofsvold
Robert G. Porter

INTRODUCTION

This is a transcription of a taped discussion between retired U. S. Food and Drug Administration scientists. It is one of a series of taped interviews with persons who have retired from the Food and Drug Administration.

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.

TAPE INDEX SHEET CASSETTE NUMBERS: 1, 1-R, 2, 3, 4

TOPIC: History of Science in the U. S. Food and Drug Administration

DATE: 6/29/78 PLACE: Rockville, Maryland LENGTH: 290 Minutes

(Note: Tape 1 was so poorly recorded that it was dictated on tape 1-R for more accurate transcription. Following tape 1-R, the trancription picks up the original tape at about 5 minutes into side B of tape No. 1.)

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	7	4	Fredrick Garfield - opening remarks.
	13	7	Elizabeth Kelly - opening remarks.
	15	8	Robert S. Roe - outline of career
	28	15	FDA reorganizations, their effect on FDA science, and changes in enforcement policy and program priorities. (These themes reappear throughout the recording.)
	29	16	Changes when Dr. Goddard came to FDA in 1965.
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	1	18	Program Planning: Crawford - Larrick era.
	12	22	Reorganization of 1948.
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	12	32	Effect of reorganizations on scientific work.
	14	33	FDA science and enforcement philosophy.
	21	42	Development and enforcement of jam and jelly standards.
	23	44	Research vs. regulatory work and petition review.
	35	49	Organization of Bureau of Biological & Physical Science
	40	51	Jam and Jelly Standards.
	45	54	End of tape 1-B.
2-A	0	54	Jam and Jelly Standards continued.
	14	61	Tomato Products
	16	62	Canned Salmon.
	28	68	Organoleptic Training (Fish, Eggs, Cream).
	32	70	Early Spectrophotometer and instrumentation in general.
	40	74	Pesticide methodology and tolerance setting.
	45	83	Lunch Break, end of tape 2-A.
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	30	100	Cooperation with industry scientists - conflict of interest.

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TOPIC: History of Science in the U. S. Food and Drug Administration

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	14	115	Congressional pressure on FDA.
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	24	120	Congressional pressure - moldy raspberries - Nelson Rockefeller's influence.
	28	122	Aminotriazole in Cranberries.
	32	124	Use of instrumentation to identify horseradish adulteration.
	36	126	Glass slivers in bottled beer - Anhauser Busch.
	41	131	"Glass" fragments in canned seafood.
	45	133	End of tape 3-A.
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	2	134	Botulism.
	6	136	Atomic explosion tests - fallout - market basket.
	10	138	Sanitation - Grain program - political influence on tolerance for filth in grain.
	20	143	Congressional influence re butter standard, dry skim milk, color additives.
	22	144	Sterility of drugs and devices.
	26	146	Discussion of "Good Manufacturing Practices".
	34	150	USP, AOAC relations with FDA.
	38	152	Sampling, representative samples.
	43	155	Scientific achievements re pesticides - EPA's role in pesticides.
	45	157	End of tape 3-B.
4-A	0	157	Early concerns about PCBs and adverse reactions to drug
	1	157	World War II - work for Army - effect on FDA.
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This is a recording of a meeting which took place at Rockville, Maryland on June 29, 1978. The purpose of the meeting was to interview retired F.D.A. scientific employees who could contribute to the history of the Food and Drug Administration which is under preparation by Dr. James Harvey Young of Emory University. Present at the meeting were Dr. James Harvey Young and his assistants, Richard MacFadyen and Terrance Gough. Also present were the following employees of the Food and Drug Administration: Wallace Janssen, Fred Lofsvold, Nancy Ross, Elizabeth Kelly and Robert Porter. The retired F.D.A. scientists who attended the meeting were Fredrick Garfield, Robert S. Roe, William V. Eisenberg, and Glenn G. Slocum. Mr. Eisenberg, actually is still a current employee of the Food and Drug Administration. The opening statement by Dr. Young was not recorded. He had opened the meeting by asking the four scientific guests to give an introduction describing their career with the Food and Drug Administration. The recording equipment did not function during part of these introductions and the tape begins with Dr. Young asking Mr. Eisenberg for his opening statement.

Young: Dr. Eisenberg would you next give us your opening statement?

Eisenberg: I can leave this curriculum vitae with you.

Young: Give us the highlights and it will help with the questions.

Eisenberg: I joined the Food and Drug Administration in December of 1937. The Food and Drug Administration was in the Department of Agriculture at that time. I joined the Microanalytical Division. It was being enlarged because of the 1938 Act. It included coverage of increased F.D.A. authority over inspection of plant relative to sanitary conditions. They hired four people at that time, and our mission primarily was to develop methods aiding enforcement of Section 402 (a) (4) of the law. It really was the inaugural of a new era, and a new forensic type of science relating to microscopic methods for detecting indices of contamination related to insanitary conditions under which foods were produced. I worked as a Junior Microanalyst. My training was chemistry and biology and my graduate work was in mycology, the study of mold counts and mold counting methods. The incorporation of moldy materials was covered by the 1906 Act. Under the 1938 Act, we can take action, without analytical evidence, based on factory evidence. Another part of the work that our group covered dealt with the area of chemical

microscopy. This involves chemical microscopic methods to identify food and drug ingredients. This was an excellent tool in the area of quackery. Later it became a tremendous tool in the area of counterfeit drugs in techniques to determine the manufacturing source, to give the administration jurisdiction that would prove that the drug had moved in interstate commerce. I became head of the Microanalytical Branch later, when the branch merged with the Bateriology Group and we became then, the Division of Microbiology. All of my career was in Washington, but I had an endless amount of field work and experience in the field laboratories both from the training standpoint and field work dealing with factory investigations, both in the food area and in the drug area. About ten years ago, when the Food and Drug Administration was separated into almost separate administrations, I elected to stay with the Bureau of Foods as Chief of the Microanalytical Branch. The drug group that I supervised moved over to the Bureau of Drugs. Later a major part of that staff moved into the Drug Enforcement Agency. The area of counterfeit drugs and the proof of manufacturing source is, today, still a tremendous tool of the D.E.A. The technique later became known as the ballistic method for proving the

manufacturing source of drugs. My present title is Assistant Director of the Division of Microbiology and I am now largely engaged in International Food Standards Programs and also, as advisor to Microanalytical Branch in all matters dealing with filth and decompositon.

Young: Fine, that's great.

MacFadyen: When was the split made between foods and drugs in the administration?

Eisenberg: About 1970. Charles Edwards was the Commissioner. That was a major break, the separating of drugs and foods.

Young: Fine. Well, let's move on with the introductions. Mr. Garfield, if you will be next.

Garfield: I came with the Food and Drug Administration, in St. Louis, in 1939. I worked in St. Louis as a chemist until 1949. In 1949 I was made Assistant to the Chief of the District as Legal Officer. I was transferred to Washington in the early '50's. I came in for a two year training course. I was the first one to come in and I never left. I stayed on the rest of my career in Washington. I became Chief Chemist in the Bureau of Field Administration, which meant I was Chief Chemist of all of the field districts in 1957. I held that position until 1960. At that time, I became Deputy Director

of the Bureau of Field Administration. We went through so many reorganizations, I don't remember all of the titles that I held. At one time I was Director of the Division of Field Operations, then we reorganized again into the Bureau of Regulatory Compliance.

I was Deputy Director of that Bureau. At that time, we brought together what was the old Bureau of Field Administration and the legal end and review of cases in Washington. It brought two bureaus into one. Then, when the Drug Abuse Control Amendment looked like it was going to pass in Congress and responsibilities for drug abuse control, which was the non-narcotic drugs, was given to the administration, George Larrick, who was Commissioner then, wanted me as special assistant to him for drug abuse control to set up the Bureau of Drug Abuse Control. I think he was very farsighted when he decided to set up the Bureau as a separate entity rather than part of the drug activities of the Food and Drug Administration because he saw, at that time, that it was likely that particular unit would eventually be separated from the Good and Drug Administration. That's exactly what happened. Well, I was Special Assistant to the Commissioner for about a year then went back to my job as acting Director of the

Bureau of Regulatory Compliance. Then Goddard came along, but that's a separate story. After awhile, I was transferred as Deputy Director of the Bureau of Drug Abuse Control. Then the Bureau of Drug Abuse Control was separted from the Food and Drug Administration and transferred to the Justice Department. I became Assistant Director of the Bureau of Narcotics and Dangerous Drugs. I was in charge of the Office of Science and Drug Abuse Education. We were reorganized about 12 times; don't get me wrong, the whole thing didn't reorganize, various portions reorganized. Then, in 1972, the Bureau of Narcotics and Drug Abuse Control was combined with a number of other agencies, and became the Drug Enforcement Administration. I became the Assistant Director of that administration. I was in charge of the Office of Science and Technology. I retired in 1974. Since that time I have been working as a consultant.

Young: So, for a number of years, you were acting out of F.D.A?

Garfield: Yes. Since 1968 when the Bureau of Narcotics and Dangeous Drugs was established.

Young: Thank you. Miss Kelly, would you like to say a few words?

Kelly: I really didn't prepare anything.

Young: Well, we were just having introductions before we got into a more free form.

Kelly: Well, some of the highlights. I came into the Food and Drug Administration in 1938 as a stenographer. Later I transferred to what is now the Bureau of Drugs as secretary to Mr. Larrick, who was then acting chief. I then became secretary to Dr. Herwick, his permanent successor. In 1945 I went to work for Dr. Elliott (Interstate Division) and remained there two years. In 1948 I was transferred back to the Bureau of Drugs to set up a library, and I have been here ever since. Over the years most of our work has been in medical reference, a great deal of it involving legislation. One of the highlights was the early work that I did with Dr. Kerlan in the '50s when we developed the first pilot study on the reporting of adverse reactions to drugs. The Bureau now has an elaborate drug reaction reporting system, which was established as a separate unit in 1970. I don't know whether anyone realizes it, but Mr. Larrick had the idea for this system back in 1941, but the war came along. After the war the Bureau got started on the idea of establishing a national reporting system. One of my responsibilities, when I changed back to the Bureau of Drugs, was to set up a library and also to set up for the drug reaction program.

Young: You had a great diversity in your duties since you came with the Food and Drug Administration.

(Mr. Roe's opening remarks did not record. The following outline was submitted later.)

OUTLINE OF CAREER - Robert S. Roe

September 1925 - July 1930

Appointed as a Junior Chemist (P-1) as of September 1925 at the Chicago laboratory of the then Bureau of Chemistry, Department of Agriculture, where I spent over 2 years each in the Food and Drug laboratories, respectively, and some months as "acting bacteriologist".

July 1930 - March 1934 Washington, D. C.

Assistant to the Chief, Import Supervision. At that time the headquarters administration staff was organized in two divisions: Interstate Supervision and Import Supervision.

March 1934 - May 1937 San Francisco, California

Assistant Chief, San Francisco Station.

An important production area for fruits and vegetables, fresh, canned, dried, and fishery products.

May 1937 - July 1943 Seattle, Washington

Chief, Seattle Station

Large production of fruits and vegetables, fishery

products, including salmon, tuna and shell fish. Some 25,000 cars of apples were annually shipped from orchards in Washington, Oregon and Idaho. A state law in Washington required that all shipments exported from the state be inspected and certified by the State Department of Agriculture for compliance with the state grade and quality requirements. (This was a marketing law to prevent shipment to out-of-state markets of low quality fruit.) Although the state Agricultural Department was not in sympathy with FDA spray residue requirements (lead, arsenic, and flouride tolerances), they agreed to a program that required washing of fruit to remove spray residues and sampling and analysis of lots for shipment to insure residues within tolerances as a basis for issuance of state shipping certificates. We maintained surveillance over the operations, including inspection and checking of private laboratories that did the analytical work, and considerable sampling and analysis of samples of fruit being shipped. The state and the shippers agreed to this because of desire of growers and packers to avoid seizures of fruit at destination and unnecessary extensive sampling of fruit in shipment or at destination.

Comparable arrangements were made with Agriculture Departments in Idaho and Oregon. In Oregon the examination of samples was done in state laboratories.

This program on the whole was very effective in insuring the shipment of clean fruit - fruit meeting pesticide residue tolerances - from the Northwest, one of the heaviest "spray areas" in the country.

Another program unique to the Seattle area was the "Better Salmon Control Plan" which was inaugurated during my first year at the Seattle Station. (I had not been involved in the development of the plan. I believe it had been developed by the Commissioner's Office and perhaps the Western District Director with representatives of the salmon industry. But I was the first Station Chief to administer the plan and much to my amazement it worked very well!)

The plan contemplated that those packers who wished to operate under it would provide the Station with complete information on the quantities of canned salmon packed by date and the code marks used, etc.: that their packs would be checked by the National Canners Association laboratory in Seattle; that where their examiners encountered bad material, such would promptly be reported to us and the packs involved

held for reconditioning; that if FDA examiners found bad lots not reported by the canners such lots would be voluntarily held for reconditioning under our supervision.

This type of plan was feasible because practically all U.S. packed canned salmon was packed in canneries in Alaska and Washington; and most of the Alaska pack was shipped to Seattle for storage in the dock warehouses from which lots were subsequently withdrawn for labeling and distribution. It is my understanding that canners had pleaded for some relief from FDA sampling of shipments in transit or at destination that resulted in seizures all over the country when violative lots were encountered.

July 1943 - August 1952

Director of Los Angeles District

This is an area of large production of citrus products, other fruits and vegetables; canned tuna and other fishery products; pharamceuticals, vitamin products, dietary preparations, an area rife with fraudulent medicinals and health food promotions.

The gamut of possible violations was encountered in the extensive and varied operations in this District. We usually had an active court calendar. A number of

Supreme Court decisions emanated from cases originally brought here. (Attorney Arthur Dickerman, who presently is still a consultant to FDA, would be the best source of information on the significance of some of the decisions from these Los Angeles cases.)

August 1952 - October 1954

Director, Division of Program Research, Washington, D.C.

I succeeded J. O. Clarke in this position at the time of his retirement.

This was the planning office for the development and preparation of the project and program plans.

October 1954 - June 1956

Associate Commissioner

Coordination of the activities of the various headquarters and scientific divisions, and special functions.

June 1956 - January 1965

Director, Bureau Biological and Physical Sciences

Organized the then seven Scientific Divisions (Antibiotics, Color and Cosmetics, Food, Microbiology, Nutrition, Pharmaceutical Chemistry, Pharmacology) into a scientific Bureau, and served as the Administrative Director of the Bureau.

January 1965 - May 1966

Director, Bureau Scientific Standards and Evaluation

A reorganization of FDA in January 1965 included the splitting of the Bureau of Biological and Physical Sciences into two new bureaus: Bureau of Scientific Research and Bureau of Scientific Standards and Evaluation. I was assigned to head the latter. BSSE was assigned responsibility for the scientific review of petitions for regulations setting tolerances for pesticide residues, regulations pertaining to food additives; development of food standards regulations, antibiotics and color certification programs. Laboratory operations directly supporting these standard making and certification operations remained with BSSE; but all other research functions went to B.S.R.

May 1966 - July 1967

Associate Director, Bureau of Science

Another reorganization occurred with the arrival of Dr. Goddard. This included the rejoining of the Bureau Scientific Research and the Bureau Science Standards and Evaluation into a new Bureau of Science, to which I was assigned as Associate Director.

(The recording continues)

Scientists
6/29/78

Young: Well, thank you for helping us see you within the historical pattern. Now we'll just experiment, with the help from your memory, to see how it might aid us and how we would go about planning a book that would be from the starting of the enforcement of the 1938 Act, up more or less arbitrarily, to the 1962 Law. And so, we're going to do this in an entirely informal way and you should keep in mind that we want your help with things that we shouldn't miss, with things that are important transitions, important trends; and since I am a layman, a historian, and not a scientist, it's in the area of the FDA science, most particularly where I personally feel a lack and where I want to be fair in getting it included. Your suggestions here as to what are the important transitions; what are the important developments; what are the innovations. As I said in my letter, and how the science influenced the total mission--everything else that happened, like these reorganizations which you mentioned, influenced the science competence. These are the kinds of things that we would like to get clues from you about. Let's just begin with this matter of the reorganization. This came

up as a major matter just sort of spontaneously, what every one of you, almost anyway, said was a factor, since it changed you around and your responsibilities to some extent. If one were writing a book in this period, which is the case, how big a role, (looking at it from the point of view of the scientist in FDA) should the reorganizations have? Can we think about the backup of science in a regulatory mission without paying much heed to the reorganizations, or should they have a fairly prominent interpretive role? Is that a good kind of question to kick around for awhile?

Garfield: When we talk about reorganization and I think it should be an important part of the history of the Food and Drug Administration, I think that one of the things that needs to be explored is the change in philosophy of the organization. The internal advance to the Commissioner level that existed until Larrick resigned, and what has happened since then.

Young: Organizations, you are saying are the shadow of something bigger?

Garfield: Right. And I think that the Food and Drug Administration changed tremendously when that change in

policy occurred, to bring in from the outside a Commissioner who was an M.D. instead of someone who had come up through the ranks.

MacFadyen: When did that happen?

Garfield: It happened in 1965.

Young: I think Mr. Larrick retired in December of 1965 and Dr. Goddard came in the next month. So, this is really going into volume three, but let's not neglect that because it is.

Garfield: Other things to be considered are the tensions that developed as a result of reorganizations and proposed reorganizations, even though in many cases, the people involved were doing the same thing under a different title.

In the field organizations, for instance, the reorganizations had little influence on the field's major responsibilities. Basically, the field organization, chemists and scientific people did pretty much the same thing, but most of this is pretty much outside of your period.

Young: Well, let's not neglect it because I do hope to get volume three and you're here today.

Garfield: Of course, at that time, it was a big decision as to where the emph asis would be on what the Food and Drug Administration would do. Up until that time

it was pretty much across the board what kind of activities would be done. Drugs were paramount and esthetics were in second place.

MacFadyen: What do you mean by esthetics?

Garfield: Filth in foods and sanitation.

Slocum: They (FDA) practically abandonded emphasis in the economics area and economic violations created more actions under the F.D.& C. Act than any other activity.

Garfield: Economics became essentially non-existent. The notices of judgment that covered the actions on violations had a tremendous influence on so called "voluntary compliance". These guys weren't taking any chances, but when the reporting of those cases dropped off, we began to see a little hanky panky in the way they operated, and I think the same thing applies.

Young: In other words, the industry suddenly realized that if you weren't in the plant they...

Garfield: I think the industry is very sensitive to regulatory actions. I think there are more economic cheats today because the Food and Drug Administration isn't taking any actions and they know it.

Eisenberg: During the entire era of 1938-1962, we had this so called three-ring circus, where the priorities were set up. Health related, sanitation and economic. That

was the priority. Those three priorities existed. That made a lot of sense. Health related activities were most important. Anybody would tell the Food and Drug Administration that's what the public was interested in and sanitation, I think, was the next major area that consumers are concerned with. Economics, to some extent being a third area, but some people may feel much stronger about it.

MacFadyen: When you say economics you mean...?

Eisenberg: Short weight, substitutions of cheaper productions.

Young: The way to find out the comparative emphasis at any given time among these three categories would be how?

Garfield: Go back to the program system. The programs that were written set up what the field organization was going to do.

Young: Would you care to explain the program system and what kind of documents would be in the archives?

Roe: Yes, there should be lots of documents on the written programs that were set up. There are many angles to the matter of programming and the matter of reorganization. If I can make a few comments? First, on our programming the setting up of programs and activities there

were several points we had in mind. One, we wanted a reasonably uniform action throughout the country. We didn't want San Francisco emphasizing an activity on certain types of products and not be active somewhere else. They didn't have to be all the same, but we wanted reasonable uniformity so that we could bring consistent pressure on the industries in all parts of the country at the same time.

Cleaning up sanitation in factories or whatever it was. We did have the three categories of health and filth and economics, that is, as to priorities. It doesn't mean we would only work on health hazard violations and not economics. All of those are important.

Young: Do you know if this went back to Campbell's original planning about the time of World War I?

Roe: Yes, I think that's right and Charlie Crawford had much to do with setting up the original planning concept of...

Slocum: The original approach to this, as I recall, and I think you'll back me up on this, was: Every year there was a conference involving the three original districts, Eastern, Central and Western. During that conference there was a program planning session where division directors would come in and join with them. These

are our problem areas. These are health problems. These are our adulteration problems. These are our economic problems. And out of this they would build a program for the coming year allocating resources to these various areas, and this has gone on since then. When Mr. Roe came in to head up program planning, they literally then planned this on a national basis for all the Districts.

Roe: As a District Chief, I used to come in about annually, or about every other year to Washington, to a conference at which, as Glen points out, among the things discussed was the program for the following year. That is, what products we were going to work on; what types of violations we were going to look for; what the problems were in various areas. It didn't mean that we were restricted entirely to those programs. If complaints came in from some source, or a new problem developed, of course we were supposed to get right in and investigate it and get the facts reported and maybe a revised program set up. But it did serve as a guide to promote a certain degree of uniformity in the pressures brought throughout the Country and as a basis of where we would spend our funds. That is, every type of violation you encounter, if you decided to prosecute it, you would tie up your witnesses and your funds and some

of them would not be as important to consumers as others. We wanted to concentrate our efforts, as far as we could, on first things first. That was the slogan we used, and certainly, violations that involved danger to health, they were number one priority. Those must be investigated and dealt with as promptly and thoroughly as possible. The outbreak of a food poisoning case, a drug injury or something like that whether it had to do with any program or not, that was something to get right at. Next came the esthetic violations. A matter of filth or spoilage that didn't directly involve a health hazard perhaps but certainly was very objectionable--the packing of a rotten food or a dirty one, or one insect infested or rat contaminated. And then third, the economic violations. Just because they were third, didn't mean tht they weren't quite important. Where substantial weight shortages or misrepresentations, watering of fruit juices and that kind of thing, it was important and we had programs set up on it, but it was the third category in terms of priorities.

Young: The program would be a document that had national percentages that weren't firm, but suggested?

Roe: That came up somewhat later. First there weren't documents, or not many of them sent out. There were instructions at these conferences where the programs

were lined up. Now that was when the field forces were set up in three districts with headquarters in New York, Chicago and San Francisco. As I recall, there were six stations in the Eastern and Central Districts and four stations in the Western District. Later on, there was a big field reorganization. Those districts were abolished. The Chief of the Eastern District, well, Alan Rayfield came in at that time to head up what was the Division of Field Operations.

Young: This was really before the dynastic system came to an end?

Roe: It came in 1948 and J. O. Clarke, who was Chief of the Central District in Chicago, came in to head up the new division of planning. I think they called it Division of Program Research. And John Harvey, the Chief of the Western District came in to head up the Division of Litigation.

Young: What are your recollections about what were the main reasons for this reorganization?

Garfield: Well I think there were a number of reasons. Actually, it eliminated a layer of supervision where recommendations had been directed to the Districts, they now went directly to headquarters.

Young: Did speedier transportaton and communication make this more possible than it had been?

Roe: Oh, I think so, yes. No doubt. And incidently, it brought back to some extent, not very much, the system that existed earlier, when the 1906 Act went into effect. Originally, I wasn't, of course, here then, but it's my recollection that the laboratory work was directed by a Chief Chemist in Washington; the inspection work by Chief Inspector Walter Campbell; and there wasn't at first too much coordination. The laboratory didn't know what samples were coming in and vice versa. But these were separately directed from headquarters. I wrote a piece, as I recall, when I became Director of Program Research and Crawford was Commissioner then and asked me to review the historical set up and I did write a piece on the organization. I believe it was in one of the Food Drug Law Reviews.

Young: That is the Food Law Institute Journal?

Garfield: You know, I think if I were writing this thing, the story of reorganization, I think I would emphasize the swings from central control to decentralized control. This, in a large measure, is what happened. First we had strong central control and then there was an attempt at decentralizing and then back to central control and along comes Goddard and he decentralized control. Explain that this happens from time to time, but it parallels the thinking in Government in general.

Slocum: But there was never real relinquishing of central control to the field until Dr. Goddard came in as Commissioner in 1966. There's one aspect of the time we're talking about that concerns planning. And that's the term for "selective enforcement." "Selective enforcement" was almost a necessity because of the limits on numbers of people and the amount of money that was available to us. But it turned out, I think, to be a very, very fine system and I think, it was as good as what we have now. We didn't have the resources to do all the things we wanted to. So the effort and an essential part of the planning system was to define the industry subject to enforcement. What are our problems in each and every food and drug firm? What part of the industry is actually in violation or suspected to be in violation of the law? This was done through the plans so that the emphasis would be placed on those parts that needed it over the years.

Young: The judgment came up from the bottom.

Slocum: It started from the field...

Young: As well as the knowledge of the people at headquarters.

Garfield: Well, I think the first attempts to computerize actions taken by the field and control of activities of the field had a very profound effect on

the kind of attention that was paid to consistent violators and the potential violators, and the attention to be paid on just a routine basis to the industry's operations.

Young: Fred, when did that begin?

Garfield: I think it was in the early '60's.

Porter: We went on the first computer, I think, in 1961 or 1962.

Lofsvold: We went with the computer at the Department in 1963.

Garfield: Yes, but I meant when we went over to the IBM system.

Lofsvold: Oh, well that was much later; that was in 1965.

Garfield: That was a real attempt to point the finger at those organizations that were consistent violators.

Young: It was an effort to move to quantification from the best impressions that the earlier system had.

Garfield: The earlier system was a manual system.

Young: Which were somewhat statistical.

Slocum: There were annual reviews of programs and plans. Didn't you have annual reports breaking down your time showing how it was in comparison with the prepared plan?

Young: But this was getting it quicker and more precise. That was its goal.

Garfield: I think that manpower was in short supply and it was necessary to concentrate your efforts in large measure, where they would do the most good.

Roe: There were some problems on this matter of planning, how much time there would be on different projects. I'll comment on it in a minute. First, while I have it in mind, I would like to point out that there was another pendulum swing that occurred over the years in Food and Drug operations and that is the philosophy of prosecution versus education. There would be a period when we were hot on laying the law on these birds and then a philosophy that well, we ought to spend more time in education to help them understand the law and the regulations and comply with them.

MacFadyen: Well, can you identify some of these periods in terms of time?

Roe: No, I don't think I can.

Young: Was this tied to the broader political atmosphere?

Roe: Probably to some extent, yes.

Garfield: Most of it started in Goddard's time when there was a swing from regulatory work to enforcement by regulation.

Roe: Well, it was before that time Fred. The time I'm thinking of, because I left shortly after Goddard came

in but it was in preceding years.

Garfield: Yes, there was voluntary compliance and education, but I think there was a distinct change in philosophy.

Eisenberg: You remember the Citizens Advisory Committee in Larrick's time. One of their recommendations was education. Let me mention one aspect of organization and reorganization that I think played some role in how we were moving. As Fred said, or Bob said, central to decentral and back to central and it swung back and forth. But one aspect of that swing was the criticism leveled at Food and Drug, that our enforcement was not uniform countrywide, and I think the elimination of the three districts and the so called coordination of all of the stations with the elimination of the districts, to some extent, offered a better means of uniform enforcement. Even to this day, there are still critics that one station is operating with a stronger hand. We have that in our system of justice. If you want a good judge, you go to someone in Iowa for instance... When we moved, in 1939, out of the Department of Agriculture, I think that there was a major change in philosophy of Food and Drug enforcement, out of a so called producer oriented or producer service department which the Department of Agriculture was, to a consumer oriented

department, which was first the Federal Security Agency, and later, D.H.E.W.

Young: Living through that change, do you really think that made a great difference in the functions?

Roe: Yes, I think so and this might be recalled that that was during the first Roosevelt, the F.D.R. administration, you will recall that Roosevelt asked Congress for broad authority to reorganize the government. In fact, he asked for a Department of Health or something of that kind. The Congress turned him down on that but they did give him broad authority to reorganize the government within the existing departments and bureaus. And what he did at that time, as I recall it was shortly after the Social Security Act had been passed and they set up the Social Security Administration to administer that important and expansive law.

What President Roosevelt did was to set up the Federal Security Agency and he transferred to that agency, all those functions of government that had to do with consumer protection, consumer welfare and health. Food and Drug went from the Department of Agriculture; Public Health Service from the Treasury Department, the Office of Education from wherever it was. He set up, in the Federal Security Agency, the Department that he asked

the Congress to authorize, but he set it up as an Agency. And I think I was at Seattle at that time when we changed from the Department of Agriculture to the Federal Security Agency. Organizationally, it seemed to me as a very sound thing to do because it concentrated in this new department, or what was to become a department, those functions of government that had to do with consumer protection, public health and so on. We had been something of an anomaly in the Department of Agriculture. I recall that Henry Wallace, as Secretary of Agriculture, was said to have been quite pleased when we were transferred out because we were one of his real headaches. The reason was that the Department of Agriculture basically is concerned with the promotion of agriculture, the farmer; whereas Food and Drug sometimes came into conflict. Spray residue on fruits--here we were seizing fruits that the Department of Agriculture was helping the farmers to produce and to protect from insects by spraying.

Young: Did you really see how higher-ups in agriculture were leaning on the F.D.A. to be more gentle in connection with the enforcement of spray residues?

Roe: No, I don't think we had too much of that. At least I wasn't close enough to it at the time to really know.

Slocum: There was just a little by-play. I don't know whether it shows in the records or not, but Walter Campbell was moved from head of what was F.D.A. to Director of Regulatory Services for the whole Department of Agriculture.

Roe: That's right.

Slocum: Then he asked to be removed and put back as head of F.D.A., showing, literally, his displeasure of the situation at that time. I don't think you'll find that written anywhere.

Young: Well, I just--I know how they leaned on Wiley, back in the very early years.

Roe: Oh, I think there was much more then, than when we were there.

Young: Now, I just--you say this was an important transition, and I'm trying to get at your impressions--your recollections of how it was an important transition, from the point of view of the mission.

Garfield: I think the whole thing boils down to having a regulatory agency, within a service oriented organization. There is a different emphasis and the two ought to be separated.

Slocum: I wish somebody would say that real loud now.

Young: Well the Agriculture Committee's still got your appropriation. So that in a sense, that problem exists there, although not administratively.

Roe: Well, that's the problem, of course, with the Congressional Committee and personnel standards there. There are some interesting comments to be made on that. I recall one thing when I was in Seattle, I would occasionally get into hassles with the industry up there. Some complaint was filed in Idaho against me on some action that involved pesticide residues on apples. Senator Borah was then representing Idaho, and there was a power in the Senate, and I didn't know it until some time afterwards, but he, in effect, asked for my scalp because of the complaint from his constituent and Henry Wallace did not take my scalp. And I didn't know anything about it until long after.

Young: Well, Wallace may have been a different kind of Secretary of Agriculture than some may have been, and somewhat more independent and more consumer oriented.

Eisenberg: Well,...

Young: You wouldn't say that?

Eisenberg: He was a farmer himself.

Young: I know that.

Eisenberg: And I think he realized the inconsistency. I think he was aware of it. I think his sympathy lay with the farmer.

Young: He did reverse Tugwell on spray residue limitations at one point, making it more liberal for the farmers, as I recall.

Slocum: Another aspect that I'd like to get into but I know it'll change the trend here and now, but I think it has to do with the fact of the management.

Young: How about these things we've been talking about--the kind of oscillations that you described--in their impact on the Scientific Bureau in Washington that you were in? Did the changes in structure in the field have any detectable influence upon the science of the agency, or were they kind of more on the regulatory side and sort of irrelevant to the science?

Eisenberg: Well, I think, when we gave the districts autonomy and let them act on their own and develop their own expertise, to some extent they relied less on Washington. Our particular organization there, we had a background of working very closely with the districts. We continued to do that, and I think to some extent that we operated as mavericks, you know, we just continued to talk to the districts and we had a better relationship.

But as newer people came in, some of them never knew the...almost didn't know that the districts existed. And the movement of scientific research from Washington to the districts, I think to some extent was greater in Goddard's time than any other time when we attempted to give the districts more autonomy, or even the old days where the three districts, the Western, Eastern and Central operated autonomously. Communication was sometimes a little rough between districts; and one district would say, well we look at it this way and we don't care what the Central District, or the other districts...

Young: That is to say, scientists in one district would say.

Eisenberg: Yeh. They would take an independent approach sometimes.

Slocum: It seems to me that the research, at least in the Washington Divisions, was extremely, prominently oriented toward the mission, the job of enforcing the law. To a very large extent carrying out of the scientific mission involved close coordination with the field, actually going into the field, working in food plants, and working with the scientists and the inspectors in the field.

Young: You were on the road a lot?

Slocum: My first 10 or 15 years I spent about a third of my time in the field--field assignments--and I got to know personally almost every inspector and chemist in the whole field organization. I think that has been gradually lost, beginning really, back in some of the early reorganizations under Larrick, until the present time.

Garfield: I'd like to comment on this. I think that close working relationships that existed between Washington and the field had changed considerably. In Food and Drug, and I don't know what it is now, I think it's probably still the same. If there was a violation of the law, the chemists and inspectors would testify as to their findings. But if there needed to be an interpretation by an expert, in the presentation of the case in court, the expert always came out of Washington, and he fortified the evidence that was submitted. This made for a...rather close association since the Washington research effort was directed towards support of the field.

Young: There was almost always a legal person that went, as well as a scientist wasn't there?

Garfield: No, not necessarily. But in the organizations that I went to after I left Food and Drug, the

picture was reversed. Chemists were trained and qualified experts by themselves, so that there was no special research group that would fortify them, if they testified as to the evidence. They could also be cross examined as experts and they would maintain their own position.

So, I think, that the Food and Drug situation is somewhat unique as a regulatory agency, with its close support from headquarters. And I think there are many units now in Food and Drug, as I understand Food and Drug, who are not necessarily regulatory oriented. They're doing more of a basic type of research. And I think that you can see that, since I'm with the A.O.A.C., and certainly in the number of methods that are developed that are being used by the two oranizations...

Young: Research seems to be going in another direction.

Eisenberg: Yeh, one aspect of that--it's sort of a minor aspect--was, that in the old days before Food and Drug hired anybody, I think one of the questions they asked, was the extent of whether you had any...whether you were squeemish or had any second thoughts about punishment of an individual for violation of the law. In other words, were you police oriented. And if you

weren't, they didn't hire you. You had to be willing to go into court and mete out punishment. Now whether we do that today, I don't know...

Roe: I never heard of that.

Slocum: I never heard of it either.

Lofsvold: That, I think was a standard question to investigators, certainly, and inspectors.

Eisenberg: And chemists?

Lofsvold: And to chemists, because we had a couple of sad experiences where we hired people who finally, after they were well trained, had moral scruples against appearing as a witness to send anybody to jail.

Garfield: When I was Assistant to the Chief in St. Louis, I went out to handle cases, legal cases in courts and I think this is one of the first contested actions that I handled. The case was down in Arkansas; and the defendant was some canner who came in dressed in overalls as though he were a farmer, although he was doing several million dollars worth of business when he appeared, as requested. The court found him guilty and sentenced him to two years, and then later on he placed him on probation, but he sentenced him to two years. I had the most uncomfortable feeling I think I have ever had because here I was pushing the case and there was no

real help, from Washington. And I was putting this poor old farmer in jail for two years. And I was tremendously relieved to find the court had placed him on probation.

Young: What was the issue, particularly in the case; do you remember what it was?

Garfield: Some sort of sanitation case. But it's the kind of thing that really sets you back sometimes. In many cases, as far as the chemist is concerned, he would testify and then would go on about his business. They were rarely present at the sentencing. It wasn't as much a problem until you really go to the point where you were handlng the cases.

Young: So you had sort of a moral feeling that kind of coincided with this tri-partite system of priority. You didn't feel that badly if it were an unscrupulous cancer remedy, as you did where there was a little filth in vegetables through inadvertence.

Garfield: Not inadvertence, it was a continuing thing. We don't bring criminal cases lightly.

Eisenberg: The climate today, Commissioner after Commissioner, in the last few years want to upgrade the scientific image of the Food and Drug Administration. And today, a number of the scientists in Washington

really don't even know they're in a regulatory agency. Maybe it's just as well, at least they're completely research oriented and developing concepts and new knowledge which, to some extent, is related to enforcement. But, I'm gonna develop it and turn it over to the policemen. You go ahead and do it. You need the numbers and you need the stick, but don't involve me. I think we have those two types of individuals today. Don't involve me in any police action or enforcement.

Young: In an earlier period, no matter what kind of basic research you were engaged in to improve the science for regulatory purposes, you also thought of yourself as a potential witness.

Eisenberg: Yes, everybody. When I joined in '37, Campbell's philosophy was that the Food and Drug is an enforcement agency. In fact, he didn't want to take on any function that did not relate to enforcement, and when they attempted to enlarge--during the war years, for instance--when they intended to give Campbell authority to examine foods for the Army and new grading, and essentially service oriented, he said that it would really disorient Food and Drug efforts; and I think he simply turned down the...

Garfield: Well, that wasn't true in drugs, I think it was true in foods. I think this ought to be something we ought to talk about--Food and Drug in the war effort.

Slocum: This brings me to another thought that I never liked. I've been called a policeman by so many colleagues in other agencies, the old Public Health Service, and so on; and really, I think in a degrading way, you're a second class scientist, and this idea has existed for a long time. It is untrue and I think when they really come to know the people and the scientists involved, they do change their minds. It has existed for a long time, and I think it's a very bad thing. If you can deal with it, I would like to see that image changed.

Garfield: Well, I used to take the position, more so after I left Food and Drug, and was more involved in prosecution cases, that I was the fuzz, but I wasn't very fuzzy. I was on the scientific end of the business.

Young: Well, part of the impression I've gotten, and I think this is what Dr. Slocum is citing from these other scientists, had to do with the fact that science was being used for some other purpose than merely contributing to knowledge. Isn't that it? There was some kind of a vision of science as a pure discipline and here, I'm speculating, tell me if I'm wrong.

Slocum: It's awfully hard to say. Mr. Roe will recall that when the F.O.B. No. 8 was dedicated, Secretary of H.E.W., John Gardner said now we've got a fine building; now we're going to get good scientists. He literally said this. He had no word of praise for Commissioner George Larrick, his deputy Mr. John Harvey, or anybody else that had worked their tails off for years. Their whole careers were spent in enforcing the F.D. & C. Act on a scientific base. And this idea, I say, has always been hanging there with no real realization or basis. Some of my colleagues in the Public Health Service, of which F.D.A. is now literally a part, were, in fact, doing the same scientific strides we were. And yet, they said you guys are a bunch of policemen. They said this openly, at meetings and things of this sort. They didn't want the image of policemen in any shape or form.

Young: I've known and respected scientists in the agency, but I have had the feeling that the fact that there were such practical elements to the scientific effort, that it was so mission oriented, had meant that it's only a kind of an idealist, who believed in the mission of keeping the food and drug supply pure, who would like to go there. There would be a lot of other kinds of scientists who wanted to be "pure", and so you'd be in trouble competing with academia for good young minds except idealists.

Several: That's true.

Young: Now is this image wrong? Did you have trouble in the competition getting good men and the ones you got had a kind of--their heart in the task--was the reason you got them? Is there any truth in this?

Slocum: At the time, I think it made it really more difficult. I definitely do.

Eisenberg: I think there were other aspects of hiring--I think economic aspects are important--and the availability of jobs elsewhere, of course. Right after the war years when scientists were at a premium, we had to take warm bodies, practically to do some of the jobs.

Young: Pay scales weren't as high as industry?

Eisenberg: Well, it was more than that. Industry... there were a lot of jobs in industry and they were more interesting, in the sense they were research oriented and greater challenges, I think.

Slocum: Time alone. Just the time required to get all the papers and get an appointment made--three months, six months, a year sometimes. You lost people all the time, to industry because of that. They could be offered a job at a meeting and report the next week.

Eisenberg: Another thing was the pay scales were very important, because industry--they had no restraints at

all. They could offer a guy three times what he was worth knowing they could--if he didn't turn out, they'd just eliminate him at the drop of a hat--let him go in six months. If we hired a person, the bureaucratic red tape of elimination was monstrous.

Roe: Well, there are problems there all right, but I think it's amazing that we got as many top notch scientists as we did have and do have. At least up to the time that I'm familiar with it, they were really a competent, dedicated bunch. Two things I'd like to comment on on this research: I think what Fred and the others have said about the expertise developed in Washington is right, and I might illustrate it with just a very simple example of it. Enforcement of the fruit preserves standards, jam and jelly standards required the development of methods of analysis first with the various constituents of fruit, but more than that, there wasn't just one thing you could rely on to tell how much fruit juice was in here...the composition of fruits varies from season to season and from area to area--and what was involved there was the gathering of fruit of all kinds in the different producing areas at different periods over the years, and making complete analyses to see what the normal constituents are and the range of

them. And the field stations were involved in getting some of the samples, but also, the scientists from Washington would come out there to have first hand knowledge of the types of fruit produced and the way that they were sampled, and get the information from various stations throughout the country and then work up a program of how to interpret the analyses that come in on the samples collected from the grocery shelves, to establish that there was a shortage of fruit. And here was an area where we needed the expert advice of the scientists from Washington, usually because the field scientist was familiar with the methods of analysis, he made the determinations, but he hadn't usually been involved on the complete background study and was not in position to give an expert interpretation as to what the results meant. And here's where it was important to call for the scientist to come in and do that.

In some cases, the field scientist did have the experience in development of methods and development of a basis of interpretation and could, to an extent, be the expert on the case; but usually, this was not the case. One other aspect of research versus regulatory work and what is the function of the Food and Drug

Administration. Well, I think all of us agree it's a regulatory agency and basically concerned with administering the law, and is not primarily a research agency. And yet, when I was head of the Bureau of Biological and Physical Sciences, I had many times, some difficulty in convincing our business office that it was appropriate that we have certain research going in fields of toxicology, pharmacology, and chemistry to back up our responsibility of evaluating pesticide and food additive petitions that came before us. The point there of the business office seemed to be that, "well, you shouldn't be doing any research, your scientists review the petitions submitted by industry." My position was that for my scientists to make an adequate review of the petitions coming before them, and to evaluate the methods used and the results of the toxicology, it will soon detriorate unless we have people there that have had their hands in studying these methods and working out the situation; so that we were able to maintain some work on our own on studying the toxicology of products so that we knew whether information presented by a petitioner was reasonable or not, or fully out of line. There were many instances where our chemists from the Divisions of Foods, held up petitions on the basis they

didn't believe the chemistry was what the petitioner said it was, because of their own studies of those types of compounds. And I recall one case--I don't remember the product--where the petitioner was quite upset and appealed and complained, and his head company was in Switzerland, and they brought over their chemist from Switzerland and he sat down with our chemist and said we were right...Here, without some background studies and research on the part of our own review scientists, we would have missed it. I'm convinced of a lot of things of that sort. Now my objective was, my hope was, to have, particularly in the pharmacology area, as well as the chemistry area, a group of scientists who would, part-time, be on review and part-time on research. This didn't work very well. I never had enough people, and some of the scientists just wouldn't do review work, and some scientists like the review work weren't too hot on the research, and so we had them on both ends. But at least it was a help to have both types in the same branch that was responsible for reviewing certain parts of the toxicology and petitions that they had a backup there on their evaluation. This was a constant problem. I think Glenn's outfit was involved to some extent on it.

Slocum: That was a point I wanted to bring up a while

ago. There are two aspects of it, really. Number one--and this goes back to Mr. Larrick's regime and after the bureau system was instituted. Up until the point I'm talking about, we had a very small administrative services group, I would call it, which included budget, procurement, personnel--all of these services. In total we had from about 30 to 50 people probably at the most in these services. They really worked for us. They wrote the job descriptions, they looked up, described and ordered necessary equipment. Really, they were an excellent service group and supported the scientists and scientific mission. And then at one of the Commissioner's staff meetings there was an announcement of the creation of a new Bureau of Administrative Management, with 292 positions all filled. They stopped working for us and started working for them.

MacFadyen: When was that?

Slocum: Not too long ago. Leo Miller was the Assistant Commissioner for Administration, whenever that was, and I would guess it was probably in the '50's, sometime.

Roe: Yeh, I think so.

Slocum: Now I'm not kidding you; this really changed the situation. I had to hire an assistant just to take care of paper work, literally--I couldn't do it--there was not sufficient time to manage a research program and begin to carry out all the activities that this required.

Garfield: Well, I think, Glenn, that what this thing really relates to is jumping from a small organization to a big organization.

Slocum: It does, but the whole orientation was changed, and I'll tell you, it's ah...

Garfield: Well, I think that exists in any large organization now.

Slocum: Scientists work for the administrative end instead of the reverse.

Garfield: Instead of expediting what the scientist wants, the scientist has to convince the other guy that he needs it.

Slocum: The only point I want to make here is that for a man on a scientific mission it is far more difficult, it requires much more manpower to do the same thing, and I still think it's the cart before the horse.

Young: But you had a strong subjective feeling that things were changed.

Slocum: Well it's there. It's gotten worse in the meantime. There are layers and layers of management now that weren't there before.

The other thing Bob just alluded to...F.D.A. received from outside sources, I think at least two recommendations, that it establish a research organization completely divorced from enforcement work.

There was not a single division director who agreed with this concept. The two areas, research and regulation, had to be kept related. This came up two or three times, I think, when Mr. Roe was head of the Bureau of Biological and Physical Sciences.

Eisenberg: And it's still coming up today.

Slocum: And we continued to oppose it successfully. The other related aspect was, again the thing that Mr. Roe mentioned: Do you take scientists from their scientific divisions and put them in review operations where they're completely divorced from the laboratory? This exists today. Now I can only say anything about it by hearsay, but I hear that it doesn't work well. But these people are divorced from their scientific colleagues; they are burdened with terrific review obligations. But it's a thing we fought against hard, and successfully at the time.

Young: In your area, when you had the double responsibility of the scientists that Dr. Roe was talking about...

Slocum: Actually, in my area of microbiology, as in Bill's area, this does not come into play. There has been some separations...drugs, for example, from the foods, and so on...but... But the

review functions by and large, were done in the other Divisions such as toxicology, chemistry and the other areas. Now they have literally been separated from the scientific divisions--for the food additive reviews, and this sort of thing.

Roe: I'd like to make a comment on the organization of the Bureau of Biological and Physical Sciences. When that reorganization took place, I had been Associate Commissioner, and I was assigned to organize and set up the Bureau--the seven scientific divisions. They had been operating, to some extent, somewhat separately, and not too well coordinated, and our hope was in setting up a Bureau, was, we would set up an overall scientific team. That was our aim. I was not sent over there to set up the Bureau to be the Chief Scientist of the administration. I wasn't. I was sent over as the administrator to be the Administrative Director of the Bureau. Somewhat different type of organizational set up than exists in any other scientific bureaus that I know of around government at that time. The scientific expertise was to and did reside in the division directors--Slocum, the expert on Microbiology and Dr. Lehman in Pharmacology at that time, and Vorhes in Food, and so on; and the basis of scientific responsibility, the

responsibility, ultimately, of the scientific decisions within those given divisions to the directors who were experts in that field, and I did not undertake to change any of the scientific operations. My function was to administer the bureau and set it up, to organize it, and to get going as a scientific team where we could coordinate the activities of the several divisions. I think we were pretty successful in the whole, in accomplishing that so that when a problem came up, we didn't send it just...we might not send it just to one division but would set up representatives of the divisions that might be involved on some aspects of the problem, to get together and work out a plan for dealing with it. We got better and better coordination, but the thing I wanted to bring out was, I was not posing as the chief scientist of the organization but the administrative director, and that's the way it started out...

Young: In writing a book that you hope will be readable, you don't only describe structures and trends and make generalizations, but you tell stories. Looking at the science side, and explaining the scientific side and its contribution to the total mission, what are some good stories that we might look into that would be worth investigating and considering to be told in a book?

Garfield: I think that the one that I mentioned concerning the standards, the jam and jelly standards, as an example of the complexity of establishing the standards...and there were a number of cases that went to the Supreme Court. I think if you were to trace the number of packs, of jams and jellies that were put up, the complexity of analyzing the data from statistical studies...these are some very impressive stories as far as I'm concerned, for anybody who would read this. The government just doesn't arbitrarily set up a standard by some long haired person.

Young: If you were going to illustrate the standard making approach and the scientific role, you'd think that jams and jellies would be a good one to take.

Roe: Well, I think you could make a good story out of it. Go back to the "Bred Spred" case.

Young: I've got that down...

Roe: I was the original analyst on that case in the Chicago laboratory. I analyzed the "Bred Spred" which was a diluted jelly or jam which is what we were trying to prove. The first trial was in Kansas City, and the second trial on the second case, in Detroit; we lost both of them. I was a chemist witness, and gave the

results of my analysis of those products. My previous experience in industry had been the plant control chemist in a paint factory. I remember one of the questions on cross-examination, wasn't it much harder to analyze jam and jelly than it was a paint? And I said no the contrary was true. We had some standard methods for some of these constituents in jam and jelly, and we didn't have any standard methods in paint. So they didn't catch me on that one. And then, the expert from Washington, Victor Bonney, I think it was, came out to give testimony on the interpretation of the results of my analysis. Now the reason we lost the case was not because of defective testimony on my part or the expert's part--it was a legal basis. What is your standard? We said well, everybody knows that housewives make jam and jelly with a cup of fruit and a cup of sugar, and this stuff is far below any 50 percent or 40 percent or 30 percent of fruit. But the court wound up and said, "Well, there isn't any...you haven't any basis to set up a standard" (I think we had an administrative standard). Now you can read the cases and check up on that. That was a long time ago.

MacFadyen: This is pre '38?

Roe: Oh yes, right. And that sort of court experience--this and other cases, led to the authorization then, of food standards under the new law. So then they set up a food standard, and presumably when those regulations were validated, then we could go into court and the testimony be confined to showing that the product under the suit deviates from the standard. And the standard becomes the legal standard.

Young: So you were saying that the process of making that standard is a good example to show the scientific competency of the agency...

Garfield: Well, from a number of standpoints, one is to establish the elements that would be used. Secondly, the statistical interpretation of the thing--a very complex situation, with variations from field to field and...

Lofsvold: Could I enlarge on that and just give you a little idea of what happened? When I first worked in Seattle, we were trying to establish standards. One of them--a typical one--strawberry jam, strawberry preserves. Part of the process to get the authentic chemical data on which to base methods and the standards, involved an inspector going to a factory where they were packing the frozen strawberries, (many of them in those

days packed them in huge wooden barrels), and watching the process, making sure that the strawberries went through the normal plant procedure of washing and draining and use of sugar, drawing samples of those as they went in. And then finally, after the barrel had been headed, drilling holes around the rim and putting in wires and lead seals to make sure that that barrel couldn't be opened. The barrel was then shipped in the normal course of commerce, to somebody like A&P Store's, jam and jelly factory in New York. Another investigator and a chemist would go over there and when A&P opened that particular barrel and made it into jams, and take samples of that product. By analyzing the jam and the raw fruits originally collected, you have then a full history of that particular barrel of fruit from the time that it was brought in from the field, until it's made into jam and jellies. You can say that the chemical constituents that you analyzed for represent nothing but strawberries. Nobody tampered with it. And this went on all over the country for several years, to accumulate data on the variations in chemical content from year to year and place to place.

Eisenberg: You know, an interesting sidelight of analyzing jams and jellies is a practice sometimes used.

A manufacturer was making seedless raspberries, say. You have the seeds left over. Then you can take these seeds and put them into another product that didn't have fruit, and the added seed made it look like it contained fruit. So we had a method to detect naked seed.

Slocum: Let me give you an example of a story on this, too. He developed the method for naked seeds...The seeds were separated and then dried out and then... (inaudible).

Garfield: I remember examining a raspberry jam and found naked seeds all over the place. Something looked funny about the whole thing, so we went out to the plant where they actually manufactured them, and they had a particular machine that they removed seeds in part, from the process there...not the seeds, but they comminuted the product by putting it through this machine. Instead of having whole berries, they'd have a fairly uniform mixture. But this had...teeth that would work this way ...and it actually stripped all the pulp off of the seed. And so as you looked at the product, you thought they had added back the seeds... And here we would have taken the regulatory action against the firm for adding the seeds back, and I'm sure we would have lost the case, and put them through a lot of expense. So, even

with a situation where everything just seemed to be as clean cut as it could be...

Eisenberg: You've got to be familiar with the technology of these...

Janssen: I would like to relate this story from the standpoint of the industries, the jam and jelly industry. I was editor of a journal called Glass Packers, during all this time, and one of the topics that we covered intensively and continuously was the fight for standards of jams and jellies. It began in the late twenties, at least the Glass Packer's coverage of the matter began in the late twenties.

Now the preserve industry, at that time, was involved in a very serious economic problem of competition from these substandard products. The firms that wanted to make good preserves and compete with the American housewife, and get her to buy her preserves at the store instead of making them herself---those companies found it very difficult to meet the price competition of these people who were putting out the fake preserves. And they felt very keenly that the American consumer was being swindled by their competitors. And they felt it in the pocketbook. And they also felt it from the

standpoint of industry, long range industry progress, the industry had to put out good products in order to increase the market. And there were companies that were leaders in this philosophy for example, the American Preserves Company in Philadelphia was headed by a Quaker named Wayne Metzger, and Wayne Metzger was the ring leader of the industry group that backed up the Food and Drug Administration. They had their own little laboratory and their own chemist, a man named Waldy, and they analyzed products, and there was one incidence where they even turned in to the Food and Drug Administration, a couple of members of their own Board of Directors, for putting out substandard stuff. Well finally, this struggle to get a legal standard went through a number of stages. There was, of course the effort to support the McNary-Mapes Amendment. But the solicitor of the Department of Agriculture vetoed the application of the McNary-Mape Amendment to preserves and jellies. He said that this amendment was calcualted to provide for standards for canned products, you know, corn, beans, tomatoes and greens and so forth, in tin containers, and it was not intended to set standards for jams and jellies. Then the industry went to, well I'm not sure of the sequence, but they went to the Federal Trade

Commission to get some standards, they used the N.R.A. Code Authority system to try to get standards. They sent their witnesses to Court to help the F.D.A. They were involved in the "Bred Spred" case. I think you'll find a good deal of this is recorded in the records of the Glass Packer and the National Preservers Association Library.

After the 1938 Act was passed, one of the early food standards upon which a hearing was held was the one for jams and jellies. I attended those hearings, and I recall how well set up the agenda was, and how the National Preservers Association collaborated in testimony to establish the standards. They worked directly with Daniel Forbes, the attorney for the N.C.A. They worked with Mike Montel who was the attorney representing the F.D.A. in this hearing. And they worked together just like clock work. I think the hearings lasted only about two weeks. There was none of this adversary struggle that has characterized more recent Food Standards hearings...and pretty soon they had a standard. Well then we began to have... This was the sort of thing that came to me as an editor of this trade journal. There were preservers who were little small

business guys with little technical experience, and they claimed they didn't know how to make preserves so they would meet the standard. And after I'd heard this story in some detail, and a number of them, I decided I would see if I could fulfill my role of trade journalist and I went down to Washington and I visited Mr. Sale and Dr. Osborne, two scientific types, and they were experts on food processing. I told them about this plea or complaint or whatever, and said now, "could you fellows fix up an article that would explain how you make preserves to meet the standards." Well they listened politely, but they turned me down. They reflected what was then, a very common viewpoint in the Food and Drug Administration, that the F.D.A. was not there to give advice on how to comply. That was an obligation of the industry, to figure out how to comply and if you gave advice on how to comply, you might encounter this coming back at you in a court case, and you might lose the case. Well anyway, they very definitely thought it was unwise to do.

Eisenberg: Anything you say would be held against you?

Janssen: Yes, that's right. The F.D.A. could learn from industry, but industry couldn't learn from F.D.A. That was the kind of the attitude. And we did learn a great deal from the industry...still do, as a matter of

fact. Anyway, I wasn't ready to give up and I went to Commissioner Campbell and I told him the story. And I don't think he hardly asked any questions. He just picked up the phone and called Dr. Osborne and he said I have a visitor here, Wallace Janssen. He's been telling me about his interest in getting information about how to comply with preserve standards. It strikes me he's got a good idea. Why not give it a try and see how it works. So they wrote the article. It was a long article and we published it in two installments of the magazine. The Presevers Association ordered about a thousand copies and got it out to the industry. I was told it was the bible of the preservers.

Eisenberg: And when you came with the Administration...

Janssen: I kept on trying to...

Eisenberg: You kept doing that...tell the story to the industry.

Janssen: I believe in...that much compliance can be had through communication between the two parties who were most involved in compliance...

Eisenberg: There are those articles that you helped me write for the Glass Packer on the tomato story.

Young: Oh, you wrote some on the tomato story?

Eisenberg: Yes. And I gave a talk too, before the National Canners Association.

Young: I did an article on Wiley and tomato catsup that will be in the first volume and so I'm kind of interested in tomatoes. Are there tomato stories that would be interesting in the second volume?

Janssen: The depression was a major factor in all of this, and I remember a preserver whom I talked to one day said, "You know, when I come to work in the morning, I don't know what I'm gonna make that day in order to cut the price another two cents a case." That was the way it was when he had this spiral that Franklin Roosevelt called it--the vicious spiral of cutting quality, cutting wages in order to cut prices and the economy went down, down, down the drain.

Roe: There are two angles on the tomato industry you've mentioned that I can comment on. Yes, I think that is an area where you've got a couple of good stories. One of them involves the matter of insect fragments in tomato products such as catsup and puree. When I was stationed in San Francisco, I went out on some inspections of tomato products canners in Oakland and down along the East side of the bay. It was, as I recall, the first year that we had a corn ear worm infestation in tomatoes in Calif.

I went into one plant and was horrified to see them grinding up tomatoes with a lot of worms in them. I remonstrated to the plant chemist and he said, "Oh, we've trimmed the mold out," and he said "to hell with the worms. You can't find them after we get them all ground up." So I reported that back to the office. I don't know that that started the investigation, probably it was already going on in Eisenberg's unit--the development of the worm fragment method, which is a very simple operation to find the worm fragments in the ground-up tomato products. The method was available and in use before that season was over. As I recall, we seized a good part of the product of that particular plant in East Bay. The plant chemist's remark to me, "We're getting the mold out," reflected the fact that industry was well familiar with the Howard mold count that had been developed by Dr. Howard, a predecessor to these fellows in Micro Analytical Division. Howard made many trips to the field studying the matter of mold in tomatoes. He developed this procedure, a count of the microscopic fields containing mold fragments. You can always find a few fragments of mold filaments. Howard demonstrated that the presence of mold fragments in more than a certain percentage of the microscopic fields definitely indicated the use of

some pretty moldy fruit. So, that method had been well established and the canneries generally were watching for mold and sorting out and trimming their tomatoes to remove moldy material as they were in this cannery that I visited. But they thought they could get by with worms and wormy stuff. The insect fragment count procedure was an important development in the control of not only tomato products but many other products where insect fragments depict or represent a bad condition.
Another type that might lend itself to some interesting discussion. When I was at the Seattle station, one of our big projects, as I mentioned, was canned salmon. The big problem there, one of the main problems, was the packing of rotten or partly spoiled fish. This had a big background of problems up in Alaska where there were over a hundred canneries perhaps a hundred and fifty, at the time I was at Seattle, putting up canned salmon. In Alaska they have very high tides, 20 foot tides are common. Fishing boats had to return to the canneries "on the tide." Often, if they hadn't caught very many fish, they'd stay out until the next tide, and when they came in they had some pretty old fish. Some of them not so good, stale and decomposed. The efficiency of the cannery superintendent at that time was judged, in part, on the number of cases he had

packed per ton of fish brought in. So, he wasn't being too careful and wasn't likely throwing out anything he could get into the can. Well, how do you detect a bad fish? It was a matter of organoleptic factors--odor, appearance, etc.--not everybody could be a good salmon examiner if he didn't have the right kind of nose, the sense of smell.

Young: How would you train a person to tell?

Roe: Well, we'd train them. The inspectors and the chemists that had an interest or facility for detecting odors would be trained in this way: They would go out to the canning factories and pack fish that had let lie around at various stages--so they had fresh fish that they knew was good and sound when it first came in, and they had other fish that they packed under different stages of spoiling.

(Mr. Roe added the following explanation of the above statement: The prospective examiners would observe deliveries from fishing boats at a cannery and would select a number of fish and carefully observe the condition and appearance of the fresh fish. They would watch the immediate preparation and canning of some of the fresh fish and would identify and retain some of the canned material for later examination. Other fish from the same delivery would be allowed to age and spoil. At various times during succeeding days observations would be made of the changing characteristics

of the aging and spoiling fish; and at these times some of the fish would be canned and the cans identified and held for later opening and examination. The samples of canned salmon so prepared thus consisted of fresh fish and fish in progressing stages of spoilage and decomposition.

The trainees later would open and examine the samples, relating the appearance and characteristics of the material--particularly the odors--to the observed condition of the fish at the time of canning.)

Young: And the canners were cooperating?

Roe: Yes, that was necessary to enable the packing of special packs for experimental purposes. (And I believe the canners often retained some samples for study by the NCA examiners.)

In contested court cases involving canned salmon charged to be adulterated because it contained decomposed fish, frequently the canners' "expert witnesses" would testify that their examination of samples did not reveal decomposed fish. Resolution of such conflicts in "expert testimony" based on subjective organoleptic examinations would be helped if objective chemical evidence were available.

This led to studies on the chemistry of the decomposition of salmon and the development of laboratory tests to detect

and measure the products of decomposition. Such tests have also been developed and applied to other fish products and other foods.

Young: When did they begin to come in so that they could first be used in court? Just as a rough guess, because salmon had been something I'd thought of as a good example.

Slocum: Well, it goes back to World War I actually. Dr. Hunter, a microbiologist from Rhode Island, joined F.D.A. during World War I. and Bill Spaulding, I think, from Seattle District, went to Alaska in '17 and '18 and put up experimental packs and they became the first specialists on salmon decomposition. And then there were literally dozens and dozens of court cases all over the country resulting from the shipment of spoiled canned salmon.

Roe: That's right. Everybody packed rotten salmon. I don't remember the percentages but...I understand during World I there was a tremendously high, 25 to 30 percent of the cans in a lot had bad fish in them. That gave canned salmon a very bad name. The soldiers who had been fed canned salmon over in France wanted no more salmon. Some of the background was due to the pressure, at least in part, it was pressure brought by the Food and

Drug and its predecessor agency in cleaning up the salmon --that involved changes in the fishing procedures. And rules were set up within the industry that a fishing boat had to come in on the tide whether he had many fish or not. And a certain way of handling the fish from the fish traps, and that kind of thing that helped out on the clean-up on the packing. And then the development of our own experts in the field stations for examination, and the gradual reduction of the percentage of bad cans that they'd let go by before bringing a case. It wasn't that we wanted to let any bad salmon get packed, but the practical necessities of the thing on a deal like this you have to...you can't prosecute every shipment with everybody, so you pick out the worst, and make the best case in court and gradually bring enough pressure so that they can get this problem cleaned up. We had a percentage guideline that was used to what cases were developed...

Young: But that's really sort of a first volume story, isn't it?

Slocum: It really is. One story about a court case- ...what was the woman's name that worked the micro-

analysis in San Franciso so many years?

Eisenberg: Tilden.

Slocum: Tilden, yes. She was a good salmon smeller.

Eisenberg: The fastest nose in the east at the time.

Slocum: They developed these terms of "taint" and "stale", and so on, and they had to explain these terms to the court and to the jury and so on. And they put her on the stand one time in one of the cases, and the lawyer started to kind of ridicule her..."taint, stale"...Don't you have any better names than that? She said, "Oh yes, sometimes I call 'em 'stinkers'. And she got off the stand right away.

Eisenberg: Actually, one of those interesting...a very succinct commentary on this...on stinkers...is the case where--it was also a rotten fish case based on odor, where the claimant--the defendant--actually opened a can and ate. And the judge said, "Well that just proves any damn fool will eat anything."

Garfield: I suggest you check some of these schools, training schools and interesting features...ah, fish schools, fish smelling schools...during the period that you are interested in...cream tasting schools...the

problems associated with those, and egg smelling schools--frozen eggs...

Young: That was very early, wasn't it?

(several talking at same time)

Eisenberg: That was after '38?

Young: It wasn't that they didn't have bad egg cases earlier...

Garfield: The training--the actual training...

Young: Were these centralized in Washington?

Garfield: Well, I ran the first fish school in Boston, in about 1951. There were egg schools, there were cream schools that were held in St. Louis I know of while I was there. This was the kind of thing where you developed your experts, such as Al Weber, who was an expert from way back. And then you might get into tea tasting. That has been a very controversial thing...I don't know whether you want to get on to that; it's relatively minor, but...

Lofsvold: Before we leave this...along with this...the people in the Washington laboratory were working quite hard to develop chemical indicies, too, that would be objective tests that anybody could apply--and without the specialized training. For example, the ah...frozen

eggs. Work that Fred Hillig did, virtually all of his career was on this.

Garfield: You still had to depend on the organoleptic because the other was too time consuming.

Roe: That's right. The organoleptic examiner can run through a lot of samples fast...and then you apply your chemical test to those he found bad, for backup.

Young: Are hallmark developments in things like this--chronicled in the annual reports?

Slocum: To a certain degree, yes I would think so.

Roe: The chemical tests for decomposition...(everyone talking)

Young: ...and then if there was some fine point we thought we ought to investigate, then we might be able to go through records behind it.

Eisenberg: I think the schools are important because they trained you to sniff and to be able to categorize and classify the various types of smells.

Young: There may be a number in the decimal system which...

Slocum: In the annual reports, a thing like these cream schools and fish schools, etc., would have been regarded as routine, and you probably wouldn't see much about it in a report.

Young: I didn't mean that, I meant it would be mentioned when a breakthrough occurred, that was like he mentioned.
Garfield: There are no tests, really for decomposition in fish that are worthwhile. Even today we still rely on smellers. In shrimp, it is very problematical, but for eggs, yes.
Young: There are tests in eggs?
(several talking)
Janssen: A good nose can distinguish in the order of 16 billion different odor variations. This is an indication of the sensitivity of this organ.
(inaudible)
Slocum: There are two things. One that's not in my field at all, but Ed Haenni related to me recently (one of our colleagues also retired) and you may remember, Wally. He related the story. I told him I was going to attend this meeting. He was talking about Paul Clifford's spectrophotometer. Now, such things weren't available commercially. I suppose they'd been tried; but Paul was very ingenious, a very fine chemist in the Bureau of Foods, and he simply set to work and built his own spectrophotometer. This became the standard instrument for everything. Fred Hillig would use no other

than that one. Ed told me the story that he saw it in the hall and somebody was going to throw it out, and he resurrected it, and you showed it in the display.

Janssen: It's in the museum.

Slocum: One of the first spectrophotometers, before they became available commercially.

Young: And this was a contribution to the basic art or the basic science. And that was one thing that I wanted to have you think toward...and to point to things like this in which the contribution was developed in order to get the job done. It was an innovation of great significance.

Slocum: Well, I think you could probably document this, too.

Young: And this would have been about? Would you say in the '40's, '50's, something of this order?

Roe: I think it was in the late '30's.

Slocum: Maybe so.

Lofsvold: We have a paper out at Denver, of Jonas Carol, some years ago, where he was in on that, and he described the history of that particular instrument.

Eisenberg: Well you know, along that line...

Young: We should say, I think, in honor of his memory, that he was invited to this meeting.

Garfield: Incidentially, regarding this business of instrumentation, we want you to know a very significant development...that is, the program the Food and Drug Administration worked up with Georgetown Institute on Advanced Instrumentation. I think the first graduating class that came out of that school was in 1964, but the idea started around 1962. I think a number of chemists in Food and Drug that were trained at that institute, not only from Washington, but the field, revolutionized the work of Food and Drug Administration, not only for regulatory purposes, but for the research efforts of Food and Drug. The F.D.A. and many other agencies benefited from the training which the chemists received at that institute. I know F.D.A. sent 45% of their chemists there.

Young: That's a tremendous thing. I have written another question. A paper that Wally wrote said that in 1938, F.D.A. could detect parts per million and by the '60's, it was parts per billion. And I said what stages should be noted in such a development as that. And you're saying that's one facet of instrumentation.

Garfield: After the war, the development of electronic equipment revolutionized the way of examining evidence although there is still some wet chemistry done.

Young: Now what are the problems of this? If this can be done, what kind...how does this impact on regulation? Were there difficulties that arose from the skill that came through instrumentation?

(several talking)

Roe: Tremendous impact.

(several talking) (The gist of the conversation was that the sensitivity of the instruments became greater and greater. There was some mention of the Delaney amendment.)

Roe: ...There were no residues detected of certain compounds but as method sensitivity increased, we find that you do detect something. And this just raised havoc with the "zero" concept and the pesticide amendment handling and so forth. Now, I recall at one time, that the general counsel of the department seriously wrote a note to the Commissioner saying that we should stop this research on increasing the sensitivity of methods. That we ought to cut this out as we're just making more problems for ourselves. We've got methods enough right now to handle the policies and so on. This is research work that you shouldn't be in. And I had to argue with the Commissioner on this, that goodness, that is basic.

I said it won't do any good for us to stop research. The Laboratories all over the world are working on development and improvement of methods of analysis and it's important that we be in the forefront of such research. And I think we were on pesticide methodology. We have some of the best chemists in the world on this. Fishback and Cook and Mills and Ramsey--fellows that you could well interview on this matter.

Young: I'm in pretty good shape up to 1938, because I did have a student do a dissertation on pesticide problems up to that points. But you're saying...

Garfield: What I'm talking about is the chemical identification of pesticide residues without knowing, at the time you undertake the examination what pesticides were used on crops.

Young: And this was in the new generation...?

Garfield: This was developed in the Food and Drug Administration, this was a tremendous breakthrough...

Slocum: Wasn't this a reaction, really to the introduction of the wide variety of organic pesticides subsequent to World War II?

Roe: Oh, yes.

Slocum: Before that, it was pretty easy because... there was such a limited number of pesticides used on

apples, we had methods adequate to determine lead, arsenic and fluorine.

Roe: Yes.

Slocum: But after the War then, we all started to be...and it has continued to now...this vast variety requires a whole...

(everyone talking)

Young: F.D.A. was at the cutting edge of this. That's the point I'm making. Now these are the kinds of things that I want to know, because we want to reflect the science of the agency and its innovative quality...

Roe: There's a couple of examples on that I would like to give you, but first, let me comment on the days of lead and arsenic and flourides when I was Chief in Seattle. We had our problems on the residues with lead arsenate, and I remember naively saying, "Oh, if we could just get a good organic pesticide to do away with these inorganics, we'd be fine." Well we've got the organics now and the problem is tremendously multiplied. Well, what I was going to say... On this matter of methodology, on the increased sensitivity, we have applications in other areas that are important too. Some of the things that come up on pesticide chemistry, I think, would be of interest to you. I recall we had

tolerances set on certain crops for malathion, an organic pesticide, and one called E.P.N., a separate tolerance. And one day one of the young pharmacologists came down to my office and said "Chief", he said, "we've been doing some work on malathion and E.P.N." and he says, "you know, if I feed a mixture of those two to test animals, it pumps up their toxicity a hundredfold. And I said, "now wait a minute, you say if you feed a mixture, or E.P.N. is fed first, and then malathion, you get a different reaction?" "Yes." Well, I called down Dr. Lehman the Chief pharmacologist, and a couple of the others and I said well what does this mean? We have tolerances for both of these things and yet together, the toxicity pumps up a hundredfold, this may be pretty serious. I remember one of them said "oh, don't worry Chief, they don't use these on the same crops", they're used separately. And I said "well, now wait a minute, suppose I made a fruit salad with apples from New York and E.P.N., and pears from Virginia with malathion" ...and then everybody got excited. I said my gosh we've got to do something quick here. Potentiation seemed to be the problem, and if this happens here, where is it going to happen elsewhere? We have three other petitions before us right now on organic phosphates,

and we've got to know they potentiate with E.P.N. And so we called in the reviewers on those petitions and said hold up everything, we've got to have more data. And, of course, then we began hearing from the hill and the White House, and I remember one of the Senator's office called up and said we understand Roe has changed the rules. I said, "Yeh, he has," and this is the reason. And we didn't hear any more from him...Well, we, of course, got busy and did some work and studied this further, and the way it turned out was that what we wanted to find out, what causes this potentiation. What are the chemical structures involved here that you can anticipate on other products coming in or other products on which we have tolerances. Well, as I recall the studies finally brought out this; that with the larger amounts used first in the test it does pump up the toxicity, tremendously, but in the area of the tolerances, there was very little change. What we concluded was going on here, we noted that the malathion was one of the lesser toxic organic phosphates and this is what we concluded, that there is an enzyme in the liver we called malathionase that destroys malathion up to a certain level so that it was less toxic than some of the inorganic phosphates. But, E.P.N. destroys the malathionase, so when E.P.N. is fed with it or prior to it, the organism gets the full bump of this malathion. That turned out to be the answer of this malathion.

That turned out to be the answer there, so it didn't give us any guide as to the chemistry of the products to look for, but this was something that we continually worried about, when are we going to run into the next one. And the next one involved heptachlor as I recall. Heptaclor was a chlorinated hydrocarbon which was a fairly toxic one.

Young: Well, just finish this and we'll turn it off and have a lunch break. We've been going hot and heavy.

Roe: Well, on the heptachlor, and I recall when that petition came in, they wanted tolerances on alfalfa, for instance, and some other food products. We'd been very leery of granting any tolerances of chlorinated compounds on feed crops. We didn't want the stuff getting into the milk. D.D.T., for instance, they didn't allow tolerances on alfalfa because it would go right into the milk, and we were trying to keep the milk clean. We kept cow's milk pretty clean; we didn't do so well on mother's milk. We didn't think that heptachlor would get into the milk. So we went out to Beltsville, in cooperation with the Department of Agriculture and fed some cows, and, by George, the damn stuff didn't get through, so the tolerance was set. Then a little while later, somebody saw a report from the University of Illinois that heptachlor epoxide was pretty toxic and was a residue on fruits out there. And it was

a breakdown product of heptachlor. So we had a conference in the Bureau Office and, what does this mean? Where are we on this business that haptachlor on leafy surfaces oxidizes to the epoxide? What dces the expoxide do with milk? So we had some more feeding experiments, and the epoxide went right through in the milk. So we published a proposal to the regulation to cancel certain tolerances on the epoxides. But here again...the chemistry. Now maybe we should have anticipated that, because certain other related chlorinated compounds have oxides develop somewhat in the same way. But this just emphasized to me the importance and the necessity of maintaining a strong research on the chemistry of these products so we can anticipate. We didn't anticipate on that tolerance, but we found it pretty quick and took corrective action; and I anticipate that every once in a while we find that some tolerance has got to be changed, or the data didn't mean what they thought it meant. So, the problems of Food and Drug are manifold and increasing tremendously, and it's almost a no-win proposition, because the technology and the chemistry of today is bound to find things that we didn't know about previously.

Explanation of above remarks by Mr. Roe

E.P.N. - Malathion

A tolerance for residues of malathion, an organic

phosphate had been established on a number of fruits and vegetables. Also a tolerance for E.P.N., another pesticide, had been established on some of the same crops. Animal feeding tests in our pharamacology laboratories revealed that when E.P.N. was fed to animals shortly prior to feeding malathion or when a mixture of the two was fed, the toxicity was much greater--about a hundred times greater--than would be expected on the basis of the separate toxicities of the two compounds. This immediately raised question as to whether the established tolerances were really "safe". It was thought that the apparent increased toxicity represented an example of "potentiation". If so, we wondered whether the toxicity of other organic phosphates for which "safe tolerances" had been established (there were several) would be potentiated by either E.P.N. or malathion. Also we had under consideration petitions seeking tolerances for three additional organic phosphates. We concluded that action on these petitions should be held up and petitioners asked to undertake further studies to establish whether or not the toxicities of the compounds for which they sought tolerances would be enhanced in the presence of E.P.N. or malathion.

We also immediately undertook further studies which con-

firmed the enhanced toxicity when the dosages fed were at levels causing acute effects. But when fed at the lower levels causing chronic effects--and definitely at levels in the neighborhood of the established tolerances --toxicity was not significantly different from that expected on the basis of the individual chronic toxicities.

Hence, it turned out that our established tolerances in this case were "safe" after all. Also, the further studies led us to conclude that the observed enhanced acute toxicity from a mixture of the two compounds was not due to the phenomenon of "potentiation"; that the liver contained a factor that enabled de-toxification of malathion to some extent and that this factor, which is assumed to be in the nature of an anzyme--malathionase --was destroyed by E.P.N.

Our investigations did not reveal chemical structures or other factors in these compounds that would enable the anticipation of prediction of other similar occurences.

Heptachlor

A petition seeking tolerances for heptachlor, a chlorinated hydrocarbon, on a number of food crops, included request for a tolerance on alfalfa. We had not granted tolerances for chlorinated hydrocarbons on feed crops because of the tendency of such compounds to appear in

the milk. We were trying to keep milk clean. (We did keep cow's milk free of residues, but didn't do so well on mother's milk.)

The Heptachlor petition contained feeding tests which purported to show that heptachlor did not appear in the milk when fed to cows. We were skeptical. So, in cooperation with the Department of Agriculture we arranged for feeding tests on cows at Beltsville, which confirmed the absence of detectable heptachlor in the milk. The requested tolerances were established.

Later, a publication from the University of Illinois reported that on leafy surfaces heptachlor oxidized to the epoxide. We had a conference in the Bureau office to consider the possible significance of this report in relation to our established tolerances for heptachlor. If it readily oxidized to the epoxide on leafy surfaces, then the residues on crops would consist in part, at least, of the epoxide. We concluded that we weren't for sure whether our method of analysis would detect and measure the epoxide; whether the epoxide would appear in milk when fed to cows; whether the toxicity of the epoxide differed from that of heptachlor.

Additional work in our laboratories was immediately undertaken which revealed that heptachlor epoxide readily went through to the milk, that the epoxide was

somewhat more toxic; that there was need for revision in methods of analysis.

Steps were taken to cancel the tolerance on alfalfa and to make certain revisions in other tolerances. (I believe that more recently heptachlor and heptachlor epoxide tolerances have been further modified or cancelled.)

These experiences emphasize the need for maintaining strong research programs in chemistry and toxicology to support the tolerance making and enforcement responsibilities.

They illustrate, also, some of the factors that inevitably will--from time to time--require changes or cancellation of tolerances. Improved methods in determining and evaluating safety, increased sensitivity in methods of analysis, and other unanticipated developments are sure to upset some previous "certainties".

Young: You wanted to ask a question?

Questioner: Well, maybe I better hold it.

Young: Let's hold the question. We've been here steadily in a concentrated fashion, and let's flex our muscles, just a minute or two, and then we've got lunch. It's right here on the grounds.

(Lunch break)

Eisenberg: I'm interested in your remark about the legal profession, really having a greater appreciation of history

than most other professions and it's evident, of course, in their education, and also in their current, uh, the practical thing that they work with. They've got to go back. They can go back to history to get a judge to overturn a decision based on the legislative history or the social history.

MacFadyen: But I think the problem with lawyers is although they use history more than other professions, they also misuse it, because of the nature of...

Eisenberg: Well, it's a tool for them.

Slocum: Well, first of all, the first attempt to take bacteriology into the districts...look, maybe we're waiting for...

Young: Is the tape going?

Porter: Yes, we gave up the other apparatus and have a different recorder.

Young: Well if the tape is going, if we jump the gun a little bit, I don't see any reason not to have it transcribed, so what question were you asking Dr. Slocum?

Lofsvold: Well, I was asking...telling Glenn that it seems to me that for a long time in the early forties and fifties, F.D.A. was preoccupied with insect fragments, rodent hairs and other indices of filth, and rather neglected the use of bacteria as an index, except in some cases of...oh, specialized ones like crabmeat

and pecans. And other agencies in the public health field, states some federal agencies were doing a lot more work than we did, and I wondered why it was we didn't get into that?

Slocum: First of all, all microbiological work was centralized in Washington, and with a relatively small staff. We were primarily trouble shooting. Where there were known health problems associated with food contamination those were the ones they picked out. Now the first effort, let's see this would be not too long after '46 because there was a disagreement between Dr. Hunter, Division Director and the three old districts about who would direct bacteriologists in the field...to whom are they responsible. And this was never settled. Dr. Dunbar took it upon himself about 1950 to put funds in the budget for establishing four field bacteriology labs in four districts, namely one man each in San Francisco, Chicago, New Orleans and Philadelphia. It wasn't successful because there was not enough support. The bacteriologist washed the dishes, made the culture media and did the culture work--he did everything. But the supervision was left in the Division of Microbiology. Then it was separated. One of these times, you know, when they were talking about getting a better balance between the field staff and headquarters staff. But literally it never really took off until they decided to

really centralize the operation in Minneapolis. And I think they did add stature to the staffs of these few isolated districts. San Francisco had a pretty good sized staff. New Orleans always had a pretty good one before they were moved to Dallas. I think those were the two main operations. Then when we began to go into the whole idea of establishing microbial limits for food, we were concerned about some of the newer grocery products, ready-to-eat foods like pot pies, dinners and a whole variety of dishes of this sort. And there were increasing microbiological problems. That time they began to train inspectors in bacteriological inspections and establishing working teams of bacteriologists and inspectors. Bacteriologists from the field were first trained in here and then back to the field to work with inspectors. So the resurgence really came along in the late '50's and '60's, but it was a matter of staffing, pretty much up till then, and again the organization.

Young: Was this a change, mainly marked by the need, the growth, the expansion required because of the new kinds of foods or were they missing some things they should have been paying attention to in the earlier period?

Slocum: I think your former statement is probably correct. You see, beginning in the early '50's there was a drastic change in food technology and food production went from fresh foods. That is really where bacteriology became an

important aspect of the production, health, sanitation, and even quality of products.

Young: The botulism thing, after the mid '20's died down and wasn't any problem to evoke trouble until way later.

Slocum: Way, way later. In the early '60's then they began to have a whole new pattern of...That's an interesting story too, by the way.

Eisenberg: Let me answer Fred's question, though from a little different point of view. Your question was, why bacteria standards or bacteriological methods were not used in the same manner in which we proceeded by use of filth, insect fragments, rodent hair, mold, etc. Now it's interesting that bacteria were used way back in the early days when Howard started, for instance, he started with a bacteria count, a direct bacteria count, he started with a yeast and mold spore count, and he started with the mold count. He had three handles on taking action against violative conditions and violative practices relative to the tomato industry. The mold count was used essentially to act against the use of rotten food which is called primary decomposition, the bacteria count was used primarily against what he called secondary decomposition where the rotten fruit was pulped, put into tanks and instead of being packed immediately, was left to sit there for it to settle

and the bacteria and the yeast took over and they used that technique. And later, of course, that practice was eliminated and the method became obsolete and to this day only the mold count has survived as a practical tool. Now the other aspect that we don't even use bacteriological methods today; we don't have any standards, and it hasn't moved in the same direction with the broad coverage now and the expansion of the insect fragments or rodent hair and the mold counts to just a myriad of products. One of the reasons is this; that it's really a layman concept of bacteria being present almost everywhere. It's on our hands, and that, and you're dealing with numbers. Not from the health standpoint, but in the same way that insect fragments, mold count and rodent hair were used against filthy conditions and filth which don't necessarily represent a health hazard, and which the Government does not have to prove, you know, under our section. You can start out with produce essentially with a zero base, in otherwords, a good apple, or a good pear, or good spinach doesn't have any insects on it; it doesn't have any mold on it; it has a zero base. Unfortunately, with bacteria, you don't have zero bases to start with so when you get into court everybody knows well, here, nobody wants any insects...

any aphids in his spinach or his broccoli, and nobody wants any cut worms in his spinach, or coddling moth in his applesauce, and we don't want mold because everyone recognized mold and they cut it away. So you essentially start with a good normal crop or a good normal fruit or vegetable that has no mold. It's got a zero count, it has no insect and no rodent hairs there. So that has helped us expand and it has a regulatory climate. It provides a regulatory climate, which has allowed for expansion and which industry, of course, has recognized. And whereas in the bacteriological side, to this day they are fighting us. And only a few years ago, Glenn, we had the uh...we started with bacterial standards for pie...what pie was that again...gelatin and pot pies, we started...we recently withdrew them. We pulled them back; so we're still fighting that battle.

(Interruption)

We pulled them back because industry opposed...

Slocum: Well, there are lots of...this is a very complicated situation. The first standards for gelatin, dry gelatins, were industry developed and promulgated for their own use. And they were pretty tight. They separated the edible products of gelatin from the fraction used for glue and sizing, etc. We could possibly, if you exceeded the count limits or specific organisms content

by considerable degree prove adulteration or anything else. The limits are so tight, they're simply what the industry found were attainable under good practices, regularly, day in and day out. To use those, unless you had an abritrary standard set under the law, that would have force and effect of the law, you'd be helpless. You couldn't really support a case. There are all kinds of ramifications of this sort. What would be a good finding on one food would be horrible for another. There's just all ramifications. The case I wanted to mention to you, as perhaps a story of some interest, is...the one about staphylococcal food poisoning. This, in effect, is a type of poisoning that was rediscovered in 1930. We know now, looking back at earlier literature, that outbreaks happened before 1930, but there was a bad outbreak then and somebody found large numbers of staphylococcus in cream pie, or something. I've forgotten what the foods were. And the University of Chicago scientists researched it pretty carefully and found large numbers of staphlylococci which when isolated and grown outside of the food and fed to volunteers, made them violently ill. Now this organism is probably the most common cause of food poisoning outbreaks today. In the United States it involves a wide variety of food, meat, poultry,

all your moist meat and poultry products...pies, bakery products with cream filling...a whole host of foods. Recontamination is very common in kitchens and restaurants and places of this sort. It's a very common problem, and inevitably involved foods that are manufactured, shipped in interstate commerce. The example I'm thinking about is cheese. Now the problem we have with investigating outbreaks from any food, whether it's local or interstate commerce, was that evidence was always indirect. There was no way to measure the poison, the toxin, itself. All you could do, literally, was to make a count to find out how many organisims there were of that before, then you would isolate them...in pure culture...grow them in artificial media, and feed the filtrates to humans. Humans are peculiarly susceptible to it. Monkeys can be fed but they're perhaps 50 times as resistant as man, so you have to feed them large amounts. Cat tests by injection, are not specific, and again, they're relatively insensitive. So we needed, very badly, to have a direct test for every toxin. We hired a man out of the Navy after World War II, Dr. Ezra Casman...

Young: How do you spell that?

Slocum: C-a-s-m-a-n, who worked first in antibiotics and then transferred to my division, and this was his sole

research effort for a great many years. First of all, to try to isolate and purify the toxin, if at all possible; he never quite succeeded in that, but he did concentrate it and purified it to a considerable degree. This is a very difficult chemical operation that had been done with one or two other toxins. But he got it, partially purified and concentrated so that he was able to immunize laboratory animals, rabbits specifically, and produced an antitoxin which could be used in measuring the toxin. The details of all this were very complicated. It just required years and years of effort. But eventually, he ended up with what they call a slide diffusion test in which you had little wells and an agar plate, and you put your anti-serum in one well, and you put your unknown toxin material in the others, and you'd get zones of precipitation, which you could actually see and measure; which not only identifies the toxin but also gives you some idea of strength. And this has become the standard; other tests have been developed since then. This has important practical applications. Again, I can't place this exactly but I would say probably in the late '50's or early '60's. When Melvin Laird was a Congressman from Wisconsin, one of his constituents had a cheese

factory there; and evidently they had had trouble over a period of one or two months when some, or a large part of all the cheese produced was toxic. We never could find out exactly what happened. The result was, however, that something like six million pounds of cheese had to be destroyed. There was no possible way to separate the good from the bad. There were outbreaks associated with this cheese. There was no question about it. Later on, and this may be a little bit after '65, in fact I think it was about the time I retired, the same thing happened to a very large cheese company in Wisconsin, and they were able to test every individual lot. In fact, a man and wife team of PhD's went to the laboratory and were trained to apply this test; and they ended up destroying something like a half a million pounds out of several million pounds. This is a practical demonstration of a value of a test...

Young: And it was sure and it was speedy.

Slocum: That's right. Very specific. No, it's not speedy, it's a very difficult test. That's where most of the new tests that have come along are trying to speed this up some way, so it can be done in a day or two. This would take perhaps a week.

Young: But this is another example of a regulatory problem that confronted basic research, an innovative thing that effects the whole field way beyond regulations.
Slocum: Oh yes, very, very much so. Many universities such as the University of Chicago, and the University of Wisconsin were and are doing similar food research and many, many other agencies are getting interested in this. That was a real break through, I think.
Janssen: Did Laird communicate with the Food and Drug Administration about his constituent...
Slocum: He talked to me almost every day for I don't know how long. He would call me directly, he found out who was working on it. And I haven't had the honor of talking to Mr. Laird lately.
Garfield: You know there was another development in Food and Drug, I don't know how important it is, but I think it was a basic kind of development. The law requires that...the law has prohibition against food products that are themselves contaminated or if they're manufactured under unsanitary conditions unless you can show that what the inspector saw in the plant actually ends up in the end product. Food and

Drug began a study of specie identification of insects, which resulted, I think, in a definitive piece of work where storage type insects can be identified, just finding one of the mandibles of the mouth, or...fragment of a leg. You can actually identify the different species of insects. I think it has ramifications beyond just regulatory control for those who are interested in this particular area.

Young: Is this tied to any given scientist, or was this more...?

Garfield: Yes, these were all Food and Drug scientists. It was the work of many people in the field who took different aspects of the thing under Eisenberg and Harris and Dean Kurtz, I guess in Washington.

Young: And this was right after the 1938 law?

Garfield: Yes, this was done in about...

(interruption)

Eisenberg: A bit later, but it was really triggered by the 1938 law, to develop responsibility for the...or to trace the contamination to the door step of the individual who was responsible.

Garfield: It made it much easier to develop cases, but it was a definitive piece of work and is a most interesting thing--the drawings that have been made, the accuracy...

Young: I was trying to place it in time. Do both of these developments show up in the scientific literature?

Eisenberg: Yes.

(Everyone talking)

Slocum: I would think some of this would be in the administrative reports of the early sixties.

Garfield: And in F.D.A. reports as well.

Young: And probably cited in the annual reports.

(Everyone talking)

Garfield: There is a book...what was it...Food and Drug Manual No. 1, or Food and Drug Technical Manual No. 1, has some aspects of it. You might want to check that...

Young: That would probably be in the library.

Garfield: Yeh.

Janssen: These publications have many hundreds of drawings of the parts of different species of insects, whereby you can identify what particular part...

Roe: Another item that has some aspects that would make an interesting story, I think, is aflatoxin. A toxin developed from the mold aspergillus flavus. It came up, I believe, the first time I was aware of it, or we were, was a problem in peanut products in England. The peanut meal sent there from a certain country in Africa and used as an animal feed was causing a lot of problems to

the animals. It turned out to be this toxin, aflatoxin. This lead to investigations as to the prevalance of the possibility of this mold; aflatoxin in peanuts in this country and in other products. And it was found it was a problem and this I believe is not only a pretty serious toxin, but it's a carcinogen, a liver or stomach carcinogen in very small amounts, and the problem came up as to how to detect it and how to measure it and get up some methods for examination of products. Now I don't recall all the details but I do recall that we did, in the bureau, quite a lot of work on it and Food Division and Dr. Slocum's division. I think it was a cooperative project between those divisions because of the bacterial aspects and pharmacology certainly was in on it.

Slocum: This started just about 1962.

Roe: Yeh, somewhere in there. It is my recollection that we were trying to identify this toxin, and we got into...it was pretty complex, as most of these problems are, and required some modern, fancy instrumentation of which we had some, but not all. And it's my recollection we were, for a while, in sort of a race with M.I.T. in the identification of this material. And it's my recollection that, subject to Glenn's check...that

M.I.T. beat us on the identification, but made the identification on purified material that we had supplied to them. They had better instruments than we did.

Garfield: Well, it's not just one material now, it's a whole variety.

(Discussion)

Janssen: F.D.A. became aware of the problem at the very time it surfaced and they persisted in following up on it. Year after year the annual report will show how we kept after aflatoxin.

Roe: I recall discussing at the time we were looking into this aflatoxin business, that over the years when I was a district chief and handling the examination of imported materials, often times we would have a moldy or a wet shipment of wheat or other grains detained at a port of entry, then the question, what to do with it. Sometimes the importer would want to sell it for animal feed. Well we knew, or at least were aware of instances where moldy animal feed had been pretty bad for the animals. So I usually would be guided by that, by the State veterinarian as to whether in this particular state they wanted to use this stuff or required it be destroyed because some of them said, "oh this is all right for this type of animal", but most of the time

they turned it down and rejected it. But not always was moldy grain toxic to animals but often it was. This aflatoxin business came up, I think we concluded well, the indications are that an aspergillus flavus is involved here, if it's aflatoxin, and that's pretty serious. Maybe some of the other molds and decompositions don't provide toxins of that kind.

Young: You mentioned M.I.T. In connection with these case histories that you're referring to, did the scientific side of F.D.A. have direct liaison with university scientists and with industry scientists and with trade association scientists, in episodes of this kind or were the walls pretty high?

Roe: Well, I think we had pretty good contact on things like this, with uh...

Slocum: With aflatoxins, I would say yes, there was excellent coordination.

Garfield: I think if you go back to the journal of the A.O.A.C. starting way back, you would see the methods developed, and the people that were involved in development of methods. You'll find there are industry people. Seminars and conferences are just almost continuous. You can go back to the 1900's...

Young: Wiley was one of the...

Eisenberg: Contact with the industry--very much, very great. Even in the Howard mold count, going back to the early days of Food and Drug. Howard worked very closely with industy, he got a lot of support in developing, and proving methodology from trade associations, especially can companies, academia. He found some opposition too. They were your greatest critics where they thought you were going wrong, but there was good contact.

Young: This was OK. This was used to be a legitimate enterprise to consult...I mean you...

Eisenberg: Oh yes. Legitimate interplay, I think, and cooperation...

Young: Were there ever periods when, in the scientific side, relationships betwen F.D.A. and industry were more arms length, and other times when they were more warm and close; or is this sort of swing back and forth, more on the regulatory side?

Roe: I think there is a swing there too.

Eisenberg: A swing, and it depends also on the topic. For instance, on microbial standards. Industry now is almost wholeheartedly against them.

Slocum: On the basis of which they have been attempted to apply.

Lofsvold: Isn't there a basis for differentiating, too, from currently, when we're so involved in petitions that industry is presenting and consulting with our scientists, versus, in an earlier time when we didn't have the authorities that we have now for new drugs and food additive petitions, and so on. Then we were talking strictly on methodology that each side had an interest in. Now it's the industry that has an interest in convincing our scientific people to approve something that they're trying to promote, where before, we didn't have that kind of a relationship.

Roe: Well, yes, I think, and my personal opinion is, that we've been a little too free with letting ourselves be imposed on by the industry people on pressing their petitions. I think it's certainly appropriate that we discuss with their scientists the problems, but we've been a little too easy to let them come in just any time they wanted to, and press us this week, and then again next week, and I think maybe that's been improved somewhat now but we found that we wanted to have an open door business; we didn't want to be in the position of being any more bureaucratic than we had to be; but I have felt that there's much of the time of some of our scientists that has been wasted and they've been imposed on by the

industry people pressing too hard and too frequently on bringing in new data this week and a little more next week. We ought to get those petitions in good shape to start with and then when we have some questions, sure we want to get their background and point of view. But it's a very difficult thing to handle in a regulatory agency.

Young: It's what the issue is and what the goal is that is more important. But the time period, in the '20's for example, people who I think were minded to be tough regulators like Campbell; in the kind of political climate that there was, if he was going to get anything done, had to be very cooperative with industry. And so, the political climate, at least as I watched the quackery part, has made a lot of difference in the relationship between regulators and industry.

Roe: Well, I think it has, and I think also there has come to light certain various scandalous situations with respect to inadequate data submitted with some petitions and falsified lab reports on the part of the industry consultants. This, of course, raises very serious and difficult problems as how to cope with it. And we just don't want to be in the position where you're buddy, buddy with the petitioners when you're trying to pass

on this data, but on the other hand you don't want to be stand-offish and not engage in proper interchange and discussion of the data.

Garfield: Well, I have the feeling, and I'm trying to be objective, because I've been in the Food and Drug and I'm out of Food and Drug; that there is a degree of laxity in the Food and Drug Administration in the examination of various kind of petitions. I'm not talking necessarily of food petitions, I'm talking of new Drug applications, etc.; and you see that the length of time has been increased exponentially as compared to what it was a number of years ago. I can recognize some of the problems that Food and Drug faces in clearing these things. Also, when you consider the cost to the industry in the development of a petition or a new drug application until the drug is cleared. I think I can understand why the industry would press to get these things through. They're anxious to move in many cases. Food and Drug is reluctant to move in many cases, and I think if you were to search the records, there would be enough instances to show where Food and Drug has been derelict in performing promptly, in some activities. Somebody goes off on vacation and the damn thing sits on the guy's desk for a month. Maybe somebody else could

work on it. There are several petitions that come in at the same time, there is a limited number of people who can examine the petitions. Congress has attempted in the law to set time limits for reviews of certain of these things.

Young: It's just existential that these are delicate relationships and there may be judgmental differences about them.

Janssen: Nowadays they're trying to devise procedures and put these on record...procedures to regulate. The Commissioner has held meetings to discuss this whole matter and that's one way of preventing improper contacts and conflict of interest situations and so forth, by requiring that meetings be put on record; that officials have to keep a calendar of who they see and talk to and all that sort of thing. In those days we relied on the integrity and good sense of the officials and their staffs and even the secretaries who often listened in on conversations and made notes, for the boss, about what they'd discussed. And then very often, right after this telephone call, a memorandum for the file would be dictated, and this was all done because it was good bureaucratic procedure to do it. Now the Commissioner did discuss this and others did discuss this in speeches

which referred, for example, to the F.D.A.'s "open door policy". And then there was Dr. Dunbar's creed of the Food and Drug Administration, which recognized the necessity of communication between the experts of industry and the Food and Drug Administration.

Roe: Well, this is a real problem and I recognize the validity of some of Fred's comments on this, that we haven't always been as efficient and effective as we should have been in handling petitions. I got the impression that's been particularly the case in the new drug area. But we've had some of it too in our bureau, but I think we've tried very hard to organize these reviews and coordinate the chemistry they've used in the toxicology reviews where both groups participated in joint conferences. My thought is that we've perhaps been too lax, being too accommodating; having too many conferences on some of these problems; where obviously they were trying to press for some reversal of our opinion. But I think on the whole, considering the complexity of the problems and the limitations of staff and all of the difficulties involved that on the whole Food and Drug has done pretty well in the handling of these petitions. The ones I'm familiar with are the pesticides and the food additives, of course. And certainly

I have the highest regard for the competence and the integrity of the scientists of our bureau who are working on these things. It's been a very, very difficult problem and will continue to be, and likely will get worse rather than better.

Slocum: I just wanted to make a general remark that, in my nearly 36 years of experience, in my contact with technical people from industry, I've gained far more than I've given. The only bad thing I really ran into was some shopping by industry representatives trying to get the answer they wanted. I ran into this more than once, where people would go from my office to somebody else's office if they didn't like my answer. This was the practice which some industry persons were using occasionally at the time. I only had one experience where I, at a meeting I accepted a meal from a long time industry friend and was reminded of it afterwards.

Young: We've given several examples of innovations that were important within F.D.A. and more broadly than F.D.A., that came from the agency's scientific competence. These have all had to do with foods, which is natural because your activities were mainly involved with foods, though maybe not exclusively so. Are there things in

the area, that one of you did mention, of the newer nutrition, the vitamin area, and also in the area of drugs, in which you might point to similar cases that might be looked to about innovations in F.D.A. science?

Garfield: I think so. I think the whole vitamin situation is a good example of development of methods for estimation of vitamins in various kinds of foods, not only vitamin preparations intended as vitamin preparations, but vitamins in food products where the problem is much more difficult. I think the same thing applies in the case of the rauwolfia alkaloids which were used in the reduction of high blood pressure. Food and Drug was very innovative in that particular area. I think they were very innovative in the natural estrogens and synthetic estrogens. I think Food and Drug was the leader.

Young: Was this a bioassay approach?

Garfield: Not only bioassay, but chemical. Actually, the identification of the various substances in the natural estrogens is a very complex thing and is very much related to cancer and diethylstilbestrol, and the offspring who have been treated with diethylstilbestrol. And I think in the antibiotic field Food and Drug was just absolutely fantastic, where we have developed

methods through the years, and the problems of control of the production of this anitibiotic where the Congress has swung from one side to the other; where everything had to be examined by Food and Drug and certified to the point where let's not have as much certification contol and let's leave it to the industry, and now they're swinging back again so that everything has to be certified. I think that in itself...

(Inaudible)

Roe: I'm not sure of the status, but much time was spent there in the development of a chemical assay for Vitamin D, and I don't know just how it's fared, or what the situation is now. But in the field of nutrition, yes, I think there are several areas there that are of considerable significance. Not only the matter of the assay of vitamins and the development of procedures for checking on vitamin potency in various products represented as containing vitamins. But also, it is my recollection, that one particular activity there involves the identification of the cause of some infant illness from baby food, due to, I think in part, certain vitamins. I don't recall all the activity, ...all of the angles to it...but I think this is an area where you could get some very pertinent information from

Dr. O. L. Kline, who was at one time, the chief of that division following E. M. Nelson. And I think there's several very significant developments in that division on nutrition problems that really are quite important and do indicate the leadership of those people in certain aspects of Food and Drug.

Janssen: It could be relevant to some of the interests of today, and I think that the manner in which the national foods fortification, the enrichment policy developed under Nelson ought to be put on record because a lot of people have forgotten that we did have a national policy in this area a long time ago. What we have now is still partly based on that.

Roe: That's right, the enrichment of flour and...(interruption)

Young: In the early 1940's basic requirements that were set up?

Janssen: There were principles in policy that were summarized in articles that Nelson wrote and publications by the National Research Council.

Young: These are areas, not perhaps that we haven't mentioned within the area, except maybe the rauwolfia and so on specific things quite with a degree of narrow precision that we did with regard to food. Are there

within these areas, something more specific, or is this the kind of thing that we ought to see Dr. Kline about?

Garfield: Dr. Banes, too.

Roe: Oh yes, Dr. Kline on nutriton, Dr. Daniel Banes on pharmaceuticals and drugs, and under Banes jurisdiction, or he and his colleagues like Jonas Carroll and others over in the division of pharmaceutical chemistry, did some outstanding work on methodology on important drugs and the interpretation thereof. One of the cancer quackery remedies, Krebiozen, you probably have heard of, and the problem came up on an effort to identify what is...what are the ingredients of this Krebiozen problem. And here's an example of where we did call on outside help because we realized that any work done in our own laboratories would be suspect by certain of the people on the hill who were interested in Krebiozen and on the Krebiozen promotors themselves. It is my recollection on our studies on that product, we did employ four outside scientists from four different universities to work with our scientists in working on this problem and identifying it so we had some top notch scientific reports ready to go on our problem here, which it turned out, I think to be just a bit of crude oil or petroleum...

Eisenberg: No, creatin.

Roe: Creatin, that's right.

Eisenberg: Our laboratory actually identified Krebiozen, and then we brought in an expert from the University of New Mexico, who worked in my lab and verified what we had found, and I brought in Mary Marode from the Department of Interior, who was an X-ray crystalographer who verified it; and we brought in Beaman, from M.I.T., who did mass spec and verified it...

(Several talking)

It was funny, though, you know...you mentioned legislative pressure, Paul Douglas, the liberal Senator from Illinois. I guess he was a user of it, and Paul.

Young: He was a friend of Ivy.

Eisenberg: He was a friend of Ivy, yeh, you're right. That was the connection.

Roe: This was a tragedy of Dr. Ivy.

Eisenberg: Unfortunatly, Ivy went a little berserk.

(Several talking)

Young: Let me tell one story. The dean of our medical school asked Ivy's old professor, Anton J. Carlson, who as much as anybody was a Food and Drug witness, par excellence. In Carlson's last year he mentioned what had happened to Ivy? And Carlson was a sick man at the

time, and as they walked along the boardwalk, Carlson answered the question of my dean by saying, "Thank God my problem is here instead of here." (gesturing heart instead of head.)

Eisenberg: Right, yeh. I think everyone recognized Ivy was a great man at one time. But Douglas did ask the names of every witness, every Food and Drug witness...

Garfield: There's one thing that I found intriguing from the administrative standpoint. It was the change of philosophy within the Food and Drug Administration from, say the early fifties up until the middle sixties as far as drugs are concerned. The early position of the Food and Drug was you cannot fool the doctor. He knows so much that you don't have to put all this stuff down in the labeling, you don't have to provide him with circulars, you don't have to provide him with a lot of stuff until the present day, when the doctors know not a damn thing. You have to hand feed them; you have to provide them with all the background information so they can really understand what the hell they're doing, and the importance of all these drugs. I think that in itself, could make a very interesting chapter, developing the evolution of the changes in enforcement philosophy...

Young: And obviously, it comes in some measure, from the broader environment. It comes from the revelations to some degree of the Kefauver hearings.

Janssen: In those days, the information that is now demanded...what we used to call the official brochure, didn't have to be in any such a thing as that provided it was available, if it was in the medical literature it was assumed that the doctor had access to it and would read it.

Young: This is Richard's game because his dissertation, and we hope soon to be book, was on the Kefauver investigations and the law that came from it. So that, I don't know...things may have happened within F.D.A., as well, but certainly there was great pressure from revelations in the broader environment.

(Inaudible)

Garfield: Well, I think that it depended a good deal on attitudes, too, of those guys that were directing as I remember...this goes back quite a few years to when the first oral contraceptives were allowed on the market. I was handling drugs in Food and Drugs from the investigative standpoint and we received five reports of young women who had died, presumably, of taking the oral contraceptive, embolism, etc. We reported this to the

old Division of Drugs and the answer came back, we don't need to investigate that, that is ridiculous, in all the studies that were made of these drugs before, nothing like that had happened...On the other hand, the drug company sent teams of doctors out there to investigate each of these cases, because this was a tremendous market at the time...tremendous potential market. Now, I don't remember the outcome of those five cases, as to what the findings were of those teams of doctors, but over the years...as the contraceptives were used, it was well established that these were the things that could happen. And I think that it's the attitude as much of the physician and people who were in charge at that time, over what happens now; when you get an entirely different group of young doctors who come in and who are willing to question everything and who are interested in the Freedom of Information Act and all those things. I think Ralph Nader has had a tremendous influence in what he has done in changing attitudes, not only within the Food and Drug Administration but attitudes throughout the entire medical profession. I think that could be a very interesting chapter.

Roe: Another aspect, perhaps of that, following the Kefauver hearings, and the thalidamide episode and all

of that, the view seemed to the rife in congress and committees handling these matters...that only M.D.'s were scientists, and this kind of reacted badly to our bureau and agency, except for the medical aspects of it; perhaps resulted in a string of M.D.'s as commissioners, that some of us have remarked a bit adversely here today. But there was that feeling on some of the congressional committees at that time, well the M.D.'s are the scientists. Some of us didn't quite have that point of view.

Young: Congress has come into this a couple of times, and Congressman Laird...ah, Senator Douglas, and so on. From your experience, what about the role of congress and congressional committees. From your working experience, was there through time, a significant change, as far as it had an impact upon you.

Roe: Well, I can think of one that was quite significant. Have you heard of Congressman Tabor, of New York ...the baby beet episode...Well it did have quite an impact, and the background briefly is that a constituent of Congressman Tabor, long ago, wanted to put out a product called baby beets. And he was taking big mature beets and cutting them up into little...(Interruption) ...Well at any rate, through the congressman, he made

contact with Food and Drug and wanted an approval of his business of cutting up mature beets into little pieces and calling them baby beets, and the administration would not approve that, much to his and Congressman Tabor's distress. Tabor was a member of the Appropriations Committee and when the Eisenhower administration came in, Tabor became chairman, and immediately Food and Drug appropriations were slashed, and this was our first experience, at least my first experience of a R.I.F., reduction in force. We actually had to run a reduction in force to stay within the appropriation.

MacFadyen: Was this a direct result of this...?

Roe: This was our punishment for not approving the baby beet machine. Now this became very serious. This was along about the early fifties, wasn't it? Fifty-two, fifty-three, it came in and the...

Young: Right after that, I think there were no more F.D.A. employees, perhaps even some fewer than there had been in 1941.

Roe: That's right. Now this was a time when there had been hearings by another committee of congress on the matter of new chemicals, pesticides, food additives, and about the time of the enactment of the pesticide amendment. We in the Bureau of Science realized that our

responsibilities on pesticides and food additives were going to tremendously increase with the review of petitions, and so on, and our toxicology division needed to expand, particularly, but here we were faced with running a R.I.F., and with cut appropriations. It was about that time that Crawford, who was Commissioner, got the Secretary to set up the Citizens Advisory Committee to kind of look into things and see what the facts were. That was one aspect of it. And I think about that time, the National Institutes of Health, the National Cancer Institute was starting a big program on cancer chemotherapy problems, and they had an appropriation to carry out some expansion of their work in the National Cancer Institute. One of the things that they wanted done was the running of the toxicology on certain drugs or chemicals that were being proposed as cancer therapy. And I recall Commissioner Larrick called me in, that he had had a request from this institute...would we accept some of those funds and expand our pharamcology to run some of the toxicology on these chemotherapy agents. I recommended that we do it, on the grounds that it would enable us to expand our laboratory and staff somewhat, while we would have to use it on this work for the Cancer Institute, at least it would give us some background

preparation for what we foresaw, the increased work on the pesticides and chemicals. And this enabled us to build a new laboratory. Oh, it was a great laboratory in the sub-basement of the south agricultural building; making over old garage space down there for animal rooms and for our scientists down in the hollows there, but this did give us at least that possibility and we did operate. We didn't do all the toxicology for them, they had other agencies working on it, but we did do some of it, and that went on for several years. And that was one of the interesting aspects of the Tabor cut and the baby beets, and...

Janssen: The story is told in the paper that I gave at the symposium at the American Historical Society that Harvey Young organized in 1962. Later on, Ralph Nader had a group of people, young college kids, who were under the direction of a co-worker colleague of Nader's ...working under Jim Turner. These college kids were given free run of F.D.A. offices, and I was out having my gall bladder removed or something, at the time, so I was away from my office and they camped in my office and looked through a lot of my papers. I never found anything missing but I did learn from one of the teams that they had been there for weeks. Anyway one of the papers

they found was a reprint of the 1962 symposium. They latched onto the beet ball story. And they found out that later on Commissioner Larrick had seen the impracticality of prohibiting this practice of cutting large beets into small pieces. It wasn't worth the insistence that Commission Crawford had given the matter. Crawford was concerned that the beet balls would be mistaken for baby beets therefore they were outlawed by the standards. He stuck to that position even though the chairman of the Appropriations Committee didn't agree with it. Well, Larrick did bring about a change in F.D.A.'s policy...they could do this...as I recall, they could do this if they would label these beet balls for salad or something like that. Well, anyway, because of that, "The Chemical Feast" book contains a page or two that the whole thing that what I had written was a publicity ploy, a contrived publicity ploy to demonstrate the integrity of F.D.A., an integrity which they didn't deserve because Larrick had done what he did. They absolutely perverted the whole situation, it was a gross distortion, as were may of the inaccuracies in "The Chemical Feast". I continue to hold that against Turner. I think it was dity pool on his part -a distortion of the facts. We had the R.I.F.

We did fire those people. The interpretation they gave to it is totally inaccurate.

Slocum: Well, I've always...I don't think I've ever heard anybody else say this, but maybe Fred and Bob - I always felt that this left a gap in F.D.A. management. There were two-year classes, as I recall, of inspectors and chemists that were lost.

MacFadyen: Wasn't there a R.I.F. the second year as well, following that moldy raspberry episode thing in the same Congressional district?

Eisenberg: Well, sure. The moldy raspberry was an example of another element of Congressional pressure, this time by Clair Hoffman, of southern Michigan.

Lofsvold: Well, there was a moldy raspberry seizure in Tabor's district that occurred almost simultaneously, too.

Eisenberg: But actually Hoffman was the one who got hit hardest, because they had a much larger industry in southern Michigan. You're right about Tabor. Tabor also had the...he may have talked to Hoffman probably. But Hoffman got in...incidentally, Nelson Rockefeller ...it was during the Republican administration. Nelson Rockefeller was the man on the white horse on this incident. Now Clair Hoffman got in and he would make speech after speech about Food and Drug getting in there and

destroying this industry, and as a result of that we went and made a special survey, and I had a terrific trip out of it. I camped myself in Benton Harbor, Michigan, right on the shore there; we set up a laboratory for a month to do a study. So it was real nice. I had to take my family along with me because I was gone that long. So we were at Benton Harbor for a month studying black raspberries, and as a result of that we did a...we published a hell of a good report, and actually had to give them a tolerance. We came out... This is the first example where we came out with an announced tolerance other than the ones we had with tomato products. We had so-called administrative tolerance, but here we told the industry just what they could meet, under the most adverse conditions, you ought to be able to meet this guideline, and we came out with flying colors with it. Nelson Rockefeller, incidentally, was before congress, supporting the Food and Drug. He was Undersecretary of H.E.W., supporting Food and Drug against Clair Hoffman's onslaught in this, and we had to take some raspberries up to the hill to show what a high mold count raspberry looked like and what the deception was. The reason I enjoyed that trip is because not only was I doing the survey, but I had

to meet with local farmers and defend the Food and Drug. And I had to meet with the Chamber of Commerce and all these people, telling just what the hell I was doing there, and why we were practical, and I said...at one point I remember I met with about forty farmers who brought in their raspberries. I told them that you didn't have to...what they claimed was, we can't take a microscope out to the fields and look at every damn raspberry with a microscope and see whether they pass or not. But I said, you bring in any pack you want, I'll look at it and show you where the defects are and how you can see without a microscope, and whether they'll meet the guideline. They brought them in there. I told them this was no good, and there it is. There's the whiskers, you know, and just have them pick this, you know. And I...and you met with...a city slicker like myself meeting with a bunch of farmers and talking to them in farm language. It was a hell of a great experience.

Garfied: You know, I think this might make an interesting chapter crises within the Food and Drug Administration. They can deal with aminotrianzole in cranberries and monochloracetic acid in wine, that was another one.

Young: When?

Garfield: The monochloracetic acid was in the late 40's.

Roe: Cranberries was when Arthur Flemming was secretary.

Eisenberg: And you want to bring in neutron activation analysis of cranberries, because that's very important in determining whether the cranberries came from New England or Wisconsin, or from the State of Washington; because that became very important...

Young: This is a scientific breakthrough.

Garfield: But even the methods here for the aminotriazole and monochlor acetic acid were developed by Food and Drug on a crash basis. And take this thing of the berries and you can come up with crises that caused Food and Drug difficulties...

Young: I'd certainly have the cranberries as one of the major ones.

Roe: This cranberry situation required the development of a method of analysis in one big hurry, and under pressure, because these stocks have been seized and they had agreed to allow some segregation, and we didn't have a method to examine the stuff, and the Bureau got to work and came up with a method under serious pressure. That kind of thing is the sort of backup we had to do every now and then.

Garfield: Say, there was one other that I think you might be interested in...

Eisenberg I'm going to have to leave...

Young: Before he goes, if we get these things taped, there are certain vivid statements that you've made that we might like to get into the final version of direct quotes. If we should write you a letter, asking clearance (interruption)...If you want to see the quotes that I ultimately have used, you'll have to wait a while, but would you give me clearance in advance if I wrote you a letter and asked you to sign a statement?

Everyone: Oh yeh.

Young: Okay...I...

Eisenberg: Let me just say, before I get away...I've got another meeting, but there was an example of a scientific breakthrough, I think to some extent in instrumentation, plus an older method in the so-called horseradish cases. Wally hinted about the effect of economics and adulteration, where a fellow, in the case of jam came in and said, "Well I'm going to try to make this two cents a pound cheaper today, somehow". In 1930, I hadn't been with Food and Drug only five months, when the prices of horseradish suddenly skyrocketed. I guess there was a crop failure, or what have you, and they still had to make a ten cent jar of horseradish.

Well, the only way to make a ten-cent jar of horseradish was to use parsnips for the horseradish, and put a little bite into it. And that was widespread. Everybody was making horseradish out of parsnips, plus a little horseradish, and they added some bite to it, mustard oil, or whatever it was. Well, later, apparently the practice died out after we caught about 25 of them, I remember, by developing a microscopic method which discriminated, based on the histology of the root. Now later, there was one company in Bronx, New York, that just persisted in selling the stuff. We went to court in Boston, and Jonas Carroll and his IR spectometer was used to fortify the microscopic evidence, and we came out with flying colors there, even though we had a scientist on the other side from...some eminent scientist from New York University, who tried to discredit our testimony. This is fairly well documented. If you're interested in the story I don't want to go on to it, but it was the first example of IR spectotometry to identify not only the essential oils from the parsnip to show that parsnip was there, but he distinguished between the addition of isothiocyanate, mustard oil, which had been added. Of course they always add a little horseradish. You see it gets very complex, and the essential principles of the horseradish, he got these beautiful peaks, you know the IR

peaks distinguishing, which very well won that case and outlawed the practice. I don't think horseradish today is any...We've got a real handle on this...

Slocum: Say, Bob Roe may remember this story. I've got one from outer space. Remember the time I got a sample from outer space?

Young: What was that?

Slocum: Well, a spaceship landed in the backyard of a farmer in Michigan or Wisconsin...(inaudible)

Young: Let's have a minute's break, What do I push. Stop.

Garfield: Well, during the war and after the war, there was a shortage of glass. People were asked to bring out their old beer bottles and their old soda bottles, so that the industry could continue to put beer in bottles. At that time, beer in cans was just being developed. The State of California, for some reason or other, started an examination of beer and found glass in the beer. Turned the beer bottle upside down, and they could see these little slivers of glass slowly settling in the glass bottles. And in particular, they found large slivers of glass in Budweiser, Anhauser Busch beer. I was in St. Louis at the time. I was the assistant to the chief. We got a call from Dunbar, and they examined this stuff in Washington and found large

quantities of glass slivers in Budweiser, and we ought to go down and have a meeting with Mr. Busch and tell him about it and see what he wants to do. But he thought that the brewery ought to be shut down until they found out what was causing the glass in beer. We called for an appointment and Mr. Busch was not in, but his immediate assistant was an attorney and we went down to the brewery. And they had one of these big reception areas. They would put large numbers of people through the brewery and after they took the trip through the brewery, they'd bring them back to this place and would give them as much beer as they could drink.

So this assistant took us into this reception area and we sat down. Pretty soon, here comes a waiter with a towel over his arm and said, "What'll you have gentlemen?" The assistant looked at him and said, "Bring us three glasses of water." Well, we told him what the story was and he said, "Well, this is serious." He said, "I'll have to call Mr. Busch." Mr. Busch was at home; this was August Busch, Jr. He said "I'll have to call him down here," and he left and came back in a few minutes. He said Mr. Busch has called a meeting with the board of directors at 12:00 this afternoon, and we're supposed to be there. So. at 12:00, sure enough there's this big board room

with tremendous, gorgeous table, very thick carpet on the floor, great big silver ashtrays, and so forth. Busch was sitting at the head of the table and Roy Pruitt who was my boss, on his right, and I was sitting next to Pruitt on his right. Old Busch was smoking cigarettes, and he was flipping the ashes on this gorgeous carpet, he didn't use the ash tray and I figured, well when he gets to the end of that cigarette, I'm just waiting for him to put it on the floor and crush it with his foot, but that he put in. Well anyway, we told him what the story was, and he says "We're going out into the plant and we're going to find out what the problem is". Well it turned out it was the washing machine. They were bringing these bottles in...they were dumped upside down and then washed with a strong detergent, alkali detergent solution. They had fingers that would come up into the bottles and flush the bottles out. Apparently many of the bottles were quite old, and glass tends to crystalize on storage for a long time and as these fingers came up, they would touch the edge of the bottles, which would further cause the glass to crack, and put the cap on, pressure cap, and slivers of glass would break off and drop into the bottle.

Anheuser Busch is a pretty big brewery as you know. They had about nine bottle washing machines there. Busch says, "Close the first one down...I'm going into this washing machine to find out what in the hell is going on." He says, "I want to see the machine operate, but I don't want any water in there. He just had his clothes on, and walked right into it, and he established this thing was coming up. He could here the click. He says, "Shut this thing down", and went to the next one, and the next one, and he shut the whole brewery down. He said, "Post notices on the bulletin board, that anybody who is involved in beer bottling can stay home until further notice...(inaudible) They continued the can operation. ...and right then and there, he came back into the board room, they held a meeting and they ordered nine different bottle washers - he authorized them. We were invited back about... well, there was one other step, he also said that there was a tremendous amount of inventory of beer out around the country, and he assigned, I think there were... I forgot how many members of the board were there. There were about a dozen and a half members of the board, but I think they had about two dozen warehouses but they sent each member of the board plus a specialist in to supervise the candling of every bottle of Budweiser beer in the

warehouses before they would allow them to be shipped. Any of them in which they found glass... They started this and Budweiser was shut down, and we came back two weeks later. In the meantime, studies were undertaken, I don't remember whether this was before your time, Bob, or not. Lehman had undertaken some studies of feeding glass to animals to see whether they would have any difficulties, and we got the word that anything that was ...any piece of glass that was less than 7 millimeters was okay. Thats between a quarter and a third of an inch in length.

When Busch heard this thing he says, "I just don't believe it." he says, "It just can't be so." He told his assistant, he says, "You call the Commissioner in Washington and ask him how big these pieces of glass can be." The guy called and came back into the board room and says "The Commissioner said 7 millimeters." He said, I don't believe it." He said "Get the Commissioner back on the phone." and said "Bring me a phone." And said "I want to hear him say it." He called Dunbar again and Dunbar said 7 millimeters. So he said, "Gentlemen, we are free, we don't have to worry. I don't think they ever found a apiece that was that size."

It was an incident where the scientific studies showed that this glass was not a harmful substance.

Janssen; "I remember that but there were other products where there were glass fragments. Of course, the first one was the brandy and other liquors of Europe--a lot of imports, and then, later on, we found...

Garfield: In ampules and...

(several talking)

We also found it in a lot of products that went into jars.

Janssen: I remember how amazed everybody was that a fragment this size would go through the gut of an animal apparently without ill effects...I still don't believe it, I agree with Busch.

Young: There was a risk of a law case that might have been tricky.

Roe: I think so.

Garfield: That isn't anything you might want to print, but I believe it was interesting. It was one of the crazy things you run into.

Roe: Another item, canned seafood, particularly shell-fish, canned crab and so on, they're often...They develop crystals that look like glass, particularly during the early part of the late war, when I was stationed in Seattle. We had imports...previously had

imports of canned crab made from Japan. Every once in a while, some irate and worried consumer would come into the office with a can of crabmeat and say, "It's glass," and they, of course, thought the enemy was deliberately poisoning our food; and it wasn't glass. It was a complex phosphate salt that develops in such products under certain temperature conditions. What we would do was put it in a test tube with dilute acid, and it would dissolve; and I remember one or two customers who wouldn't believe it. They thought there was a trick there that would dissolve glass, what I put in there. I said, "Well, it didn't dissolve the test tube did it?" So, we would convince them and tell them the next time they run on this at home, put a little vinegar on it and see if it dissolves. If it doesn't why come on in here with your product and we'll trace it down. But there was a lot of that during that period, and naturally the consumer would be concerned if he bit a piece of crabmeat and got a hard particle.

(The following is an explanation of the above remarks by Mr. Roe.)

"GLASS" Fragments in Canned Crabmeat

Crystals of a complex phosphate salt resembling glass fragments sometimes occur in canned fish products--particularly shellfish. They form under certain conditions from constituents normal to the fishery

products. We would occasionally receive complaints from customers who thought the hard crystals encountered in a canned product was glass. Many such complaints were received at our Seattle office when I was stationed there during the early part of the late war, --complaints with respect to canned crabmeat which had been imported from Japan. Many worried consumers thought the enemy had deliberately contaminated the product with ground glass. That it was not glass was apparent when the crystals dissolved in dilute acid.

Slocum: One of the main reasons for putting section 402(2)(a)(4) into the act, was the difficulty sometimes in examining a product in commerce objectively and proving unsanitary conditions in the plant or even danger to health. I think there's good legislative history on this, probably by Walter Campbell, himself testifying before committees. We had...I think I mentioned this earlier...we had numerous outbreaks of food poisoning from crabmeat. Retrospectively, many years later, we are pretty sure it's an organism we couldn't even test for. The most common cause of food poisoning in such cases is Vibrio paraliemolyticus...somewhat related to the cholera organism but it produces violent food poisoning. It requires salt and other special conditions for it to grow. Well Section 402(a)(4) helped a a great deal in our crabmeat campaign. We literally tackled the whole industry, East Coast and West Coast, and

cleaned up that industry, both from an inspection point of view going in the plants and really almost demanding that they clean up and taking action against them if they didn't do it. The same on nut meats and other products. There may be a continuing story there that should be spelled out.

Young: Now this is after the Seafood Amendment. This is, indeed after the...

Slocum: Not any part of the Seafood Amendment, it's one of the primary reasons why (a)(4) went in there. The kind of evidence to show it was prepared, packed or held under unsanitary conditions. You don't even need any objective evidence as a matter of fact.

Young: But this tied back to...It's like the principle of good manufacturing practices that got broadened later on.

Slocum: Well I think this may be a fairly good story for this. Another thing you mentioned, botulism. It occurred to me afterwards. One of my men, Dr. Dunnigan who is deceased, unfortunately, came to us out of the army and he was interested in botulism. One time in the late fifties I guess it was, he came to me and said, "You know, we have antitoxin to use if necessary to detect types A and B botulinal toxins but not Type E, which seems to be more common now." He said, "I doubt if there is any available commercially. Do you mind if I work on

these and produce bigger supplies of A and B, and also prepare E?" And he did. He went ahead and did this; and literally, those were the only supplies of type E antitoxin available in the country when we came up with the canned tuna fish episode in '63 and the smoked fish in '64, both caused by type E. It was his foresight, really, that led to it, and we loaned it to other laboratories to use. That's a little sidelight I thought you would be interested in.

Young: Yes, well, but the journals right before those episodes were saying that as a commercial thing the day of risk from botulism is dead. I found plenty of quotations to that effect. And so you had it when it was needed.

Slocum: Yes, that's right. Largely through the foresight of this one man.

Roe: It was kind of a surprise to us, wasn't it, Glenn, when the type E problem came up there on the Great Lakes?

Slocum: Oh, very much so.

Roe: Another aspect of the botulism business may be of interest from the field standpoint. A case of botulism means, usually food poisoning of some kind, and in the northwest when I was in Seattle, the only source of the antitoxin in that area at that time was the Oregon State

Department of Health. We had arrangements with the Oregon State Department of Health, whenever they got a call for the antitoxin to notify my office because that always means a food poisoning or a suspected food poisoning and we wanted to know what it was, if a commercial food to follow it through. And so every once in a while, we'd get a wire from the office and we'd get right on it. And I've had inspectors get to the place long before the antitoxin ever got there to see what it's all about.

Young: A couple of months ago, it was in San Francisco, and I had a nice long visit with Dr. Geiger, who, at 93 is still alive.

Slocum: The Dr. Geiger. I'll be darned.

Young: Yes.

Slocum: He investigated the only type E outbreak that wasn't caused by a fishery product. It was in mushroom sauce. In '42, I think it was.

Roe: Who was the man at the institute there in California that...Meyers...was a botulism expert.

Slocum: Myers, Dixon and Geiger. They were the three.

Garfield: You know, talking about Geiger, you might want to look into the work that Food and Drug did during the atomic explosions, testing for fallout of radioactivity. It just engulfed the Food and Drug Administra-

tion for two or three years, an intensive campaign to protect the food supply by the efforts undertaken by the Agency in setting up counting equipment and the food basket sampling program. That went on for years.

Janssen: The total diet study took priority.

Roe: I think so. I'm glad you mentioned that, Fred, I had meant to, because what was done there when the bomb testings were going on and fallout was of concern, we not only brought in samples of the agricultural products from the areas suspect, but we set up a widespread food basket program. That is, every two weeks or so, our inspectors would buy food products in stores in various parts of the country. And send in and it was all mixed up, and as I recall, the diets were set up as to what would be a normal diet for a 16 or 17 year old boy.

Young: The research was all done in Washington?

Roe: Yeh, and we would...we consulted with the Department of Agriculture as to what foods should be selected for this kind of a diet, and then every few weeks, the market baskets would be collected at stores in various parts, and come into Washington, and they would mix the whole thing up and run it through for radioactivity. And sure enough, it showed up following bomb tests, we were watching the radioactivity range. Well, we got that

started and then decided, will this be a good thing to use these samples to check on pesticide residues in normal diet? And so that was undertaken, and for a long time during the first years of it, we found very little evidence of residues in the diet as consumed under those conditions.

Janssen: I still have the can of pemmican that the Navy had gotten for us to check on it, in twelve cans from the South Pole. The last time I looked at it it was still in good condition, that is from the outside. There was no swell or anything, and no leaking. No leaking and no smelling...

Roe: In connection with that, we had to know what's the normal radioactivity of foods. We had to hustle around to get samples of foods packed before any bomb tests had occurred. One set of samples we got from the South Pole, where Admiral Byrd had had a cache of foods from years before.

Young: He also had a case of Lydia Pinkham's. And the question of why, even his supply officer was unable to determine.

Garfield: There was another situation I think that really needs exploiting because Food and Drug, did a tremendous amount of work on it, again going back to the question of sanitation problems, and contamination in food, candy in particular, as I remember very distinctly. At the time that I first came into Food and Drug and we would examine

a sample of candy...we used 50 grams of material, about 2 ounces. You found some insect fragments, but you rarely found the rodent contamination either because of the method used or the fact that the sample was so small. Great effort was then made to examine larger quantities of the material. Methods were developed to, say, examine a pound of candy at a time. It was quite a job to be able to pull out a few insect fragments or rodent hair out of a pound of candy. But the methods were developed, and it's amazing, the number of mouse droppings and rodent droppings that were found in peanut type candy bars, similar to Snickers, Baby Ruth, or anything that used peanuts whereas we were not finding it earlier.

Young: What was the time, roughly?

Garfield: About 1940 or so, or a little after.

Roe: This all derived from the sanitation portions of the Act of '38. Prior to that, just because a plant was unsanitary or dirty, we couldn't do anything about it unless we found evidence of contamination in the product as shipped. Then when it became illegal to ship a product from a plant that was unsanitary, then the matter of cleanliness and sanitation of the plant became important. The way the Food and Drug started in to enforce that measure, was to start...well, an example is bakery stores. To examine bakery plants that were putting out bread and bakery products for interstate shipment

--were they clean, or were they not. Then we'd follow through on that. Well, one of the problems the baker had, was the flour he was getting clean, or the corn meal, and so on. So we started first with the bakeries and pushed back then to the flour mills and to the grain handling establishments, and that was the direction of it. In connection with that, we wanted to get some background information before we got to the field and the farmers and the grain storage business. What are the facts with respect to contamination of corn that goes into making cornmeal, for instance? Then we found that it wasn't very good, and we made an extensive survey throughout the country on corn and other grains as to contamination with rodent droppings and the manner of handling the grains in the field and so on and the distinction between feed grains and grains going to milling purposes. And we set up a tentative basis for action on the grain when we got our program facts together. What was it...?

Garfield: It was a pellet per pint.

Roe: A pellet per pint or pound and we were starting to enforce that program when the administration changed. The Eisenhower administration came in. As often happens with a change of administration, the new group coming in campaigned pretty hard about these bureaucrats and the incompetent people of the government, and you know they apparently believed it themselves when they came in, and it took some time for the

new secretary to get acquainted with what was going on and what it was all about. And, that was Mrs. Hobby.

Garfield: I remember that very well. Aiken was the chairman of the Agriculture Committee.

Roe: Yes, and he'd been pressured by the farm groups to call off this business of Food and Drug's work on grain. It was going to ruin agriculture and everything, and that came to the new secretary and the program was stopped.

Janssen: Stopped for 17 months, then Mrs. Hobby ordered it reinstated.

Garfield: It was doubled after that. But then there was some interesting statistics that came out of that.

Roe: The program was reinstated with the help of Nelson Rockefeller (then Under Secretary, HEW) and Bradshaw Mintner (Assistant Secretary). I was designated the representative of HEW to deal with the Department of Agriculture on this matter. Agriculture had not been happy with our program, but we got them onboard. As indicated, the tolerance was doubled (2 pellets per pint) in the reinstated program.

Garfield: The interesting thing with some of the presentations, I don't know whether you want to put this in a book, but it was demonstrated that when a rodent defficates, he also urinates at the same time. They estimated that if you had a pellet per pint of wheat you would have 50 gallons of rodent urine in a carload of wheat.

Janssen: The grain sanitation program at that time was and maybe it still is, one of the most coordinated and was a deliberately planned campaign. The FDA set out deliberately to clean up the grain supply in this country and made very detailed, extensive plans, strategic plans, to do it. There was an educational phase followed by an enforcement phase.

Young: You didn't spring it on them suddenly.

Roe: We knew we couldn't change this thing overnight and we didn't want to.

(interruption)

Garfield: It even went beyond that in analytical methods, too, because Eisenberg and Harris evolved methods of soft X-rays to examine the grain and established a hidden infestation of insects in various kinds of grain...

Slocum: Methods that are still used today...

Janssen: Despite the opposition, we had covert cooperation of the Grain Dealers Association, and they fought us at the same time, and they sort of helped us too. And the result was, I don't know the source of this, but within a couple of years or so afterwards, half the grain storage capacity in the United States was rebuilt.

Young: So this got back on track after the...

Roe: Oh, it had enormous effects and it had...New elevators being put up, and old ones junked. Tremendous effect--it probably saved a lot of grain from being ruined, as a matter

of fact under prior storage...

Garfield: They took care of it. They sent all the crappy grain overseas.

Roe: I believe that rather complete reports on the grain program have been published in the AOAC Journal and other publications. Janssen doubtless can provide references.

Young. There's the beet story and there's this story of some kind of trouble, at least delay in programs because of some sort of pressure group. We come to a new period today, in which Congress has even been enacting things that delay or stop programs. Earlier, are there other examples of this that you can think of where either pressure from the executive branch or from the congress has caused a serious delay or cessation of regulatory programs?

Roe: Of course, back to Teddy Roosevelt on saccharin.

Lofsvold: And way back, Bob, the Congress, didn't they enact butter standard amendments about 1923 that said butter shall have 80% butterfat?

Young: It was a lower standard than the FDA was using.

Roe: What the department...administration had tried to do on butter was 82 1/2% fat. Congress then took over and by law, established the standard for butter at 80%, all tolerances allowed for. That took part of the bite off of it, because certain tolerances would be allowed under the 82 1/2%, but also Congress, in the butter law, authorized the coloring of butter, as I recall. So butter is one of the products that's colored that doesn't have to be labeled.

Janssen: Then there was the lobbying effort by the soap industry, kept that out of the definition of cosmetics.

Lofsvold: Subsequent to the '38 Act, we established a food standard for light skim milk, and the industry said they didn't like that term, skim milk, and they finally got the Congress to write statues that said that the right name for it would be non-fat dry milk solids, or some euphemism for it, and again the Congress substituted their judgment for the Agency.

MacFadyen: Weren't some of the coal tar colors being taken off the certification list, and there was a kind of an interim legislation to allow it to be used, coloring lard and Texas oranges, and...

Janssen: Yes, Red No. 2, and this was specifically permitted by Congress...That happened before the Color Additive Amendment. There was also a time limitation, or until a substitute color should be available.

Young: So there are some examples of this kind of thing before the most recent periods.

Janssen: Congress butts in when their constituents holler loud enough and they change our minds for us. (Inaudible)

Slocum: You asked earlier about drug action. There was a question in the early thirties, whether or not things like surgical sutures, dressings,

and that sort of thing were actually drugs within the meaning of the law. And we did make a case, I think it came up in 1937, where dressings put out by Parke Davis were seized. They were marked sterilized and were not sterile...and we went to trial in the Southern Circuit of New York, and the judge did hold that it was a drug. I don't think it ever had to go any higher than that. I belive that the 1938 law was more specific in requiring that products intended for medical use and this sort of thing, and sutures, solutions and so on, should be sterile, by the very nature of their use. And we did start quite a program about that time. We had already plugged in surgical dressings.

Young: You extended the definition of the dressing to other products.

Slocum: To other products, and also the USP changed their monographs for dressings, for sutures, for all injection products...to require sterility, and most of them were official drugs. So starting from that point, and we began...I went out in '38, I remember, involved with parenteral injection products manufactured practically all over the country, just to study how they sterilized, and some of them were using very outmoded methods. We started a regulatory program then. The same is true of all other types of products. There was

a bad outbreak in St. Elizabeth's Hospital here in the District...surgical sutures that were badly contaminated, and they were using chemical sterilization, of all things, which couldn't be effective. So that whole field got a thorough airing.

Young: Before the law was changed.

Slocum: Well, no. It began just about the time that law was passed, and in addition to that, Dr. Dunbar went over to the Department of Defense and agreed to test without charge, all sterile drug products that they procured for the armed forces. And I was in charge of that program and we had to get results out in five days. Thousands and thousands of samples.

Young: I remember, that same definition was applied to contraceptives, wasn't it? And that began a program in that.

Garfield: There's one other area that I think you might want to look into in the drug area that I think is most significant and that's the development of good manufacturing practices regulations. I assume that you have this in mind someplace along the line, but I think...

Young: Does it precede the 1962 law?

Garfield: I think so.

Lofsvold: It wasn't in the statutes specifically.

Garfield: No, it wasn't in the statutes, it was regulations.

Young: How did you go about setting up the regulations if it wasn't in the statute?

Janssen: Well, in the grain program, we spelled out what they should do.

Slocum: I have a feeling...we started this field in the food area first.

Janssen: We have GMP's for grain storage and so on, really, and...

Roe: Well, we had regulations for it. It wasn't enforceable as a law, but it did...

Garfield: I don't remember the exact dates on it. I know how it was set up, because I was involved in it but I can't put the year on the thing. I think that this has, more than anything else led to the general use of generic drugs at least as insisted by the commissioner at the present time, generic drugs being the equal of brand name drugs. You could trace it back.

Young: It's certainly in the '62 law, but you're suggesting you'd begun this kind of thing?

Lofsvold: Well, I think that the first attempt to formally write GMP's as regulations came after the '62 amendment. I think we wrote the first draft in Philadelphia. But I think the consideration of good

manufacturing practices as the criterion for legal action, I think we had, as long as I've been around. Because when you chose what case you were going to proceed against, one of the things that you had to consider was whether it was profitable for the industry to do it better than this, or what is the normal kind of product that results from what a good manufacturing plant does. I think we made that kind of judgment all the time in the cheese plants or anything else.

Garfield: That may be true, but it was never put down on paper.

Lofsvold: Not as a regulation, but...

Roe: No, not as a regulation, and perhaps not under that term, nomenclature.

Garfield: What we did was to bring in a number of drug inspectors from the field in Philadelphia and New York, particularly, since they had the largest amount of drug business. I led a team that worked on this, and we had somebody from the Division of Drugs.

Roe: Frank Wiley.

Garfield: Yeh, Frank Wiley. And we sat together and we outlined when a drug inspector starts an inspection, what does he look for--and just working from that, we were able to outline the procedures, duplication of

formulas, and batch lots, and so on. This thing knocked around for a couple of years, and went to Julius Hauser, who was in the Drug Division who wrote many of the drug regulations, and he put the stuff into regulation language and it was finally published.

Young: And so industry had this as a notice to what they had to do.

Garfield: I think as a result of that, it led to significant improvements in terms of what the industry had to do in order to comply with the law. It also set down, later on, the regulations were modified...the types of control they had to maintain over the finished product, and yields, and repackaging.

Janssen: This was set down way early.

Garfield: It's in the regulations--good manufacturing regulations.

Janssen: Was this after the 1962 law?

Garfield: I think it was before. I'm just trying to remember, cause I don't think I would have been that much involved in it.

Janssen: Current good manufacturing practices were what the contact committee was after in all of their activities.

Garfield: What contact committee? I don't know what you're talking about.

Janssen: The criteria for law cases wasn't it?

Roe: Yeh, I think antibiotic regulations contained requirements along that line long before, you see, for the antibiotic manufacturers.

Janssen: Somebody's researching this now.

Young: In the late twenties, there were the two contact committees from the two then pharmaceutical trade associations, who met with FDA to determine what the state of the art would permit, with regard to the quality of parenteral drugs. And after they got those agreements as to what the state of the art would permit, FDA issued those as regulations. And so, here was an example of rather formal cooperation, and whether this was just tolerances with regard to active ingredient level, or whether it had something that might be called good manufacturing practices...

Garfield: I don't think those were good manufacturing practices.

Slocum: Weren't those primarily limits, and so on in the National Formulary and the USP? I think that's where they were translated. Rather than any formal FDA regulations.

Young: That did lead me to ask a question I had written here. That is, the interaction between the USP standards and FDA needs, I take it sometimes FDA has changed

after the USP has come out, sometimes FDA has made advances that USP has adopted. Any rough spots here?

Slocum: No, I think the coordination here was excellent. Some of us...well, I was on the sterile products committee for example with USP and NF for a long time ...actually on the committee. But we also received the monographs for new editions. These were reviewed by drug chemists, by microbiology and the necessary people.

Young: Before they were finalized?

Slocum: Before they were finalized and then, if necessary you would go to a USP convention and go over these things and resolve any differences, where ever it could be.

Garfield: Well, there were some advances that were presented to the USP but I think most of these were through the AOAC. Methods developed perhaps by Food and Drug or other agencies and then adopted by the AOAC and these presented to the USP revision committee. But there has always been a very close working relationship. I don't think there have been any significant problems.

Roe: That's right. Dr. Daniel Banes would be a source of authentic information on it. He is now with the USP, but he was a long time in the pharmaceutical...he was Deputy Director of the Bureau of Biological and Physical Sciences. He could give you the real facts on the

relationship of the USP and NF work and the pros and cons on its.

Slocum: One of the things we were involved in pretty heavily, with NIH eventually, was the sampling of sterile products, ampules in particular for sterility. Well, they had an old percent sampling rule, ten percent of the lot, but not less than three and not more than the. In some of these big lots and so on we finally realized from sampling theory and statistical studies that this rule was completely inadequate. We had a heck of a time effecting a change but we kept pushing and, I think, it may have taken a couple of revisions, but eventually everybody accepted it. It was all revised and their schedule is now a modern acceptable one. As a matter of fact, the failure to act on that beforehand was one of the reasons that the Salk vaccine caused trouble initially. When you take a minimal sample of three units from a lot it is just simply not enough to detect contamination and other defects.

Janssen: The development of statistical yardsticks in enforcement had been an important step.

Garfield: I think most of that had come after '62. Food and Drug used to have a square root rule and that was the bottom line.

Janssen: Didn't we have a mathematician before?

Slocum: Lila Knudsen worked with us on the drug sampling long before.

Garfield: Yes, there was some sequential sampling.

Young: What do you mean by the square root rule?

Garfield: They sampled the square root of the number of cases in the lot. If there were 100 cases they would take a sample out of ten--not necessarily take 10 cases but take samples out of 10 cases.

Young: Right.

Porter: The Inspectors Manual that we had...here and there we had more specific instructions but with no instructions then you always used the square root rule. You always had to know how to do square roots.

Garfield: That was before the days of the calculator.

Young: They gave a special course for people expected to sample big shipments.

Slocum: In 1948 we really concentrated heavily on the sampling of ampules and we took two areas where we knew there were deficiencies. So called intermittent sterlization which doesn't work when you are dealing with a substance that is not nutritive--something in which the bacteria won't grow, or low temperature short time processes for certain types of heat sensitive products. We came up with some fifty separate lots of badly contaminated solutions by applying statistical sampling to these things and re-

ally going into it thoroughly. Combined with good inspection to look at their own quality control records and all of that. Almost in one year, we got that industry straightened up, But a lot of effort went into that in one campaign. As a matter of fact we had a group of special inspectors and microbiologists and they went into every plant all over the country and did an in-depth survey of every process they used.

Janssen: FDA came out on top in that regard but in regard to particulate matter - I was with the Pink Sheet at that time and we did a special report from Syracuse, New York at the trial of the Bristol case which the FDA lost. Particulate matter is still a problem isn't it?

Several: Yes.

Slocum: This is one of those cases where they found they could inject glass particles and particulate matter and it didn't make a bit of difference to anybody, if they were sterile.

Lofsvold: We are having more of a problem now with the new device law. What kind of standard do you have for particulate matter in tubing, catheters, and that sort of thing?

Janssen: I wanted to ask for comments about the impact or consequences of the transfer of pesticide tolerance

setting to EPA.

Garfield: That's after '62, Wally, isnt it?

Janssen: After '62.

Young: Well go ahead, I do intend to live long enough to write a third volume.

Janssen: We talked about the expertise of the FDA and how it was developed and our problems in connection with pesticides, but it seems like the major achievements in a scientific way as regards pesticides and in regard to FDA took place before that switch. Didn't that take FDA out of the research end of pesticides?

Slocum: I retired in '65 with Larrick and Harvey and EPA was set up after that, so I don't know the impact of it.

Roe: Well, EPA was after I retired in '67, so...

Garfield: Well, I think the thing is - they are involved in pesticide formulation more than they are in setting...

Janssen: They set the tolerances now.

Roe: My biochemist daughter is with EPA, she had been with Agriculture and she was transferred with that registration group of Agriculture to EPA. There is an organization that has been continuously plagued with reorganization and nobody seems to know what its all about, I'm afraid. They are having a struggle and I

think there has been transferred to EPA much of the development of the - passing on the regulations both as to the registration of pesticides used on crops and the tolerance development.

Young: FDA still seizes foods that don't measure up but somebody else makes the yardstick.

Janssen: We've got a huge thing going right now - it hasn't broken in the papers yet - but it involves spinach, I think, and a new pesticide that I haven't heard of before. It is a big operation getting underway.

Roe: EPA came into being - probably organizationally it may have been a good idea to assemble there the agencies of government having to do with those areas of consumer protection that also hinge on the aspects of - well, stream pollution and other pollution aspects of our environment. It came into being at a time when government was pretty well disrupted and set up under political conditions that were...well, politicized it too much. There are good people there - sent over there - but it has had a bad start.

Young: Well, there's probably some political angle in almost every severance of function from FDA and addition of function to it, which will need to be looked into more in the most recent period than any other period.

Janssen: Well, another one I wanted to ask about was nitrosamines. I remember that a long, long time ago FDA began to look askance at nitrosamines. We found out they were carcinogens and this was in the annual report a good many years ago. This one's still cooking.

Slocum: Henry Fishback was talking about potential problems with PCB's way, way, long before this ever occurred. He anticipated that this would get into the food chain. A very substantial problem of the future and he was sure right.

MacFadyen: In regard to the addition of functions, before she left this morning, Miss Kelly mentioned something about George Larrick developing the idea in 1941 for the first pilot study of adverse reaction to drugs, but this had to be put off because of the war. And that brings up the general question of how the second war affected FDA. Did you have to take on a lot of additional functions which pushed regular work out of the way, and if so, what...?

Slocum: My Division tested all sterile products for the Army without charge. Dr. Dunbar, who arranged it in the first place, said afterwards that his big mistake was not going after a bigger appropriation to cover such activities.

(Several speaking)

Janssen: At that time he didn't. His greatest error was being too patriotic during the war.

Slocum: Now what they did in my case was to put me in charge of a program and we just set aside people to do it.

MacFadyen: What types of programs?

Slocum: Well, in this case, we just agreed to test every sterile product, every lot of sterile products, any kind that the...primarily the Army bought. Navy didn't participate too heavily in this, but we tested every lot. They had their own inspectors. The Army had their inspectors in the plant. They took not full samples, but small samples of every lot produced. We ran them and we had 'x' days to get the report back to them, and we had to follow it strictly.

Porter: Well, we did other drug analyses too, didn't we?

Slocum: Oh, sure.

Garfield: You got into antibiotics...

Slocum: Pharmacy, chemistry, antibiotics, pharmacology...a lot of other divisions were involved in this, and as far as I know, it was all done without exchange of funds.

Garfield: Right. Actually, St. Louis work was done (I was there at the time) for the Navy, cause the Navy

purchasing office was just a couple of blocks from the FDA office in St. Louis, and the number of atabrine samples that went through the laboratory was just absolutely fantastic. There was a tremendous purchasing, and after the war when they started closing down various medical depots we participated in the examination of the lots of drugs to find out whether they could be sold as surplus. Examinations were made and sometimes just visually when they were condemned. There was just never any question raised as to the...I participated in a good many of them. You just walked into the place and you'd take a look at the stuff and if it didn't look good, say gone. They'd take it out and destroy it. Some of the stuff you'd look at and decide well it could be sold because it was relatively new, and others where it was questionable, samples were taken into the Food and Drug labs and they were examined and results went back to GSA whether it was released or condemned. At least I know in St. Louis, there was an awful lot of the stuff done. And then I know for the Veterans' Administration, St. Louis was the center for examination of large quantities of food that they bought on contract. Quality was established. Invitations to bid were issued and a number of lots, or a number or responses were received. Samples would come in and they

would be examined and Food and Drug would advise the Veterans' Administration which met their requirements; which did not; which were regarded as the best; which were not. I was deferred during the war because I was working on drugs and Food and Drug established the policy at that time, as I remember, they did not ask for deferment of all personnel and any time someone's draft status would change, he was to report to Food and Drug and Food and Drug would decide on an individual basis whether they would ask for a deferment or not, and, generally, if deferment was requested, it was generally allowed.

Lofsvold: But at the same time, an awful large number, high percentage, of our experienced people both inspectors and analysts in the laboratories did go into the armed forces.

Garfield: Yes, some of them that were in the reserves there was no question about the reserves, they all went in. And some of the guys, I guess, enlisted. There were a good many of them that enlisted.

Lofsvold: We were left then with lean replacement for experienced people with some different kinds of workloads that we had to carry in addition to sampling

directly for the military.

Young: And rough problems?

Lofsvold: Yes, for example, the military encouraged the building of a large number of cheese plants in the northwest where I happened to be, that produced additional cheese for government purchase, started up by people who had not been in the cheese business before--collecting milk from people who had not delivered milk for cheese purposes before. We had some horrendous sanitation problems. Of course there were all kinds of shortages and there were all kinds of fancy swindles that they could come up with to substitute materials being put into products.

Porter: Remember the special gift packages for soldiers?

Lofsvold: The sample box that the person looked at when he placed his order was great, but the one that they shipped didn't have all that fancy merchandise in it.

Roe: I almost spent the war out on the Navy dock in Seattle, inadvertently. I went out there at the request of the Admiral to confer on some problem on their food delivery...I forget just what it was. I had to have a permit to get in the place, which had been sent to me, which I had and when I was in the Admiral's office talking with him, I remember I rolled up something and threw

in his wastebasket, so when the conference was over and I went to go out, they stopped me at the gate, I didn't have any permit to get out of the damned place; and I thought, what's happened to this? Then I remembered I threw something in the Admiral's wastebasket, so I had to go back to his office and retrieve it. Sure enough that was it.

Slocum: I had an appointment with Carl Baumbach the next day and the papers were all made out for a commission in the Sanitary Corps, the day that Dunbar agreed to do all this testing. And I spent the last two hours of the day with Drs. Ben White, Hunter and Dunbar trying to decide that I wasn't going in to the Sanitary Corps and would stay in the Food and Drug Administration. Miss Kelly's remark reminded me of something that I've always been infuriated about. She is absolutely right. Larrick not only had the adverse drug reporting program, but the organization of, indeed, a new drug petition. He had a whole block of things of this sort, and in fact, had moved on them. He had started the voluntary adverse reaction program at 50 or 100 hospitals, and Humphrey's staff committee, you know the committee with...I forgot his name now, literally crucified him because he hadn't done this ten years before. They raised hell with him.

They called him all kinds of a bad administrator because he hadn't actually done this, perceived the need and put them into effect a long time before and this to me was about as unfair a thing as I've ever seen.

Janssen: He had been a particular friend on the Hill and a friend of FDA because he was working on the Durham-Humphry Act and they were personally sort of acquainted. I think Humphrey was campaigning for the nomination then, and he stabbed Larrick in the back.

Slocum: He did it. He'd praise him one week and stab him the next.

Janssen: He made Food and Drug a political spring-board.

Garfield: Well, Larrick recognized the need for a Department of Consumer Affairs when I was a Special Assistant there; they would have meetings in the morning. They were informal meetings. He'd get to work at 7:00-7:30 in the morning, he'd wander in and sit down in the office and pretty soon had a gang sitting with him and just discussing various kinds of things up until the time work was supposed to start and everybody would get up and go out. He'd raise all kinds of things and he would kind of philosophize thoughts that were crossing his mind, and he talked about the Department of Consumer Affairs.

Slocum: Did he have it pretty well outlined in his mind as to what agency that should be in?

Young: Do you know if anybody ever took private notes on those sessions?

Garfield: No, you might find some correspondence that he had on this thing with some of the people up on the Hill. I am quite sure he had this thing pretty well mapped out. I know when we went up on th Hill on these drug abuse control amendments, I know he talked to Congressman Rogers about that. He may have put some of these things down on paper.

Young: Do you have any idea how he developed his ideas. Were these morning informal conference sessions in which he was testing out ideas he'd already developed or was this a sort of...

Garfield: We think it was ideas he'd developed. Sometimes he'd just toss something out. Somebody would toss something to him and he'd pick it up and think about it and bring it back up again. He varied on this, but these were the informal ones, you know, that started before working hours.

MacFadyen: When was that?

Garfield: 1964-'65

Janssen: Well, I remember one of those very well. This was where the public warning on the Hoxey treatment was

worked out. Mrs. Hobby had insisted at all times that she would not decide any matter unless it was fully staffed out, in other words she had to have the initials of all her lieutenants on the paper before she'd even look at it. So it went to the Surgeon General...no, it first went to her General Counsel. He wrote a memorandum saying it was legal, but he didn't think it would work. He thought it would only send more patrons to Hoxey. Then the Surgeon General got it - he was political too -and he chimed in with the view that the opinion among public health educators, at the time, was that public warnings did not work. That education against quackery did not work. You couldn't protect the public this way. In view of the Laetrile situaion - I don't know.

Slocum: Maybe they were right.

Janssen: At any rate, I felt that we got the turn down. We couldn't take it to Mrs. Hobby because of what her lieutenant said about it. And I was urging that Larrick go over their heads and go to Mrs. Hobby. He said, no, one of the best ways to lose his job was to disagree with City Hall. Well, then later, Mrs. Hobby got through with her tenure and Folsom became secretary. Folsom delegated all kinds of authorities to the different commissioners, including the authority under Section

705, to issue information about the Food and Drugs Act and we warned the public. Larrick was praised editorially in the AMA Journal and all over and it worked. But the climate was different at that time. After the warning came out, cancer victims stayed away from the Hoxey Clinic in droves. We had an inspector down there to count the cars, and based on a car count, about 6,000 people stayed away during the first three weeks after they had been officially warned. And then he hired Gerald Winrod to revive the business...and Winrod got the business back up again--from the Bible belt. Well then, at that point we converted the public warning into a post office poster and it worked again.

Young: Was there any reactions, about the present poster?

Janssen: The present poster, I think has not worked. And a very clever, remarkably clever paraphrase of it has been put out by the cancer people. I don't know what part of it, which organization has put out this counterposter, but you ought to see it.

Young: I do want to see it.

Janssen: Yeh. It's called FDA warning, not Laetrile warning, FDA warning. Then it was set up in type exactly like the other one, and lambastes the FDA for its high handed job on activities against Laetrile.

Garfield: Well, after Larrick left and Harvey left, Winton Rankin, Deputy Commissioner, took over. There was a period of time there that the Food and Drug was just kind of in limbo in selecting anybody to become Commissioner. I don't remember how long it was...

Slocum: Not very long.

Young: I thought that Goddard was appointed the next month after Larrick passed.

Slocum: Well, he came right on when Mr. Larrick retired.

Garfield: I remember I was sitting in Rankin's office and Wally came in and he says to Rankin, "Have you ever heard of James L. Goddard?" Rankin says, "Who is James L. Goddard?" Wally said "He's going to be the next Commissioner of Food and Drug Administration. Well, I thought Rankin was going to go clean through the damn floor. He expected to be appointed as Commissioner, and then I think he had some more information. I'll never forget that particular situation. Here was a guy who was acting Commissioner of the Food and Drug Administration and the Secretary didn't pay him the courtesy to call him over to tell him about it.

Young: Was that Cohen?

Roe: John Gardner.

Young: John Gardner, that's right.

Slocum: Because, well we left on the December 30th and I came back the next week and Goddard was on board to talk to one of the training classes.

Garfield: Food and Drug was kind of kicked around from time to time.

Slocum: Well, when did Malek do the job on...on Winton and Kirk? That was not too long after. They were about the only two left in the old regime.

Janssen: That was '69, ah, the expiration of this whole...

Slocum: That was really close to - Goddard.

Young: There was a Commissioner Committee appointed.

Roe: That's right.

Young: That picked Goddard and at least nominated Goddard to the Secretary, and I can't remember much about that, except that I do know Boisfeullet Jones, who earlier had been the Associate for Health and who came from Atlanta, he might know. He was a member of that, and I'm not sure whether he had much of a role in regard to Goddard or not.

Roe: Well, there were two other members of the committee that I recall. One of them was Jim Cardwell and the other was Rufus Miles. Rufus Miles and Jim Cardwell were on that committee, and...

Slocum: Boisfeullet was already on board then, too, I

think, wasn't he?

Roe: Who?

Slocum: Boisfeullet Jones.

Roe: I don't remember the other members, but Gardner appointed this committee to select...

Lofsvold: This was LBJ's second term?

Roe: Yes, his first elected term, I think so, and I always felt it was ironical that the committee appointed by John Gardner, the apostle of excellence in his writing, selected for us Goddard. You've heard some comments, today Dr. Young, that some of us have been disturbed about the situation that emanated from Goddard's appointment.

Young: Are you speaking to both Goddard as an individual and to the ending of the system by which, since at least Campbell's day...

Roe: Well, of course previously, the Food and Drug Administration, from the viewpoint of us old timers, has been one of the respected career services of government. The Commissioners came up with through the ranks and were long time workers in the department; and had a great background of experience and knowledge of the law and the purposes and all of that. It seems to me that we had, perhaps, gotten into a bit of a rut as bureaucracies do, a bit ingrown, and that we needed some shaking

up. Both Mr. Larrick and Mr. Harvey, who we think very well of, highly of, and long time employees, but both of them were in rather bad health the last few years of the operation and weren't able to exercise as strong a hand as perhaps was needed. My personal opinion is that Food and Drug probably needed some shaking up, but I've always felt that it wasn't necessary to burn down the house to roast the pig--that this change was too drastic. Dr. Goddard talked well; he made a fine impression on outside audiences and some of the ideas he propounded were real good. But I had some contact as a Bureau Chief with him, and I soon concluded...well, I'm 65 this year, it should be a damn good time for me to get out. It was obvious the new regime would like a change and things were changed. But it's been distressing to me that there has been a period here, with the Goddard administration and one or two after him, that things have been pretty wobbly and not so good. I haven't met Dr. Kennedy. I have heard him speak and have attended meetings where he was and have followed some of the statments as reported in the press, and to me it looks very good. I think he's getting things back on the track, or at least he shows real understanding of what it's all about, and I feel encouraged.

Roe: Now Food and Drugs bad period, of course, coincides with the bad period of government, generally, to some extent, and there has been a breakdown in the public confidence in government. There's been a breakdown apparently in the integrity in some areas of government and competence, and we're in a very disturbing and distressing period. I think--not only just Food and Drugs, but the whole government--and not just the government, the whole damn society in some respect. So it's hard to pinpoint all of the causes and effects, but to some of us old timers, the big break that occurred was the M.D. appointment of Goddard coming in represented a distressing and great turmoil that hasn't completely subsided, yet, I understand, although I haven't been close to operations since then.
Slocum: All ongoing systems were abolished, period. All middle management was wiped out. Decision making to the minute detail--he took. He overruled technical decisions by experts in several Divisions, one case I have heard about, probably to show who was boss. He was doing this kind of thing all over the place. The worst criticism I've heard in recent years, and I believe it started with the medical orientation of Dr. Goddard, is that scientific research

has suffered terribly in FDA. Now that's a serious charge. I don't know whether it's true. I couldn't document it if I had to.

Roe: Well, I think that there's some basis to that. It was a sad time. I had some experiences with him that I don't suppose it is necessary to recount, but if they indicated to me that I just can't get along with this. But fortunately, I was at a stage where retirement was in the offing anyway, but I was quite concerned about some of my younger colleagues; of what I left them with under this situation.

I had not looked forward to retirement, having been working hard with Food and Drugs for anyway 42 years, and that was my life; but fortunately, the way things worked out, I did some part time consulting work for the World Health Organization, particularly Pan American Health Organization and got eased into retirement very nicely. I traveled in Latin America and worked on Food and Drug problems three months...well, traveled in Latin America, all of Central America, and South America, three month's assignment in Costa Rica, two months in Thailand, and some other operations in the Caribbean, all on Food and Drug problems. By the time I got

through with that, we then did some travelling on our own and retirement's been great, but it wasn't planned that way, exactly. But Goddard helped.

Slocum: Well, your Volume III is another thing that--it might be worth--that I'd like to think about. And that is the shift from what I called before selective enforcement, to what I regard as the massive sampling survey type of thing, without relation to conditions of production. They've done this in connection with microbiological standards, for example. They don't know anything about pack conditions under which they were produced. They simply run 2,000 samples from all over the country. They gather massive data through the automated system. They accumulate it, and most of it hasn't been analyzed. In fact, it certainly hasn't been published, but there have been any number of surveys. Now these things cost anywhere from $250,000 to $500,000 a job. They do this for pesticides and for other things. They take the place, literally, of informed sampling based on knowledge or production areas, production plants and all of these things.

Janssen: Did they draw a contract with an outside organization?

Slocum: Sometimes. Am I right?

Lofsvold: Well I don't think that's exactly right, Glenn.

Slocum: OK.

Lofsvold: At least I think what's happening is that that has been added to the selective sampling.

Slocum: Maybe that's more correct.

Lofsvold: And for a different kind of purpose, not for direct enforcement of the statues, but to gather data for some other purpose such as standard setting, or to just have general information about what is the status; are there are problems with canned peas or any of these particular products we are analyzing? I would agree with you that it takes a tremendous amount of resource. I'm not sure that the data from my point of view is really that directly related to what I think our mission is. But I think it was a fact finding sort of operation, rather than an enforcement operation and at the risk of offending the scientists present, I think that's what happens when you put these kinds of priority decisions in the hands of the individual bureau. Wouldn't it be nice if we knew all about this particular product and sold the idea that we ought to do this. And so we spent a hell of a lot of money that might, in my opinion, have been spent better somewhere else.

Garfield: Well, I think from a management standpont, you cannot remain static from regulatory enforcement activities. You have to keep experimenting almost

constantly. You don't have a staff large enough to do the job the way it's suppose to be done. And I personally see nothing wrong in some of these types of surveys, but I'm not sure I would spend a half million dollars just to find out whether you've got a problem in canned peas, for example. But I think there are certain areas that are critical to the national health area where this kind of survey provides certain kinds of information, and it provides a certain amount of assurance and security, for administrators, that there are no problems in these particular areas. If you do the thing soundly, and do it on a statistical basis--I'm not saying that the Food and Drug is doing it statiscally or not--I think that there is some room...I think there is room for that. I think that as an administrator, I would have to make some decisions as to how much manpower and what quantity of funds I wanted to expend on this particular thing, and of course there's Oversight Committees and there are others in Congress who look at these things and decide whether you know what the hell you're doing or not. But I think I would hesitate to be too critical of this kind of operation.
Lofsvold: Well, I am afraid I'm pretty skeptical of...
Garfield: I don't know, Fred, what the extent has been.

Lofsvold: The other thing is, I think that outside pressure, outside of FDA, and pretty much throughout government requires us to do some of the things that we do that are additional overhead to the way operated in the 1950's or 1960's.

Garfield: You can expect it in any kind of regulatory operation, even when its selected, as Glenn suggests, that the percentage of hits that you get is going to be relatively low, even on selective sampling, you're apt to hit 25% of the time. I'm just pulling that figure out of the air. And if you run a general survey, the number of hits may be 1%, or whatever, way, way below, and you have to balance that against what you're trying to achieve. If you don't go whole hog, I don't see too much wrong with that. I think if I were with Food and Drug I would not say no to that kind of sampling, but I would watch...

Janssen: My impression is that if we were to line up all the studies, especially the contract studies that we have done in the last ten years, and take a good hard close look at them, there's a hell of a high percentage of them to have turned out to be useless.

Garfield: Well, you've got the compilation now. There's a book that...I'm not talking about regulatory studies, I am talking about research studies.

Janssen: You're talking about research studies now? No, I mean regulatory studies...

Roe: I'm very skeptical of some of those, Wally, but this matter of survey samples, as Fred points out, I think there's a place for that. It is a matter of judgment to some extent and a matter of allocation of your funds and time and effort, but there is a field for survey samples to find out where there maybe problems that exist that won't show up on your field surveys, and then lead back to it.

Janssen: You're talking about analytical?

Roe: Yeh. Some of these contract deals like you mention on consumer surveys, and that kind of thing, I think there is definitely some waste there.

Young: It seems to me the biggest problem of FDA statistically, from the point of view of the total impact, is extrapolation, the kind of evidence they have with the animal studies and one thing and another is that they've got to extrapolate into a major hazard, and it causes action to be taken that upsets so many people. With Congress, quite unlike your day, it seems to me, on a day by day basis, looking down the necks of FDA, which really wasn't true. At appropriate times, and maybe on another occasion or so, as in that beet situation, something would come from Congress. But the

oversight is just as intense and constant. And it's looking at lots of things that are statistical things you know, the kind of evidence that there is that have to extrapolate into a potential public danger.

Slocum: And it's also triggered many times by rather wild statements that are unverified and this sort of thing.

Garfield: Well, I've heard Kennedy talk, where he had said that a significant percent, and I don't remember what the percent is any more, of the manpower headquarters is taken up with satisfying the questions that are submitted to the Food and Drug Administration by the Congress and various committees. And he says he would like to see far less of that kind of pressure so that he could use his manpower to do something constructive--some of the things that he wants to do, but he's unable to do them because he has to satisfy these guys, and I can well understand his position.

Young: That's part of the total environment, too that you have...

Garfield: But I don't think that pressure necessarily existed back in the time when we were...There was some of it, but not...

Roe: Not to the extent that it does now, but...We had a lot of manpower taken up in preparing for hearings for

Congressional Committees and so on, but I think from what I read and observed, its much greater now.

Janssen: When I came in 1951 the FDA was virtually unknown to the general public. There was very little which was covered by the press, very little. The press didn't regard FDA as a news source. It was only when somethng like sulfanilamide happened that you heard from them at all. Nowadays, the FDA has become major news source. We get more publicity than all the rest of H.E.W. put together, and this is increasing, its accelerating. News conferences, which were almost unheard of then are almost a weekly occurrence now. I think this is one of the reasons for the abundance of requests from Congress. Freedom of Information -- 35,000 requests were worked out this year. It is likely to go to 50,000. So the staff has expanded greatly based on requests under F.O.I. The more public interest there is in the Food and Drug Administration, the more political interest there's going to be in the Food and Drug Administration.

Garfield: There are a hell of a lot of commissioners, Monday morning commissioners...like the three of us sitting here.

Young: And vice versa, the more political interest, the more public interest.

Janssen: We cannot deny the right of the public to know, but if the public really starts to work on us, trying to find out about things, the whole Food and Drug Administration will be answering letters or phone calls.

Roe: This is a real problem, I think. I think there have been some good effects from the F.O.I., but there's also been a tremendous burden, and I think it'll get worse.

Lofsvold: Don't you think that there is another thing to consider, too. During the period we are talking about--up to 1962. The kinds of things that we were dealing with then were pretty clear cut. Nobody's in favor of filth in foods, or spray residue on apples, or things of that sort. People were against sin. They didn't worry about it. But now, the kinds of things we deal with, there aren't clear cut answers. There's not a general public agreement about some of these questions, for example, saccharin.

Young: There's even less public agreement about the old fashioned kinds of things about which...then there was public agreement, like Laetrile.

Slocum: I was going to say, the reasons some of the questions are difficult is because they are in the public domain. If they were left to the scientists and

their administrators, then I think some more sense could be made out of them without all of this...

Lofsvold: But now, everybody's an expert, on carcinogens, for instance. Everybody that reads the paper has an opinion.

Slocum: Well, I'm waiting till turnips and cabbage and a few other things, natural foods, are cited as potential dangers and it's coming, just as sure as we sit here.

Roe: We do know some of them, of course.

Slocum: We know some of them contain things which may cause concern.

Lofsvold; Well, you know, 20 years ago, there was some guy that did a study he called the geography of milk and he came out with the conclusion that in all parts of the world where milk was a part of the diet, there was cancer and those countries where they don't drink milk--no cancer.

Roe: Well, I think the developments since the war, the great mass of new chemicals, beginning with D.D.T. and all the others that have been developed, pesticides and the industrial chemicals of various kinds has injected into our environment a great many new chemicals that never existed before, and of which little is known

about. There is nothing known on the toxicity of them. We had cancer before, but there's an increase in cancer that probably is related to our environmental conditions.

(Break in the recording)

Garfield: Well, I would agree with Bob, that considering the time, I'm not talking about looking back now, but I think the approach was proper. It was one of these things where you just sit on it forever and never get it done, or you make a decision, you make an administrative decision. If you're flexible enough to correct the incorrect decision...If I had the choice, if I were to do it over again and know just as little then as I know now, I'd do it again. I don't have any real problems with it. If you were to undertake studies on all of the GRAS list, it would just be impossible, there aren't enough pharmacologists to take this on.

Roe: Oh, that's the point. There aren't enough pharamacology laboratories in the whole world to test all of the things that would be...

(Interruptions)

Garfield: And the studies are becoming so complex now, because you're talking infinitesimal amounts of materials...

Young: As scientists, are you in agreement with FDA's present position that giving large amounts for short terms is the equivalent of giving smaller amounts over long terms?

Slocum: I'm not.

Roe: Well, I don't think...

Garfield: I would say yes, I agree with it.

Roe: I don't think it equates, though, but I think the procedure in testing, as I understand it, now or was when I left -- I don't know any better way to do it at the moment. In the long term feeding tests on rats, for instance, the two-year test is essentially the lifetime of the animal. Longer tests on dogs and other animals. But the problem of translating what does it mean when you get it. You've found out the toxicity for that species. You've got to try to transfer it to man, and you assume man is so much more sensitive, and your question involved the large amounts used. Yes, I think you have to...I think maybe it's gone too far, using larger amounts than are consistent with the practicality of the whole situation, but I think you have to use fairly large amounts in order to get an effect in the animals. If you don't get an effect in them, you haven't measured anything. You've got to find out what kind of a toxic

reaction is it, and find out if you can, the no-effect levels on the species, hopefully reached on two species, and then leave a lot of margins in translating it to effect on man. Well, it isn't too satisfactory, but what other procedures do we have? I don't know. Dr. Lehman has spoken adversely on these animal tests in recent years because he felt that we've got to get some other tests on humans, some biological tests. Well, that's fine if we have them, but until we have such, I don't know what else to run it on, but the types of animal testing that are being done. But admittedly, that would be a very difficult and hazardous situation.

Slocum: The idea of using the exaggerated doses--was evidently sound, as far as I'm concerned--far more than would normally be consumed by human beings. This, however, has become the so-called "maximum tolerated dose." If it is not, if it produces any adverse effect, it isn't "the maximum tolerated dose." And I think there are some examples, but I couldn't cite one if I had to now. In other words, there are built in systems to handle some of these things at

reasonable levels, but not...you can overwhelm these easily. Well, there's no distinction here, at the present time if it's toxic, even at this maximum dose then its bad, period. That's the conclusion.

Young: This is the way the FDA is made a joke by the strong pro-saccahrin forces, and not only made a joke, but it's also the basis of some kind of criticism from a scientific position that disagrees with this, and as I'm just curious about...

Garfield: Well, I think Food and Drug is working with the consensus of scientists, it is not unique. Many substances that are fed at the same high level do not produce cancer. It's a different kind of substance therefore, there's no correlation, but apparently enough work has been done so that they feel that there is a correlation. If you feed at a high enough level and cancers do not result, you feel it is safe.

Young: Then contrary - wise is Laetrile.

Roe: I think you have to use exaggerated levels in all your animal feeding tests but I think maybe we've gone too far in that exaggeration in some cases where the test material was beginning to form a considerable part of the diet of the animal, replacing the...then you're getting into a really artificial situation and really overwhelming the animal too far. Now the thing that has

pushed us on that, I think is the Delaney Amendment, where you're trying to find out, does it produce cancer? Well, you can...I think perhaps they've gone too far and haven't left enough judgement on the part of knowledgeable scientists as to how to interpret. In excess feeding of some of them, but I don't know, on the whole, I think that the procedures followed have been the best available. As Fred suggested, Food and Drug has tried to follow the consensus of scientific opinion. Now, there have been different opinions on this thing, and one of the things I did in the last few years I was in the bureau, was to ask for an advisory committee in this area to evaluate the problems in determining safety on chemicals in various foods. My argument...my request for that was based somewhat along this line, that I requested, or proposed, or recommended such a committee to point out that our scientists had this very serious responsibility of passing on the safety. These chemicals proposed were pesticide residues or food additives, all of these things. But it was important that they have the benefit of the reviews of the scientific committee generally; that there were differences of opinion within the scientific community as to what is

a proper test procedure; what is the proper evaluation of the results of the test for instance, on DDT which produces tumors under certain conditions. It was then designated benign tumors, but there are certain scientists in the area that say this is, in a sense, the beginning of a carcinogen. And I think that it's extremelly important that we have the interchange between the scientific community generally, and our scientists so that there's no question but what we have the support generally of the scientific community with our people. There are some differences within our own staff on how this should be done and how it should be interpreted. I was frankly beginning to get worried at that time, just where are we? There are differences even on our own staff and differences in the outside community. Let's be sure. Well, a committee was set up, I don't know just how far it's gone, but the point I wanted to make, I remember many times asking Dr. Lehman about DDT. He said "What about it?" Some people say this is a carcinogen. "No", he said, "it's not." He said there's a distinction between a tumorogen and a carcinogen. And I think he was following the consensus of scientific opinion at that time. But now DDT is labelled the other way. I think there's been more acceptance of the other opinion as a scientific truth.

We're in a very difficult and a very hazardous operation here, trying to determine what is toxic; what is a carcinogen; what is a proper test; and how do you evaluate the results of the test that you had. It is not going to get any easier.

Slocum: One opposed scientist who will shout over and over again to the public that it's bad, that's all you need though, to destroy anything. I've been lucky enough to attend meetings in the last year or two where some of these questions have been discussed pretty thoroughly. There's a very strong consensus now that saccharin is a very weak carcinogen. I think scientists pretty well accept this. Nitrosamines are strong carcinogens. I'd like to have had them identify these things, but I just don't see how the present testing, you know, where it all gives us answers that really are reliable.

Young: Do you think there's a cockpit in which scientists can gather and can reach a consensus that's broader than at present, or is this just...

Slocum: Have you been following the Virgil Wodicka Committee...the what's the name of it now...?

Young: No, I'm afraid I haven't. What's it's auspcies?

Slocum: Well, it's a kind of consortium. I think it's supported by several groups but its mission is, I think

FDA is part of the support, is to devise a system of testing of all kinds of compounds to determine their safety, and they are coming up, and there have been some preliminary reports here of the decision tree type of operation. They start with the usual short term tests with acute doses and so on. They, rather early in the stage, if there's any evidence of toxicity at all, they go to the type of metabolism. What is the metabolism of the drug, in a species of animal that they can predict it in man. How is it metabolized; what are the end products; what happens to them, are they secreted or are they stored? And right on down to your long, very long term tests.

Young: Victor Wodicka, you say?

Solcum: Virgil Wodicka. He was the former Bureau Director of Foods.

Garfield: That looks like a very promising operation. I think a lot of people have a lot of faith, it's going to produce something quite useful. And give you points, where you say okay, we can stop at this point, it is either too toxic or essentially harmless and there's no point in testing further. Literally, if you've got to go through the whole tree it is going to be

very expensive.

Roe: Well, obviously, this is a very expensive and time consuming operation, and with the hundreds, if not thousands, of chemicals that may be coming up for tests there just aren't facilities available for doing the kinds of tests that we're doing now.

Slocum: This is a broad based study. I'm sorry I can't just remember the auspices and all, but I think you'll find a number of people in FDA that'll know all about it.

Janssen: I have a quote someplace, a paragraph that Wodicka wrote about safety being kind of an abstraction, the absence of harm, and how difficult it is to prove the absence of something. He spelled this out very neatly.

Slocum: There was a symposium of this at IFT last year. If you have the Journal of Food Technology, I think you will find...probably in the fall...All the people at the symposium will be listed there.

MacFadyen: If the Delaney Amendment had not been added; it was added rather hastily at the end of the legislation...would the FDA have had the trouble with saccharin that it's now having?

Slocum: The commissioner said publicly, that even without Delaney, the evidence is such that he really felt it

necessary to ban it.

MacFadyen: Because the FDA took the position in '58 or so when Delaney insisted on the cancer clause, that it didn't make any difference, and it didn't add anything new to the law.

Slocum: We took some action where the Delaney clause could have been used but FDA elected not to use it.

Roe: Well, when that was first proposed, the Food and Drug opposed the Delaney Amendment on the grounds that it's not desirable for Congress to legislate on specifics of this kind, that in evaluating the safety of a product, we certainly are not going to okay a product that's a carcinogen. And so we felt at the time it wouldn't make any difference on that, but that it was a bad precedent for the Congress to try to legislate on a thing that involved really a scientific judgment, and appraisals of appropriate tests and the results of the tests. Then later, when the amendment was in effect, the department reversed the view and said, well we would oppose the abandonment of the amendment, when there were some proposals made to rescind it. I don't know just what their position is now, except that I think it's much, as Fred has indicated, that Food and Drug feels that it really would do about the same thing either way. Now actually, until recently, the existence of the

amendment hasn't really made any problem except in certain veterinary or animal feed products where there was a revision made that permitted them to be fed to animals, at least for a while, as I recall, provided it didn't put in any residues in food products of the animals.

Slocum: The part that bothers me is, you would think that with all the testing (there's been a fantastic number of tests in saccharin) results are pretty much equivocal until the Canadian study came along. Now, when you stop testing? You know, this can and does go on endlessly, as long as anybody has a question about it, it's going to be tested all over the world, and it is, literally. I guess you could probably test water long enough to find that a little too much of it is bad for you. I am sorry, I'd like to ask to be excused.

Young: Maybe we all should adjourn at this point, and really, I'm most grateful to you for coming and...

Slocum: I lived close by in Kensington if you should want to call me, or if I could run over any time, and I'd be very happy to help.

Roe: It's been most interesting to me and I was glad to participate.

Porter: This concludes the June 29th tape.