

HISTORY OF THE
U. S. FOOD AND DRUG ADMINISTRATION

Meeting for the purpose of discussing
the history of FDA administrative
practices and policies with retired
FDA administrators, Rockville, Maryland,
June 30, 1978

Attending: Dr. Ralph Smith
Arthur Checchi
Gilbert Goldhammer
Elizabeth Kelly
Wallace Janssen
James Harvey Young
Richard MacFadyen
Terrance Gough
Nancy Ross
Fred Lofsvold
Robert Porter

INTRODUCTION

This is a transcription of a taped discussion between retired U. S. Food and Drug Administration administrators. 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.

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Food and Drug Administration.

DATE: 6/30/78

PLACE: Rockville, Maryland

LENGTH: 295 Minutes

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This is a recording of a meeting which took place at Rockville, Maryland On June 30, 1978. The purpose of the meeting was to interview retired F.D.A. administrative 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. administrators who attended the meeting were Arthur Checchi, Gilbert Goldhammer, and Dr. Ralph Smith.

Dr. Young's opening statement began with a reference to the letter inviting Miss Kelly, Mr. Checchi, Mr. Goldhammer and Dr. Smith to the meeting:

Young: I was just repeating a little bit of the letter and we are asking your help in order to shape the history of this agency between the 1938 law and the 1962 law. We thought that some of you who have spent years valiantly working in behalf of the agency could give us some help about important transitions, important trends, important problems, intriguing case histories.

that illustrate points of importance. So, lets just start off the way we did yesterday by letting each of you use a few minutes to tell us what the nature of your responsibilities were, what the time period was in which you were active in the agency, and then after that we'll ask you some leading questions in order to seek your help. So, will you start out, Mr. Checchi?

Checchi: Sure. I joined the agency in 1945 as a Food and Drug Inspector in the Boston District; Boston Station in those days. I was an inspector for various typical inspectional assignments for about four years I guess and then I was made Food and Drug Officer. I'm not sure what that relates to today, but Food and Drug Officer in those days was essentially the assistant to the District Director. He held all of the hearings, handled most of the trade consumer correspondence and then pinch hit for either the District Director or the Chief Inspector in their absence. That was until 1952. In late 52 I was transferred to the Kansas City District and I served there for two years in the same basic type of job and then at the end of '54, I was transferred to Washington and I worked as an assistant to Frank Clark who was the Chief Inspector of Food and Drug Administration in

what was then the division of Field Operations. And there again my primary job was putting out the first major revision to the Inspector's Manual, reviewing Inspection Reports, helping Frank make personnel decisions on who ought to be promoted, who ought to be transferred and that sort of thing for the inspection side. And mid '56, lets see, a year and a half in Washington, then in mid '56 I was transferred to the Denver District as Chief Inspector. I was there about six months and then January of '57, I was transferred back to Washington again and was made assistant to the then Deputy Commissioner, John Harvey. The Commissioner's Office of the Food and Drug Administration in those days was, I guess five of us, wasn't it Wally? (Right) Jack Harvey, the Deputy Commissioner, George Larrick was Commissioner, then Wallis and, Winton Rankin and I were the three assistants in the Office of the Commissioner. And that job, again the nature of the things the first roughly a year was handling things for the Commissioner; some personnel matters, internal management matters, handling a lot of trade correspondence, consumer correspondence, helping arbitrate some arguments among people down below so the Commissioner wouldn't have to get his hands involved. The usual sort of thing

one would expect of an assistant. And then with the passage of the Food Additive's Amendment, the Commissioner decided that the management of the program should be kept in the Commissioner's Office and I was placed in charge of that. Writing the regulations, setting up the basic program for the management of food additives. So that for the last roughly year and a half of my stay in the Food and Drug Administration probably occupied 75 to 80% of my time and the balance of the time was general assistant duties to Mr. Harvey. I left the Food and Drug Administration in let me see, very late, I think it was November or December of 1959.

Young: Thank you. That was fine.

MacFadyen: Could I ask you where you went when you left?

Checchi: Yes. When I left the Food and Drug Administration I joined my brother's firm. He was in economic consulting, he had an economic consulting operation. They were expanding their function and they wanted to do some things that were of interest to me overseas, so interestingly enough, when I left I had thought I had cut or severed all ties with Food and Drug work. I was taking on management jobs in Europe, Africa, but a lot of people who knew me in government

called me and asked me if, since I was in the consulting business, could I give advice on Food and Drug matters, and I said well, sure. I didn't realize that the advice I'd been giving away all those years was worth money, so, I started a kind of a, or rather a Food and Drug consulting business started because I went with it. And I suppose the first eight or nine, ten years after I left government only about 25% of my time was spent on Food and Drug consulting. I was more interested in developing other areas of activity and just to complete the personal history had a heart attack in 1970 and had to give up all of the traveling I was doing. So I started, at that time, had to make a choice whether to live overseas and run an enterprise or to live at home and live in the United States and start a, build up the Food and Drug consulting practice, and I opted for the latter. Since 1970 I've done nothing but be a Food and Drug consultant and developing an organization to handle that work.

Young: You have a rather good size alumni association.

Checchi: Yes, we do. We had an alumni meeting. We haven't developed the fight song yet, but we are working on it.

Young: Dr. Smith?

Dr. Smith: Well, I joined the Food and Drug Administration in 1950 and retired in 1970--a period of about 20 years. I came in to direct their new Drug Program. I believe that my title was Chief of, well it was called the New Drug Section of the Division of Medicine at that time and then later became a New Drug Branch and then a New Drug Division. Of course, over the course of years the staff has increased enormously. When I came in, there were three of us in New Drugs. Another medical officer, Dr. Earnest Q. King, who was with the Food and Drug Administration for a good many years. I was supposed to administer him, which was impossible. And the other man was Julius Hauser who attended to the manufacturing control requirements of New Drug applications. I don't know whether you, is that all you want at the moment?

Young: OK, let's just leave it at that because you remained in the same responsibility though the name of the office changed throughout those, well...

Dr. Smith: Well, until 1966. Then I was involved in the Drug Efficacy Study. I became the liaison of the Drug Administration for the National Academy of Sciences.

Young: I see.

Janssen: Who recruited you into Food and Drug?

Dr. Smith: Erwin Nelson. You see, I knew him, he was my senior at Michigan years before that, and he later became Professor of Pharmacology at Tulane. He left Tulane in '43, and when he left, he got me to go to Tulane as Professor of Pharmacology. And then when he was made Director of the Division of Medicine, after having handled the New Drugs here, he induced me to come to Washington and that was how I came to New Drugs.

MacFadyen: Are you an M.D.?

Dr. Smith: Yes. And PhD too.

MacFadyen: In pharmacology?

Dr. Smith: In pharmacology. My M.D. is from Toronto, the University of Toronto, and my PhD from the University of Chicago, '25 and '28 respectively.

MacFadyen: The same kind of pattern that Dr. Kelsey followed.

Dr. Smith: More or less I guess.

Young: Miss Kelly you did speak yesterday while you were here.

Miss Kelly: Yes, I did.

Young: Our other guests, know you from having worked with you, so maybe you won't have to repeat it.

Kelly: No, I don't think it is necessary.

Checchi: Ah, come Liz.

Smith: Maybe you'll tell me sometime what you said yesterday.

She used to have some, ah, beautiful girl assistants in her library.

Kelly: Well, that's something, isn't it? Well, I'll pass the word on to them.

They were all beautiful.

Young: Now, you spread out over different kinds of responsibilities for your work, and I said, the kind of help you can give us. What about major turning points in the course of the agency for good or ill during the course of your experience? Where and what were you most particularly concerned with, or in a broader sense as well. Somehow or another the Agency turned direction or was made to turn direction. Is that too big a question, or does something rise to your mind?

Smith: Well, the main thing that rises to my mind are the Kefauver investigations in the 1962 Amendments; investigations beginning in '59, late '59 I believe. We had a reasonably happy life before that happened.

Young: Do you have any recollections about your

first awareness of this? Were you around when the Senator came to the F.D.A. offices?

Smith: No, I didn't meet him personally. I met one of his staff one day in Mr. Larrick's office. About three of his staff showed up and began asking questions about how New Drug applications were handled and so forth. That would be, I believe, late in '59.

Young: How did you go about internally getting up the material that Food and Drug was going to present to Kefauver when they had their chance to speak before the committee? Were you hard at work in that project?

Smith: No, I didn't have too much to do with that. I remember the Commissioner's office worrying about it and I remember Kenny Milstead talking about it to us and, coming down to consult, and so forth. Of course, the thing that comes to my mind. (Tape turned off, Mr. Goldhammer arrived)

Young: What we just concluded doing was letting each member of our distinguished panel say a few words for the benefit of your young recruits to the profession, what their association was with Food and Drug and maybe how you came in and what you have done since, as well. So would you do that, please?

Goldhammer: My name is Goldhammer, Gilbert S.

Goldhammer. I joined the Food and Drug Administration in 1935 after teaching chemistry in the New York City school system for about five years. I came in as an inspector and Administrative Assistant to the Commissioner. In 1948 the Division of Regulatory Management was formed as an administrative Division in Washington and I went over to that division. I became Assistant Director and, ultimately, Director. In another reorganization, about 1963, the Bureau of Regulatory Compliance was set up and I became its Assistant Director for Regulatory Operations. In 1964 I retired and became an industry consultant. Since 1971, I have worked for a Congressional Subcommittee of the Committee on Government Operations as a consultant. We have oversight jurisdiction for HEW, which includes F.D.A. And that brings us up to date.

Young: Thank you very much.

We'd begun to talk about the F.D.A. of your period and I had asked a kind of a broad and maybe a little bit intangible question about turning points. Dr. Smith was talking about the turning point represented by Senator Kefauver's inquiry beginning in late 1959, I believe it was. Any more on that, Dr. Smith?

Smith: Well, the specific thing which jolted not

only the Division of Medicine, it might have been a Bureau, I can't remember. And, not only the Bureau of Medicine, but the whole Food and Drug Administration was Dr. Moulton's testimony before the Kefauver Committee. I recall going over that day and listening to it and everybody was seriously concerned and the next few days were taken over by many people in the Food and Drug Administration in developing replies to her testimony.

Young: Was she a member of your shop at the time?

Smith: No, not at the time. She was recruited into the New Drug Branch in possibly 1955, somewhere around there. But before this time, she had been taken out of New Drugs by the Director of the Bureau and had been placed in another Division of the Bureau of Medicine. I've forgotten what it was called at that time, but they were concerned more with regulatory work, you know, with Gordy Granger, and maybe Elizabeth remembers what it was called. Well, it doesn't make any difference.

Checchi: Goldhammer's Raiders is what it was called.

Smith: But shortly before this, she resigned from the Food and Drug Administration and she was on her own at the time.

Checchi: I believe the division called it Division of Medical Review.

Smith: I believe that's right.

Young: Is there anything about that issue, that kind of critique that she represented, now, that might be hard for us to get at from the paper documents, either through the printed hearings or other things that you think might be helpful in throwing light on this crucial period?

Smith: Well, I don't know. Of course, there had to be an element of truth in what she said; in her testimony even though I was critically mentioned, very critically mentioned at that time. And she was, I believe, very emotionally involved; felt very strongly about certain questions and the way the situation was handled. I do not believe that she wanted to be taken out of New Drugs when that move was made.

MacFadyen: She claimed, as I recall that she was taken out because she was not courteous enough to industry. Was there any truth to that? Why was she taken out of New Drugs?

Smith: I think that the Director of the Bureau was getting pretty severe criticism from industry over

some of her actions.

Checchi: I wasn't involved there, Ralph, but wasn't ah, Barbara a very headstrong person who would not take a different opinion from her superior?

Smith: Well, I think that's true.

Checchi: Wasn't she just plain hard to manage?

Smith: Ah, yes. I would say that she was. And even after she left Food and Drug Administration, I imagine that she was hard to manage in the Federal Trade Commission. She was like that. She came from a very important family and she felt a considerable degree of self-importance, and, ah, was aggressive.

Young: You are saying there was an issue here that was later explored at great lengths that was part of the issue of the major turning point.

Smith: Yes, well, her main criticism as I recall from the testimony was that New Drugs were being allowed to go on the market which should not go; that is which were not safe. And, ah, they were going in spite of anything that she could do, or tried to do.

Young: Was this in a sense, the science of the thing getting more complicated and the pressure of numbers getting greater so that her criticism was reflecting not just the situation within the Agency, but a situation within the burgeoning pharmaceutical industry?

Smith: Yes. I think that's true. Of course, there was the new drugs which were beginning to come into existence at that time which were very active chemical agents and had the capacity for causing harm as well as good. It was the beginning of a time when the tranquilizers were being introduced and I remember a part of her testimony at least was on Promazine which she thought should not have been approved. And, of course, that was her opinion, and there was probably some truth in it.

Young: One of the questions that we talked about some yesterday with some of your colleagues who happened to be here yesterday was a question of the relationship between the Food and Drug Administration and Industry as a problem through time. And, this relates to, is there, did you notice that there were, through time, changes in the stance, whether relatively friendly or relatively arms-length between the Agency and Industry that took any kind of clue from the broader political climate. Were there times in which the position of the Secretary, the position, maybe of the President, the flavor of the Congress and so on, meant that there was a difference in the way the Food and Drug Administration did and perhaps could operate, in the way it went about its mission

vis-a-vis Industry?

Smith: There was definitely a difference which occurred at approximately the same time of which we have been speaking. Before that, certainly the New Drug people operated under an open-door policy. As far as I know, we never turned down an appointment unless there was some very good reason. As a matter of fact, our days were sometimes almost entirely involved in talking with members of the pharmaceutical industry about their New Drug Applications. And, as a general rule, they were received on a friendly basis. They had no hesitancy as far as coming into the Food and Drug Administration and probably took some advantage of our attitude. Not only that, but we undoubtedly accepted a certain amount of favors from the Industry. Nothing important, but there were quite frequently lunches, that is the Food and Drug Administration people were taken out to lunch by the visiting pharmaceutical industry. That depended a great deal upon the individual in the Food and Drug Administration. And, I at one time, before the change occurred, I felt that it was being overdone in certain instances. For example when a man would come down to talk about his New Drug Application, I have seen him take out five

or six, that is anybody who wanted to go at lunch time. This didn't necessarily mean that any favors would be returned to them, but what bothered me, of course, was that two hours were lost. You can't go out for lunch downtown without spending two hours out of the day. And that can just disrupt a good part of the day.

Young: These are episodes that indicate an atmosphere. Let's broaden this question about the climate in order to ask the rest of you to comment on the question. Gilbert do you...

Goldhammer: Well, apropos of the question of going out to lunch with industry people--it was frowned upon by Food and Drug Administration officialdom. I remember that from 1935 to at least 1960, we couldn't accept paid lunches. We were prohibited from doing so on the theory that it becomes very difficult to rule against a fellow who has been generous to you. I mean even if you don't want it, there is a subtle type of influence that is exerted on the recipient of the favor, and it becomes a little more difficult to rule adversely in such circumstances. It may not be with any malpurpose that the free lunch is offered, but it becomes difficult to be objective in a situation like that. Coming back to Dr. Smith's statement that the Kefauver hearings had

--it had a profound effect in several ways. Of course, it lead ultimately to the enactment of the 1962 Amendment, but aside from that, during the course of the Kefauver Hearings, they latched on to the Welch affair and they exposed that. And that was a factor which influenced the Congressional subcommittees which came upon the scene later, like the Fountain committee; like, Humphrey's committee. Even McClelland's committee got into the picture for a while. Because they figured that if there was some malfeasance in the Welch matter, they may be some malfeasance elsewhere in F.D.A. and they all wanted to see what the situation was. It really initiated the era of close oversight by Congress. Before that, there was practically no oversight. Now, as far as the Kefauver committee was concerned, they didn't have oversight in mind. Remember Kefauver committee was an anti-monopoly subcommittee. What they were interested in was to bring down the cost of medical care, particularly for drugs which they thought were too high because of monopolistic practices. They thought this could be accomplished through the Food and Drug Administration, if they could somehow put all drugs--generic and trademark drugs--on an equal basis so that the medical profession would have confidence in generic drugs as well as the trademark drugs. They came to the Food and Drug Administration and

inquired as to what is necessary to assure the potency and priority of generic drugs so that the medical profession would prescribe them.

(break between tapes)

Commissioner Larrick's first reply was by certifying all drugs in the same way--we were certifying the antibiotics --by certifying all drugs or by putting a Food and Drug inspector in every drug manufacturer's plant to supervise production. That was the only way the Food and Drug Administration could assure that every batch of drug would be of suitable purity or equal purity and potency. Of course, that was out of the question. So they compromised and decided to strengthen the inspection requirements of the law. They thought that it was that way they could engender medical confidence in the generic drugs. But it never worked out as planned as we now know; the cost of medicine continued to go up. But that was their purpose. Then they latched onto the Welch Affair and it became a kind of an oversight operation rather than a legislative operation. That led also to an inquiry into whether the Food and Drug Administration was adequately supervising new drug innovation. In other words, it began to be rumored, and I think this came from tips from Food and Drug employees to the Committee people, that the Food and Drug Administration was not

rigid enough in demanding proof of safety. Chloromycetin came up, and I recall the staff people being appalled when they looked over the New Drug Application for Chloromycetin, not the New Drug Application as we now know it, but the comparable thing over at Antibiotics. They were appalled by what they thought was puny evidence of safety and that served as a basis for severely criticizing F.D.A. From all of that, I remember my impression that this was going to be a deterrent on the Food and Drug Medical Officer. He was not going to want to take the responsibility, as I saw it, for making decisions because if he made a decision on a basis which did not please a Congressional committee, he could then be subject to a lot of criticism and a lot of embarrassment. I felt, personally, that this was going to slow up the process of New Drug consideration and approval. So I think that was one of the big things that came out of the Kefauver Committee, aside from the legislation. It caused a great deal of consternation within the Food and Drug Administration. It encouraged those medical officers who had a feeling that drugs were being passed without adequate proof of safety to come forward and give tips to the people in the Congress who had oversight responsibility. Apparently, there was a constant stream of tips going out by F.D.A. employees on this drug and that drug, I could glean that because

I was at that time liaison between F.D.A. and Congress. From the kind of demands or requests that were being made of me for records and other things I suspected that they were getting a constant stream of tips. Now I don't know who the tipster was, but Congress was onto a lot of things that bothered some of the employees in the New Drug Division. Was it a Division at that time?

Smith: I think so, yes.

Goldhammer: Of course the tips went, not only to Kefauver, but also to the Fountain committee.

Young: Yes, the coming of the oversight age, you are saying is one of the important transitions.

Goldhammer: That was an outgrowth of the Kefauver Hearings.

Young: Right, ah...

Goldhammer: Because before that, aside from appropriations hearings, we had almost no Congressional hearings to attend. Certainly no oversight hearings.

Checchi: I think in looking at sort of critical turning points, I agree with everything that these folks have said. I think, though, that there is a step, at least one step before that, and I am sure you have looked at the effect of the first Citizen's Advisory Committee report and the second. Bear in mind that until 1955, 1956, F.D.A. was one of the smallest and most insignificant, from a budgetary standpoint, agency in the government.

No one paid a lot of attention to the F.D.A., not the Congress, not the White House, not the Secretary.

Young: Not the public.

Checchi: Not the public. They had never heard of it. The Agency had a budget in those days of four or five million dollars and if we got a half a million-dollar budget cut, unlike today, where they can absorb a five-million dollar budget cut without any headache, half a million dollar budget cut that we got in 1953, we'd lay off people. Now, you raise the question of attention from the White House attention from the Secretary's office. Substantially, we got none. It was a bunch of professional guys; I don't want to sound or blow our horn, but basically it is a bunch of professional guys doing a professional job. Perhaps it could have been done better, or not, I am not going to defend that, but I think the key thing is that no one really paid too much attention to us. F.D.A. went up, got its budget and everyone said you are doing a good job. Go home. We'll cut you \$200,000.00 this year, or we'll give you a \$200,000.00 increase, but by and large, it made no waves and no one paid a lot of attention to it. With the first Citizen's Advisory Committee that was in 1955 and 1956, in that

period, for the first time, I believe, the political powers started paying attention to Food and Drug. Well, what is this little baby we've got downstairs here on the third floor of the HEW? What is it that they do, and more importantly, what is it that they should be doing. And it was at that time, that the Congress said, ok, we'll buy your Citizen's Advisory Committee Report and they started a program of increased appropriations. And it was, perhaps there is no cause and effect, but as we lead from that period on up into the period that Ralph and Gil are talking about, F.D.A. was then a growing Agency. You can debate for hours as to whether or not the Agency from the management standpoint was properly equipped for the growth that it undertook and you'll get all sorts of pro and con discussions, but the fundamental thing I believe is, that, you know, you talk about turning points in the Agency's history, it was after that Citizen's Advisory Committee and the second go around which came along about '60 where they said, ok, they've done reasonably well, they've done this wrong, they've done this wrong, but in principle, it should be full steam ahead, and the Agency then started to get more exposure. And with exposure it started to get more attention from

the Congress, from the public and, of course, the political powers that be. And, I think, call it traumatic, or call it whatever you will, among the influential developments in the history of F.D.A., the impact and the aftermath of the Citizen's Advisory Committee activities are quite important. Along that same period, you know if you want to pick an isolated incident, which probably is silly, but was it Flemming, the secretary who jumped overboard on the aminotriazole. And, there again, while this was not planned, of course, the Citizen's Advisory Committee was obviously planned by the Commissioner. He needed growth, and here was something that they planned for. The aminotriazole, like Dr. Moulton's testimony just kind of popped in out of the blue. And I think it had an effect because to my knowledge, for the first time in the history of the Food and Drug Administration, and certainly during my brief stay there, that was really the first time that the political master, if you will, had made an F.D.A. decision. It was the Secretary's Department, I believe that made that decision on the aminotriazole.

MacFadyen: Is this the cranberry?...

Checchi: Yes. So I think right there you had essentially for the first time, an Agency that was starting to grow

so that the Secretary of the Health, Education and Welfare gave the Commissioner a direct order as to what to do. I think that from then on, of course, with growing exposure then as Ralph said, we started down the, ah, this was after I left.

Young: Is there any implication that Secretary Flemming overruled F.D.A.?

Checchi: I wasn't there. I don't know. Then, I think another thing, if you will, that bears examination in terms of turning points of the Agency, if I can just jump ahead, and that is when the Agency went from the career oriented Commissioner to the outside appointed one. I am sure you've heard that a thousand times, so I won't dwell on it. But I do believe that coming at the time that it did along with the external factors of the consumer movement in the country and this whole shift from--F.D.A., up until 1960, that's the only time I can really speak and that's when I was there, was certainly by today's standards, and even by the standards of the 1950's, a very conservative Agency. It was based on precedent. Before it changed its course, it sweated

it out, it thought it out, it argued internally with itself, do we go this way? Because the Agency was very sensitive to the fact that having made fundamental commitments in policy, that a lot of people were gauging their affairs, public and private on the announced policy of the Food and Drug Administration, and therefore the Agency was extremely sensitive to this. And it didn't just say, well that was yesterday. Now we are going to do it this way. The Agency recognized that if it said, well, we're not going to do it that way anymore, we are going to do it this way, that this would have a profound effect on the thinking and activities of a hell of a lot of people, and that was extremely...

Young: Let me just put something in there that is a matter that interests me. If it was this kind of conservative Agency, do these later major turning points in some measure get precipitated by the fact that the job that it legally had to cover was moving faster than it's conservative approach toward decision making, let it come to grips with. You particularly had a lot to do with the additives. What I wrote here was, "What mechanisms did F.D.A. have for anticipating problems from a burgeoning technology in Food and Drugs?" Do you have any feeling that

The later problems arose because the conservative policy that you are describing considering that drugs, the chemotherapeutic revolution and, what I once called the chemogastric revolution, were such big things that you weren't quite keeping up administratively with the task that was there. Say additives...

Checchi: Well, obviously I'm a prejudiced and biased observer, but I think that, ah, we have obviously a yes and no answer here. In a sense it was not keeping up in that the Agency developed management problems in the middle and early '60's, which in part lead to the changeover. I would say that if, that the conservative approach of the Food and Drug Administration was no where near as far behind, technological developments as a lot of people would like to say. In the 1950's, F.D.A.'s problem was not it's conservatism. It was lack of funds and people. If the Food and Drug Administration in 1950's had had probably a 50% greater staff, if Ralph Smith and his people, instead of having two M.D.'s he and Earnie King and Julius Hauser who was his Administrative Officer and Chemist. So the Food and Drug Administration in the early '50's had two men reviewing New Drug Applications. Now there is no way

in God's green earth even in the 1950's that this is anywhere near an adequate staff. I don't know how many people they have now in the New Drug Review. It must be in the hundreds, physicians. Now, the problem of the Agency in the 50's was not its conservatism, but rather the conservatism, if you will, of the Congress and the political party in power that treated it in a very niggardly fashion from a budgetary standpoint. You can't grow professionally if you don't have the money to pay the people. And this was the problem of the Agency not, its basic philosophy, while conservative in nature, was kept up. It had, and it had the capability, the professional capability, it just didn't have enough of it. So, I, for one, would argue till doomsday that if the Congress and the political powers in the 50's had been more realistic in its F.D.A. budgeting, that the Agency would have kept up and would have been in a leadership role and not been dragged if you... A lot of people take the view that the Food and Drug Administration was dragged, kicking and screaming into the last half of the 20th century. And I say this is just not so. The Agency, forgive me for being...

Young: No, I want this.

Checchi: But, I just feel extremely strongly about

it, is that the fault of the Agency, the faults that the Agency finds itself in today, the severe criticism is really, ah, the Agency was undermanned and underfinanced. Now, I'm not saying it was a perfect organization. There were a lot of guys, a lot of people there that if I were God, I would have fired if had the power in the 50's and we all would. We were all there at the time. But as I say, this is inherent in any significant organization.

Young: You talk about the political climate, that didn't expand the Agency as it should have been done. It was actually the business group which sort of saw that political climate as being injured itself that played a major role, did it not, in the Citizen's Advisory Committee of 1955. So that you had a Republican political climate that might be not giving enough funds, in fact, taking away funds at that point, but you also had the regulated industries to some degree saying F.D.A. has got to have more money because didn't they play a major role in the business elements, play a major role in the Citizen's Advisory Committee of 1955?

Checchi: That's my recollection. The business community supported growth in F.D.A.

Young: Well, I asked the question originally because,

Wiley's period was quite different from the '20's. Campbell in the 20's in a quite conservative political climate, in order to get things done, had to be more cooperative with business than he had to be when the '30's climate came. And so I was thinking of these big sweeps in that regard. But, thank you for that answer because that interpretively is very helpful to me.

Lofsvold: Could I raise another question on that?

Young: Any time, really.

Lofsvold: Was there an element here too that the Agency was somewhat reluctant to really press for funds? I am thinking that Dunbar was always so economy-minded. Was there a hesitation to...?

Checchi: I was only in Washington during George Larrick's administration. So I really can't say. Gil was here during Dunbar. I'm not aware. I know during the '50's, '52, '54 when I was here, as you know the budgetary process, you work out, internally, within the department first what they will let you ask for.

Young: Yes.

Checchi: And there was no, I can only say that during the, ah, George Larrick's Administration, for the six years that I was in Washington, I never detected any

hesitancy on George's part to ask for money, and he never got what he asked for. That is he never got what he asked for in-house. As you know, the budgetary process, you go before the Congress and ask for what the Bureau of Budget will let you ask for. But, ah, internally, as a matter of fact, Fred, the basic purpose, well not the basic purpose, but one of the real reasons that Food and Drug, I think it was Charlie Crawford who started dreaming up the idea of the Citizen's Advisory Committee. But at any rate it came to being during George Larrick's day. But the whole purpose of asking for the Citizen's Advisory Committee is, my God, we need a bigger organization. And nobody will listen to us. Maybe by having this Citizen's Advisory Committee to evaluate the thing. So the mere creation of the Citizen's Advisory Committee says to me, Fred, that at least, at least the Crawford, Larrick period, there was no reluctance to seek more funds, rather very much a commitment to that.

Lofsvold: I would agree with that, but I was thinking of perhaps a few years earlier, well, ah, before Dr. Dunbar retired as to whether we'd made any move then. Do you have any idea when Crawford concluded that he should go this way?

Janssen: 1954. And it was a consequence of the "beet ball" episode, after the cut. It was a consequence of that.

Checchi: Oh, the beets, the baby beets.

Kelly: Well, what about the apple chops? Anybody mention that?

Janssen: And it was Charlie Crawford's awareness of the fact that for years the F.D.A. had been in a financial rut and unable to get the Department to go on with more money, a larger budget request. You have to remember the system that develops the budget. There are a lot of hurdles before you get your figures before the Congress. And then, I think at the time, there was ah, I think there was a lot of business influence, a philosophy I think was prevalent that it was good to have good laws, but just don't give them too much money to enforce them. That, I think, that was an attitude that existed in certain places. So, Crawford thought of the idea of setting up this Blue Ribbon Committee and he took it up with the Under-Secretary who was Nelson Rockefeller and I wrote Rockefeller a very, detailed, lengthy letter, which is in the files and he wrote him, he had other documentation and we prepared material about how much it cost to, protect the meat supply of this

country in contrast to what it cost to protect the supply of all other foods and drugs, etc., and a great deal more, of course, was being spent to insure the safety of a pound of meat than was being spent on anything else. Rockefeller supported this plan. At that time, in the Eisenhower Administration, the idea of having outside committees to study things and make recommendations was very popular and, in some respects, it was a way of putting off action, and first study the matter, and don't act until you can. Maybe you wouldn't have to act at all, if you studied it long enough. But, they appointed the committee. Now, the important thing about the committee is that it was supposed to represent all walks of life, and, it did represent major segments of the American people, but there was a very strong industry representation on it, and the important thing about that was the particular people who were involved. One of them, of the chairman, was G. Cullen Thomas. And I have heard, but I have never been able to confirm, and unfortunately, Mr. Thomas is dead now; he just died a couple of years ago, that he had been one of the Poison Squad members at one time when he was young, early in his career in Washington. He was chairman

of the committee. Then, of course, another member, a very important member, I would dare say the key member, really, was Charles Wesley Dunn, who was the Grand Panjandrum, I guess maybe or Pooh-Bah of Food and Drug Law; had been for many, many years. He was the very picture of a, ah...

Checchi: He looked more like Oliver Wendell Holmes than Oliver Wendell Holmes did!

Janssen: He, was a Mr. Tutt, if you remember those stories in the Saturday Evening Post; a unique character who fancied himself as the chief architect, guardian and supervisor of Food and Drug law and Food and Drug law enforcement and he did all kinds of things to, enhance the image; the importance of the Food and Drug laws. He did a great deal of good, really, and of course he was the founder of the Food and Drug Law Institute, the Food, Drug, and Cosmetic Law Journal...

Young: Even though he fought hard consumerist approaches in the 1938 period...

Janssen: He lobbied against important parts of the 1938 Act, but on the other hand, he, believed in a strong F.D.A. and when the Citizen's Committee report, the CAC 1 Report was drafted, it was Dunn who wrote in very strong language recommending a three

or four-fold expansion to be accomplished in a period of five to ten years and increase the number of inspectors to 1,000 and I don't know if we even have 1,000 inspectors now do we? I don't think we do. In other words, he established a goal for Congress and the Food and Drug Administration to shoot at in regard to financial resources. Well then, year after year this goal was remembered. It was not forgotten. The question was, what progress were we making toward this? And, then, we began to have more momentum and with the exception of only one or two or three years, I don't remember how many, but there were only a few years where the appropriation remained level. From that time on, it has always increased and now, of course, it is headed toward \$300,000,000.00.

MacFadyen: What was Dunn's motivation?

Janssen: From \$5,000,000.00 to \$300,000,000.00 or going on \$300,000,000.00 in less than 25 years.

1955 was the CAC 1 Report.

Young: A sixty-fold increase between 1955 and 1975.

Janssen: Now, about these Citizen's Advisory Committees, there is something about them that should be noticed, I think. One is that both of them, both CAC 1 and CAC 2 were staffed by business consulting

firms. And they listened to industry as well as to the people at Food and Drug. And, one of the things that bothered industry then and now was the fact that a business man could be a criminal under the Food and Drug Law. It is right in the law that he can be fined, or go to jail, as well as being fined, and they didn't like the position that they were in as being potential criminals if they violated the Food and Drug's Act. They didn't think they were, and it didn't sit good with them. However, they did like the idea of a law that was enforced by advice, consultation, moral persuasion, education, that sort of thing.

Young: So, you think that the shift in that direction owes a lot...

Janssen: I believe that myself too, to the extent that you can accomplish a purpose by such means, fine. But if you can't accomplish a purpose by such means, then you have to use the sanctions that are in the Act, including the criminal sanctions. I think that Charles Wesley Dunn, and many others, always felt that the F.D.A. had to be an FBI of the regulated industries as well as a scientific and advisory organization.

Young: Are you saying, Wally, that the Citizen's Advisory Committee influence was a weighty influence

in increasing the amount of regulation by other than seizure and prosecution cases.

Janssen: It resulted in an upgrading of the educational function and, under CAC 1, the information and education program was, in the first place they naturally criticized the existing effort because it was too little, and also...

Goldhammer: Was that the second committee or the first?

Janssen: And, not managed well enough, which I disagree with heartily, but, then CAC 2, that resulted in the creation of a Bureau of Education and Voluntary Compliance. Now, what had happened was that, particularly, I gave a very strong sales pitch to CAC 1 about education. (Part of Mr. Janssen's statement lost during tape change)... Attempted to hire people, and, for instance, there was one man from North Dakota that I wanted to hire who had proven his very considerable abilities running educational programs for farmers in the regard to the use of pesticides. He put out some very effective, cleverly contrived material, movies, slide shows and so forth. So I wanted to hire this man from the North Dakota Department of Agriculture and I was unable to get him because the grade wasn't good enough. So I told the CAC 2 staff people that this function ought

to be a bureau because if it were a bureau, well then the salary levels could be higher and we might be able to get some of these good people. Well, it did become a bureau, but the F.D.A. staffed it with folks from all over the Agency who were left over from other reorganization moves. It did some good, but I don't think it really reached it's full potential and then, of course, when Dr. Goddard came along, well the whole thing was scrapped. But, you've got, I think it's quite important to look at the personalities and to look at the underlying forces that are involved in one of the Citizen Advisory Committees. I think like that is the, it isn't a simple cause and effect. There are a lot of things that enter into the effect.

Young: Do any of the rest of you want to comment on the Citizen's Advisory Committees and the role as you see it that they might have made in the long-range picture?

Goldhammer: I'd like to comment on that. Before that, however, I want to trace a little the effect of the first Food and Drugs Act of 1906 on our whole enforcement philosophy and policy. And, you've got to remember that that first philosophy and policy carried over for a long time after the

new law came into existence in 1938 because we had a number of career Commissioners after 1938. They held their jobs for a long time, and people's opinions and attitudes don't change much. They hold rigidly to what they're accustomed to. So you had Campbell and Dunbar who were original people, who came in to enforce the 1906 law and, Crawford and Larrick, and they were all imbued with the philosophy of the 1906 law. They all worked under that law. I think that law lays down a policy of action. It doesn't allow for too much latitude on the part of the Administrator when violations are found. The law said, in effect, that the Food and Drug Administration will collect samples and analyze them. If it appeared that there was a violation of the law, they would refer the violation to the U. S. Attorney or to the Department of Justice. The Department of Justice, or the U. S. Attorney, will review the matter, and if he feels there is a violation, he will file a case. There wasn't any ifs, ands, or buts about it; there was very little latitude given to F.D.A. If F.D.A. believed a violation had occurred, they had to refer it to the U. S. Attorney or Justice Department. So, that was the practice when I came into the Food and Drug Administration. I was a little disturbed about that if a man violated the law, he was prosecuted, or his product was seized. And even

though the violation was not intentional, even though it was the first time it happened, it was treated like a cop catching a fellow crossing a red light. Chances are, he hands out a ticket and he is not going to be persuaded by any argument the fellow makes, even though this might have been the first time in his life that this happened. Now, that was the enforcement philosophy. If you slipped, you paid the penalty, and if your product was in violation, it was seized. In 1938 there was some moderation of that. For instance, there was a restriction against multiple seizures.

Janssen: Did the 1906 law provide for a hearing in advance of possible criminal action?

Goldhammer: Yes, it did. But almost uniformly, the practice was to refer the cases to prosecution. The penalties were very nominal. It was not at all unusual to receive a \$50 fine for the violation. Very few went to jail. So, it was more in the nature of a violation comparable to passing up a red light.

Janssen: Don't you think that the administrators felt an obligation to be tough because they knew the law was going to be weakly enforced in the courts?

Goldhammer: That's right. That may well have been it. But the later years didn't change that philosophy.

It carried through until the first Citizen's Advisory Committee called attention in a mild sort of way that perhaps F.D.A. shouldn't be that much of a cop, but be a little more of an educator and gain compliance through that approach. But it was with the second Advisory Committee that drastic changes took place. It was after 1962, I guess it was 1962, that the report came out from the second Citizen's Advisory Committee.

Janssen: And there was a Public Health man named Harvey, Dr. Harvey from Michigan was it, who put into it some very strong language that the F.D.A. ought to go in the direction that the Public Health Service had gone. And, of course, the Food and Drug felt that that was very weak.

Goldhammer: Yes, we were consternated by the second Advisory Committee Report because we felt that you couldn't enforce the law by education. The lawyers of industry knew the requirements of the law as well as the Food and Drug lawyers and it wasn't necessary to educate them. But, nevertheless, the mandate had been handed down by that committee and the Commissioner followed suit and said that, as has been pointed out by Wally. A division was set up specifically for the purpose of educating industry

working with industry, and there were seminars and instructional meetings held with industry all over the country, and so we were on the way. At the same time, there was a diminution of actions under the Federal Food and Cosmetic Act. The sanctions of the law were not brought into play nearly as much. Seizures began to drop drastically and, at the same time, a policy was created within the Food and Drug Administration for the substitution of recalls for seizures. There was no legislative sanction or authority for recalls and the Food and Drug Administration could not insist upon a recall. It was all voluntary. But it really wasn't voluntary because F.D.A. held a big stick over the firm. If they didn't recall, F.D.A. hit them with seizures. Of course, the producer recalled the goods rather than choose to appear in court to defend the merchandise.

Young: Were you part of the discussion that led to that change?

Goldhammer: Yes, I was in on some of those discussions. It was really...

Young: What was the apologia for making the change that underlay it?

Goldhammer: Well, it was a very insidious thing. Initially it was to be applied only to those situa-

tions in which the existence of a product on the market constituted a hazard to public health. That was first. Later on, recall was extended to fraudulent products and, very gradually over the years, it became a substitute for seizure and prosecution and no one person in F.D.A. is responsible for it. It was just a gradual increase in the application of the concept of recall that took over.

Young: Was it supposed to be more cost efficient? Was that part of the reason?

Goldhammer: It was thought to be fastest. After all, if you are interested in seizure as a concept of stopping the bullet in flight, you take the goods off the market by seizing them. The same thing could be accomplished, however, if you could get the cooperation of the manufacturer and have him stop the sale and issue a request to the distributors of the goods or to those to whom it has been shipped to hold the merchandise while he brought it back.

Young: Well, this is one of the big changes. The why's and wherefore's I'd be glad to have all of your comments on.

Goldhammer: Initially, it was conceived as something to be used only occasionally.

Young: It had been used in bad medicine cases

as early as...

Goldhammer: I can't recall when this came about--about the 1950's. It was after the establishment...

Lofsvold: There were isolated incidents of recall much earlier than that, Gil.

Checchi: Well, then I worked in the field office...

Lofsvold: Sulfathiazole and Doridin--

Checchi: You used to get one recall a year or maybe every two years.

Goldhammer: Yes, it was in those situations in which there was a hazard to health. Right. But those things have a momentum and it is very difficult to stop them. It grew and became the principal means of confronting a situation which exists from the introduction of a violative article. And seizures and prosecutions dropped at the same time. At all Congressional hearings when there was an inquiry with respect to recalls, the officials of the Food and Drug Administration always disclaimed any intent of substituting the recall for the sanctions of the law. But, the fact is that seizures dropped almost to the vanishing point. I remember one month in which the Food and Drug Administration made only 26 seizures throughout the country. When I was up in Buffalo in the early 1940's,

we'd make 40 to 50 seizures a month in that one district.

Young: Before breakfast!

Goldhammer. And here, for the entire Food and Drug Administration there has been only 26 seizures reported. So that gives you an idea of how the recalls took over, and became the usual procedure to handle violative articles.

Young: Now, was the fact that the Citizen's Advisory Committee Report, particularly the second, put so much emphasis on education on the Food and Drug Administration and industry in an educational rather than in a litigious posture? Is there any implication that that climate might have had something to do in shifting away from a litigious approach toward an approach which you would have to regard as less litigious and less bad publicity and so on.

Goldhammer: Yes, I think so, because the second Citizen's Advisory Committee made it very clear that they thought the time had come for F.D.A. to stop being cops. And, since Larrick took those admonitions very, very seriously, and felt that he had no alternative but to change direction, I am sure that the Citizen's Advisory Committee had

an effect in gradually increasing the applicability of the recall.

MacFadyen: You seem to be critical of this. Do you think that this was a bad turn for the Agency to take?

Goldhammer: Not necessarily. I do feel that if you get too buddy-buddy with the industry, enforcement in general is going to suffer. And in the years which followed, F.D.A.'s adoption of this policy and the way Congress has reacted to it over the years since then, I think it's an indication that the public and Congress felt that the Food and Drug Administration was in bed with industry. Such accusations were made. Especially after the consumerist movement intensified and Nader's groups in particular, began to accuse the Food and Drug Administration of being in bed with industry. As a matter of fact, I think they and Congressional Committees intimidated the Food and Drug Administration to a large extent. Morale dropped very drastically in the Food and Drug Administration after that second Citizen's Advisory Committee Report went into effect. There was a feeling among the people who were still in the Food and Drug Administration that they were being

hampered in enforcement. They didn't think it was a good thing, and dissidents within the Food and Drug Administration began to speak up.

Janssen: I think though, that Larrick didn't go nearly as far in this direction away from enforcement through the courts to administrative enforcements. He didn't go nearly as far as Goddard. Goddard really laid out the new direction. And, of course, what we have seen develop here is that education has taken the form of regulation making. Regulation writing is the new wave in education. With the strong blessing of the Supreme Court in the drug effectiveness cases, so a way has been found to educate by means of writing new laws. We've got law that spells it out now in great detail, so much detail that it's hard to find your way around it all.

Goldhammer: That's right.

Checchi: It's good for consultants.

Lofsvold: It keeps the consultants in business.

While we are on the second Citizen's Committee I have a story which may not be useful to you because all the principals are now dead. Frank Clark who was the Assistant to Jack Harvey, the Deputy Commissioner at the time that that report came in said that on the morning that they received that report

and both Harvey and Larrick had read it, Harvey said to Larrick, "George, we appointed one committee too many."

Goldhammer: Well, I know Larrick was very upset about it. He felt he had no choice. He called the F.D.A. administrative group together to tell them about the second Citizen's Advisory Committee Report and he was as glum about it as the rest of us were.

Janssen: Yes, remember that certain members of Congress--it was the gentleman from Rhode Island who had gotten the F.D.A. to appoint the second Citizen's Advisory Committee. The gentleman from Rhode Island was the man who carried the ball in the House on F.D.A. appropriations and he felt that the first Citizen's Committee had not finished the job.

Young: Fogerty thought that?

Janssen: Yes. He felt that here it had been demonstrated and recommended that the F.D.A. be expanded but how much expansion, what kind of expansion? So, he wanted another committee, and he got it.

Goldhammer: I hope you'll excuse me, I've got to make a call.

Young: Sure. Do you to comment about the Citizen's Advisory Committee Report, and these...

Checchi: I don't remember the details...

Janssen: Well, there were numerous progress reports, maybe numerous is the wrong word. There were progress reports including one rather comprehensive one on what had been done to carry out the recommendations of CAC 1 and I am sure another one on CAC 2.

Kelley: I just want to ask Wally this, what did they call it, the Baby Beet case, was this representative Tabor of New York? It wasn't the apple chops, remember that? I thought that was...

Janssen: It was the man out in Washington. That's the one that led to the factory inspection Amendment of 1952.

Checchi: Oh, the apple orchard thing.

Janssen: What was that fellow's name?

Young: Wally mentioned enforcement by regulation and this made me think of another question that I did want to pose to get your comments upon. Billy Goodrich made a speech one time in which he said that the regulated industries, especially during the period of the '30's when the new law was developing were a lot less interested in the substantive provisions of the law than they were in the administrative provisions of the law. And presumably, I think he was implying that this applied to industry later

on as well. So that regulations would permit them to manipulate the regulations in such a way that they would delay or could delay the substantive application of the law in many ways, at any rate, in some of these new ways. I wanted to raise the question if you thought this was so, that if the matter of regulations under the law and of the way that the regulated industries can maneuver in order to delay things as was true of some of the standard making and that was as true of, well I guess it was standard making in connection with the food supplement situation prior to Congress's new law in 1976-- if you think this is something that ought to be paid attention to, industry appearing to agree to certain substantive changes but none the less wanting to be quite sure that there was a system that would let them, that would force the Food and Drug Administration to move very cautiously and slowly in trying to enforce some of the substantive provisions. What's your view of that, Mr. Checchi?

Checchi: Well, I guess I've never heard it put quite that way, but basically, I agree with Gil that this has been, if you go to the Congressional hearings or read the legislative history of many of the amendments of the Food and Drug Act, this is true. There

can be very little argument as to whether or not adulterated Food and Drugs should be put on the market. Clearly industry is in a losing battle and their emphasis has been, and I think probably understandably so, in making certain that the administrative review provisions are such that they can--not necessarily delay--but I suppose a lot of people do use that as a delaying tactic. The Food and Drug Administration uses it too in the business with respect to the artificial sweetener, Aspartane. It's a two-edged sword. The Food and Drug Administration has used precisely the same delaying tactics. I really don't know of too many cases, though where the administrative review procedures have really served to substantially withhold a decision that the Food and Drug Administration wants to make. No doubt there have been some but I just don't know about that. I think in, perhaps in their color case, the industry has taken full advantage of the administrative review to keep colors on provision listings, and to proceed with additional studies. There again, there is a lot of quarrel as to whether F.D.A. should have cut them off sooner. I guess the color is about the only case I can think of where...

Young: Well, the peanut butter case is sometimes mentioned.

Checchi: Well, the peanut butter case was just a long drawn out hearing procedure. I don't know how you could more fairly do it. As it turned out, subsequently, it was a monumental waste of time because ten years later, or fifteen years later, whatever it was, F.D.A. came out and authorized peanut spread which is all the industry wanted to do in the first place.

Janssen: Well, the peanut spread, when the hearing started, when the F.D.A. proposed the standard, peanut spread was Jiff which had 22% Crisco in it. That's what provoked the Food and Drug Administration into proposing a peanut butter standard, and...

Checchi: But today, Wally, you can put out a product with 50% lard in it and still call it peanut spread.

Janssen: And call it imitation peanut butter.

Checchi: No, you can call it peanut spread. If you've got some peanuts in there, I've forgotten exactly where the thing is, but under the commonly used name reg., what's peanut butter? I believe it's 90% peanuts?

Janssen: The standard is 90% today.

Checchi: It's 90% now, but if you can put 50% in it

and call it peanut spread...

Janssen: Well, the fact is, I think you would have to admit, that a large number of products are now on the market which would have been considered adulterated.

Checchi: Oh, indeed there are.

MacFadyen: Well, that's worth pursuing.

Checchi: Well, economic adulteration. Not adulterated in the sense of containing poisonous or deleterious substances. If a product didn't meet the standard, if it had less of the ingredient that it should have, you could charge it as adulteration by virtue of it's lacking a valuable constituent.

Young: So you're saying the standards have become considerably lessened, or are...

Checchi: You'll get lots of people who will argue that the common or usual name in provisions of new common or usual name regs., virtually, abrogate all standards.

Young: When did these come? This sounds like a kind of a turning point, though maybe for volume three instead of volume two.

Checchi: Common or usual name regs., what was it, two years old? Three years old? Three years old I guess. There around the middle '70's. I don't recall

exactly.

MacFadyen: Can you explain what you mean by that?

What do these new regulations do?

Checchi: Well, under the old concept supported by the courts, if an article purported to be a food for which there was a standard of identity, then it had to conform to that standard, no matter what you called it. And you had to call it by the standardized name. You couldn't come up with a... So, if it looked like peanut butter, just to pick the thing, F.D.A. had said--it came about after a drawn out hearing--it established that peanut butter is a mixture of 90% ground peanuts, some peanut oil and some other ingredients. But the critical factor is that it had to have 90% peanuts and you had to call it peanut butter. And the physical composition had to comply with the standards. You could only use optional ingredients allowed by the standard and the whole thing was cut and dried. Therefore, substantially, the word peanut butter meant that particular food and nothing else. You could not, under the old concept, take a product which had 70% peanuts and other valuable nutritionally equivalent in every respect, but just simply instead of having peanut butter it had ground peanuts and peanut

oil or Crisco as Wally says. You couldn't put that out under any form of label because it looks and tastes like peanut butter, therefore, it proports to be peanut butter, therefore...

Goldhammer: Except imitation.

Checchi: Yes, except imitation. You could label it as an imitation, but you couldn't call it peanut spread. You had to call it imitation peanut butter. You had no choice or you couldn't market it. Now under the common or usual name regulations that the Food and Drug Administration issued in the past several years, they said no, that's not quite true. If the product is nutritionally equivalent, let's go back again to my peanut spread. If you take a product which has 70% peanuts instead of 90%, whatever the standard is, I don't recall...(break in Mr. Checchi's statement - tape change). I propose to call it peanut spread and they said that's fine, if it's nutritionally equivalent. So what the Agency has permitted here, and there are many arguments on both sides of the fence obviously as to whether this is or is not in the consumer interest, but what the Agency has permitted is a 180° turn from it's old enforcement policy of "by God it either meets the standard or it is an imitation".

Young: Well, obviously that allows greater flexibility.

Checchi: Oh, tremendous flexibility. The issue comes back down to what is the point of establishing a standard for peanut butter? I probably picked a bad example because of the blood, sweat and tears that went into peanut butter. You could say the same thing of mayonnaise, or jams and jellies.

Goldhammer: Let me give you an illustration of that, and how we prevailed in court. We had a standard for jams and jellies. A product came out on the market called Fountain Fruit. It looked like preserves, it tasted like preserves, but it didn't have the full quota of fruit that preserves were supposed to have. It was sold in the same type of container as fruit preserves were sold in--about a one pound or less glass container. In other words, it wasn't Fountain Fruit in the usual gallon containers for use as a topping for ice cream dishes sold in ice cream parlors. This product sold in the grocery store in juxtaposition with preserves. There was pineapple Fountain Fruit, strawberry Fountain Fruit, and a lot of other flavors. We seized it on the grounds that it purported to be the standardized article, fruit preserves, and it didn't comply with the composition of the standard-

ized article. This was contested and we won. Now, that might have had a different outcome in today's atmosphere.

Young: When was this?

Goldhammer: This was about 1948.

Young: And the old spread case, I guess, that went to the Supreme Court. That would have to be looked at, although there might be an issue with the equivalent nutritional value in that case.

Checchi: I don't remember the facts there, but let's say, I don't remember the physical composition.

Young: One thing that I'd like to talk about and get the same kind of very informative, and at the same time judgmental reactions that you've been making related to the inquiry that finally came under the control of Delaney and the laws that flowed from that, and then what FDA did when the laws had been passed, and with regard to the additives, you did have a major role in that. Would you speak to that, as a new kind of task and how F.D.A. came to grips with it and set it within the broader picture of the law?

Checchi: The entire amendment or just the Delaney Clause?

Young: Well, the entire amendment.

Checchi: Well, the entire amendment started way

back, really for two reasons. One, pre-food additives amendment prohibited the addition of any substance which was poisonous or deleterious. It didn't permit the Food and Drug Administration to establish a tolerance at all except under Section 406 where it is unavoidable in the manufacture. In other words, if you have arsenic in a root vegetable, you can't avoid it. It is there. Mother Nature put it there so you can't legislate it out. But you could not, under the old law add as a direct food additive any substance which was proven to be harmful in any quantity. So you didn't have to say it was harmful in a given quantity. So what we had was a law that really stifled food technology if applied technically. Now, indeed the Food and Drug Administration did agree that certain things were safe in the usual sense, but really they had no authority to permit the use of chemical additives in food. The first sort of major legislative step in the direction was the Pesticide Chemical Amendment of 1954. There the Congress came to grips with recognizing, well, these are highly toxic substances. Now we are not talking about sodium benzoate and a few other antioxidants. We are talking about something which was designed to kill and therefore, since it was designed

to kill, we must now establish a tolerance under which safe residues can be established and they came up with two factors. One was the need. You had to get a certificate as I recall from the U.S.D.A. that this particular pesticide was needed for a particular use. Then F.D.A. had to certify, and U.S.D.A. also had to certify as to the minimum amount that might be available as a residue. I've forgotten the mechanics. But in any event, it was the first time the Congress really came to grips with the need to face up to the fact that there are poisonous substances in the food supply, and they have to be controlled. Congressman Delaney also, in about 1952, 1953, I've forgotten the precise year, started holding general hearings on food additives. The hearings went on and off both under his chairmanship and subsequently I think John Bell Williams of Mississippi. In any event, when the law finally came before the Congress in 1957, late 1957 or 1958, we had the first food additive's amendment. Now, as I say, the basic purpose was to regulate, obviously, the safety of chemicals in the food. It was necessary because the administration had no mechanics whatsoever. Had the Food and Drug Administration taken a thousand percent or rather hundred percent hard-nosed enforcement attitude, there would have been very little food

processed in the country. So the agency needed it from the standpoint of giving it to the administrative latitude it needed to make the scientific judgments. Industry needed it in order to be able to proceed and so on and so forth. The Delaney Clause of the amendment, which is, interestingly enough, the only section of the Act that anyone ever hears about and talks about, came about as almost an aberration. There was a lot of discussion about safety factors, and at the time, there was a cancer scare. I think Senator Taft had cancer, and, at any rate, I think cancer was at least as bad a word as it is today. And, I think, the NIH had a Dr. Huber who was extremely vocal on the issue that absolutely it was unsafe; there was no way at all to determine the threshold level for carcinogen in the food supply and the same stories that we hear today.

Janssen: Didn't the National Health Federation get into the act?

Checchi: Everybody was in the act, Wally. Everybody was against cancer, so as the committee, as I recall, as the bill proceeded through the committee, they were asking the Commissioner, Secretary, Assistant Secretary, were asked about cancer, and, of course,

we are going to treat a carcinogen like anything else. If the substance is not safe for its intended use, it is not going to go in. There was no Delaney Clause. But each time the Commissioner testified on the issue, he agreed that until such time as the scientific community could come up with a protocol which would establish whether or not a given level of known carcinogen could cause cancer, he wasn't going to approve it. So his philosophy and the philosophy of the scientists in the Food and Drug Administration at the time was totally, if you will, pro Delaney Clause, but nobody wanted to write it in the law for the very simple reason, well damn it, we're not going to permit something that causes cardiac insufficiencies, and so on and so forth. Why single out cancer? And it was finally adopted as a compromise. And what Delaney essentially said was: Well, now look. You've told me all along you're not going to let something in food that causes cancer. And the Commissioner says, "Right." Well, damn it, I want to say so in the law. And that's how it got in there.

Young: Really, its a last minute, I guess.

Checchi: Substantially it was the last minute. It was inserted on the floor of the House rather than

in committee. It came out of the committee, to my recollection, Gil, you may recall more...

Goldhammer: That's right. It didn't have any Delaney or anti-cancer clause as reported out by the full interstate and foreign commerce committee.

Checchi: It came out of the committee without it. And it was the cancer clause finally, Mr. Delaney held out. He withheld his support from the bill, unless they put the cancer clause in it. At the time he was Mr. Food Additives, and the Congress and the House of Gentlemen went along with it.

Young: Did this cause the F.D.A. some trouble?

Checchi: Not at the time, and I am not sure that it has caused them all that much trouble since because the basic philosophy at the Agency was, and I presume that still is, that unless the scientific community is satisfied that this particular carcinogen can be used safely, we're not going to permit it. That was the philosophy. So from the standpoint of considering a given food additive petition, and approving a particular food additive, I don't think that the existence of the Delaney Clause has really made all that much difference. Other than it's been another 'T' to be sure that you've crossed; to be

sure that these studies have been done. Now, it has come up. I frankly don't know what the Agency would have done in 1959 when I was there had they had the data before them on saccharin. I presume that had the scientific community told George Larrick in 1959, we believe that saccharin is carcinogenic, my guess is that he would have done precisely what Dr. Kennedy did and issue a regulation proposing to ban it. Even though it might have been the only; even, everything else equal. The Delaney Clause forces you to do that. Now would the Commissioner and would Dr. Kennedy, in fact, have taken the same step if there was no Delaney Clause? I can't look into their minds. George Larrick is dead--and I can't look into Dr. Kennedy's. I don't know.

MacFadyen: It seems to me that at least there is a possibility that without the Delaney Clause, you could have set tolerances. In other words, the philosophy behind the food additives amendment in 1958 was that additives are dangerous used in certain, at certain levels. We can set tolerances that are acceptable.

Checchi: That is done today for every single food additive; a tolerance is set.

MacFadyen: Right.

Checchi: In theory you are absolutely correct. Had there been no Delaney Clause...

MacFadyen: But, except if that additive is shown to be carcinogenic. Then you cannot. But maybe in a small level it wouldn't be.

Checchi: Well, under the Delaney Clause, if it is shown to be carcinogenic at this level, then forget it. There is no safe level under the law. Now...

MacFadyen: But if it is carcinogenic at that level, it's well, there's no flexibility involved.

Checchi: Well, under the Delaney Clause...There is an absolutely...If it shows to be carcinogenic at any level, then even if you find a safe level, you can't use it. The Delaney Clause is a strict prohibition.

MacFadyen: Right.

Smith: I don't think that any of the authorities in cancer can set a level, at least not that I am aware of. I think that's been the trouble with revising the law. It comes down to the same objection as in 1958 or 1959.

Checchi: You had the same thing...

MacFadyen: But you seem to be suggesting that for

other additives you can set levels. If you take too much of a certain additive, it will make you nauseous. But if you take...

Smith: And, of course, one of the difficulties in determining whether or not you can set a level is the latent period with cancer. You carry out an experiment that lasts 20 years--well, is 20 years long enough?

Goldhammer: As far as Delaney was concerned, he deliberately wanted to deprive the Agency of any latitude when it came to a substance which produced cancer in man or animals. Now, you see the situation that you have with drugs? There are many, many drugs that are carcinogenic and yet they are permitted. There is no Delaney Clause for drugs and, therefore, the Agency has latitude and it exercises that latitude. And rationalizes approval of drugs on the basis of the benefits outweighing the risks. Well, you can say the same thing for food. I think that Delaney showed a lot of foresight when he perhaps envisaged that the Agency heads would get around an outright ban unless it were put into the law.

MacFadyen: Well, you could turn that around and say that the Agency also envisioned that there might be an agent like saccharin which might conceivably be a carcinogen

used in enormous quantities but that an imaginary acceptable level was perfectly safe.

Checchi: The philosophy of the Agency at the time was just as Dr. Smith has said, the scientists believed that if it were carcinogenic in a given dose, then there was no safe levels. The philosophy of the Agency in 1959 was, as I say, essentially articulated in the Delaney Clause. Now then what happens with succeeding administrators, as Gil says, Mr. Delaney says, well, okay George Larrick, I hear you, and I'll buy your story, but you and I are mortal human beings and somebody is going to succeed the two of us, so let's nail it down right now. And that's essentially what it is.

Goldhammer: You see, long before the Delaney Clause came into existence, the Food and Drug Administration had taken action against products on the basis of animal studies which showed that they produced cancer in the animals--for instance butter yellow. A long, long time ago, back in the 1930's it was being considered for use in food but it produced liver tumors in rats and that killed it without any question. Nobody questioned whether it will produce cancer in humans. The experimental animals were rats, not human beings. But, if it produced it in animals, that was enough to ban it. That was more than 20 years before a Delaney amendment. There

was coumarin, safrol--also banned without question when their carcinogenic properties were discovered.

Young: The trade papers are saying that the Congress is desperately fighting off anything that will force them into a debate about the Delaney Clause.

Goldhammer: I think there is a strong movement. Even Fountain has expressed the feeling that, well, maybe the Delaney Clause does need a little revision. The movement hasn't gotten strong enough yet. But there is another factor which is being played down. The cancer mortality rates--these are rates not numbers of cancer victims--inexorably rise, year after year after year. It's been going on for decades. I've been watching very closely, those vital statistics issued by the National Center for Health Statistics. We held hearings last year on the administration of the cancer program and we did exhaustive research on the situation. There isn't any question about it. Cancer mortality rates are accelerating.

Checchi: Does it rise demographically?

Goldhammer: This increase is accelerating whether you take it on the basis of age-adjusted or crude rates--both are accelerating. Who is going to be for relaxation of regulations against carcinogens when these facts are hammered home?

Young: What were you going to say?

Checchi: No, I was just going to ask you if it had gone up by age groups as well as total population.

Goldhammer: Well, not all age groups. It's been lowered in the very young. That's because they've been able to cure leukemia in the very young and some of the neuroblastomas, and so on. But, for all age groups beyond that, it's increasing, and, on an age adjusted basis, it's increasing and has been accelerating particularly sharply in the last three years. For instance, this year, so far, for the last 12 months, the cancer mortality rates have increased by 3.1%. That's an enormous increase for one year. That's for the crude mortality rates only.

Janssen: Isn't it true also that the rate for stomach cancer has declined dramatically?

Goldhammer: It has gone down, but on the other hand, rectal and colon cancer deaths are going up. Everybody has a tendency to dismiss it by saying the cause is cigarette smoking. Well, that's a simplistic view. It's not smoking that's responsible for the increase because cigarette smoking since 1959 has dropped in all age groups except teenagers. So, in light of that, it's extremely doubtful that Congress will disturb the Delaney Clause. But there is strong feeling among the Congressmen, nonetheless.

Young: Now when the 1958 law came about, part of the plan was the GRAS list. Would you speak to the matter of how F.D.A. set up its plan in order to determine what should be on it.

Checchi: The GRAS list, the mechanics for putting it together were quite simple. I, step one, asked the people in the records division of Food and Drug who kept decimal files to give me a list of all chemicals that we knew were being used in foods. Step two, we sat down and took this list, circulated it to the people. I think your branch got a copy, primarily the Bureau of Foods with Dr. Lehman, Dr. Fitzhugh, and Dr. Nelson and anyway, the Toxicology Department of F.D.A. with the help of Dr. Nelson from Nutrition and Lee Kline who, I think, was then running the Bureau of Food. At any rate, the F.D.A. scientific people with competence in the area. And very frankly, we just took this list and, let me go back now, our concept of GRAS at that time was perhaps something different than it is today. Our concept of GRAS meant that scientists who were knowledgeable in the field had to look at the name of a substance and say, I think that's safe. We didn't say that you have to say to us that it is safe in fact and you've got to cite all of the professional literature etc., etc.,

on which you base this conclusion. It became in our concept, general recognition was simply, 'Well, Dr. Young, do you think that root beer is safe, or do you think that butylated hydroxy anisole is safe?' If you said no, I don't think it is safe for a particular reason, that's point one. If you said yes, I think it is safe, or you could say I don't know. Now then what we did internally: First we subjected this list to all of our people in the Food and Drug Administration with competence in this area. On that list we then threw off stuff that our people said, no, there is a study here, there is a study there, etc. that throws a cloud over it. So, we'd knock it off. So, in short, we prepared to live with, and that was also circulated, as I recall, to the Bureau of Medicine. So, we came up with a list that F.D.A. scientists were prepared to say 'Everything on here is generally recognized as safe for the use on there.' So, then the next question says, okay, now the law says, 'generally recognized as safe' and that doesn't mean just Food and Drug Administration, but presumably means the scientific community in the United States. How do we reach those people? We did two things. One, we

went through American Men of Science and we picked, I've forgotten, several hundred names more or less at random. Some of them, our people knew had specific competence. And as I recall, we made certain that we got everybody on our list that the people in Toxicology identified as experts in the field. And we drafted a letter simply stating our philosophy, the purpose of the Act; we probably sent them a copy of the Amendment, I don't recall the precise details. But what we did, we sent by a letter to each of the, I've forgotten, scientists on this panel, the list. We told them, in effect, that, here is your chance to tell us whether this is generally recognized as safe. Bear in mind that if it is found to be generally recognized as safe, the likelihood of further study is slight. If you say in your judgment that it is not generally recognized as safe, we'd like to know why, because it may result in it being deleted from the list. Then, as a second step, we published the same list and basically the same description of what we were trying to do in the Federal Register. We then got all of the comments and Bill Goodrich and I sat in the Commissioner's Office; George was out that day, and we went through all of the comments. I don't remember how many

there were. But then...

Young: Would you say that you were surprised at the quantity of receipts or at the low quantity of receipts?

Checchi: I don't think we got too many comments, as I recall. I don't really remember. My recollection... I wasn't particularly surprised one way or the other. But my recollection is that I don't think we got too much of a response. I just don't really recall the volume. But it wasn't, we certainly didn't get a truckload of comments. Nowhere near what you would get today, I am sure. So then, we took that and we sat down again with our own internal people with respect to comments. Where the scientists all said it's fine, then we didn't bother our people any further. They'd been through it. Where the comments were adverse, then we'd say to our people, well he says...and our guy responded. Obviously where anybody had any serious objections, we threw it out. I don't remember that much got knocked off that way, frankly. But at any rate, that's the mechanics for having done it.

Young: Right. Did you have to have any minimum number of yes's in order to put it in, because my guess is that there were lots and lots of items that

hardly had any reactions at all.

Checchi: We didn't have. We didn't develop a model saying it's got to fit this basic criteria.

MacFadyen: How many substances were you dealing with? Was it several hundred?

Checchi: The first list?

MacFadyen: Yes.

Checchi: Oh, I don't recall. Probably a couple hundred. No more than that I think. You see, we did not have all the bulk of items on the GRAS list, the flavoring ingredients. We didn't deal with those at that point. We were looking more at anti-caking agents, preservatives, emulsifiers. I doubt that we had more than two hundred--probably less. I just don't recall for sure. That was the first list. The second list, after that became amended. I really don't know what the amending procedure was. I wasn't there. But the initial list, anybody remember how big it was? It was something, my guess is that it was something under two hundred.

MacFadyen: You say the list was amended, or the law was amended?

Checchi: No, no, the list. The GRAS list was amended several times after that, but we did not have...

We simply looked at it in the sense that basically our own people had gone through it. If no one else wanted to comment, I am sure that my philosophy would have been, well look, if we've said that, ah, ABC, we were proposing to save it. No one was objecting therefore, it stays on the list.

Janssen: Was the first list, did the first list include the salt, pepper, vinegar type of things, or...?

Checchi: No, the first list, we had that preamble on it, Wally. We said we're not going to include things like salt and pepper, and monosodiumglutamate. Things that were so generally recognized as safe that we are not going to put them on there. You see, this is another thing, and I am glad you raised that. We made clear in the initial thing, we weren't going to try to come up with a comprehensive list. The salt, pepper, apple juice type of attitude, we just said look, we're not going to try to define everything. We'll deal with the chemical names that average people don't know anything about.

MacFadyen: Well, as I recall, under the '58 Act, such things as salt, pepper, vinegar were already excluded from the coverage of the Act.

Checchi: Not in the law. Oh, they were only excluded in the sense... You see, the Food Additives

Amendment, if a substance is generally recognized as safe for its intended use, it is not a food additive, so salt is generally recognized as safe as an ingredient in food at certain levels and, therefore, is not a food additive. Now, we proposed the same thing for cyclamates, for example, was, I think, about the only thing on our list that eventually got knocked out. Saccharin is now in limbo. So, all of these things which go on the GRAS list are, therefore, not food additives by legal definition, but the basic law itself does not identify any specific substance as being like salt. It doesn't say salt is not a food additive.

Young: But, what then in the climate of opinion, or in the state of food technology, or for what other reasons, differentiates the period that you were in when you could do it the way you did it and the period now, when such a detailed review and the setting up of an endless chain of re-review is required?

Checchi: That is a good question. I don't know. I wondered at the time in 1969 or 1970, whenever it was when the GRAS list was reviewed, I wondered, frankly, at the time and I suspected that there was some empire building being done to undertake the type of review that was taken--of setting up all of the various criteria

and going on.

Young: Endless waves from...

Checchi: The Food and Drug Administration in a sense rejected our concept, its own concept adopted 12 years earlier as to what constituted a general recognition of safety. The concept of 1958 when we got out the list. (new tape)...

We took the view, all right, general recognition of safety means that we say to the scientific community, apple juice is safe, anybody object? No one objected, so apple juice became GRAS. And then we went down our list, and then if someone objected, then general recognition of safety did not exist. So it was not eligible. In 1969 or 1970, whenever the GRAS review was undertaken, reviewed, the Food and Drug Administration established criteria. They said, for a food additive to be found to be safe, you have to have this, this, this, and this. And then they rationalized. I don't mean rationalized, but they reasoned, that well, why should something be regarded as generally safe on any less evidence. So then they said, well alright, it can only be generally recognized as safe if there are extant in the literature, this type of study. And then they started the whole review again.

I suspect that there is nowhere in the literature a toxicological evaluation of apple juice. So, in my own view, Food and Drug Administration has changed probably the meaning of GRAS from what Congress had in mind, and certainly what the Food and Drug Administration had in mind in 1958 as to what constitutes general recognition of safety. It's totally different than what exists today.

Young: Because safety today in all these ways has been seen in a new light, because of all kinds of agitation for one thing.

Checchi: You see, you have this. In the Food Additives Amendment itself--how is something generally recognized as safe. All it says is by scientific study or by common use in food, as I recall. So what you have, and what the Agency has in effect scrapped, in its review, is the common use aspect. Now they are talking about only scientific study. It's all well and good to say, well, for saccharin we need scientific study and obviously all of this is good. But if you really are going to deal with GRAS as substances, and say what is GRAS, you have to look at every substance added to food and then you get down to beet juice that is added as a color

additive. Apple juice is a flavoring substance. You get all sorts of additives to food or ingredients to food which potentially are additives, but really when you come down to it we have no scientific evidence of the safety of turnips, and yet you will grind up turnips and put them into a beef stew. To me here is where Food and Drug Administration says, well, turnips are GRAS because we've been eating them a long, long time. But sodium benzoate, because it is a chemical name, can only be GRAS if we've done all these studies. Well I just don't see that.

Young: So this is a change, and then you always have to ask why does it come about, and that was partly why...This is speculative. I'm not asking you to commit yourself as a scientist as to the reasons, but I just...

Checchi: A scientist I am not. I think that it came about probably as a result of some empire building within the F.D.A. Now, it may well be that if the Commissioner in 1970 had said, okay, we'll review the list, but we're going to review it the same way we created it. We are going to turn around and we are going to simply say to the scientific community here are the substances, we recall

to your attention, these substances are on the GRAS list and then restate for them the pros, you know, the stakes. What's involved when you say something is GRAS. And I just wonder if the Commissioner had been turned around in 1970 and put it back to the scientific community and told them, we don't have any scientific evidence, and the law says, common use in foods, so on and so forth.

Young: But there is a growing social alarm about small quantities that maybe arises from some aspects of the consumer movements and other things like that that may be factors. Excuse me, Fred, you had something you were...

Lofsvold: What. I was just wondering is this, what's this young lady's name?

Young: Nancy Ross.

Lofsvold: Is this somewhat comparable to what it seems to me was our changing view on new drugs, that now, unless there are studies on something, it has to be considered a new drug while originally perhaps we were more inclined to accept the judgment of people who were knowledgeable whether there had been thorough studies or not? Are we in a situation now where nothing is recognized as true unless

it is buttressed by some long-winded lengthy acceptable study that proves the point. Where, formerly, we were more inclined to accept the opinion of experts, just from their own evaluation and knowledge?

Young: The judgments of those experts even though they hadn't made those particular tests.

Goldhammer: Well, I think that the judgment of the experts is still relied upon in determining whether a product is a new drug. Under statutory definition, a new drug is one which is not generally recognized as safe among the experts qualified by, etc., etc. If there is a substantial difference of opinion among the experts, obviously it cannot be generally recognized as safe. The definition turns on the word, generally. And, of course, there has been a lot of discussion as to what that word means. Does it mean it would have to be unanimous? If there is but one dissenter, does that mean that it is not generally recognized as safe? And what the courts have said is a significant difference of opinion among the experts. That would rule out just one being sufficient to say it is not generally recognized as safe. How many must dissent? That's never been determined. If there is a substantial difference, it doesn't

have to be a majority ruling one way or the other. If half a dozen people, if they are well qualified people, say that they can't recognize it as safe and thousands and thousands of others say they recognize it as safe, that might be sufficient if those six who say they can't recognize it as safe and are well thought of scientists and highly qualified. So I think that still holds.

Smith: Yes, but how about the recognition? Must the recognition?... We are saying now, I think, that recognition can only be based in food additives; on whether there have been well controlled studies that are acceptable to the experts.

Goldhammer: Well, that's only the determination of the safety of a food additive. Now if it is generally recognized as safe, it is not a food additive. I think that there is a recognition that a product may have some potentiality for harm which was not apparent before. For instance, the question of whether salt is safe in view of salt's role in hypertension. You could make a case that it wasn't safe, certainly for a segment of the population. But the great majority of products are still in the category of acceptance of safety because of their

long history of use without apparent ill effects. But some day, someone may do a study and upset the apple cart. But I think the principle still holds. Don't you think so?

Checchi: Oh, I do, but you then, you mentioned salt, let alone alcohol. You know, no one around this table is going to agree that alcohol is safe, and there is no scientist that is going to agree it is safe, and yet all flavoring substances and, well, there is alcohol in the food supply. And sure, in very small quantities. No one is going to get drunk. But it is there. And yet, Food and Drug is saying that it is generally recognized as safe, and yet on the other hand, Commissioner Kennedy wants to put labels on bottles of alcohol that says don't drink this if you are pregnant, and so forth. I just think that the whole business of, let's take a real look at what is generally recognized as safe. And that's what I did, but F.D.A. has said, well all of these chemical sounding substances that are on the GRAS list have got to be looked at just as though they were food additives. But these non-chemical sounding substances, those are okay. And I just don't think that that is the proper way of making the division between what we do

test and what don't we test?

Goldhammer: Of course, the Congress back in 1958 when it passed the Food Additives Amendment was aware of the uncertainties of the term "safety", and they commented on it in the report to accompany the bill. They recognized that everything has a potentiality for being unsafe. Water, oxygen. They commented on that and gave some guidelines to the administrator. Well, it was actually giving guidelines to Congress, but it really was aimed at the Food and Drug Administration. The guidelines were that you should take into account not only this use, but the use of the same product in other foods, or a comparable chemical which might have a synergistic effect. Congress said take all of that into consideration in deciding whether an additive is safe. Then the test will be that you have to be reasonably certain that no harm would befall the public. And that has been troublesome. When am I reasonably certain? I've always said it's a gut feeling. You just have a feeling that this isn't going to hurt anybody, and if you feel that way, it passes.

Checchi: The point, enough is enough is enough.

Smith: Probably a related matter is that early under

the New Drug Law, I think even up through to somewhere around 1960, and it should be the General Counsel's Office saying this instead of me, it should be checked. There was never a case taken to court on a New Drug charge. And I often asked why, and the answer I got I didn't understand, but it had something to do with the fact that it may destroy the definition of a New Drug, or undermine the whole New Drug Law. And then, about 1960, somewhere around there, one was taken. It was a skin preparation. It might have been Clearasil. It was something that had an antibiotic in it. And they won it. And after that, why, they had no hesitation.

Young: But there seems to be more... In other words, there were cases which you thought should have been taken to court in a scientific sense...

Smith: Well, for example I remember, do you remember Pago Palo?

Lofsvold: Yes. It was the vine that made you viril.

Smith: It was for male potency, and it came from Haiti and the Dominican Republic and there was a millionaire in Dallas who had a government agreement for control of the drug from the Dominican Republic, I believe. And there was some outfit in Chicago that

put it on the market. We called it a new drug in the New Drug Division, but the General Counsel's Office, why, this is an old remedy, an old family remedy. Why, we'd be laughed out of court.

Checchi: I think what you want to bear in mind that as I recall these cases, Food and Drug did go after the product under different sections of the law.

Smith: Right.

Checchi: We didn't leave the product on the market.

Young: And most of the ones that you are speaking of are of similar kidney to this. They weren't really drugs that were put out by reputable firms, or is there a borderline here?

Smith: Well, there is a borderline. Of course, I imagine the grandfather clause came into it too.

Janssen: I remember that Pago Palo. It had lots of color to it. There were all the elements of a good musical comedy in that product.

Lofsvold: It was a devil of a lot of work, too, because it arrived from the Dominican Republic in New York in small packages filling many mail bags that we had stacked around the office. We had to open each package and detain it.

Young: Well, I am not sure if this is exactly the

note on which I expected to end at noon time, but Nancy has done a fine job of providing some lunch for us, so let's take a lunch break. (Conversation was already resumed when the recorder was turned on after lunch.)

Goldhammer: Vermont maple syrup shipped up to Vermont from New York State, Pennsylvania, Ohio. Strangely enough, most of the Vermont maple syrup comes from states other than Vermont. It also was shipped to Vermont from Canada. There was lead in maple syrup. All those seizures were consolidated up there and we went to trial. I testified with respect to my sample collections of maple syrup. I made the statement that I had tried to confine my sampling to grades two and three, which means that at that particular moment I set myself up as one who could distinguish between grades two and three. Of course, the claimant's attorney went after me hot and heavy. He asked whether I could tell the difference between grades two and three. I had to say yes. So that left me wide open. He brought out a bunch of samples and asked me, "What's this one?" "What's this one?" "What's this one?" I gave my answer in terms of "Well, this approximates a two." "This approximates a one." "This approximates a three." I went through

through the whole list of them. At any rate, I survived it because the claimant's attorney didn't move for my impeachment. We had been instructed by Willis who was the General Counsel you remember Dan Willis from Washington? He came up there to work with the Assistant U. S. Attorney. He had earlier gathered together all of the witnesses and cautioned them about being right in the lion's den there in Vermont. He said, "Be careful whom you speak to. Don't speak to anybody you don't know. Even if it means being rude. Don't speak to anybody," he admonished. Well, that left an impression on me. After I testified there was recess. We had lunch. After lunch most of us were sitting on the porch of the hotel in Barre, Vermont, when an elderly man approached and sat down on the rocker next to me. He was smoking a corncob pipe; his hair was wild; he was wearing a suit that looked as though it had never been pressed, with one cuff down and the other cuff up. He said in a foreign accent that my testimony had been brilliant and I thanked him. Then he started to talk about the case. And I said, "I'm sorry, I can't discuss the case." I didn't know who he was. I thought he was a local yokel interested in sounding us out. But he persisted; he kept persisting and I kept repeating "I'm sorry, I can't talk about the case." Ultimately I

had to leave. I got up and walked away. Well, we got back into the courtroom after the lunch recess. The first witness called was Dr. Anton J. Carlson. Who should walk up and take the stand but this guy--this local yokel who had been sitting next to me. He was very eminent at that time. Naturally, I was flabbergasted to think I was sitting next to the great Anton J. Carlson and wouldn't even give him the time of day!

Smith: I used to take lectures from him.

Young: Oh, you did? You describe him. Because I really some day want to write an article about Carlson as the consummate expert on the stand for the Food and Drug Administration.

Smith: Well, I never have seen him on the stand, but he was a very forthright person, there was no side or anything like that. He tried to be entirely honest and commonplace about everything.

Young: Did he fraternize with his students?

Smith: Yes. He was very approachable. He used the laboratory sink as a urinal.

Checchi: Everybody did in those days. I thought that's what it was for. That's why they were low.

Young: In his lectures, did he ever use Food and Drug cases to illustrate his point that you remember?

Smith: Not that I recall. Of course, I had probably

never heard of the Food and Drug Administration in those days either.

Lofsvold: There was another story about him somebody told once that he was on the stand testifying for the government and on cross-examination the defendant's attorney was intimating that he was a kind of professional government witness, that he always supported the government, and he said, "No, no, young man. It is true that I have testified several times for the government, but twice against!"

Young: I was looking over some cases just the other day, and I had forgotten which ones they were, and ran across two more cases that I hadn't know about at which he testified.

MacFadyen: What was he an expert in?

Smith: Physiology.

Young: I wrote an article on the Electreat Mechanical Heart case. You remember that one? He testified twice. Once in Kansas City and once in Peoria on that one. He was the kind of witness who could turn the fellow's questions around and, in a kind of off-hand way, almost make the lawyer look silly by the way he would answer the question sometimes.

Checchi: What in the world was he doing testifying

in a maple syrup case?

Goldhammer: How come I testified?

Checchi: No, Carlson.

Goldhammer: Oh, he was testifying as to the dangers of lead.

Checchi: Oh, I see.

Smith: Well a standard saying of his that is usually mentioned was, "Vat is the evidence?"

Young: Did you ever talk to him about Ivy? When you were getting up the Krebiozen case?

Goldhammer: No. I think he passed away before the trial. But there is a story told of him. Dr. Carlson had had a heart attack. When he was asked about Ivy, who had become a proponent of Krebiozen, he said, "I'm glad I'm sick over here (pointing to his heart) and not up here (pointing to his head)."

Young: Which is about the best explanation of what happened to Ivy I guess as anything.

Goldhammer: It's hard to explain what happened to Ivy. It was very interesting in that Krebiozen case. I was sitting at the counsel table right next to Ivy. If I turned around like this, I mean if we turned around simultaneously we'd bump knees. There was Ivy, Stephen Durovic, and Marco Durovic. We sat like that for nine months, and throughout the nine months, Ivy always

came in shabbily dressed. He wore the same suit--he never changed his suit in those nine months. He was trying to give, at least I thought he was trying to give, the appearance of extreme poverty. But from the day after the jury went out to deliberate, he came in dressed as nattily as he could. He looked like a different fellow.

Young: That doesn't prove anything, but it says something.

Goldhammer: Well the three of them came in like that. Marco Durovic came in with the same wine stained vest. We saw that vest for nine months.

Checchi: They were good-luck suits.

Lofsvold: Gil, whatever happened to the Durovic that went to Europe? The last I heard he was ill. Did he survive?

Goldhammer: Well, I hadn't heard. But Marco Durovic died. He was the lawyer.

Lofsvold: Yes, the lawyer that stayed in Chicago.

Goldhammer: He didn't move fast enough. Stephen went to Switzerland, then to France, and then back to Switzerland.

Janssen: Is Krebiozen around anywhere now, Gil?

Goldhammer: No.

Young: It's not even in Mexico?

Goldhammer: No.

Smith: You know, Krebiozen gave the Food and Drug Administration a good name from the scientific standpoint when they detected from that minute amount what it was...

Goldhammer: You mean the methylhydantoin?

Smith: No.

Goldhammer: Creatine. But then, creatine doesn't dissolve in mineral oil, so what was actually added to the mineral oil was l-methylhydantoin which is a derivative of creatine.

Smith: But NIH had a much larger sample than F.D.A. had and they (interrupted)

Goldhammer: But what they did was run spectographic curves. They ran a spectogram of it. That was a fortunate thing, because with that spectogram F.D.A. was able to track it down as creatine.

Janssen: Who was the inspector in Chicago who had a great deal to do with this case and is still alive, I think?

Goldhammer: Sherman.

Janssen: Roland Sherman. I talked to him over the telephone about it when I was writing my article about

it, about the cancer cures. I put into that article the fact that there had been a jury tampering investigation, and a member of the jury had been prosecuted and convicted and served the six months...

Goldhammer: Served two years.

Young: How was that tampering accomplished?

Janssen: I can give you some facts. Sherman told me, but I couldn't put everything into the article, it was too long.

Goldhammer: Well, during the course of the trial, a contact was made between that juryman and Ivy. This juryman was a union man. I think he was president, or top man, of the International Meatcutter's Union. The union had taken a position long before the Krebiozen trial that the government should give Krebiozen a test. There was national agitation for the test going on at that time. The union was pro Krebiozen it seemed. As a consequence of that meeting...What did you say?

Janssen: How did the meatcutters ever happen to be pro Krebiozen?

Goldhammer: God only knows. The outcome of that meeting, during the Krebiozen trial between Ivy and the juryman, was that Ivy came down and addressed

the meatcutter's union meeting in Springfield, Illinois, at which time he propagandized the meeting. That was one thing. The other was the journeyman's demeanor and actions with the other jury people during the course of the trial. He was at times threatening and assumed the role of the hatchet man on the jury. At least one woman on the jury received an expensive gift from him.

Janssen: Now, he was connected with the meatcutter's union?

Goldhammer: He was the president or top man of the meatcutter's union.

Lofsvold: You know, that was kind of history repeating itself. As I remember, those two Koch trials in Detroit in the early 1940's you had the same kind of problem. I don't think we ever proved anything. We got a hung jury both times.

Goldhammer: Well, it's not good for a trial to run that long. The longer it runs, the greater the opportunity for a hung jury.

MacFadyen: Any result on that hung jury?

Goldhammer: No, no one was convicted except the jurymen.

Checchi: Well, at least they got somebody.

Janssen: Nevertheless, Krebiozen went caflooeey after

that.

Goldhammer: Oh, that killed it. (Some conversation lost as tape was turned over).

Young: He was trying not to let laetrile into it anymore than he possibly could, and so, he told the jury this is not about laetrile, to the point that when the jury got into the jury room and they had the vials of laetrile which had been submitted as evidence they hid it under the table so that they couldn't even see it. It was a psychological thing, They in words, virtually exonerated McDonald and said so afterwards, but, at the same time, they were sorry for the widow of the man whom he had been treating who had died. And, so, they said, we're going to give her what it cost her. It cost her \$15,000.00. And so they actually brought in a verdict of \$15,000.00 which does leave a legal mark on him if it isn't overturned. Even though, they themselves didn't think he was exactly guilty. So it was a funny trial. It satisfied nobody, except it satisfied me more than if they hadn't given her the money.

Goldhammer: I had an interesting experience with McNaughton. Yes, that's his name, from Canada. We had some action against laetrile and he came down to

the Food and Drug Administration seeking a reversal of the action. At that time I was head of the Division of Regulatory Management and, therefore, it was me who talked to him, and I gave him no encouragement. He said, "Well, where can I go from here if you turn me down. I said, "Well, you can go to the Commissioner, and if he turns you down you can go on to the Secretary of the HEW Department and if he turns you down, then, I don't think you'd have any further place to go." I said, "If you were American, I would advise you to go to your Congressman." Some 10 years later I was with the Fountain committee and we were holding an oversight hearing of F.D.A. It was about the time that the Food and Drug Administration approved the IND for laetrile. Do you remember that?

Several: Yes.

Goldhammer: F.D.A. then quickly reversed the approval because the Surgeon General was formerly from California and he had investigated laetrile there. As a matter of fact, he was instrumental in getting a regulation passed in the Legislature in California to prohibit laetrile from being marketed there. Now he was the Surgeon General, and therefore was a little bit above the doctors who then headed up the Bureau

of Drugs. He got them to reverse the approval. Well, the Committee was not going to get into that but somehow, the National Health Federation got the idea that we were. They came down to the hearing loaded for bear. As a matter of fact, they were distributing statements that they were going to testify. They had never been told that they would be permitted to make a statement, but there they were handing out prepared statements to the press as their testimony at that hearing. The National Health Federation had asked us whether they could testify. I was the one who persuaded both Fountain and Del Goldberg, who is the professional staff member of the committee that we had a tight schedule and we didn't intend to get into the question of laetrile and their testimony was not germane to the purpose of the hearing. I didn't want to suppress their speech and Congress is very sensitive to that point. So they were not given permission to testify, but nonetheless, they went ahead and mimeographed testimony and gave it out to the press at the time of the hearing. Fountain brought the matter up and required that they recover all of those statements. They were then told in public, "You don't have the right to testify here, and I'm not

going to let you testify." Well, at the lunch recess, I came down to my office and who was waiting for me there, but McNaughton. He said, "I am here because of you." I said, "What do you mean, because of me?" "Do you remember when I was in your office at F.D.A. you said that if I was an American citizen you would advise me then to go to my Congressman as the avenue of last resort?" He said, "Well, I am here."

Janssen: Is he now an American citizen?

Goldhammer: I don't know. He came in with the most beautiful young wife, one of the most beautiful women I have ever seen. And, about two months later she died, suddenly. No, McNaughton is very much alive. But...

Young: Describe him, Gil, as a person.

Goldhammer: Well he was a dynamic fellow. He was like Hoxey. He was a fugitive from justice in Canada. He was involved in the marketing of securities and the whole procedure was not quite kosher. He had been indicted up in Canada, and he was staying away from there. But I would say he was a dynamic fellow. He was very persuasive and very persistent. And he finally made it go when no else could.

Young: You credit him with having gotten it off the ground.

Goldhammer: Plus the National Health Federation.

Young: Right.

MacFadyen: What is the National Health Federation?

Goldhammer: An association of health food and non-conventional treatment and adherents.

Lofsvold: It is an alumni society for people who have been convicted of violating the Food, Drug, and Cosmetic Act. (Several talking but a question was asked about McNaughton).

Goldhammer: Well, it is a prominent family. His father was Commander in Chief of the Canadian Forces during World War II.

Young: And he himself was a test pilot, as I understand it.

Smith: I met him probably, I don't know...

Goldhammer: Yes, he'd been over to you.

Smith: It must have been before this because I don't remember...

Goldhammer: Oh, he had been over to the Bureau of Medicine.

Smith: He was a good looking fellow. He was tall, with a black mustache.

Young: When I was out in California recently I mentioned this in a talk and a professor of the University of California Medical School named Saunders who, whatever his major medical field was also was interested in the history of medicine said that Krebs Jr. had been a research assistant...

Goldhammer: A biochemist.

Young: For Saunders and that he'd had to fire him because he got stationary of the department and evidently wrote letters that were promotional in connection with laetrile in such a fashion that he was implying that the University and the Medical School was backing him up, so out he went on his ear. I am not exactly sure when this was, but this was fairly early in the venture.

Goldhammer: I don't know how the National Cancer Institute's going to come out on it's study, but it isn't the kind of study that the Food and Drug Administration would make. It isn't the kind of study that we made in Krebiozen for instance.

Young: It's a retrospective study of cases?

Goldhammer: Well, it's supposed to simulate what we did in 1963 and '64. But they haven't done what we did. They've asked the doctor to report in and left it up to that. What we did is that we took the claimed

benefit cases and tracked them down. Everyone that we could get a hold of.

Young: Same as in Hoxey.

Goldhammer: Right, but we didn't have it as a voluntary thing. In other words, we would research the past history of every name that was proposed by them as a cure or as a benefit. We would seek the cooperation of the person and get from them their history--visiting the doctors that they told us that they went to. But we didn't rely...In other words, we didn't advertise and say, "Look, we want cases." We took the ones that they relied upon to promote their product.

Young: I really think F.D.A. should still do that with this case, because I think this is such a big case in its implication to the law in a lot of ways that it would be worth the time and effort for them to do it. But I really don't know.

Goldhammer: I don't know why they turned it over to the National Cancer Institute. It was F.D.A.'s problem more than the National Cancer Institute's problem. Here was a promotional scheme that violated the Federal Food, Drug and Cosmetic Act, so it was a job of the regulatory agency to prove that this

was a fraud.

Young: How many Congressmen, roughly speaking, have co-sponsored the Symns Bill that probably, as much as anything, results from the...

Goldhammer: It's not a majority. It's an appreciable number, but not quite a majority.

Young: Do you think this poses any risk to the efficacy provision, or is this symbolic somehow?

Goldhammer: Well, it would if it were passed. I don't think that the Symns Bill will get off of the ground. But, it certainly would have hamstrung the Department.

MacFadyen: What will the Symns Bill do?

Goldhammer: Well, it would give so-called "freedom of choice." In other words, if a person wanted to use a quack remedy, that's his business. It would undo the efficacy provision of the law, too.

MacFadyen: Is it broad or is it just aimed at allowing the use of laetrile?

Goldhammer: No, no it's broad.

Lofsvold: Actually, that's what it does. It just strikes the efficacy language wherever it appears.

Goldhammer: That's right.

Young: And I hadn't heard there was as many as two

hundred. I guess the last time I heard it was 120 or something.

Goldhammer: It's up close to two hundred. I don't have the exact figure. I do know, it's not a majority.

MacFadyen: Would you say that this bill would result to a large extent from the diminution of the power of authority in the society since the late '60's?

You know, Watergate and all that. Can you see that?

Goldhammer: I think so. It's a turn away from the philosophy that preceeded it.

Lofsvold: You've got to remember also that Symns comes from the state of Idaho which is probably one of the most conservative states that I know of, and he is, I don't know whether this Symns has had any experience with us but 20 years ago, the Symns family had a big orchard, and...

Young: Oh my goodness. Not another one of those!

Checchi: You don't have to say any more.

Lofsvold: Symn's Sunny Slope Orchard and I used to collect apple samples there for lead arsenate back in the early '40's and we had some problems there.

Young: Richard wanted to ask some questions about the Welch case which he gave a paper about and wants to get the paper published. Therefore, with you here from this period, would like to see what else

he could discover.

MacFadyen: Yes, there has been virtually nothing brought up about the Welch case, and when we broke I was asking Dr. Smith for your comments on Welch. You said that the Kefauver Hearings obviously shook up the F.D.A. and then you went ahead and said that the thing that really shook you up was Moulton's testimony. I anticipated that you were going to say that it was going to be the Welch case.

Smith: Well, you see, I really had no direct contact with Dr. Welch.

Young: Because the divisions were so separate.

Smith: Yes.

MacFadyen: Could any of the other of you comment on the Welch episode? What kind of person was he?

Checchi: King Henry I.

Goldhammer: Well, the history of the Welch Case stems from a writer for the, let's see if I can remember his name.

MacFadyen: John Lear?

Goldhammer: John Lear, right. The Saturday Review of Literature. Perhaps somebody gave him a tip. He had interviewed Welch and Welch was not very cooperative, he didn't give him any information. This antagonized Lear and he brought

the matter to the attention of the Kefauver Committee knowing that the Kefauver Committee was holding hearings on Food and Drug Administration at that time; not necessarily oversight just hearings relating to bringing down the cost of medicine and to determine whether there was a monopoly in the marketing of drugs. This was an anti-monopoly subcommittee of the Judiciary Committee of the Senate. Bringing the Welch matter to the investigators of the Kefauver Committee, brought the staff people of the Kefauver Committee into the Food and Drug Administration. As I said earlier, I was at that time liaison at F.D.A. I received them and gave them the files they wanted to look at...Made their job a little easier. One day, five of them descended upon me--five staff people from the Kefauver Committee. They wanted the files of the Antibiotics Division and there was a time there when we weren't sure we were going to give them...Ultimately, we let them have many of the files of the Antibiotics Division and they got enough information from those files to justify hearings, which they held. You know what the story was. Primarily, it was Welch's work for a journal with someone whose name escapes me.

(Ibanez) Yes. There were others in the Division of Antibiotics who also received small sums of money

for work done--doctors and some of the chemists who were working there. The sums involved were very small. But the Kefauver Committee was intent upon exposing them all. I remember one hearing when Kefauver was absent, and a Senator from Colorado was batting for him and presiding over the hearing. I've forgotten his name.

Checchi and Lofsvold: Gordon Allott.

Goldhammer: He was inclined not to expose all of the other people in the Division of Antibiotics, but the staff was exerting every possible pressure to bring out the names of the people in the Antibiotics Division that had received money from the publisher for articles written. Ultimately, the Senator from Denver prevailed and their names were kept secret, but you know about the exposure of Welch. I think that it was an unfortunate thing, but it provoked other Congressmen to look into it. I know that the people from the Fountain Committee descended upon us. They are colleagues now. Two of them came to us. They were exasperated because they had tried to get information about Welch from F.D.A. but F.D.A. would not cooperate, would not let them see the files which were ultimately seen by the Kefauver Committee

people. They felt that the Food and Drug Administration had discriminated against the Fountain Committee, and that only sharpened their desire to investigate the Food and Drug Administration, which they did, of course, quite extensively later. That was before my time with the Fountain Committee.

Young: That's one aftermath of the episode. What other aftermaths from the point of view of F.D.A. and its mission...

Goldhammer: Of Kefauver?

Young: Of the Welch case.

Goldhammer: Oh, well, the Welch case also opened up the matter of chloromycetin, chloramphenacol, and the alledgedly shabby kind of research that had been done; the safety data being so inconclusive. Yet it was approved and marketed. That brought in the Humphrey Committee. There was a chap by the name of Cahn who was a staff man for Humphrey. He was an avid operator, and he got into the picture because of the shabby research. He wanted to look over other drugs in which the evidence of safety had not been established. So, F.D.A. had a whole series of hearings with Humphrey and that brought forth Nestor. Apparently, there had been some previous

contacts between Nestor and Humphrey. And, of course, I think Nestor had had an impact on the Food and Drug Administration.

MacFadyen: Isn't it John Nestor?

Goldhammer: John Nestor. He testified before Humphrey accusing the Food and Drug Administration of passing drugs without adequate safety evidence, and he mentioned specifically Entoquel at that time. Entoquel is a drug which was approved for use in elimination of disorders of children, and it resulted in the death of several children.

Smith: Children's cathartic. I don't remember, were there deaths?

Goldhammer: Deaths or injuries. There may have been a death or two, I don't know. Entoquel came off the market as a result of that. Nestor testified before Humphrey's Committee about that.

Smith: Wasn't that the time, the general period, when there were two outside committees set up? One to examine the scientific handling of the new drugs and antibiotics, and the other to look into the chloramphenacol?

Janssen: The financial situation of the Food and Drug employees.

Goldhammer: Well, no, that was an inves-

tigation by the Justice Department.

Smith: No, there was a man's name, who was chairman of... There were three men. One was Sloan of Ohio State University, one was a, I believe an ex FBI man, or a safety man, and then there was a chairman, a lawyer.

Janssen: Was there an IRS man on it?

Lofsvold: The Welch affair resulted in a departmental investigation of the financial holdings of every professional employee of the Food and Drug Administration.

Smith: Yes, I remember, we had to...

Lofsvold: And the chairman of that was from another department. I don't remember which, and he was assisted, one of his people with him was a fellow named Costello who was the chief IRS Agent in Philadelphia, and I believe that the second person was also with an IRS background. A questionnaire went out to every employee, at least all of the professional employees to list all your holdings and where you got it, and then, some people who had some kinds of real estate or other financial holdings were interviewed in person by this group, which travelled around the country, and some people on the East Coast, I was in New York, people that

were interviewed there were summoned down to Washington for that purpose. I didn't have any money so they didn't ask me. But a few of our fellows, Charlie Wayne, the Drug Inspector, a bachelor who is a very sharp operator in the market, had at that time accumulated quite a bit of money and they wanted to know exactly how he had done this. Nothing ever came out of it as far as any other employee having any other problems as far as I know, but it was a rather damaging thing as far as the morale of the people.

Young: That's what I thought. There had never been an example within the Agency, an Agency with high morale, like this at all. I ask you if this is so? It was not only the questioning of integrity that was implied. I was doing research in the Agency and heard a lot of complaints there, but it was at high levels, the sense of hurt that people who had trusted what Welch had said, including the Commissioner himself, had, at being so deceived. Now I've said the hypothesis, I wish you would comment on it.

Lofsvold: I would agree with that except that there had been some very few problems before that

Lofsvold: No, Wendell Vincent.

Goldhammer: Oh, Vincent, oh yes.

Checchi: But I think that the important thing is the point that Fred made. As a sort of a fall out of the Welch affair and the subsequent investigation, and I was gone by then, but I'd only been out three years, so I guess I probably picked up more rumors from my friends within the Agency than people within the Agency. I think that that had an extremely destructive effect on the morale, not that Welch was canned or whatever; investigated, but really that they themselves were painted with essentially the same brush. And the type of investigations, as Ralph said, of making out all sorts of forms, and then if you had more than 3¢ in the bank you had to prove that you were an honest man, which of course is contrary to our principles of justice. I just think that whoever launched and directed the investigation of the financial ethics of the Food and Drug Administration's staff just did a very poor job. I think that the morale from that point, the morale has suffered for other reasons. As the Agency grew, there were problems. The morale in the early '60's was not one what one would like. But I think that the follow-up type of investigation

that was done with employees finances just about soured a hell of a lot of people within the Agency. Going back to Welch himself, what kind of a guy he was, I think that most people would agree that probably he was one of the most able administrators that Food and Drug Administration ever had. Those who worked for him loved him like a father, and everybody else hated him with a passion. They didn't call him King Henry for nothing. He built an empire within the empire and he built a moat around it and he protected it like the Medieval kings of old. Now, I don't know what all the fact was. Even Henry's dissenters within the Agency, and I must admit it has to be those of us without the fact who really question as to whether he has done for justly in that it had been known for quite a long time, so the story goes. You'll have to check the records on this because I don't know the facts, but my understanding is that the, well see Henry was the editor or editor-in-chief or...He had a public connection with this magazine. This was not a behind-the-scenes affair. His name was on the masthead of the magazine in an editorial capacity. It was public knowledge, and he made no effort to conceal his connection with this publication.

In the beginning when the journal started, they sold a modest amount of reprints of scientific articles prepared by, some F.D.A. people, contributing articles. This gave the publication or the venture some financial stability and also gave the promoters who were Welch and Ibanez and I don't know who else, a modest income. It's my understanding, as I say, I'm not alleging this, I think he, you've got to check the files if you are going to write a Welch story. But that was known in the Department and the Food and Drug Administration that Dr. Welch was making \$500 a year or \$1,000 a year, whatever it was, at a given point in time. Subsequently, my understanding of the situation is, the sale of reprints and the financial returns from this publication grew from the proverbial 12 pound ham to the whole hog. He made a pot full of money. And then, all of a sudden, the same basic thing that produced a small amount of money was immoral simply because it grew to where it was providing Henry with a hell of a lot more money, I understand in outside income, than his then GS-15 salary. But the principal was the same. The source of income, the method of deriving income, all this remained constant, but the only thing is that the quantity jumped from a relatively modest sum to

an apparently a very appreciable amount, \$60,000.00, \$70,000.00 a year in the '60's which was a hell of a lot of money. And, as I say, but quite apart from the effect on Welch himself which obviously was disastrous, the unfortunate part of the Welch case, I think was the immediate attack, if you will, on the integrity, not only of the people within the Division of Antibiotics, and certainly they should not have been singled out either, but on every individual professional employee of the Food and Drug Administration. As Fred says, Charlie Wayne happened to be a good investor, bachelor, and he's got to sit down and explain it to somebody, how is it that he could make so much money on the stock market. Well, it's nobody's damn business how he makes it as long as he doesn't own Food and Drug Stocks, which none of us ever did. Gilbert was the only smart investor. He bought Penn Central Railroad. I remember he (laughter)... But basically this was the, as I say, you've got to check the facts on Welch if you are going to put that in. But the effect on employee morale, I just think was one of the major disasters. Young: What about on George Larrick himself? Did any of you observe him after the revelations about the size of the income that Welch was getting?

Goldhammer: I think they were loyal. They weren't ready to dump Welch. Welch was a good friend. He used to have get-togethers at his home, he had a swimming pool. The Commissioner would attend

Smith: Sure. I think that I have a picture of the swimming pool with Tilly sitting there.

Checchi: I was a little fellow in those days. Nobody would invite me to the swimming pools.

Janssen: I have a picture of the pool with Gilbert sitting there.

Goldhammer: No comment.

Checchi: You see the fact of the matter is that Welch did not conceal, if you will, in real terms, his income.

Goldhammer: Oh, I would disagree with that. Harvey asked him point blank what his income was. Harvey so testified before the Kefauver Committee and he told Harvey it was none of his business.

Checchi: Yes, I agree with that. What I mean when I say conceal, I don't mean that he was really willing to reveal his precise income, but his lifestyle, his open lifestyle reflected an income substantially greater than the...

Janssen: I don't think so.

Checchi: Ah, come on, he bought a house out at Manor

Country Club...

Janssen: He had a house at Hillsdale, and that's where the swimming pool was, and then...

Checchi: Then he bought another one out at Manor...

Janssen: And it was not a house that a Director of a Division could not afford in those days.

Checchi: Well, I never visited his...

Janssen: The swimming pool was built by Welch himself and some volunteer help from the guys in the Division.

Checchi: Yes, but then didn't he subsequently buy a big house out in Manor Country Club?

Janssen: Well, he may have, I don't know.

Smith: I understand that he moved out there to get rid of the swimming pool.

Young: I mean he said he was getting a modest honorarium. Wasn't that the words that, ah...

MacFadyen: Well, as I recall, at one point in some of the memos Harvey asked him exactly where he made money and Welch said I'm making an honorarium of about \$3,000.

Checchi: That was earlier on.

MacFadyen: Well, this was, no this was when he was way up in the thousands.

Janssen: The bulk of this money was the total profit

from the sale of reprints and the percentage of the advertising also.

Lofsvold: But weren't the reprints bought in very large quantities by drug companies who never distributed them?

Goldhammer: That's right. But there was no violation of the law. I think we can say that. The Department of Justice convened a Grand Jury to look into the Welch matter along with some of the cases of false statements to the government in the matter of anticholesterol drug, Mer 29. They found no violation, no indictable violation of the law in the Welch affair. So what he was doing was not illegal.

Janssen: He got his pension too.

Goldhammer: Yes, he got his pension. As a matter of fact, I think, he retired early because he had a heart condition and retired on disability.

Young: They let him retire in order that he could get his pension.

Janssen: But Dr. Flemming left no doubt. He publicly dismissed Welch.

Young: Right. I wanted to ask, this question...

I've often wondered about this, and there is no reason

for it to be true at all. But, I wondered if, at this time when there were all kinds of pressures building up, if the fact that, in a basic sense, because of the size of the money, Welch had deceived George Larrick, who was his friend. He'd been asked several times, and he'd always given an answer which was essentially untrue, disguising the size of the amount. Whether, the impact of this deceit from an old friend which not only was deceit to his friend the Commissioner, but which was bound to be a terrible blow to the prestige of the Agency, which had had a very clean record, I wondered if that had any impact on George Larrick's health?

Janssen: I don't know about his health, but I do know that he was, he was really shook up. It was a traumatic event for him. He was very low after this.

Checchi: You must understand, George Larrick's health started to fail on him about the time I came to Washington the second time around, about 1957. As a matter of fact, the first two months that I was in Washington, I was using Larrick's desk. He was away out on sick leave, and, at least in '57 and on sporadically, George Larrick had medical problems. I am sure that the Welch episode

certainly didn't improve them. Now to the extent to which they contributed to his health, I have no idea.

Janssen: The thing that the Welch affair did to the Food and Drug Administration was that it corroborated as regards to the F.D.A., the standard, the conventional wisdom of the academic community and all who are students of government that all government regulatory agencies become corrupted by the people who they regulate. It is very common. I suppose every class in American Government all over the country hears this at one time or another. But, here is the Food and Drug Administration thought to be an exception to this up until the Welch case. So the Welch case really damaged the public image of the F.D.A. a great deal.

Checchi: But it shouldn't have, if we can philosophize. Let me take, for example, I think that the Welch case, it did have that effect, but I think in part because Food and Drug, or external forces, contributed to it. Let's go back and look at a smaller sense. When I was in the Boston District, we had a District Director, Cyril Sullivan. He was canned for being too close to industry, or allegedly so. Now then, in that case, of course,

the stakes are different, it was 12 or 14 years earlier. Whatever the circumstances, they were certainly different. The reaction of the Food and Drug Administration then was that it had what it regarded as a sore, it plucked it, and the rest of us in the Boston District, we sat around and said, well, one bad apple in the barrel. Is it going to be assumed that the rest of us are criminals? And Charlie Crawford, the then Commissioner treated us all precisely the opposite. There was no, now we've got to look and see about Monty Rentz, Andy Allison, Jim Lockree, Harris Kenyon. Now we've got to turn around and undertake an investigation both covertly and overtly of the morals, the ethics, of every guy in that job, as they essentially did in the Welch case. In the Sullivan case they did not do that. They said okay, it's done, there are no more problems. Everyone else in the District, we were left alone, we got promoted on up the ladder naturally, in pretty much the same rate as people in other Districts. There was no discrimination, no identification of, no one was tarred with the brush simply because he was associated with him, and I think Food and Drug handled it very well with respect to those of us who remained. I think...

Janssen: But in those days we didn't have the back-
drop of the Kefauver Committee.

Checchi: Well, that's right. In the Welch case it may
well have been out of the F.D.A.'s hand. It could very
well be that George Larrick could not have done a
damn thing about making all of you sign financial
statements, declarations, etc. As I say, it is per-
haps difficult to draw a comparison between the Sul-
liyan case and the Welch case. I think in a sense
there is a parallel in that there, the Agency was per-
mitted, if you will, to handle it in a very profes-
sional and a very intelligent manner so that no one
else got scared, either personally, nor did any-
one feel any antagonism toward the Agency which was
critical. Morale did not suffer. Whereas, in the
way that the Welch aftermath was handled, a lot of
people in Food and Drug said, well, son of a b. I've
been working for this bloody Agency for 30 years and
now all of a sudden they are asking me to prove my
loyalty and honesty and dedication.

Young: Yes, I'd heard that, when I was doing research.
That was a time that we were consulting, and I was
in this room with 8 or 9 other people. Seems like
space problems are perpetual. And they were red in
the face I remember just...

Janssen: Well, today, we have a further consequence that in a sense adds insult to injury. That is that in our Agency--and we have it throughout the government--it is now a professional job to monitor the integrity and potential conflicts of interest of the people of the Agency. And there is an office set up called the, what do they call it?

Lofsvold: Policy Management Staff.

Janssen: Well, it's in the Policy Management Staff, but they have a group that has several people and they have nothing else to do except to annually quiz the employees on what stocks they own and so forth. They made a business out of the presumption, there's a bureaucratic category now, based on the presumption that the employees of the Agency are, may be crooked.

Checchi: Right after, do you remember, right after the Welch thing they had Henry Roberts moved in as the in-house cop. What was the title they gave him? Poor Roberts. Everybody hated him. I don't think he's ever gotten over that.

Lofsvold: You know, your Sullivan case though went a little further than that. They not only didn't discriminate against the staff there, but they replaced

Sullivan with a man who had just come from Boston a year or two before, and I believe promoted one of the Boston people to his job as Chief Inspector. Didn't Shelby Gray come back?

Checchi: Yes, what they did, you see Shelby Gray was...

Lofsvold: And I was told at the time by a man who had reason to know that one of the reasons Shelby was picked was because they wanted to demonstrate that there was no suspicion about anybody else.

Checchi: Oh, Shelby had never been in Boston.

Lofsvold: Hadn't he been there as Chief Inspector?

Goldhammer: Yea, I think he had been.

Checchi: Shelby was a Resident Inspector in Charlotte.

Goldhammer: Was Rankin Chief Inspector there?

Checchi: Rankin was Chief Inspector early on, and the Rankin was replaced by Monty Rentz. Monty was Chief Inspector from, let's see, for about three years. Then they replaced Monty. Monty was transferred to Atlanta, I believe, and Shelby came in. Then they started the investigation with Cyril, then when Cyril was canned, Shelby moved up as Chief Inspector, but Shelby had never worked in Boston. What they did do that gave us all, well...

Goldhammer: Shelby was Chief Inspector in Philadelphia.

Checchi: All right, then Shelbey came to Boston. Shelbey was Chief Inspector during the Sullivan period.

Lofsvold: But he was just moved up then to take...

Checchi: He was moved up, yes, I think as part of the, let's see what's going on sort of deal. Then, what they did, the move I think you are probably referring to is when Shelbey moved from Chief Inspector to District Director rather than to go outside and get one. They moved Harris Kenyon who was one of the District Inspectors from operating to Chief Inspector. And the same thing with Jim Lockrey. They moved Jim up and me too. All the promotions that they made at the district for the next two or three years were all district people. They didn't bring anybody in at all. So we discriminated against you fellows.

Lofsvold: There is another aspect of the Welch matter though that I think might be of interest to you. I suspect that one of the reasons, although there were several, that Welch got into trouble like this was because his division was on a different kind of relationship with industry at the time as the rest of the Food and Drug Administration. Antibiotics,

you know, came along the latter part of World War II, and I believe that Welch was recognized as one of the scientific authorities on the subject as well as being an excellent administrator and was very instrumental in setting the first standards for penicillin, which were, essentially, of course, to properly control the uses of the product, and that from then on, he was right in on all of the development of the new antibiotics and the derivatives of the old ones.

The inspections that were made in the field, a good many of them at least initially, were made by division people out of Washington rather than by field people. We had the certification requirement then which gave him, in effect, the life and death control over the activities of these firms.

Young: In a much simpler cataclysmic form than anything else.

Lofsvold: Yes, that's right. And there developed a relationship between the people in antibiotics and the people in the regulated industries that was quite different than that that existed in the field. I never experienced it myself, but early in the time that I was Chief Inspector at New York, it would be around '56, '57, somewhere in there. I remember assigning one of my better inspectors to go out with

a representative of the Division to visit one of the larger antibiotic manufacturers. And the man said to me, "I don't want to go". "Can you get somebody else"? And I said why not? And he says, "I am embarrassed". "I've been out with those people before and when they go to the plant, it's all buddy-buddy and the things they talk about initially are where are they going to the theater and where are they going to dinner that night". And he says, "The relationship is not a healthy one, and I just don't want to be part of it". And this is a working inspector who was making this kind of statement. And apparently that was...

Checchi: There is a reason, it doesn't justify it, but the reason is simply this. That the Division of Antibiotics as opposed to the rest of the Food and Drug Administration was designed as a service function. It certifies antibiotics for a fee, it inspects foreign plants for a fee, and it is, as Fred points out, it was set up immediately after the war, perhaps during the last year of the war, as they had this new wonderful drug and they didn't know how to do it. A whole, virtually separate function was set up to assist. The Division was created to assist the antibiotic industry to establish, to help them establish good manufacturing practices. They didn't use

the term then, but we do now, to get started. There was a fee paid for certification, and contrary to traditional F.D.A. work, the only other certification function F.D.A. did at that time were two. One was the seafood thing, and the other was insulin and color. But the antibiotic thing was set up more than simply the certification service, but it was actually set up to assist these people to start to develop the most important drug of the century.

Lofsvold: And it was self-supporting...

Checchi: And it was self-supporting. It had gotten no appropriation from the Congress. In fact, it went the other way. Funds, certification funds were used to help to pay for an inspector, and a chemist and so forth. So this group saw it's mission and Dr. Welch saw the mission of the Division of Antibiotics as it was then called, differently than Gil saw his image, as a regulatory manager, or I saw mine as a Chief Inspector. I was in enforcement at that time.

Young: And it was different from other drugs.

Checchi: Different from Ralph's job. This was not a service function. Ralph's responsibility was not to help, although he did, obviously. His specific assignment was not to help to develop these procedures, to get the product out. He would help the guy and

say look, you ought to do it this way, but fundamentally, his was a review function. Our's was an enforcement function. Here you stuck into the Food and Drug Administration what was virtually an out and out service agency designed to help this industry for a fee. And for that reason... And they recruited outside in a sense, so that the philosophy was different.

Lofsvold: Well, Welch was not a career F.D.A. person. He came from the State of New York, I believe.

Checchi: No, he was from Connecticut, and then he was transferred, he came to Food and Drug about '41, '42, didn't he Gil, somewhere around there?

Goldhammer: Yes, somewhere around there. He was a microbiologist.

Young: Was he in academic life before? Or was he in industry?

Goldhammer: I think he worked for the State.

Checchi: Yes, I think he worked for the State of Connecticut Enforcement, then he came in... I think he was the head of the Division of Microbiology, and then when they set up the Antibiotics, they put him there and then they set up this task force almost to start an operation that was in philosophy, a function totally alien to what the rest of us were doing.

Goldhammer: And yet the law which set that up was a

regulatory law. It defined antibiotics in terms of misbranding, adulteration, as though it were any other drug and it provided for the same kind of actions, so that as far as the law was concerned, there was no basis for this being considered separate and apart as a function which is not related to the general function of the Food and Drug Administration.

Checchi: It boiled down to a question of personalities. King Henry was a very strong man. He wanted to set up that way, he was very good at it, he was very persuasive, and he had his way.

Smith: It was my understanding that the Division of Antibiotics brought in more money than it cost.

Checchi: Oh, it did, unquestionably.

Lofsvold: Their laboratories were the envy of all the other scientific divisions.

Young: It is an interesting point to suggest, and I'm sure, not relevant, exactly, but, the factories in which the penicillin was being made by the pharmaceutical companies had almost entirely been built with government money during the war. They tried to get private enterprise to undertake this, but they wouldn't do it. I've read about the way those Englishmen came on over here and so on, and; it was Florey who came over, I think. Did he come to the Food and

Drug Administration, do you remember, when he was out here scouting early in the war to, ah, you don't remember that. He went to fermentation people and he went to a mold person in the Department of Agriculture before he went out to Peoria where they had the big mold stuff. Anyway, they tried to get the American factories to do this as private enterprise, and when they wouldn't do it then they put up the money.

If F.D.A. was doing a service, granted it was being paid with regard to antibiotics, they'd already been done a big service by the establishment of these factories with federal money during the war.

Checchi: It's all part of the same basic philosophy, we need the drug. We'll do what the hell we need to do to get it out, in acceptable form.

Young: Get it in time for V day. Richard, do you have anything?

MacFadyen: No, I think that pretty well exhausts the...

Smith: As far as morale is concerned in the Division of New Drugs, I think that the happening which hit us the hardest was, or the man who hit us the hardest was not Senator Kevauver or Mr. Fountain or anybody like that. It was Senator Humphrey. And his famous, 'Who's minding the store'? speech which I imagine was written by Marcus Kahn.

Janssen: Julius Kahn.

Smith: Julius Kahn, yes. Where he made the statement in words to the effect that the only people with any scientific standing in the Division of New Drugs were Dr. Kelsey, Dr. Nestor, and Dr. Seigel. That left the rest of the Division feeling pretty low.

Janssen: And, he, I can't quote him, but the language was equally, if not more contemptuous with regard to Commissioner Larrick. This ex-inspector who didn't have, who was not a college graduate and who was not a scientist and all that, and he had no business running an agency like Food and Drug Administration. He really attacked Larrick a number of times. Also, the F.D.A. was a horse and buggy operation in the computer age and Humphrey was a salesman for the computers in the Food and Drug Administration. He really broke the ice and got us going and this new business of trying to put information in and push buttons and get answers out. Which I think has not turned to be to our advantage and a success.

Young: That may be, but I remember a conversation when I was there when they had one computer guy. He was also sitting at a desk in this room I was in. The first computer guy that they got there; a great big heavy set fellow.

Smith: Not Weisberg?

Young: No. But there was conversation with, I think, Kenny Milstead was involved in which there was an admission that maybe before that, there should have been some looking into the computerized approaches, and some of those things.

Goldhammer: Well, I remember that Danny Banes was on some sort of a committee--this goes back to the 1950's --to look into the potentiality of computers. So, F.D.A. was aware at a very early stage of the benefits of computerizing some of their procedures.

Checchi: Even if they'd been the world's outstanding experts, the appropriation; we didn't have enough...

Goldhammer: Getting an appropriation of three million dollars, even though the dollar was worth a dollar then. Still, it's a pretty small appropriation for such an important function.

Porter: But even so, the first computer that HEW had was ordered by the Food and Drug Administration for the Food and Drug Administration and then taken delivery by the department because...in the intervening time they decided they wanted it, and the first program that went on that computer wasn't scientific at all, it was field accomplishment data.

Young: Can you roughly date that?

Porter: Sure, well '61 or '62. We were still on that computer when I came to Washington in '63, I'd say '62.

Young: I'm talking about '55 or '56 when this fellow came, was sitting at the desk, and I was listening to some of these conversations.

Goldhammer: Well, the Food and Drug Administration was aware at a very early date. It set up a committee of which I remember Danny Banes was a member. He made a report at one of these almost daily meetings that we used to have in the Commissioner's Office. So serious consideration was being given right along.

Young: How were decisions developed as to new programs, new ventures, modifications during the period when you were there? What kind of formal or informal mechanism at high levels was there to handle a thing like this or any other major decision?

Goldhammer: Well, very often it was by assignment by the Commissioner. The problems would be aired at these daily meetings. As a consequence of what was said, he might indicate that, well perhaps we ought to have a committee, and he would name somebody to set up a committee to look into it. There would be reporting back at some future date. Of

course the division heads, the bureau heads were to be alert to developments and changing concepts and so on and report. We had a pretty good system in those days of keeping the entire Washington personnel acquainted with developments. There would be a monthly meeting in the auditorium of HEW that stimulated thinking on the part of everybody including division heads and the Commissioner's Office on what needed to be done to improve operations.

Lofsvold: Wasn't there at the same time, Gil, a kind of a tradition and philosophy of frugality that in an area like computerizing results and things like this, we were reluctant to divert funds from enforcement activities or things more directly connected with enforcement; the things that we viewed as overhead.

Goldhammer: Well, money matters of course dictated what we could do. There's no question about that.

Lofsvold: We were very conservative about putting money into things that were not directly productive; applicable to the mission.

Checchi: To get back to what Gil said. This meeting. There used to be, see the hours of F.D.A. used to be 9:00 to 5:30. 8:00 every morning there would be a meeting in the Commissioner's Office of Bureau Directors,

Division Directors, and the Commissioner's staff.

Young: This was a group totalling roughly, at this point.

Checchi: Oh, it would run from 10 to 15 depending, you know there was no mandatory requirement, no attendance taken. But let's see we didn't have bureaus in those days.

Goldhammer: Division Heads and the Commissioner's staff people used to be regular attendees.

Checchi: So we had, what, eight divisions? Something like that.

Goldhammer: There would be as many as 20 people there.

Checchi: So what you had was every morning you'd have this rump session. Now the scientific people used to not attend as regularly as the other folks simply because their offices were over in south Ag. and we used to meet in the New building in the Commissioner's office. So regularly you'd have the five of us from the Commissioner's Office, ah, then it would be Steve, you or Ken, Rayfield, Jerry Holland (Bureau of Drugs) and then occasionally, always Bob Roe, occasionally one or two of his Division Directors. And that's where they used to kick around things, what we ought to be talking about thinking about, this about that ah, peanut butter hearing what the hell are we going to

do? And it was a sort of rump session, no formal agenda to discuss basically what are the problems; you'd kind of go around the room. What's going on in your shop, Gil? Well, in those days we might be prosecuting Koch or Hoxey or somebody. Gil would fill us in and maybe somebody would have a suggestion, they'd come around to Wally and so on and so forth. It was an excellent means of keeping those who had to know what was going on abreast of what was happening throughout the Agency and to get input from your colleagues. Now then, the second thing as Gil said, was the monthly staff meeting that met in the auditorium. Then there was the other formal Division Director's meeting that we had once a month I think. And that was a more formal meeting with an agenda.

Young: Did everything go down to the field through whatever the head of Field Operations was at that point? Or was the field...

Checchi: Primary contact with the field was the Division of Field Operations.

Goldhammer: We used to have a weekly publication in the Division of Regulatory Management; a pink sheet. This would keep them informed and keep them abreast.

Checchi: Then there was the news, the weekly newsletter

that your shop got out; the "Food and Drug News".

Janssen: Well, the "Food and Drug Review" was...

Checchi: "Review", yes monthly.

Janssen: Then there was the report on enforcement and compliance which was the record of the different cases that had been terminated and some information about them if they were important enough. The difference between the "Food and Drug Review" and the monthly report on enforcement and compliance was that the "Food and Drug Review" was internal and the other thing was available to the public.

Young: Internal, but also to state regulatory officials.

Janssen: That's right.

Checchi: And retired people...

Goldhammer: There was another thing we used to have...

Porter: Some of them (retired folks) ask for something like that now. The retired people wish there was something like that now.

Checchi: To comment just, excuse me gentlemen, just to finish on Fred's comment about budgetary considerations for computers and things, were we stingy in that respect? I don't frankly remember the discussion on computers specifically during my period, but again in the formulation of the budgetary process, these weekly discussions, the daily discussions. The Agency

in those days saw it's mission, the Commissioners of the time saw the mission of the Agency as regulatory, as enforcement. The current Commissioner has tended to see the mission of the Agency as scientific with a regulatory support. The reverse was true in the '50's. We saw ourselves as an enforcement agency who needed science to get the job done. So, priorities were developed. The priorities that we had for our funds were developed toward enforcement as opposed to science gathering. So, as I say, I don't remember the discussion, as you say, with Danny working on the computers or a lot of things that then were going along but, generally I would say that if it were being discussed in the context of getting a piece of good laboratory equipment for use either in the field or in Washington for methods of development or analysis, the laboratory equipment would win as opposed to a computer in those days.

Young: And the atmosphere was completely open. Anybody could say anything, question anybody else's point of view. Is this so or not?

Goldhammer: Yes.

Checchi: I remember one day I thought I was going to get thrown out the window when I commented about the attitude survey. The trouble with the Food and Drug

Administration is the morale stinks.

Goldhammer: In addition to the Commissioner's meetings, once a year we would hold a District Director's Conference in Washington to which the District Director, and perhaps the Chief Inspector might come. The Chief Chemist might also come. There would be a formal agenda and the problems of the Food and Drug Administration would be aired with the field people. Following this, a summary of the meeting would be circulated throughout the Food and Drug Administration of some of the decisions that were made. This was a regular thing. I don't know whether they have that now, Fred, where each year the Directors, District Directors would come to town.

Checchi: We have one every week now, Gil.

Lofsvold: Well, not quite that bad. This year we're only having the District Directors in once. The Regional Directors get together about, this year it will be about four times. We do have separate national meetings about every other year for Chief Inspectors, Chief Chemists, Chief Compliance Officers.

Goldhammer: So, you'd have formal programs, papers delivered and so on.

Janssen: Tell us about these red phone conferences that you have.

Lofsvold: Well, it's a species of staff meeting that we have every week, on a regular scheduled basis using a telephone link that we can get everybody together on a conference call.

Young: On technology when did you first use an airplane in connection with that F.D.A. business?

Lofsvold: Well, Jack Harvey came into Spokane, Washington in August of 1939 by airplane to interview me and that was one of the, I don't think we'd been using them very much at that point. In those days you had to justify the use of airplane rather than train on the ground that it was a saving in per diem and salary to get around that much more quickly than you could by riding a train.

Goldhammer: Well, by 1940 it had changed. In 1940 I was in New York as an Inspector, and I went to California to testify in a court case. I used a plane that took about 23 hours to get out there...a DC-3, I think.

Young: This was the first time you used a plane?

Goldhammer: Yes.

Lofsvold: I think there probably were earlier flights than '39 but not much earlier.

Porter: In my interview with Sam Alfend, he tells an occasion when he, on short notice, had to go

from I believe (it's in the interview) but from St. Louis to like Indianapolis or some place. I think it was even back in the '20's, but it might have been the early '30's and he went in a three-place plane; two people behind and one sat up by the pilot. That was probably one of the earlier flights.

Goldhammer: The Seattle District people going to Alaska would use planes regularly. That was the only way they could get around in Alaska.

Lofsvold: Well we started chartering up there about 1941 or 2. Prior to that they had to make their way around by catching rides on cannery tenders, boats that went between the canneries. But we started chartering in the early '40's sometime--float planes to fly the guys into the small canneries.

Janssen: Reminds me about a little chore I had on one of the first trade papers I worked on; the "Northwestern Miller". One of these chores was doing the fifty years ago column and I remember the item that I found one time, a news item it was, the Smith Milling Company has installed a telephone. It was important enough to make the paper.

Checchi: Now all they need is someone to call.

Lofsvold: Harvey, you want to talk about this transportation. The Food and Drug Administration had been

going for quite awhile at least under the name of Bureau of Chemistry before they ever started using automobiles. I think that out West that some of their earliest usages were in the very late '20's; '27, '28, that late. And I know there's a story that Jerry Martell, the retired Import Inspector loved to tell at New York that when he came to work in about 1926 or '27, maybe '28 there was a story around that the station had once owned a car, a Model T Ford, but it wasn't anywhere and nobody knew what had happened to it. And finally somebody told him, well the last time I saw it it was over in this corner of the basement. And he went down there and the corner of the basement was full of steam coal for the boilers. Well, Jerry took his shovel and spent most of the afternoon and, sure enough, when he dug far enough, there was the Model T Ford. He spent a week or two cleaning it up and used it then as the sole vehicle that the Food and Drug Administration owned at New York for several years.

Young: Well, I ran across some interesting material about the typewriter early in the first decade of this century where they were weighing whether to get some typewriters in order to conduct business. I

mean the technology by which an agency operates is expressive.

Janssen: Sometimes they also referred to the typewriter as the two-legged person that operated the darn thing.

Young: I just wanted to go back to something we were speaking of earlier during the Larrick period when you were serving. While you were in the field during this period, did you feel apprised enough to feel quite fully part of the enterprise and not shut out so to speak from what important things were taking place?

Lofsvold: Oh, I think we felt very well informed, particularly on regulatory matters. I talked to Gilbert practically every day. I think from New York on the cases that we had pending or someone on his staff. And we were generally, I think, quite well aware of what was happening in Washington even though we did not get to Washington as frequently as we do now. And we did not have the advantages of teletype service or the tie-line telephone and that sort of thing. We knew what was going on.

Goldhammer: Well, it was a smaller organization. That's possible when you've got a small organization.

MacFadyen: The system of management you've been

describing is one of centralization of decision making and decentralization of operations. I just wonder approximately when the Agency adopted this. I imagine some time in the earlier period it wasn't quite this way that people out in the field had much more leeway in what they were going to do. Would you say that?

Goldhammer: That's true. With a telephone... No, it was the reverse. It was greater centralization. I remember Dunbar making the statement that with the telephone and the ease with which you could now reach the field and talk to them that, "We (this is Dunbar talking) in Washington could give greater latitude for the District to assume responsibility because if something went awry it could be stopped within a matter of minutes". So, I think the tendency was great centralization in the beginning where Washington was to make all of the important decisions. But with communication becoming improved that the tendency was to delegate the responsibility to the field and let them have greater latitude.

Checchi: But Gilbert, at least when I left the field, we still didn't have authority to refer cases to the United States Attorney. All the final decisions on seizures except a few direct reference like butter

and some fresh fruit, berries and what not; all seizure recommendations had to be cleared, had to be actually made in Washington. Prosecutions and injunctions, also.

Goldhammer: Well, the philosophy there was that you had to have checks and balances. It was recognized that when you brought a man into court you could be hitting him unfairly.

The Food and Drug Administration wanted to be sure that this was a case and so there was review at the District level. By the District, I mean Eastern District, Central District, Western District, the Station level, the District level, and Washington before a case was decided to...

Checchi: And I think that's wise even today.

Goldhammer: It is.

Checchi: Uniform application.

Goldhammer: Yes, that's right. But I think after the Second Citizen's Advisory Committee Report there came a time when there was a feeling that there were sixteen or seventeen different Food and Drug Administrations. There seemed to be a chaotic period there when they delegated a lot of authority to the District Officers.

Lofsvold: That was subsequent to Goddard.

Goldhammer: Right.

Lofsvold: '66...

Goldhammer: There was a lot of confusion. The Districts didn't know what was expected of them. They were suddenly given a lot of administrative authority, latitude, and there was a feeling that there were now sixteen or seventeen different Food and Drug Administrations.

Janssen: Wasn't that related to the destruction of the centralized monitoring and supervision of enforcement?

Goldhammer: Yes, that's right. And that's when morale suffered an awful lot.

Janssen: I think we went back essentially to what prevailed under the old system, that was abolished, because there were three little Washingtons instead of one place.

Lofsvold: Yes, I think you can make this distinction that prior to 1948, when the three geographic Districts existed, people who were in the stations, I was for instance at Seattle, the District Office was San Francisco. People in the Stations had very little contact with Washington headquarters. They looked for guidance, they submitted their work to the District Headquarters. They received back advice from there

sometimes after referral to Washington but often on the District's own authority. Then in the period '48 to '66, after the three geographic Districts were abolished and the Stations were elevated to be Districts, then in that period was the one I'm talking about where we talked all the time to people in Headquarters and received advice, guidance, supervision from them. Then in 1966, when Goddard changed the organization by setting the Districts out as independent, giving them autonomy so to speak, and at the same time destroying some of the Headquarter systems which had provided us with information, with guidance, advice, supervision. Then we got into this period of chaos when we, those of us in the field, as experienced managers of field offices did what we thought was best and in most cases tried to follow traditional values and traditional policies as we understood them. But in the case of a few individuals who had some theories of their own, going off widely divergent and over a period of four years, we did develop a wide divergency from one to the other. That came to an end then in 1970 when Edwards as Commissioner recentralized the management of the field by creating a position of Executive Director of Regional Operations.

Young: But, for volume two, what led to the decision

to end the three Districts in 1948?

Lofsvold: I don't know and I asked that question of some of my older retired colleagues when I was trying to put together a speech last year. Gilbert would maybe be the best authority on that. I have a suspicion that part of it was the divergence in policies among the three existing Districts.

Goldhammer: Three Divisions were created in Washington simultaneously. The Division of Regulatory Management, was to be the specialists in casework, but was not to take over the function of the District which had been known as the Station up until then. They were to assist the District in the discharge of the District's responsibility.

Young: The new smaller Districts?

Goldhammer: Yes, it was the District's responsibility to handle the cases that they developed. They were to work with the United States Attorney directly and assist the United States Attorney whenever necessary. But cases of national importance or precedent cases were to be initiated, taken over and carried through to a finish by the Division of Regulatory Management. In this job, the District

would assist the Division of Regulatory Management in acquiring the evidence which, in the judgment of the Division of Regulatory Management, was necessary. At that time it was called the Division of Litigation, but its name was changed in due time because of protests from the General Counsel's Office to the title, Division of Regulatory Management. Then there was to be a Division of Field Operations which was to coordinate and supervise the operations of the new Districts, the smaller Districts. And then there was the Division of Program Planning. I think it was Crawford's idea; the elimination of the three Districts. I think he had in mind that these three Divisions headquartered in Washington would take up the slack left by the abolition of the three Districts and he felt would make for a more efficient enforcement.

Lofsvold: Well, these functions that you're describing are the ones that were taken from the three geographical District offices and then centralized in Washington.

Goldhammer: Yes.

Lofsvold: And it was Crawford's decision, I know that.

Janssen: I reported this for the pink sheet when this happened. And I might be able to find the story, but anyway, the main thing that I recall about it was the

three little Washington business and the inconsistency. And I recall very distinctly that many times, calling on Campbell, Dunbar, Crawford and Larrick, that the Commissioners of the Food and Drug Administration were always bothered by the problem of insuring equal treatment under the law that people in Wisconsin didn't get treated any differently from people in New York State and so on. This was a difficult thing to achieve given all the variables in this situation, but that was something that preoccupied them a good deal...and they had it in the back of their minds all of the time. And there were two other things. One was continuity and another one was consistent policy. In other words, a policy shouldn't vary from month to month and if possible not from year to year. The policy of the Food and Drug Administration should be such that it could be relied upon by people who are making plans and spending money and business and so on and the consumer is entitled to this too. So that was the underlying philosophy, I think, that accounted for some of these changes.

Checchi: My recollection is the same as Wally's; is that really it's uniformity, unification, avoiding a duplication. There's one other factor and that is

that these three Food and Drug Administrations were run pretty much as three separate entities. There was very little cross-fertilization of personnel. You would be hired in one District, you'd generally stay there unless you happened to be a klunk where they wanted to move you back and forth, or you happened to be very brilliant and the administration insisted you get moved back and forth. By and large there was very little cross-fertilization within the Food and Drug Administration.

Young: Were the three District Chiefs, what were they Chiefs? As men, as human beings, did they have somewhat different styles or philosophies?

Checchi: Oh, absolutely. There were three different personalities totally.

Young: The way you respond so enthusiastically to this suggestion, it might not be a bad idea to give a brief profile of the three key ones so that we get what lies behind your response.

Goldhammer: I could speak of Wharton and I guess you can too. He was a very domineering individual. Everybody feared him. You didn't cross Wharton. He didn't take kindly to being contradicted. And he was regarded as a hard task master. Now that much I know about Wharton -- he was a feared man.

Lofsvold: To give you a clue, the late McKay McKinnon, one of his favorite stories was that he worked for Wharton for ten years until he found out that the eye with kindly gleam was his glass eye.

Young: Now this is personality. What about Food and Drug philosophy? Anything distinctive about him?

Goldhammer: Well, he was a rigid enforcer and we were all schooled in that. There was no question in our minds as to what was expected of us-- dedicated service and rigid enforcement and playing the game by the rules. He was a good administrator; while he was feared, he was a good administrator. And I understand that the idea of abolishing the Districts had been in the minds of the Washington officials for a long time. But they waited until after Wharton died before they put through the plan.

Lofsvold: Retired.

Goldhammer: Or, retired rather, right.

Checchi: It gave them the opportunity to do it.

MacFadyen: Does that mean he was feared upstairs as well as down? They took due regard to his dominance.

Checchi: He was an original Inspector.

Young: Were you going to speak about the Central District?

Checchi: No.

Lofsvold: I can speak a little about Western, because that's where I started, Bob also. John L. Harvey, Jack Harvey was Western District Chief at the time that I came on board. I went immediately from Seattle to San Francisco and spent two months down there. And Harvey took a strong hand in personally instructing this group of twenty-five neophytes in the intricacies of the new Food, Drug and Cosmetic Act. He was at that time about forty years old, I guess, and was one of the most dynamic, striking men that I'd ever seen. I was in no green hand, I was twenty-six and out of school quite a while. But he was at that time a very handsome man; very articulate, an excellent speaker and an inspiring kind of leader. And it was, would you agree, Bob, it was a real treat to be around the man?

Porter: I remember I wrote back home for the first time in my life I'd been in the presence of a truly great man.

Lofsvold: This was the way he impressed us. His style of management was quite different from Whatron's as I understand later after I went to New York and learned something about how they operated previously there. The Eastern District was very tightly controlled with work planning right down day by day

and the rules were rather rigidly enforced. Things in the Western District were, again I think a reflection of Harvey's personality, were sort of free and easy. And as long as you got your work done there weren't very many questions asked. It was about as hard living, hard drinking crew as I ever was associated with. Well, to give you an example, even in those days it was a cardinal sin to use the government automobile to transport people other than on government business. But in the old Western District if a guy were married and he went out on a three or four week road trip and he didn't take his wife along people wondered what was wrong. (End of tape caused break in Mr. Lofsvold's statement). ...Gave a lot of freedom to the individual operating Inspector who was out and away from the office was pretty much allowed to do things he thought needed to be done.

Young: Now does that, when you say that, were you following up leads that had been given to you or were you finding new cases?

Lofsvold: Well, you went out with a bunch of assignments, things that you were to look at either routinely or because of some other reason, but in addition to that, because of the distances you find yourself in a town where no Food and Drug Inspector had been for

six months or a year. And so you were supposed to look in the telephone book at any likely looking addresses, go around and see what was there, and if you saw anything that resembled a violation, collect the evidence to support a legal action.

Checchi: Did you have surveillance reports?

Lofsvold: Oh, yes.

MacFadyen: Was this ever dangerous?

Lofsvold: There were little incidents. The dangerous part came later.

Goldhammer: There were some incidents where there was obstruction to an inspection. As a matter of fact, an Inspector one time found himself in jail because of his attempts to make inspection. But on the by and large there wasn't any opposition.

Lofsvold: A few people were threatened especially in Alaskan salmon canneries.

MacFadyen: Put in jail for trespassing, is that it?

Goldhammer: I don't know just what the charge was that landed him in jail, but he was doing his duty as an Inspector and nothing more. It was in a small town, the sheriff arrested him.

Lofsvold: I think the Central District was somewhere in between. It wasn't quite as free and easy as out West and it wasn't quite as regimented I believe.

Goldhammer: I remember J.O. Clarke when I first met him and worked with him. His office was right next to mine. I was impressed with his easy going style. I was used to Wharton and he seemed to be the direct antithesis, perhaps he maintained rigid control in his easy going way. But he was a wholly different personality from Wharton.

Lofsvold: But each of these guys in his own way was a leader.

Goldhammer: Yes.

Lofsvold: And the people who worked in each of the Districts swore by their operation.

Goldhammer: And there was a spirit of competition among the Districts.

Lofsvold: You bet there was.

Goldhammer: I mean by the Eastern, Central, Western Districts and the Stations within that District. The competition was directed in a sense to the uncovering of violations. And there would be a score card kept so that you could compare different Stations as to the number of violations that were uncovered. So that there was a challenge to the Inspector to do more than just a routine day by day job. We were indoctrinated with the idea that we were a policing Agency and that our success would be measured by the number of

violations that are terminated. And perhaps that's right.

Janssen: Look at the 1977 annual report and you'll find a very small type of table at the very back that will tell you what the score is on the number of cases.

Goldhammer: Seizures, that's right.

Lofsvold: Well, it's a different kind of ball game now. You could not operate an agency this size, even the field force this size by the way that we were able to operate when the total agency was less than 2,000 people, or less than a 1,000 really.

Goldhammer: No, when I came in there were only 77 Inspectors throughout the country and that included the Chief Inspectors.

Porter: I think there were only 90 some when I came in which was a few years later.

Goldhammer: We had an appropriation of \$900,000, a little over \$900,000.

Janssen: Didn't both Harvey and Clarke come to Washington then to head up the new Divisions and then Wharton retired or did he die or what happened?

Goldhammer: He retired.

Janssen: Wharton retired and the other two came into Washington.

Checchi: Well, the plan was: Harvey came in and ran the Division of Litigation, Bureau of Regulatory Management. Clark came in on Program Planning. Wharton was offered the post of coming in to run Field Operations. These were the three major operating Divisions. Wharton opted to retire. Rayfield was heir apparent so he became...

Lofsvold: There was another little thing in there. The real heir apparent, most people including the man himself thought, was the Chief of the New York Station.

Checchi: Charlie Herrmann.

Lofsvold: No, McKay McKinnon.

Checchi: Charlie Herrmann.

Lofsvold: In '48

Checchi: Mack had already gone.

Goldhammer: McKinnon was Director of the Eastern District, or Assistant Chief.

Lofsvold: In 1948 when the reorganization took place, Mack was sent to San Francisco which he regarded as a banishment.

Checchi: What was Charlie Herrmann then?

Goldhammer: Charlie Herrmann was Assistant Chief. He was under Wharton.

Checchi: He was Assistant Chief of the District.

Okay, right.

Lofsvold: He was the wonder boy and I met him once a year later, no, the same fall of 1948, at a conference here, at the railroad station and as we rode up in the cab, Mack was commenting about his recent transfer to the West Coast when he thought he was going to get the Eastern District. He said all those years I went along thinking I was the crown prince then the damn thing turned out to be a democracy.

Young: Mr. Checchi, did you want to say anything about these people?

Checchi: I was going to talk about Jack Harvey since I worked for him for three years, but I just can't add anything to what Fred said about him in terms of his character. He was a hell of a nice guy; a leader. And he was a kind of a fellow that I could go in; I remember one day we were laughing. We used to argue like blazes all of the time. He was the kind of a guy you could go in and argue with and we used to be there until 6, 6:30, 7:00 at night a lot of times. And I had a little office just off of his and I was in his office and I was arguing, I've forgotten the point, it doesn't really matter, so finally he slams his fist, "All right Tilly, I've had it". And he said, "I'm the Deputy Commissioner,

you may think I'm wrong, but I've got the right to be wrong, by God this is the way it's going to be". I'd get mad and I'd say, "God damn it, just because you have the right to be wrong, don't abuse it". I slammed the door and walked out. And I sat at my desk and fumed. A minute or two later the door opens and Jack, did you know Harvey? You knew Harvey.

Young: Yes, a little.

Checchi: You know he was a little guy, stuck his head in the door and says, "You all right"? I says "yeah". "Well, let's go home".

Smith: In that connection, I remember Mr. Harvey talking somewhere and talking about you. You were there. And saying, "Tilly can take both sides of an argument and argue vehemently on both sides". And Tilly said, "And lose both of them".

Young: Well, all of this is building a picture of the importance of scale as a factor in trying to understand an enterprise. Because you knew virtually everybody except maybe the last couple of recruitment years of Inspectors and Chemists. If you'd been along awhile and had these annual meetings and maybe got transferred a few times, you got to know virtually everybody and I take it that gossiping about what was going on was rather a constant thing among you.

So that you learned a lot by the kind of stories that you're telling as it was happening and felt yourself part of a common enterprise. Competitive within but proud as facing outward toward the rest of the world.

Porter: We thought we were part of the Food and Drug Administration and not just employed by the Food and Drug Administration.

Several: Right, right.

Young: And so that when you ballooned into such a tremendous big thing and particularly had all those revisions which began in the '60's.

Janssen: We have since become compartmentalized and the internal communication has deteriorated.

Young: It made it a quite a different thing.

Checchi: I'll give you a good example. When I was first in Food and Drug, I was in the field when Dr. Dunbar was Commissioner. I met him once in my life while he was Commissioner. He retired about '52, '51, '52 something like that.

Janssen: Late '51, a few months after I came with Food and Drug.

Checchi: Okay, and I didn't get to Washington on assignment until December of '54 so our paths...

As I say I met him once. It was Rankin who brought

me in and introduced me and Dunbar very graciously said, "Oh yes, we met in Boston" and all this and I figured he had been well briefed. But at any rate, then I saw him once after that at a FBI banquet or something, I think he was guest of honor, I've forgotten what it was, but I have seen that man exactly twice in my life. When George Larrick let it be known that I was going to leave the Food and Drug Administration, I got a phone call. And I took it and oh, my secretary who was fairly new to Food and Drug says, "Somebody wants to talk to you". "Some guy named Dr. Dunbar and he says you'll know him". I asked him what firm he's with. And he said, "Well, he will know me". She says Paul Dunbar. I said, "Gees, give me the phone". So I pick it up and he says, "Tilly"? "Yes". "This is Paul Dunbar". "Oh, hi Dr. Dunbar". He says, "I hear you're leaving the Food and Drug Administration". I said, "Yes". He said, "Do you mind if I come in to talk to you"? And he says, "I've got to be in town" (the next day, I've forgotten). And he came in, as I say I'd only seen that man twice in my life, and I had not spent in sum total more than twenty minutes in his presence. And he came in, he had followed Food and Drug to the point even when he was in he knew, as you say, you

knew everybody if not by face by reputation. He came in, sat down, had a long talk with me and he said he was disturbed, he said he'd been following my career. He thought I had as good a chance to be Commissioner as anyone else. You know he was talking up and damn, I almost cried when he got through. And he said he was disturbed and he says, "Why is it that a man with your promise and your accomplishments with the Agency would leave"? So I had to sit down and explain to him that \$12,000 a year with four children, you know in those days government salaries were low and the Food and Drug was the lowest of them all. And he kind of philosophized, but I nearly cried. Here was a guy, he cared. And this sort of thing, as you say, the Agency was small. You knew everybody if not by face you certainly... I've known of Bob Porter, but really this is about the second time I've ever seen Bob. I've known of Fred for years. As a matter of fact I've seen a hell of a lot more of Fred since I left Food and Drug Administration than we ever saw of each other before. But I dare say he knew about as much about me as I knew about him. And that was a lot, during the days at the Agency. And it really was... You didn't work for the Food and Drug Administration, you

belonged to it.

Young: In this context did the shadow of the great colorful founder, Harvey Wiley, have any role at all?

Checchi: I don't think so.

Lofsvold: Our God was Walter G. Campbell.

Young: Yeah, that's understandable.

Checchi: We were with the Church of Latter Day Saints.

Young: Wiley possibly injured his image by the kind of stand he took.

Lofsvold: The people that we worked for came in the Campbell era and so when any historical things were related to us it generally related to the time when Campbell ran the outfit.

Young: And he really was the one that had created the outfit that you were working in.

Lofsvold: That's right.

Young: More than Wiley has rather. Yeah, I understand that.

Janssen: The thing, the kind of conduct that Dunbar, visiting Tilly, that's the way they got people to make a life work of the F.D.A. He recruited me, boy that was one of the happiest days of my life, that I could belong to something like this. It was great. I remember when he retired instead of allowing them to give a party for him, he gave a garden party at

his home in Somerset. And everybody in the Food and Drug Administration was invited.

Young: Yeah well, just to be quite frank about it, it was still so much that way that I almost felt that way myself when I came in the '50's and you were interested, that I was interested in some aspect of your activity and made me feel quite at home. As I was just talking about the technology of it, the first time I saw George Larrick, he came down from his office which was way down the hall, in order, himself, personally, to duplicate a letter at this one machine which the Agency in say '55 or '56, whenever this was, had. A sort of wet process where the thing came out all sappy. But he came down and he did it himself and I mean he wouldn't of had to. He just, I suppose, chose to. And walked back. Which said something about photo duplication, but it also said something about the enterprise. And he was just as cordial to George as the guy who usually did this photo duplication, I think that was his name, as to anybody else. I mean he knew everybody on a first name basis and all that.

Porter: He knew everybody in the whole country on a first name basis.

Goldhammer: You know, as for the Agency being parsimonious, let me give you one illustration. I came into the Food and Drug Administration in Baltimore, 1935. One of my early assignments was to come to Washington, D.C. to do some investigational work. Now this required that I take street cars from one destination to the other. And I used three street cars at 10 cents apiece and put that on my expense account. My expense account bounced. Why didn't I buy three tokens for a quarter? Now that's an actual occurrence. And I had to have an explanation, but I didn't have an explanation that would have been allowed as to why it was necessary for me to pay three separate 10 cent fares.

Checchi: What was the explanation?

Goldhammer: I hadn't expected that I would take three streetcars. In one case, I didn't make contact, so I had to go to my next one.

Lofsvold: Harvey, here's an exchange of correspondence that I took out of a file on one of the Ginger Jake cases of the early '30's that illustrates this point of how they watched the dollars in those days. You can take that with you.

Young: Okay, well.

Porter: Well, you know when I was resident in Salt

Lake City in 1943 and 1944, we weren't allowed to have a telephone. We borrowed, used the telephone of the agency across the hall when we needed it. And they agreed to accept calls for us.

Goldhammer: Well, you know we have that situation in Congress. We can't make long distance telephone calls unless it's an emergency if you want to call somebody. In the ordinary course of business, let's say a man in California, I have to wait until 5:00 P.M. At 5:00 P.M. our FTS is activated and we're not charged for a long distance telephone call. So, I make my call then. If, let's say, I have to call someone in Pittsburg who operates on the same working schedule as we, I might not reach him after five. I've got to somehow finagle it so that someone else gets a message to him that he's to call me or else I have to reach him at home after 5:00 P.M. But that's how tight Congress is.

Young: That's certainly not the picture that we get out in the...(inaudible).

Goldhammer: Well, that's how it is and, you know, we're embarrassed to have to say I'm sorry, we can't return your call, will you call me because we have no authority to make any long distance calls.

Young: Can't members of Congress themselves do so?

Goldhammer: Well, members of Congress today have an FTS line open all day. The thinking is that Congressmen have to keep in touch with their districts at all time. Very often I have to go up to Fountain's office if I want to make a long distance call. I can't make it from our subcommittee's phone.

Lofsvold: They're on the FTS system, just like the executive branch I think because...

Goldhammer: It goes beyond that, I think it's an absolutely free call. I don't know they manage that.

Lofsvold: It is from here. Any place in Washington on FTS is.

Goldhammer: Oh, is it?

Janssen: Is it true that if you are in travel status, you couldn't collect for your first transportation in the morning because you were going to work then.

Goldhammer: Yes.

Janssen: Nor could collect for your last transportation because you're going home then.

Goldhammer: That's right.

Checchi: When you're an Inspector on six bucks a day per diem you had to be an accountant, didn't you? We could figure out all the angles.

Porter: The worse thing about it is that when they disallowed an expense account, they didn't just take that item off and pay the balance. The whole account

was tied up until you got it all straightened out.

Goldhammer: That's right. I think it was \$2.50 per diem when I first came in. Then it was raised to...

Lofsvold: In '39 it was \$4.00.

Goldhammer: 3 and 4...

Porter: I think it was about four and a half when I started, but you could get a hotel room for \$2.00, so it really wasn't as bad as it sounds.

MacFadyen: I wanted to ask you when you were talking about the smallness of the Agency in terms of the Inspectors. Did you have the sense that when you went out into the field that there were so many violations that you couldn't reach because of the smallness of the Inspectors, of the number of Inspectors?

Checchi: I felt ten feet tall when I was an Inspector. Never felt inadequate.

MacFadyen: In other words, you said there were something like 77 Inspectors.

Lofsvold: Depended on where you were.

MacFadyen: I mean was that an adequate number? I guess is what I'm saying.

Lofsvold: It wasn't, of course. I was at Seattle for a long time; from '39 until '55. And, for example, in sanitation kinds of violations, they were difficult to find there. The climate was not conducive to the

growth of insects. The warehouses mostly were fairly new and in pretty good shape. Then in 1955, I was transferred to New York city. And there we walked right past violations, that in Seattle we would have been enthusiastically gathering evidence and prosecuting, because we had so many worse ones around that we had to give attention to first. Part of it was staff imbalance. The staff at New York was woefully small for the amount of work load there was there in terms of regulated industry. But part of it was the difference too. The difference in climate, the difference in old, old facilities, and things of that sort.

Porter: Well, in Denver we had about five Inspectors when I went there and our territory at that time went from Canada to Mexico. So that at any one given time it was normal to have only one Inspector in town in Denver. And the Director himself taught me how to collect samples and he'd go out with me quite a bit and this is kind of different than it is now when the new Inspector often doesn't see the Director.

Goldhammer: And the states didn't participate as today. Now, there are grants given to the states and they take over some of the inspectional activities of the Food and Drug Administration. I think that came into being with Goddard who felt that the states should be

handling insanitation. In the first place, he didn't think that insanitation was that important.

Lofsvold: Well, he talked about getting the states to do that but the actual paying the states contract money came about in the early '70's.

Porter: We got help because in Denver when El Paso was in our territory, and that was an awful long way from Denver, we had state and city people in El Paso that regularly collected samples at our request.

Goldhammer: Yes, they were delegated...

Porter: They were delegated and when an inspector was in El Paso, he would usually go in and explain why the last time their records weren't quite adequate and how there really would have been a better way to do it and so on. To kind of generally train them to do it exactly the way we wanted. But they were very willing to do it.

Goldhammer: Of course the feed cases that were developed, were developed by the states and we would take over the action and defend it in court, in federal court. But the states would gather the samples and make the inspections and so on.

Lofsvold: That was especially true when the firm that was responsible for the violation lived outside of that particular state that found the violation.

They could not reach them criminally and so we regularly prosecuted cases involving animal feeds deficient in protein and things of that sort because the states were not able to assert jurisdiction.

Janssen: It was the truth that there were not enough Inspectors. There had been an expansion in the supervisory category and accounting, bookkeeping, computerizing, and so forth. There'd been a big expansion in that. I have a handwritten memorandum some place telling about the first civil service examination for Inspector and there were over 2,000 applicants who took the test in different places and there were 26 appointments. But only about 29 or so passed out of the 2,000 applicants.

Goldhammer: Do you remember when that exam was given?

Janssen: That was in 1906 between the passage of the Act and the following June.

Lofsvold: That was one of the things we did was develop that examination during that period.

Janssen: Well, then when I wrote a story about the F.D.A. in 1936, when the F.D.A. occupied the labs in the South Agriculture Building. I think at that time they had about 200 Inspectors and the budget was about \$1,250,000. And the new labs, equipment in the new labs had a cost almost a quarter of a

million dollars. And in 1955 when the CAC I study was made we had only, I think we had less than 300 Inspectors and we had 800 and something employees total.

Checchi: In '55 we only had that many?

Janssen: In '55 it was nearly 900 employees total.

Goldhammer: In 1955 all we had was a four million dollar budget.

Janssen: About five million dollars then. CAC I of course recommended a thousand Inspectors and I don't think you've got a thousand Inspectors today have you?

Lofsvold: I don't know.

Janssen: Well, I don't believe so.

Goldhammer: I think there were about 600 in 1971, 660 or so.

Lofsvold: We haven't increased.

Porter: You're probably right because that's about the time I went to Denver.

Lofsvold: I would guess that it's somewhere around 700, 750.

Young: Well, what's the budget now? What did you say the budget was?

Janssen: Points made by Crawford in regard to these recommendations for the first committee was the fact that many plants were visited only once in six, seven, eight, nine years.

Young: Another thing that might be graphed so to speak if one did look at figures and kind of go along with a figure that was often employed how much per year was spent by the Food and Drug Administration per citizen. And I remember, I think at the time at the beginning of the effort to get the 1938 Law was six cents.

Smith: I remember after I came in it was four cents.

Checchi: Around two cents in the '50's.

Goldhammer: In the 1930's it was a penny.

Porter: That's what they told me when I was hired, it was a penny, but I didn't check their calculations.

Smith: About a dollar now I guess isn't it?

Young: Well, the budget in 1975 was \$200,000,000 and so that would be about a dollar.

Lofsvold: I think it's \$280,000,000 this year.

\$283,000,000 I believe is the figure for '78.

MacFadyen: What I'm still perturbed about what to do with these figures because what you're implying is that the level of inspection was woefully inadequate in terms of numbers. All right what does that say? Does that say that the food supply in the '30's, '40's, and '50's was dangerously insanitary?

Checchi: No, you can't say that. You've got to bear in mind, I can't quote the figures, but there's a far

greater percentage of fabricated food used today than there was then; the population has gone up so you can't even just take the dollars and adjust them for inflation and say well, alright, this is a valid comparison. It isn't because the population has increased by 50 to 60 million maybe more since the middle '30's, certainly 55 since the '40's. The types of drugs that the inspectional need has increased substantially. If you were to take the needs of the '50's and look at the Food and Drug Administration in 1950, my guess is that I don't care what the CAC said about a thousand Inspectors and all that, but if you just simply say, look we've got, here it is 1955, we've got 200 Inspectors, then you get a bunch of professionals like you have around the table here to say well, dollars and cents aside, what do we need to do a reasonable job in terms of our current responsibilities, I don't think anyone here would want any more than double the force. Possibly something less. So I think you've got to be looking at these comparative figures you still have to look at the needs and the state of the industry and the additional requirements that have been put on the Food and Drug Administration by subsequent legislation.

Young: Drugs got infinitely more complex. Foods got

more complex.

Checchi: Food additives have gotten more complex. You got color additives legislation you didn't have. You've got the, also the Food and Drug Administration has radiation health. It has new devices.

Young: Biologics.

Checchi: The burden is totally different too.

Janssen: The level of compliance may very well be better than it was in those days, but I haven't seen anything yet that's very convincing to establish that.

Lofsvold: Well, I think the standards in many areas have changed too. We are demanding more say.

That's been a constant problem like sanitation, we are much more demanding now of the industry than we ever were in the late even the late '40's, early '50's.

And one of the reasons that Tilly mentions because foods are prepared and shipped vast distances. So we're conscious now of and active in the bacterial contamination area where at that time our bacterial work was, Slocum talked yesterday, was limited to a few things like crab meat, some of that stuff.

Smith: With new drugs there's no comparison between the requirements say in 1950 and the present time. And even between 1950 and 1960 there was a gradual tightening of the regulations, maybe with no change

in regulations and particularly in the manufacturing controls. And, of course Julius Hauser and Earl Meyers had something to do with that. Well, Julius came in about six months before I did and Earl Meyers probably a year later than I came in. And they began demanding more and more.

Young: And so much of the work is pre-marketing before and, except in the most rare case where somebody does something crooked, litigation doesn't even enter into the work load. Isn't that so? I mean so that the shift over from litigation type approach to other type approaches is built in some large measure the very laws themselves.

Checchi: Well, it also attributes to the fact that we look (tape ended here and sentence doesn't continue on next side).

Checchi: You probably only got about 40% of your professionals in the field and about 60% here. As you say, you have pre-clearance requirements that you didn't used to have. So while the Agency has grown the proportion, the whole responsibility is on the Agency. Two things have changed. One is I think the burdens that have been placed on the Agency have forced change. And secondly, is the one thing we haven't really talked about today and that is that the

philosophies of the new type managers your getting; starting with Dr. Goddard, Dr. Ley, Dr. Edwards, and Schmidt and now Kennedy have gotten away from the career Food and Drug Commissioner who used to think in terms of regulatory approach. Yes, they did make changes, but they were careful. They were programmed changes and they were enforcement oriented whereas today your Commissioners are activists. They're out there making changes they don't like the old policies. Why change them? The old Commissioners didn't change policies. They changed policies, but it was slow, it was careful. There's a lot of digging went in before a philosophy was changed and today on the other hand, not arguing the pros and cons of it but simply recognizing the reality that the Commissioners of this decade; they're activists.

Young: It's not only their own ideas, it's no doubt that they also bring mandates that comes from Secretaries and the President and the Congress.

Lofsvold: And another thing is that they don't have to live with their decision, they know they're gone in three or four years.

Checchi: Where the old guys, they'd have either, I've got to live with this decision or my deputy who I know is going to succeed me is going to. So the

decision making as I say, when I commented earlier today, that the old F.D.A. was conservative, but careful I suppose is perhaps a better word than conservative about changing. They did make changes, they made lots of them. But before a change in policy was undertaken, there was an awful lot of soul searching done and it was really an in-house decision to change. We didn't have the outside pressures that Dr. Kennedy has. No where near it.

Young: And now-a-days it would be just almost certain that any change in the political complexion or the party of the Presidency would mean a change of the Food and Drug Commissioner.

Checchi: Oh, I would expect that if Ronald Reagan becomes President in 1980, that we'll have a conservative Food and Drug Commissioner and a lot of the innovative work that Dr. Kennedy has done for better or worse has gone down the tubes. I think Food and Drug has gone from a very conservative, career organization, totally non-political, to an Agency which is no different than the Department of State, Agriculture; any other government entity which is now really responsive to the political party in power.

Young: And since executive-legislative balances sort of teeter too, and F.D.A. is involved with both of

them, it makes it a very complex thing.

Checchi: It struck me as humorous. I was just reading Commissioner Kennedy's statement when he signed this agreement with Governor Carey of New York to inspect plants. Quite apart from the merits of the deal, but the thing that struck me as interesting was Commissioner Kennedy's statement, he commented this is consistent with the Carter Administration. It was a semi-political speech, if you will, that this is consistent with President Carter's. Well I never heard George Larrick, or Jack Harvey, or their predecessors ever mention the name of the President or the party in power in a public speech. I never heard them say that the actions of the Food and Drug Administration is part of the President Kennedy's, Johnson, or Roosevelt so on and so forth is what the President wanted. Never happened. In fact probably the reason it didn't happen because it never was. These were policies, as I say, we were a little Agency nobody paid a hell of a lot of attention to.

Young: Well, actually the flavor of Hoover and Coolidge as compared to Roosevelt, who did truly influence what F.D.A. in those two periods was doing. But I agree perfectly about they're not going to say so.

Checchi: The influence has to be there. I mean that clearly when I was here, Eisenhower was the President, and you had the influence.

Janssen: Maybe we have less inhibited speech writers now.

Checchi: You had to be damned sure you didn't offend the boys in the White House. As you were in the Commissioner's Office you were sensitive to the fact that the great white eminence sat there and you had to be careful. But you didn't pay him homage in public speech.

Young: You did seize Mountain Valley Water though and not realizing quite that the President was drinking it in the White House.

Checchi: We did seize the damned diced peaches too, didn't we, Gil?

Goldhammer: We sure did.

Checchi: Baby beets, rather.

Goldhammer: Baby, yeah.

Lofsvold: We paid for that. We were talking yesterday about that and generally about the problem of political interference with F.D.A. decisions and mentioned here awhile ago, I did, McKinnon's sudden transfer to San Francisco that he always attributed to the fact that Oscar Ewing, who had been the General Counsel

of Merck and Company became Secretary or Federal Security Administrator and McKinnon had personally forced through a prosecution of Merck and Company, the Dorial case which had involved the death of several people around the country. When I think probably all concerned would have been happier to have let the case die on the vine. But the Assistant U.S. Attorney and McKinnon had personally come down and gone to the then Attorney General's Office with the Deputy Administrator of Federal Security and forced through this case which resulted in a nolo plea and a maximum fine and a lot of unfavorable publicity for Merck. So when Oscar Ewing, the Attorney for Merck became the Administrator of the Agency, the parent Agency, Mack always thought that his banishment to San Francisco was directly attributable to that fact. And I believe he was right. Oh, after he'd been out there he went totally native and you couldn't have got him out of San Francisco.

Goldhammer: Periodically Crawford would be reminded of that Merck prosecution by Ewing.

Young: Is that right?

Goldhammer: Yes. And I remember one time some canner in Indiana complained to Ewing that the Food and Drug Administration was bringing cases unjustly and

that is provable by the fact that F.D.A. loses an inordinate number of cases. Ewing had Charlie Crawford up there and when this accusation was made, Ewing expressed some sympathy for that position and he referred specifically to the Merck prosecution as being an unjust prosecution. Well, that really aroused Crawford. He was angry as can be and he stormed into my office after that meeting and told me what had happened up there. He said he wanted from me an analysis of all the cases in the last twenty years or so and I was to come up with a tabulation to show how many we actually lose. Well, it turned out that it was an absolutely insignificant number of cases that we lose. Where we lose them, of course, are among the contested ones. If our case is not contested I consider that a vindication of the government's position. But the number of cases that we lost even among the contested ones was very, very small.

Checchi: Never lost them on the fact did we?

Goldhammer: Very little. There were always some extenuating circumstance. Prejudice...

Young: Well Ewing, I don't know this might have just been accident or carelessness, but he really got the Agency in considerable trouble with regard to his efforts to control special dietary products at one

point by a position he took. Which might have been in negotiating some kind of an agreement with Mrs. Alberti or something like that. Once he had signed the document it limited markedly what F.D.A. could do in that area. Well, I think that's... (inaudible)

Janssen: He used to hold a food standard or other action on his desk. This was before the massive delegations that took place, well after Mrs. Hobby's time. I guess the biggest delegation period was in Folsom's tenure. But anyway, he used to get these things for his signature and they'd sit there for months and months.

Young: So this is all to say that the political complexion of the Secretary's Office does have various kinds of influences; sometimes subtle and sometimes not so subtle.

Goldhammer: Well, it didn't influence Crawford because Crawford, in his statement to me, said this was the last time he was going to stand for that; that apparently Ewing had been bringing it up periodically, he was going to put an end to it.

Lofsvold: Mr. Crawford was quite a forthright man, too.

Young: Well, do any of you gentlemen on this side of the table have any further questions you'd like to

put to our guests?

Lofsvold: You know one thing you haven't talked about at all, Harvey, and I don't know whether it's of interest to you or not, but the decade from 1938 to 1948 and well into the early 1950's, too, was I think kind of remarkable for the way that the F.D.A. got court decisions which interpreted and expanded various sections of the statute. And while I was down pretty low on the totem pole in that time, I'm kind of curious, maybe Gil could say. Were those really planned or were we just taking advantage of situations as they arose in the normal course of business?

Goldhammer: Mostly, it was an opportunistic thing. The violations were there, we thought we had a case and we brought it. We got an extra dividend if it went to contest by the expression of law. Some of them went up to the Supreme Court. Some were planned. Now the cancer quackery cases were very well planned. And we anticipated losses. We anticipated victories. And we were generally right. But for the most part I think the law simply arose unexpectedly. We brought an action which we thought was in the bag; instead there was a contest. In some cases, it went up to the Supreme Court--for example, the Dotterweich case.

That was a routine case. No one ever planned that.
Young: Who read the law imaginatively in order to bring cases that sort of went beyond what perhaps dull literal reading of the law might have foreseen? For example, on the quackery side, the accompanying word, of labeling accompanying was, it seems to me, very imaginatively handled in taking things to court. Was this planned?

Goldhammer: Yes, I think so. In this nutritional quackery, we were up against the lecturer. How do we handle the lecturer? We deliberately put into the regulations for special dietaries and for drugs that intended use could be gleaned not only from the written word, but also the spoken word. Then we had the directions for use provision. We said in our regulations for directions for use, that the directions would have to include directions for all conditions for which the drug was intended. Now that was planned. And it was planned because of the problem of what to do about the guy who circumvents the law by advertising or by lectures.

Young: It was done by Regulatory Management? Did the General Counsel's Office have a role in the imaginative figuring out of either regulations or...?

Goldhammer: It was done by both. We had theories on how to go about solving this problem. The Commissioner's Office had theories. The Commissioner had theories. Larrick, for instance, had a theory that we could control the purely intrastate sale of prescription drugs without prescriptions. That was Larrick's idea. And we put that through and we got favorable verdicts on that. The Sullivan decision, did we have authority? Now then it was up to the General Counsel's Office to devise the rationale for the action and to set it forth to the court. There the General Counsel's Office took the position that interstate commerce prevailed until last sale to the ultimate consumer. That was an argument from the General Counsel's Office. The Supreme Court accepted it and made it law.

Janssen: I think the greatest, most important Supreme Court decision maybe of all of them were the drug effectiveness decisions of 1973. Now you can go back and see a very definite thread, pattern, from the definition of new drugs in the 1938 Act, the definition of substantial evidence of effectiveness in the 1962 Act, and the Court of Appeals decision, in the Penalba case, and the Supreme Court decision in 1973 in the four drug effectiveness cases. The pattern is there and ended up of course with the

Supreme Court saying that the F.D.A. regulations had administrative finality and that it had primary jurisdiction in deciding the status of drugs. And that the way to get even-handed enforcement was to issue regulations that all had to comply with rather than to go after individual violators one by one. Which process produces endless litigation and leaves some people at liberty to do what somebody else is being prosecuted for. It all makes a pattern that fits together. Now the pattern I think results from the fact that the same people were involved through a great deal of that process. And of course one that we think of particularly is Billy Goodrich.

Checchi: But I don't think though that Food and Drug, certainly not in my day went looking for a case to establish a point. I think it was probably the other way around that Food and Drug in putting together their regulations foresaw a lot of developments and wrote their regulations and then if a case came along that fit it, they'd take it. But I don't think, certainly in my experience as an Inspector, and in Washington, I don't recall anyone ever said now, we got a nice little legal theory here, let's go and find a case.

Goldhammer: Yes, they had some cases like that.

We'd select the jurisdiction...There would be cases which we felt needed a favorable judge. Now we sought to bring a case against a thyroid preparation, It was the Marmola case, a weight reducer. That was deliberately planned. Simmons, the Chief Inspector, arranged for that. Even to the point of bringing the action in Judge Stone's jurisdiction.

Lofsvold: And he and Simmons were buddies.

Goldhammer: Yes. As a matter of fact, Simmons went up there and asked the Judge whether he would be receptive to the case in that jurisdiction. So there are situations in which we plan a case very carefully because there's a legal principle that we're testing out and we want the most favorable jurisdiction for it.

Young: Well, there were other examples of and I think that some of these food supplement cases show it.

Where the Food and Drug Administration would bring a case and then the people involved would think of some new way to avoid and the Food and Drug Administration would have to bring a new case and then there would be a new way to avoid. And each time they brought a new case, they'd have to develop a theory that would seem to make the law applicable

to that new case in the court. And I remember that in connection with the labeling accompanying the medicine where they'd send the labeling separate from the product.

Goldhammer: That was Kordel.

Smith: Those early 1940's cases in the Ninth Circuit, there were about five of them that go along that way. And there all we were doing was taking advantage of the ingenuity of the regulated industry. When we got a decision knocking off one scheme of distribution, they came up with another one and so we responded.

Young: Right. But you had to use ingenuity in fashioning the response.

Lofsvold: I can remember one though that we, I was in on the careful planning of it. It didn't quite turn out the way we thought it was going to. The Cardiff case when we were testing the authority for inspection, Dr. Cardiff was an apple dryer in Yakima, Washington. He had consistently refused to allow F.D.A. inspection over a period of several years. Along with some of the other young turks of the day around that area, we kept advocating to our superiors that we ought to really find out whether we really had the authority under this Section and bring

a case against Cardiff. Finally the situation arose where his only competitor in the same town had been inspected and found to be insanitary. We had brought a prosecution case against him. So we pointed out that it was manifestly unfair that Cardiff would continue to get away with not being inspected. And so we finally got reluctant agreement from first the old Western District and then from Washington to proceed with the case. So we went in, got the refusal and brought the action in the District Court in Spokane where we had a real friendly judge who duly found in our favor, with a little reluctance. The case was then appealed by Cardiff to the Circuit Court and they found against us. And we appealed to the Supreme Court and they found against us on different grounds. I guess ultimately it worked out well because then we got later a congressional amendment that gives us the current authority. But there all of our careful... We got a decision all right, but it wasn't the one we wanted.

Janssen: That was partly in the written statute and partly in the legislative history and the latter part of it hampered us greatly.

Lofsvold: Well, the other problem was our timing wasn't very good because the time the amendment for

the inspection authority came up was I think the only two years in the last fifty years that the Republicans have controlled both Houses of Congress. So we got some restrictions in there that we might not have got otherwise.

Goldhammer: Well, the law there was a case of poor workmanship on the part of Congress. They knew that this inspection provision was fraught with danger. Would it be construed to be an illegal search? So what they said was let's make it voluntary. With respect to inspections the section of the law said you first have to ask permission to make the inspection. However, in the prohibition section of the law they said it is prohibited to refuse inspection. Of course, there's a direct inconsistency there. You're not really giving him the opportunity for a voluntary decision as to whether he should permit inspection, because if he refused to permit inspection, he would be violating the provision which says it is a crime to refuse permission. So the court simply threw it out as being inconsistent.

Young: Are the facts of that Cardiff case interesting so it might be not only a case of significance, but a readable story?

Lofsvold: I think it is.

Goldhammer: Oh, yes.

Young: I'm looking for that too. Case histories that will make readable stories, at the same time be significant.

Checchi: As a result of the new factory inspection provisions, in addition to written notice of inspection, you have to leave an observation of findings. And that was fine until the Freedom of Information Act comes along fifteen years later, and makes what had started out to be a confidential document between the Food and Drug Administration and the plant a matter of public record.

Goldhammer: Of course, you also have a Supreme Court decision, the latest Supreme Court decision which requires a search warrant for inspections and that included Food and Drug inspections. Only there, there was some dictum on the part of the court which said it shouldn't be difficult to devise a scheme whereby the court issues an inspection warrant. So, you've got the whole complicated situation and it's up in the air.

Checchi: There was one the other day, Gil, that I like, where these guys can be prosecuted if they blow one. Well, I want to wait and see that one. When is the next decision going to be made by a

government official that he can be prosecuted?

Lofsvold: Actually, we've been going the warrant thing since Camara and see...

Goldhammer: Yes, that was back in 1966.

Lofsvold: Was it that long? Ten years now.

Goldhammer: Yes.

Lofsvold: I don't think it's that long. It didn't change our operations.

Goldhammer: 1967 maybe.

Young: Well maybe we'd better call it a day. And we're most grateful for your having given us a day for the sake of history. I hope that reminiscence has been a sort of reward to you.

Lofsvold: This is what Food and Drug people do on their own time.

Porter: This is the end of the June 30, 1978 tape.