

HISTORY OF THE U.S. FOOD AND DRUG ADMINISTRATION

Interview between:
Dr. Kenneth L. Milstead
Retired Assistant to the Commissioner
and
James Harvey Young, Emory University
Fred L. Lofsvold, FDA
Wallace F. Janssen, FDA
Washington, D.C.
August 28, 1968, July 28, 1969
and February 4, 1982

INTRODUCTION

This is a transcription of a taped interview, one of a series conducted by Robert G. Porter and Fred L. Lofsvold, retired employees of the U. S. Food and Drug Administration. The interviews were held with retired F.D.A. employees whose recollections may serve to enrich the written record. It is hoped that these narratives of things past will serve as source material for present and future researchers; that the stories of important accomplishments, interesting events, and distinguished leaders will find a place in training and orientation of new employees, and may be useful to enhance the morale of the organization; and finally, that they will be of value to Dr. James Harvey Young in the writing of the history of the Food and Drug Administration.

The tapes and transcriptions will become a part of the collection of the National Library of Medicine and copies of the transcriptions will be placed in the Library of Emory University.



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TAPE INDEX SHEET

CASSETTE NUMBER(S): 1 and 2

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

DATES: 8/28/68, 7/28/69, 2/4/82

PLACE: Washington, D. C.

INTERVIEWEE

NAME: Kenneth L. Milstead

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

INTERVIEWERS

NAME: James Harvey Young

Emory University

Fred L. Lofsvold

Wallace F. Janssen

U. S. Food & Drug Admin.

FDA SERVICE DATES: FROM 1935 TO 1966 RETIRED? Yes

TITLE: Special Assistant to the Commissioner
(If retired, title of last FDA position)

Note: This transcription covers three interviews made in 1968, 1969 and 1982. The first two interviews were recorded on reel to reel tape and are not indexed here as to tape location. The last interview was recorded on cassettes and they are indexed. Transcriptions of all three interviews are included here in chronological order with continuous page numbers.

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NO. NO. ON TAPE NO.

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- 2 Planning and Decision Making in FDA - The 1948 Organizational Structure.

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Young: This is an interview with Dr. Kenneth L. Milstead in his office at 1812 K Street in Washington. Dr. Milstead is Science Associate of the National Association of Broadcasters Code Authority, a position which he's undertaken very recently. When was it you came?

Milstead: May the first of this year.

Young: May the first, and this is August 28, 1968. I am James Harvey Young of Emory University. Kenny, you spent thirty-one years with the Food and Drug Administration, isn't that so?

Milstead: Yes, that's correct.

Young: And would you mind starting off by reviewing chronologically the positions you held from your entrance in 1935 as an inspector?

Milstead: I came in, Harvey, as a chemist, not an inspector.

Young: Right.

Milstead: In 1935 I entered the Food and Drug Administration in Chicago as a junior chemist. In April, 1938, I was transferred to the St. Louis District, but stayed there only until September when I went back to what was then the old Central District office in Chicago. In 1942, I was transferred to Cincinnati as the Chief Chemist and, about a year later, I was transferred back to Chicago again to the

District Office in a little higher position than when I was there before. Then in '45, I went back to Cincinnati as head of the Station. At that time, they called them Station Chiefs. I stayed there until 1951, when I was transferred to Washington as the Director of the Division of Regulatory Management, and I remained as head of Regulatory Management until '61 when I was made Deputy Director of the Bureau of Enforcement. I remained in that position until 1964, when I was made Special Assistant to Commissioner Larrick in charge of the National Advisory Food and Drug Council. So, the first half of my career was spent in the field in various positions up to the head of a station, as they called it at that time.

Young: Kenny, one of the questions that is hard for a historian to understand with regard to an agency is the decision-making process that goes on. Now, from the point of view of the second half of your career, in the headquarters of the Food and Drug Administration, in Washington: How are the big decisions made with respect to what projects are going to be emphasized, how resources are going to be allocated, if a crisis develops what action is going to be taken? In your experience in Regulatory Management and then later, you were part of this decision-making process both from the point of view of the decisions

that you had to come to with those who were under you in your Division and also with respect to the decisions that the entire agency made under the leadership of the Commissioner.

Milstead: Well, the organization was set up with three units in Washington, the Division of Regulatory Management, the Division of Program Planning and the Division of Field Operations. Now, all of those units participated in the planning operation, but it was, of course, the primary responsibility of the Bureau of Program Planning and Appraisal, I believe was the correct name at that time, to develop the long-range plans for the Food and Drug Administration. They called on all units of the Food and Drug to contribute to the development of the plans which were ultimately presented to the Commissioner for approval and formed the basis for appropriations and for making decisions on what areas would be emphasized in regulatory work and what degree of emphasis would be given to Education and Voluntary Compliance.

Young: This was the structure in the last years that you were there.

Milstead: . Yes. During the period of time that I was in Washington, that was the structure. I was the second Director of the Division of Regulatory Management. When

the field districts were abolished and the three units were set up in Washington...John Harvey was the first director of this division.

Young: About 1948?

Milstead: Yes, I think that's about the date, Harvey. The primary reason for abolishing the Districts and setting up the three units in Washington, one of the primary reasons, was more careful planning on a national level. The Division of Regulatory Management was specifically set up to handle all of the court cases and did have a great deal of responsibility in determining what regulatory actions would be undertaken and how they were handled in the development and in the courts. As far as the planning was concerned, that was one of Mr. Crawford's, who was the Commissioner at that time, fundamental reasons for abolishing the Districts and setting up the units in Washington--to have better planning on a national scale. His view was, and to a degree, this was always the case in Food and Drug, that regulatory pressure or whatever approach was followed should be applied uniformly throughout the United States. Mr. Crawford thought that a better job could be done by centralizing the planning in Washington, whereas, before it was largely carried out at the District level in the three old district offices in San Francisco, Chicago and New York.

Young: Now, in that earlier period, while you were station chief in Cincinnati, how were the decisions made with respect to what the districts would do? Did you have a district conference every year in which you would go into Chicago to the headquarters of the Central District?

Milstead: Yes, we did, Harvey. That's exactly the way it was done. The three District Chiefs--at that time they were called District Chiefs--would come to Washington once a year to meet with the Commissioner and his staff, and they would discuss broad areas of operations, types of investigations, the emphasis that would be given to various projects, and so on. Then, the District Chiefs would return to their respective Districts and meet with the Station Chiefs to review these overall plans, and broad directives from the Commissioner's office (the Commissioner and his staff), and develop plans as they applied in their respective districts. Once there were district plans developed, the stations then developed operating plans, at their level. The Station Chiefs had the responsibility of putting these plans into operation and the District Chief was responsible for maintaining uniformity within his District. Now the Station Chief in the decision-making process would make his recommendations to the District Chief and the District Chief and his staff would review the

Station's recommendations and would either concur or not concur and would then make his recommendations to Washington. So really there were three levels of decision-making at that time.

Young: Things went up and then they come down again.

Milstead: Right. And the Commissioner didn't always agree with the District Director. He sometimes would agree with the Station Chief and would disapprove the District Chief's recommendation and go along with the Station Chief.

Young: While you were Station Chief, do you remember any indications of really sharp disagreement about what programs should be pursued, or were these mainly minor disagreements about the percentage of emphasis to give to this or that?

Milstead: I would think minor, Harvey. At the time that I was a Station Chief, the emphasis was mainly in the area of sanitation, and drug work. The problems in the field of sanitation were so great that a large percentage of the time was devoted to that area. The judgment as to what industry we would give attention to and how much was relatively simple. There was so much work to be done and things were so bad, sanitation wise, that it was a matter of deciding whether we were going to spend all our time on corn meal or flour or some other industry or whether we

were going to give attention to the entire food industry. We had very little difficulty arriving at this decision with the old District Chiefs. Another reason that Mr. Crawford gave for eliminating the old District organizations was that he felt that the Station Chiefs should all be District Directors and should have the responsibility of making decisions at a higher level. As a matter of fact, the Station Chiefs were probably better qualified to make most decisions because they were closer to the actual problem. Mr. Crawford felt that as far as decision-making on regulatory actions was concerned, and I think on planning, too, that the District Chiefs had largely outlived their usefulness. Others did not agree with Mr. Crawford and thought that the District Directors represented a go-between between the Administration and the old stations, a kind of buffer, and helped smooth out problems. That was particularly true in the personnel area where the old District Directors had a lot of authority in dealing with personnel matters, and I think they served a very useful purpose in that area. But Crawford felt that in the decision-making area particularly on enforcement actions they were not necessary. There was an awful lot of lost time and duplication of effort in sending the enforcement actions through old District organizations. He thought

that the review of the Station Chiefs' recommendations could be done in Washington, and that the Station Chiefs (titles were then changed to District Directors) should make decisions on a much higher level than was the case under the old three district set-up. So he abolished the three Districts and set up three divisions in Washington. The decisions on regulatory actions up to the time of the establishment of the three new divisions in Washington were made in the Commissioner's office. Later, when the Bureau of Enforcement was established, the Director of the Bureau of Enforcement was given the authority to make decisions on regulatory actions under guidelines that had been established and approved by the Commissioner.

Young: In a way this removed from the Commissioner some details of responsibility. Is that right?

Milstead: Exactly. And that was the point. The Commissioner felt that the Director of the Bureau of Enforcement, an experienced man who had available to him all of the staff expertise that was available to the Commissioner should make the decisions on enforcement actions, and that the Commissioner and his immediate staff should be reserved for making really high policy decisions involving legislation, budget and matters of that type.

but up to the time the Bureau of Enforcement was established, the Commissioner himself, Campbell, Crawford and Dunbar, were greatly involved in decision-making on a day-by-day basis. Before I came to Washington, as the Director of the Division of Regulatory Management, I believe that the Commissioner and his immediate staff, which included Mr. Murray in the drug field and Dr. Elliott in the food field, personally approved every single regulatory action that was initiated. They made the final decision. Young: The field then, in the old days, didn't have the right to inspect a factory where the sanitation was poor and immediately bring a case?

Milstead: No, they did not, Harvey. They had no such authority. Bringing a regulatory action was a slow process. Following the inspection and the collection of samples, the station recommendation, then it would go through the District Office, and then on to Washington. Often there were delays in reviewing the action in the District office. That was another reason why Crawford eliminated the District offices. Those delays would result, in many instances, in inadequate protection to the consumer. In the case of filthy merchandise, it would be distributed. We had no embargo power. Criminal prosecu-

tion and injunctions were also delayed as a result of the District review. One of the principal reasons for the reorganizations that abolished the old three district set-up was to expedite regulatory actions by delegating the authority to make decisions to people at a lower level than the Commissioner.

Young: There really was a kind of split between the types of cases that accompanied this, wasn't there, because what you've been talking about are the prima facie cases, but wasn't it so that this new set-up did bring under Regulatory Management control at the national level, important, complex kind of cases?

Milstead: Yes, it did, Harvey. That was the principal reason for setting up the Division of Regulatory Management. I remember very well Crawford's statement when he established that division, and it was to the effect that he wanted a division that was made up of specialists who devoted their entire time and attention to the development and handling of the most complex type of regulatory actions. His theory was (which I think, incidently is the right one, as was shown by what was accomplished by this approach) that there are certain types of violations that require real expertness, not only in the investigative stage, but in handling all through the courts and trials and so on.

Young: What kind of cases particularly fall within this category?

Milstead: Well, in the quackery area, for example, persistent and repeated violators...Harry Hoxsey was a good example. Regulatory Management undertook many difficult cases, but I think the great majority of them were in the field of quackery. But any case which required experienced people, not only in the investigative stage but in the trial stage was handled by Regulatory Management. The staff of that division had experience and a particular aptitude for outlining complex investigations, in monitoring them on a nation-wide basis, and meshing together information from many sources throughout the country. Mr. Crawford intended to staff Regulatory Management with people from the field and from Washington, who had demonstrated outstanding aptitude in this field of special investigations.

Young: Besides yourself, who were some of these really key people brought in to staff this operation?

Milstead: As I mentioned, I think, when we started, John L. Harvey, who was the Chief of the old Western District, was an attorney and had shown a great interest and aptitude in handling court cases. He was the head of the Division. His assistant was Gilbert Goldhammer who had worked in this

field, and had demonstrated great ability in attacking really difficult violations, in obtaining the evidence, and in handling the case in court. Then there was Van Smart, who was with Mr. Harvey in the old Western District, also a lawyer, who had great interest in investigative techniques. He was brought into Regulatory Management. This was the initial staff. Others were added later. For example, there was an investigator, out in the old Western District, named Robert Brandenburg who had worked in the Mytinger and Castleberry Case.

Young: That's Nutrilite, isn't it?

Milstead: Nutrilite, right. That was one of the most difficult cases that Mr. Harvey undertook when he first became the Director of the Division of Regulatory Management. Brandenburg worked on that case and showed that he had the type of mind and interest of a special investigator. So he was brought in to the Division of Regulatory Management. In general, we selected people of that type. The whole objective of Regulatory Management was to assemble a staff of people who had experience in handling difficult cases, and to give them freedom to pursue new cases and not to be bound by day-by-day minutiae. It was felt that FDA should have a unit composed of experts in developing and trying cases and that this unit should

operate on a nation-wide basis. The field station just didn't have available to them the expertise, scientific or inspectional, to really handle these difficult cases.

Young: It really was this team that was assembled, wasn't it, that broke the major quackery promotions in the period that followed?

Milstead: Yes, it was. The Mytinger and Castleberry decision was followed by Hoxsey and a whole series of successful cases that greatly strengthened the whole quackery program. Decisions like Kordel and Urbeteit and, of course, Micro-Dynameter, later...all of those very important decisions strengthened the law so much in the whole field of quackery and that helped a great deal. But what has always impressed me is that those decisions, and all the other significant ones in the whole history of Food and Drug control, are based on sound administrative decisions and sound evidence. They speak so well, I think, for the good judgment of all of the Commissioners. The great decisions, such as the vinegar case and the flour case under the old law and the Sullivan and Dotterweich cases under the new law have built a solid foundation for Food and Drug Law in this country. The Supreme Court has made it clear in these decisions what the law is for and its broad purpose.

Young: Now, let me just ask one question about that. Most of these major decisions were decisions that were based on seeking to interpret the law in a new and more expansive way...to look at the law and find a phrase or a clause that might be stretched by interpretation, if the courts would agree, to add to consumer protection. Where did the ideas come from with respect to these imaginative interpretations of the phrases of the law? Did they come from the members and staff of the Regulatory Compliance, or did they come in some measure from the Office of the General Counsel?

Milstead: Harvey, I think they came from many sources. Under the old set-up, some of them originated with the District Chiefs and some with the Station Chiefs. The District Chiefs, W. R. Wharton in the Eastern District, J. O. Clark in the Central District, and John L. Harvey in the Western District, were all really tremendous men who were so saturated with what they were doing that they lived the law and lived Food and Drug enforcement. They constantly sought out new areas of exploration and new applications of the law, and they instilled that philosophy into the Station Chiefs and into everybody else that came under their direction. The court decisions were an important part of our training in those days. Everybody talked about the decisions. They became a part of food and drug philosophy.

So, I'm sure that a lot of the testing of the law originated in the Stations and in the Districts based on certain factual situations. The Station and District directors would study the law and would make recommendations as to what sections of the law applied in any given case and why they applied and why others didn't apply and if the law wasn't clear, they might recommend that some new approach be tried. All of those were a part of the decision-making operation at the Station and District level. Undoubtedly, a good many of the ideas on which the decisions were based originated in the Commissioner's office and lots of them in the General Counsel's Office...all of them thinking along the same line. Now, there's no question about it, when Regulatory Management was established, Crawford's directive to the Director was to push the law to its ultimate limit; he wanted to find out where its weaknesses were in dealing with serious and repetitious violations. So the Division of Regulatory Management was charged with the responsibility of constantly exploring the limitations of the law. And we did do that. One of the last things I did as Director of the Division before I was transferred to Mr. Larrick as his Special Assistant, was to supervise a series of regulatory actions against the wrinkle removers that

came on the market with great publicity. Now, in those cases, we really applied the law in a new area to test it out. We decided, and the idea originated in Regulatory Management, to bring actions under the New Drug section of the Act. Seizures were made and all of the actions are being contested. We already have a district court decision upholding the government's position, on one hand, and we have a court decision contrary to its position on the other hand. Both of these decisions are being appealed. I think these cases illustrate how the law is continuously tested and, through court decisions, clarified.

Young: Mr. Crawford even felt that if you didn't lose a few cases, it showed you weren't pushing the law.

Milstead: He did. That was a basic concept. It went way back to Wiley's time, I believe. Crawford felt that if there was a practice that was obviously contrary to the public interest, no matter what it was, that we try to find some section of the law to deal with it, and if there was no applicable section, we would try to bring an action to clarify that point with the objective of ultimately seeking legislation to correct the whole situation.

Young: Because you could go to Congress, if you lost the case, and say, "See, something new is needed, because we've tried and failed".

Milstead: Exactly. But being careful, all the time, (and this, I think is so basic [in the background] and I'm afraid there's been a weakening in the past few years in this area), [but being careful] that the facts are sound, and that the interpretation is based on the law and not on faulty facts or poor investigations. The old District Chiefs and the Commissioner--Campbell, through Larrick--- were so trained and so experienced in gathering scientific evidence, that they were willing to test the law and if necessary, go to Congress to seek amendments. But they were careful not to get court decisions that were based on inadequate facts and inadequate investigations which might be disastrous. That was another reason for Regulatory Management. Mr. Crawford wanted to undertake the most difficult type of regulatory actions, no matter what they were. But he wanted to do it in the very best atmosphere possible from the standpoint of the evidence. He wanted the facts carefully documented before he probed the weaknesses of the law. Crawford was very dedicated to that belief and carried it through, as did Dunbar and Larrick. If there was a really serious situation, contrary to the public interest, there was no question about bringing a regulatory action. It was more a question of timing, and whether or not the investigation and the facts were

sufficient to support the government's position. But if they were, then there was no question but that the action would be brought. And you can go down the list: Mountain Valley Water, Micro-Dynameter, Nutrilite, Krebiozen and on and on. They were all difficult and time-consuming cases but the point I am trying to make is that the cases were brought and there was never any doubt but what they would be.

Young: Now, some of these cases had obvious political angles that must have been recognized. As I remember, for example, at the time that the Mountain Valley Water case was brought, the President, supposedly, was using this product in the White House, and it must have been recognized that there was some support for the product in Congress itself. As I read the evidence myself, the bringing of this case may well have had something to do with curtailing Food and Drug Administration's resources in appropriations from Congress. Was there ever any discussion as cases were being built of possible political implications of the cases?

Milstead: Yes, there was, Harvey. Many times, as a part of the "atmosphere" of the case, of what we were going to be up against, any political factors were considered in deciding where the case would be brought, that is, the

jurisdiction involved and the type of action, whether we would make a seizure, file an injunction, or bring a criminal case. All of these factors were taken into consideration, and the political factor certainly, but not from the standpoint of the decision to bring the case. I do not know of a single case where regulatory action that should have been brought was not brought because of any type of political pressure, or of being afraid of the consequences of what the political situation was. In some cases, we might have maneuvered as when to bring the case, what jurisdiction to bring it in, and so on. But that's all a part of sound decision-making and was what Regulatory Management was for, to weigh all of these factors and to ultimately recommend to the Commissioner a course of action which that Division believed would put the government in the best possible posture as far as the court or jury was concerned.

Young: So, political angles were considered in terms of the strategy of the case, but, as you say, never as to "yes" or "no" bringing a case.

Milstead: I'm sure that's right. At least in my experience, and I think that while I was in Regulatory Management, I was in on every case where there were any political overtones. Now, a lot of the decision-making on routine

cases, particularly involving filth, where there was no question about the law, and no question about the facts, did not involve Regulatory Management, or the Commissioner's office. The Bureau of Enforcement handled those. And I think it's a great tribute to all of the Commissioners who built the law on a sound basis through court decisions, that they could delegate responsibility in their area to others. The guideposts established were so sound that there wasn't any question about what the law was, and every Food and Drug officer knew in certain areas what had been decided. They were actually pretty good lawyers, you know, based on their training and experience. But at the level we are talking about, on the really difficult cases where the Commissioner himself would be involved, and all of his staff and the General Counsel's office, the way those decisions were made was through conferences. Some investigative unit, in latter years, the Bureau of Enforcement or Regulatory Management, would direct the investigation after it was decided which ones we would undertake. After I came to Washington and was here a little while in Regulatory Management, we developed what we called the "Ten Most Wanted Cases," obviously patterned after the F.B.I.'s list of most wanted criminals. It served a very useful purpose. We put in order the ten most difficult cases,

as we judged them, in the regulatory field with the reasons why we thought they were the most difficult. We then prepared a schedule to each case including the time required for development, how much they would cost, what manpower would be required, and the chances of success, and any other elements that were pertinent. Then we would review these schedules with the Commissioner and his staff and obtain either approval or a change in order of priority. Through this procedure we arrived at an understanding of at least ten cases that everybody considered of high priority. Now, there would be other matters developed along the line, unexpected problems in the routine cases or other things that we would have to get into that would throw the schedule out of kilter. But, in general, we had a backlog of these ten cases that was agreed on, that we had under continuous investigation.

Young: Now, when you submitted this to the Commissioner, prior to the discussion of it, did it get down on paper?

Milstead: Oh, yes.

Young: So I'll be able to find it in the records somewhere.

Milstead: You'll be able to find it, I'm sure.

Young: Periodic reports on what the ten most wanted cases would be?

Milstead: You will, and we listed those, and all the field districts knew what they were...everybody in the Food and Drug. We prepared in Regulatory Management a weekly report, called R. M. News Items, that gave the status of these cases as they were being developed and tried. The last I knew, this little useful publication was still being prepared.

Young: You initiated that.

Milstead: We initiated that, and we listed in that the ten most wanted cases. We listed in it the cases that were scheduled for trial, and all of the court decisions, and the progress of the trials, and such things as that. That information is available, and it would show a continuous revision as we would dispose of the one of the "Most Wanted Cases," you know. They wouldn't always be taken exactly in order, as far as disposition. Sometimes they would move to the courts in different ways, and they'd get out of line, but from an investigative standpoint...they moved along pretty much in order. Often the Commissioner put his okay on them.

Young: When you met with the Commissioner to discuss the list as it was at a given point, were minutes kept of these meetings or was this just a general free-for-all?

Milstead: It was a free-for-all. Those discussions would involve, might involve, many people, the Commissioner and his immediate staff, assistants to his Assistant, etc. For example, when Crawford was there he would have Larrick in on everything, and each one of those had somebody on his immediate staff who would be there. Then we would probably have the head of Program Planning and...well, we might have the head of a Scientific Division, if there was a serious scientific problem involved and lawyers, people from the General Counsel's office. We might also have people from the field, if it involved some field inspectors or investigators, we'd bring them in to participate. Right at the original point of discussion...

Young: One big meeting.

Milstead: One big meeting. There might be more than one, but our objective was to get the people who were going to tangle with some of the problems out in the field, and in the Bureau in Washington in the meetings so they could see how the Commissioner felt about it, to get his philosophy and the feel of the importance of the case.

Young: There was a morale factor involved.

Milstead: There was...but with the Commissioner's enthusiasm and support, things moved along much more smoothly.

Now we also had a little problem with the Division of Field Operations.

Young: Where was that located?

Milstead: That was in Washington, too. That was one of the original divisions that was set up. I think I've neglected to mention it. I was talking about Regulatory Management and Voluntary Compliance and Program Planning. There was another division called the Division of Field Operations. Now you will remember that all of the direction of the field under the old District set-up was done by the District Director. When the districts were abolished, Crawford set up the Office of Field Operations, or Division of Field Operations, at that time. They brought in as head of that...Mr. Alan Rayfield and his job was to direct the field operations, with the exception of the special investigations and the work of Regulatory Management. Well, it was primarily intended to be...

Young: Who was the head of it?

Milstead: Mr. Rayfield. Alan Rayfield who was the, I believe he was Chief Inspector, I'm not sure, at that time, in the New York District. He was brought in to head the Division of Field Operations. And it was primarily, as I understood it, to be a coordinating job, and the Division of Program Planning was supposed, under Crawford's concept,

to deal directly with the field, and outline programs across the board, and not necessarily clear them through Field Operations. They would consult with Field Operations but were supposed to have independent status as far as the field was concerned. The Division of Regulatory Management was authorized to operate independently of Field Operations, and was not required to consult with them or clear through them or anything of the type. Regulatory Management was a unit which had the authority to deal with anybody in these special investigative areas. But it never worked that way, and the reason it didn't was that Mr. Rayfield always objected to that approach and constantly complained and, as a matter of fact, put roadblocks in the way, particularly in the special investigative area and always tried to have everything clear through his office. Well, it never did. However, it created a very difficult area to deal with, and one that the Commissioner did not want to be confronted with continuously, of trying to serve as a referee between those Operations and Regulatory Management and later the Bureau of Enforcement. But it caused great difficulty, and great dissatisfaction, because the field...we wanted the field in the special investigative area and in the area of litigation to deal directly with the Bureau of Enforcement and the Regulatory Manage-

ment people. Mr. Rayfield wanted everything from the field, absolutely everything, to clear through his office.

Young: Both up and down?

Milstead: Both up and down, which represented a completely different concept than what Mr. Crawford had in mind.

Young: How was this conflict handled? The Commissioner never did clearly resolve it?

Milstead: He never did and his approach was that, particularly Larrick's approach, was that "You people should try to work this out, and you ought to know what your responsibilities are, and so on." But, it just didn't work out, because Mr. Rayfield insisted that all of the material clear through his office, and we were convinced, the Bureau of Enforcement and Regulatory Management, were convinced that special investigations could not be handled efficiently in that way. We did not want a rubber stamp between the field and our unit. In a lot of areas, it didn't matter; it was perfectly all right to clear through his office. But in the area of special investigations, he had no staff of qualified people, really, in this area, and it represented a return on the old District set-up, of imposing additional intermediate steps which contributed nothing. Furthermore, it caused confusion as to who was in charge of an investigation or case. So, we would not agree; we

would not cooperate in that area, which did create some problems.

Young: So that there were not only the different philosophies, but perhaps contributing to them and certainly growing out of them in the operation of this system, there were personal tensions, too.

Milstead: Yes. Very much so with the result that there was always some friction. Field Operations had different views as to the importance of investigations, special investigations. And they did, as a matter of fact, direct some of the field district to not give emphasis to certain investigations that we thought should be emphasized. When this became serious, we would go to the Commissioner for clarification. The Hoxsey case was a case where it was necessary to have the Commissioner issue a directive to the field and to Field Operations that they would give immediate attention to all assignments involving Hoxsey and that they would take their direction from the Bureau of Enforcement and Regulatory Management...to be specific...from Mr. Goldhammer. So that was, in my opinion, a very serious conflict that probably should have been resolved by the Commissioner and clarified as a matter of policy and not to deal with it on a case by case basis.

Young: On a general basis instead of just a crisis by crisis basis?

Milstead: Right, and I think by him perhaps issuing some clarification there, everything would have operated more smoothly. Mr. Stephens who was head of the Bureau of Enforcement and I raised that question with Commissioner Larrick several times and attempted to clarify the whole problem, but we were unsuccessful and so we did suffer, particularly in later years.

Young: Now, I wonder what the reason for this would be? Is this perhaps one of the defects of an agency that had great advantages from its members being career civil servants with high morale, that, if a case of conflict arose, the Commissioner just found it difficult to squelch a member who had been a valuable member of the team over a long period of years, or was this something in Mr. Larrick's own personal administrative view of how things should be accomplished?

Milstead: Well, Harvey, I think that Larrick had great respect for Rayfield's ability and energy and conscientiousness and devoted service, and he was trying, as he did with Malcolm Stephens and me, and I am sure all of the rest, he was trying not to discourage or suppress their enthusiasm or do anything that would interfere with their

contribution. I think he felt that we should be able to resolve the problem at our level and that sooner or later we would, and that he did not feel that it was necessary for him to take a hand in it except perhaps when it became clear that he must as he did in the Hoxsey case. We didn't agree with that, and I think that that was a weakness on Mr. Larrick's part. Mr. Larrick's desire for everybody to cooperate and put forth their best effort and resolve their differences in the interest of the organization and the public was so great that it was hard for him to recognize a situation where it was necessary for the Commissioner to say, "We're going to do it this way." I think it was particularly difficult for him in the personnel area. He was a good man and disliked having to criticize anybody. If there was any weakness on Mr. Larrick's part as an administrator and I'm not saying there was a weakness, it was because he had such great faith in people. It was very difficult for him to discipline anybody. And even though he knew that it was going to have to be done, it worried him...

Young: His kindness was...

Milstead: And he would try every way that he could think of including, I think, inordinate delay in a few instances, of letting the thing work out, hoping that either the man

would leave, or he would see the light. Or he might approach the problem indirectly by hinting that he did not approve of what was going on instead of taking direct action...

Young: I just have to ask you at this point: One shouldn't draw the implication from what you've said, should he, that Mr. Larrick had long fore-knowledge of the Welch case, of the degree of money which Dr. Welch had been receiving?

Milstead: No question in my mind that he did not have, Harvey. He had knowledge that Henry Welch was engaged in certain writing activities and he reviewed this as the record clearly shows. But I think that he had absolutely no knowledge, and it came as a surprise to him, as it did to all of us, of the extent of Henry's involvement, and the amount of money he was receiving. That was a complete surprise.

Young: And this was really the first instance in the history of the agency in which something of this sort had happened. The morale had been so high, and the sense of team participation had been so high, this was a very shocking, demoralizing thing within the agency when it was revealed.

Milstead: Yes, it was. It was the only case that I know of; Henry Welch was a personal friend of mine, and I had

great respect for him, as did Mr. Larrick and all the other commissioners, and all the people in Washington. It hurt everybody deeply because of their great respect for Henry, and, to this day, people wonder, and I do too, about just what was involved. Nobody, including Mr. Larrick and me, ever believed that Henry Welch was dishonest from a scientific standpoint. He was a tremendous scientist.

Young: Well, the National Research Council investigation demonstrated that, I think.

Milstead: He was a very capable man and made a great contribution, which Larrick recognized. Mr. Larrick thought Henry Welch was one of the greatest scientists and greatest organizers that he had ever known, and, I know, was deeply hurt when questions were raised about the propriety of his outside interests.

Young: But the suspicion was not only of a sort that would have been damaging, at any time. It came at one of the most unfortunate times from the point of view of the agency.

Milstead: Yes, it did. It was most unfortunate, and at a time when the agency was, of course, being investigated, and that created, I think, a public impression, that was out of all proportion to the real soundness of the agency. This incident really had very little to do with all the

other employees in the Food and Drug, who were solid, sound people, or with the Commissioner, or any of the Commissioners, and their great contributions.

Young: What were Mr. Larrick's strengths as a Commissioner?

Milstead: I think one of his great strengths which he carried up to the time of his death was his spirit and his enthusiasm and interest in everything that was going on in the Food and Drug Administration. I mean literally everything. He had the capacity to know, from reading and listening, about a great number of things that were going on all over the country and particularly what young inspectors were interested in and were working on. So I think that one great strength was his great enthusiasm and interest in the Food and Drug Administration as an organization and what it was doing. He just never lost that. He was interested in everything. He would meet me in the hall, when I was in Regulatory Management, and say: "How is this case coming today?" or "What have you heard about the program of this or that investigation?" This enthusiasm probably went back to the time that Larrick was Chief Inspector of the Food and Drug Administration. During this period he was interested in quackery and was responsible for setting up special fraud schools to train field inspectors to develop

cases under the Sherley Amendment to prove fraud. Larrick developed that whole program and trained the people at that time, and he trained some good ones, including Walter Simmons who used to be Chief Inspector of the old Central District. Walter was the same type of enthusiastic person that Larrick was, particularly in the field of quackery, and worked in the field of special investigations. But Larrick set up those fraud schools and was instrumental in training a corp of inspectors at that time, which they called Fraud Inspectors. And that course was very difficult, investigative type of work, and required a lot of dedication. I think this is where he got his philosophy and thinking of the need for special investigators to undertake these difficult types of cases, and in particular where fraud and quackery are involved. Now he never lost that interest and enthusiasm. He continued through the time of his Commissionership to be interested in serious violations of the law and the application of all the manpower necessary to deal with them, particularly where health was involved.

Young: Wasn't he interested in other types of violations such as filth and insanitation?

Milstead: Oh, yes he was interested in them all but such things as filth investigations became routine and the law

became clarified through decisions. We knew what we could do, and it was a matter of developing the evidence. But quackery and fraud always presented a challenge and Mr. Larrick demonstrated great strength in dealing with them in the sense that he used the law to its fullest. He was very firm but very honest, and insisted always in proceeding in a legal way, no funny kind of approach, no unfairness in dealing with industry. He always insisted on honest, fair, straightforward legal action. Even in connection with informal statements on enforcement policy or what the Food and Drug Administration believed, he would always ask the question, "Can you back it up in court?" And before he put his name on the statement of policy, he had to be convinced that it was enforceable. But if he signed a statement that took a firm position, he did so on the grounds that we were going to test it, in court if necessary. In other words, no big talk. This illustrated, I think, a difference between the Larrick philosophy--which went back to Campbell and included all the old District Directors--as contrasted to Commissioner, Dr. Goodard's approach. Now, I of course, worked with Dr. Goodard only briefly, but there are indications that under his Commissionership and at the present time, there is a wider use of what might be termed "scare type" techniques--the use of threats and publicity and

that type of approach, and not being able to back it up in court. Now, Larrick believed in the use of public information, but, I think it was a great strength of his that he would not issue a press release or make any statement with respect to an industry that he felt could not be backed up in a court case. It bothered Larrick no end, and he never quite resolved this, to issue a press release about a regulatory action. He always had the feeling, and probably there was a great deal to it, that it did great damage. Even though a legal action had been filed, the manufacturer hadn't really had an opportunity to defend himself, and he never could quite catch up to the release. His feelings about this were deep and strong. He had me to look into this one time very thoroughly with the General Counsel's Office and the Department of Justice, and the Department of Justice issued a release on that point--I have forgotten who the Attorney General was at that time--but the Attorney General issued a memorandum on the issuance of press notices covering the filing of regulatory action and took the position that it was proper to issue them. Larrick relied on this opinion, but it never quite satisfied him. Many times, instead of Food and Drug issuing the release, he asked Wallace Janssen and me to discuss it with the Attorney General and see if the Attorney General would

issue the release, and sometimes he did depending on the nature of the case. But there was something about those releases and about putting a manufacturer's name in the public press that he had been charged with a criminal violation of the law that was contrary to Larrick's nature, and he never liked that.

Young: Is it this aspect of his nature and his policy which led to the kinds of charges that came from Congressional committees sometimes, from journalists sometimes, that he was soft on industry, that he was more anxious in hitting small cases and extreme cases of fraud, quackery, but less anxious to come to grips with more subtle problems on the part of big manufacturers?

Milstead: Yes, possibly so, Harvey. However, I don't believe that those charges were well-founded. I think that the public was led to believe that possibly that was the case with Larrick, but the record would not support that. The record, I believe, would support the contrary view. I know of no serious violation of the law which the Food and Drug Administration had any knowledge of, where there was any softening of regulatory action. None, that I know of, and I know of no evidence to support any charge that Larrick or those before him followed a course that was contrary to the public interest. I think what happened

there was that Larrick was interested in industry educational programs, as was Crawford and Dunbar. Crawford and Dunbar and Larrick all gradually moved in the direction of closer relationships with industry. When I came in Food and Drug, we had a very reserved relationship with industry. FDA was a regulatory agency, firm in every sense. The old District Chiefs made a few speeches, but the idea of working with the industry and developing relationships like we now have, of having joint educational programs, was unheard of.

Young: Who really began to develop that?

Milstead: Dunbar, in my opinion. Dunbar, I think, developed the first relationship with the industry, where the industry felt comfortable in working with FDA. Dunbar encouraged closer liaison with the industry. Crawford was a pretty tough regulatory official and did not encourage liaison with industry. But he was a great man. Crawford, as a thinker, was a tremendous man, and I think a great part of the Food, Drug and Cosmetic Act was Crawford's thinking. He thought way beyond most of us, and his concepts were always in the future. He conceived the Citizens Advisory Committee, you know, but I don't believe that Crawford had a very good feel for the educational and voluntary approach. He wasn't against it, as far as I know, but he was

very strong on enforcement and believed strongly in the legal sanctions of the act. I believe it's fair to put it that way. Larrick on the other hand greatly expanded the voluntary approach. I think what was said about him at his death was true. He believed that regulatory officials should sit down and talk to industry people, and there wasn't any reason why they shouldn't talk to them, even though they were going to bring regulatory action. It was his philosophy that it didn't matter who the person was or how bitter the controversy, or how serious the violation, he would always try to talk to them and try to make them understand the Food and Drug Administration's position without any personal feeling involved. I believe Larrick greatly expanded the concept of education and voluntary compliance. Larrick was always a very friendly type of a man that the industry could talk to and did talk to a great deal. When they'd come in and visit, he was always such an outgoing and friendly guy that it was easy for industry people to talk to him. Crawford was austere, you know, with industry and believed in a strong enforcement approach. Dunbar was reserved but encouraged cooperation with industry. But even he tended to deal with industry cautiously.

Young: Arm's length.

Milstead: Yes, but not Larrick. He would have none of that. But it in no way weakened his enforcement philosophy, and I don't believe there is any evidence to support that, Harvey. I think if you'd look at the record of legal actions and the type of legal actions, it'd show that he pursued a very vigorous enforcement program. Just think of Hoxsey, and Krebiozen, and the whole counterfeit drug area. Larrick approved these actions and many others. The charges that he didn't pursue a strong regulatory policy against the ethical drug industry is not true. You have a developing picture there, beginning with Kefauver. The question of control of advertising was just developing during Larrick's tenure. We were developing the regulations and the full impact of the regulations covering advertising, and how to enforce the advertising provisions of the act against ethical drugs really came after Larrick's retirement. Sure we didn't bring many cases, but the regulations weren't in effect. The charge that Larrick was soft on enforcement against ethical drugs, I think, is unfounded.

Young: One of the other charges that was brought against the entire agency by the Citizens Advisory Committee reports, both the first and the second one, and by Congressional committees, had to do with the lack of scientific

competence, I think particularly the competence in medical science rather than in the basic sciences of the agency, and had to do with the lack of adequate scientific role in the decision-making when most of the top people had this regulatory background that you've suggested. Could you comment on that?

Milstead: Yes. I think there's a degree of truth in that. On the other hand, I don't believe that any of the Commissioners ever made a decision in the medical field without the approval of the Director of the Bureau of Medicine. Sure, the Commissioners were all untrained, as far as medical facts were concerned, but in making decisions, there was usually a lot more than the medical facts involved. I don't know what would have been expected of the Commissioner. Was he expected to delegate to the head of the Bureau of Medicine the authority to make decisions as to whether or not an article was a new drug or whether or not some action should be taken with respect to a new drug? For all practical purposes, as far as I recall, the decision of whether or not an article was a new drug or not a new drug, was essentially made by the scientific people. The Commissioner never made a medical decision. There might have been some administrative questions involved, timing or something of that nature, but the basic question of whether

or not an article is or is not a new drug is a scientific question and the decision was made by the scientific people. I think that it would be almost laughable to any of the Commissioners that anybody would seriously accuse them of making decisions involving scientific questions. I don't mean now if the opinion of the scientist was obviously wrong that the Commissioner would blindly follow it. But for the Commissioner to go against the scientific judgment of his Bureau of Medicine and his medical director would be foolish indeed, and I think there is no justification for any charge of this nature against any of the Commissioners. If anything, the Commissioners and Larrick, particularly, would lean over backwards to follow the scientific decision of the medical director.

Young: Do you remember when the second Citizens Advisory Commission Report was presented, what the reaction within the agency was to this report which in many ways was critical of the agency, including criticisms that suggestions that had been in the first Committees report had not been carried out or carried out sufficiently?

Milstead: Larrick's attitude, Harvey, was as I recall, that the criticisms were justified, that the suggestions

were constructive, so let's get on with getting the job done. I never heard Larrick, with respect to either the first or second Citizens' Committee Report make anything but a constructive comment about them. Many times others would raise questions about some recommendation and whether or not the Committee knew what they were talking about or whether we should proceed as they suggested, and so on. Larrick's attitude was that we picked the committees, we gave them full reign to make any investigation they wanted to make and to make their recommendations, and he tried very hard to implement them. Now he wasn't successful in all cases, but he tried. He often raised this subject with his staff, including me, and Shelby Grey, head of Program Planning, and Bob Roe and others and was impatient with our failure to get the things done that were recommended by both this first and second Citizens' Committee. He often asked for progress reports on many of the recommendations that he knew hadn't been accomplished, and he was very unhappy about it. Larrick had a real respect for the two Citizens' Committees, Harvey, as he did for all of the other committees that he had anything to do with. A strong point about Larrick, in my opinion, was his progressive attitude and his refusal to stick to old procedures. I think a good example was his adoption of the recommenda-

tions in the Citizens' Committee report and in a report of the National Academy of Sciences, that the agency was too ingrown and needed the help of advisory committees and outside advisers. Larrick implemented these recommendations on a pretty big scale, as you know, Harvey. The first National Advisory Food and Drug Council was appointed by him. I think the outstanding people he attracted--every single one of them he contacted agreed to serve on the Council--was a great tribute to him. It is also to Larrick's credit that he assembled many other advisory committees and listened to them. I must say that that was not the case with many of his staff, unfortunately. It was true then as it is today that there are people in Food and Drug, particularly those who belonged to the old school, that do not believe in advisory committees. This caused some problems. But that was not Larrick's approach. He believed in them, and he acted on their recommendations, and he gave them great weight and thought that they contributed, and I think it was a part of his character to accept the judgment of wise people like those on the Citizens' Advisory Committee. He considered the Citizens' Advisory Committee people and the members of his advisory councils to be very wise and knowledgeable people. He accepted their recommendations and tried to do something

about them. He was flexible, progressive, public-spirited and a fine public servant.

Young: The idea has been put to me about the second Citizen's Advisory Committee that some of the pressure to get such a committee came from industry channels which wanted to have less of a tight regulatory policy and more cooperation with industry, so that things might be settled by conversation without so much recourse to the courts, and so that the trend away from tough regulation to hopefully solving questions by voluntary compliance might be very rapidly sped up. This was perhaps to industry's advantage in that they wouldn't get so much bad publicity from the announcement of cases, and would try to ward off problems before they came up, might even prevent the FDA from being as tough about some things as otherwise it might have been. Were these rumors current, do you remember?

Milstead: Yes, they were, Harvey, and they were not unfounded. Now I don't mean that the leaders in the regulated industries had any particularly bad motives in taking that approach. As you know, we had some industry people on the National Advisory Council that believed very sincerely that opening the channels of communication between the Food and Drug Administration and the industry was a good thing, and that there were many problems that could be talked

about, and that the industry would voluntarily correct when brought to their attention. The good elements in the industry felt and have always felt very badly about the whole industry taking a beating as a result of the action of a few irresponsible people. That's what bothered Larrick about issuing notices of regulatory actions, that sometimes hurt the whole industry when it was not the whole industry that was involved. When to take regulatory action and when to rely on voluntary correction are questions that have to be weighed by the Commissioner in the decision-making process. He has to decide what emphasis will be given to the regulatory approach and how much to education and cooperation. There's really not anything inconsistent with these approaches--the emphasis may be a little different.

Historically, Food and Drug has always had what is called the "open door policy." It has always been the philosophy that industry has a right to know the requirements of the law as interpreted by the administration and should be informed. One of the functions of a regulatory agency is to inform and to answer questions and try to prevent violations.

Young: But at some times in some political climates, it's easier and more natural to have closer relations between regulators and regulated than it is in other climates, and

this was a sort of climate in which the push was to get relations a good deal closer. Wasn't there criticism within the Food and Drug Administration against what some spoke of as "jawbone enforcement"?

Milstead: Oh, yes. I think so. There's no question about it that term was used. But I think it was used by those who believed in hard enforcement. People who conscientiously believed that enforcement is the only way to bring about correction, but that certainly was not Larrick's view.

Young: So that Larrick's own personal view and temperament fit in with the kind of suggestions that were made in the second Citizens' Advisory Committee, about expanding the area of voluntary compliance?

Milstead: No question in my mind about it. He had no difficulty with that, and I think he very successfully encouraged that type of approach. I believe...also, Harvey, that the development of the law encouraged that type of approach. Prior to the New Drug section of the Act--and Elixir Sulfanilimide--where there was no pre-clearance control, we had hard law enforcement, inspection and sampling and bringing regulatory actions.

If anybody wanted to talk, yeah, we'd talk, to them, you know, but our business was not talking. Our business was

getting evidence, sound evidence, and bringing legal actions. It really was. Now, I think the Elixir Sulfanilimide episode and then the amendment of the act started a whole, new type of approach of preventive enforcement--doing something more in the interest of the consumers and in the interest of good business, besides bringing law suits. Law suits are a part of the picture, but it's an ineffective way, an impossible way, to protect consumers in this area.

Young: And all of the amendments virtually following the 1938 law in one way or another put pre-clearances in, for pesticides residues...

Milstead: In my opinion, the pre-clearance approach encouraged greatly the relationships between the Food and Drug Administration and the regulated industries. The pre-clearance approach encouraged a closer relationship. Industry scientists talk to the Food and Drug scientists, and the whole atmosphere is one of cooperation and working things out. So, I think we can expect that this approach will be extended to other areas through amendments to the act. Experience has now demonstrated that maximum consumer protection probably just cannot come about by enforcement alone.

Young: But prior to this, regulated and regulators had, for the most part and as the most natural thing under the law, met in court. After this there were many more opportunities, in hearings and in the certification procedures and in the new drug procedures, for regulated and regulators to meet each other as part of the natural ongoing process.

Milstead: There's no question about that, Harvey. And a gradual change in the whole philosophy of the Food and Drug Administration which, from the top clear down to the inspector level of how they deal with members of the regulated industry, and how they talk with them, and how they try to work out their problems. I think it's still going on, in a continuous effort. Fred Delmore's unit is setting up schools and conferences with the industry and that contributes greatly to these relationships. Maybe the public did get the impression that all of this results in a weakening of the enforcement approach and that FDA is doing a lot of jaw-boning instead of bringing legal actions. I don't know whether there's any evidence to support that. There wasn't any evidence to support it that I know about when I was there. From looking at the number of actions that have been brought in the last couple of years, I think there is a substantial falling off of regulatory actions but not, I

think, due to that reason. I think the falling off of regulatory actions is due to the direction of the Commissioner, of the emphasis that he wanted to put in certain areas. That's a judgment of the Commissioner. Dr. Goddard and now Dr. Ley have minimized enforcement in economic areas. The quackery enforcement has largely been destroyed because the old unit that was set up was eliminated, and Food and Drug does not have, at the present time, and hasn't had since Larrick left, a specialized unit devoted to quackery. That's unfortunate and, I think, sooner or later it will have to come back. FDA needs a strong and continuous overall program in the field of quackery. What is being done now is largely done at the district level, and that, I think, is very hazardous, because we are liable to get do great damage if cases are not carefully prepared. It does look to me like Dr. Goddard may have gone too far to decentralize the decision-making authority at the district level. He has not only restored the old district concept but instead of three districts, they now have eighteen. And FDA is also appointing regional personnel and while they are not right in the decision-making process, as I understand it, on regulatory actions, they are out there and what their role is going to be isn't clear.

Young: I think it's under discussion now.

Milstead: It's under discussion. Whether or not they are going to get involved in the decision-making process out in the field is an interesting question. If they do, then they're reverting back to something like the old district set-up in having an intermediate person between the district and Washington. In my opinion, I think the set-up that Crawford had in mind or a comparable set-up--Regulatory Management, Planning and Field Coordination--was sound, and I particularly think it was sound in the enforcement area, because to think that you can set up eighteen or twenty districts and control them, and bring uniform regulatory actions throughout the country and uniform emphasis and so on, to me, it's just not realistic. I believe effective law enforcement requires centralized planning and centralized control, if you're not going to get unequal and unfair enforcement. Without central control, some districts are going to emphasize, be particularly interested in, quackery, spend a lot of time, a lot of effort, in the quackery field. Other districts may not be interested in quackery; they are interested in something else and will give great attention to that field. Now you can allocate the time you want spent on a project in an effort to control that situation, but the District Director has a lot to say about how he's going to employ his man-

Power, and I do feel that, if we're really going to deal with serious violations in all fields on a national basis, it is necessary to maintain centralized control. And I think if FDA is to deal with quackery and other serious violators, it is necessary to have a specialized unit in Washington, who, in Crawford's words, "will dog the bastards every day." That was his phrase, and he was referring to health food fakers and cancer quackery...that was the phrase he used, and I think he was right. If you leave it to everybody, you don't have a coordinated program for dealing with really serious violations.

Young: I did talk to Al Barnard and, I think, in certain areas of national importance, such as the recent actions in connection with diet pills, that there is some sort of national management, although there isn't the national team of experts, as there was earlier.

Milstead: I believe that's right. But I understand that the number of people giving attention to the whole quackery area from a national standpoint has been reduced to only one or two. It takes a team. You know, when we had the old set-up, we had a lawyer in on those cases, too, that followed right along, and he was kept acquainted with the facts as they developed, and he became a part of the team, and we had a doctor and the person assigned from Regulatory Management headed up...

Young: You mean, for each of the Ten Wanted Cases, you had a team of three?

Milstead: Yes, a lawyer and a doctor, and, of course, there may have been others, but generally speaking, if it was a medical question, a doctor was part of the team. If there was some other scientific question involved, we had another technical man. But we would get the team members in on the case early and they would help develop the plan of investigation, you know, and they became so absorbed in the whole case, that when it came to trial, they knew the whole thing.

Young: Well, I take it that the three very often went to the trial.

Milstead: Yes, they usually went to the trial and handled the whole thing. They also participated in the development of the evidence. Now we used to get very serious complaints from Rayfield about the amount of time that was spent in developing cases like Krebiozen and Hoxsey. Well, we did devote a lot of time, but those cases require a lot of time, if you are going to be successful. I think the record speaks for itself, when we made a thorough investigation, and really went into a case that we were successful.

Young: The names of Dunbar, Crawford and Larrick have come up often and certainly you have given glints about their policies, their philosophies, their personalities; how about directing your attention to a kind of comparison and contrast of these three men as you had occasion to observe them.

Milstead: Campbell, I knew...but he was there only a short time after I came in. Of course, I was a chemist then, but I saw Campbell and participated in the...

Young: What did he look like?

Milstead: A fine looking man, very dignified and very formal, but friendly and smiled easily, but always very dignified. An attorney, you know, and precise--precise in his mannerisms and precise in the way he talked to people and in his actions and so on. But friendly and a human type of a man.

Young: Can you illustrate that with any incident or personal encounter that makes him vivid as a person?

Milstead: Yes, a very vivid one, Harvey. Soon after the new law was passed I was in the District Office in Chicago then with Mr. Clarke--they had a conference here in Washington to review the new law, and Mr. Campbell was still here at that time. And he assembled his top officials, Mr. Murray and Dr. Elliott and Mr. Larrick and Mr. Crawford.

Dunbar didn't participate, but he was there. Those were his top administrative people. They presided and they brought in the District Chiefs and many from the District staffs, and I believe the Station Chiefs, too. It was a pretty big meeting. And they were reviewing the various sections of the law, and the opinions that had been expressed. It was an orientation meeting. And some place during the course of the meeting, something came up where I became involved in the discussion and took a very firm position with respect to what I thought could be accomplished in the field. Now, I had been in Food and Drug about two or three years, well no, '39 the law was passed. We must have had that conference in '40; about five years I had been in, but relatively young. So I was very positive, you know, as to what I thought the law meant and what we should be able to do and could do. And Campbell sitting very dignified, sitting there and listening, and when I got through, he said, "You're pretty positive about what you think you can do." And I said, "Yes, sir, I am." Campbell smiled and he said, "That's fine, but you'd better be right." So, that's the most vivid recollection I have. But he was friendly about it, you know, and he just meant that they were willing to listen to young people, and he was willing to let young people try things. But, at the same time, I think he was

saying to me that "You must realize your responsibilities when you are so positive." But that was really the only time I saw Campbell. He came to Chicago to a meeting in which he discussed the new law, but that was the last...; he retired then and, of course, Dunbar came on.

Young: Now what sort of a person was he?

Milstead: Dunbar was a very interesting man. Did you ever see him personally, Harvey?

Young: No, I never did.

Milstead: He was a short, stocky man and a little bit the banty-roosterish type. Dunbar was trained as a scientist. He had a PhD in chemistry from Hopkins, and, as a matter of fact, worked as a chemist for Wiley. He was greatly interested in science, up to the time he retired from Food and Drug. He placed great emphasis on the scientific aspects of law enforcement and on developing the scientific facilities of Food and Drug. So, he thought as a scientist. He was logical and analytical, and followed the scientific method really in his judgments and decisions. He was very firm on enforcement matters, but friendly to industry and, as I said a while ago, under him, the first movement developed towards a much closer relationship with the industry. And Dunbar was very good with Congress, too. He worked better with a Congressional committee than did Campbell.

Campbell had some conflicts with the Congressional committees, mostly I think because of his firmness and somewhat unyielding position. I don't mean to imply that he was not right. Dunbar, I think, had a better relationship and worked a little better with the Congressional committees...The industry felt more friendly and talked to Dunbar more. Now, as far as the field was concerned, I don't think there was much difference between Dunbar and Campbell. We followed pretty much a strong enforcement policy under both of them.

Young: Do you remember any incidents about your relationship with Dr. Dunbar that make him vivid in the way that your incident about Mr. Campbell made him vivid?

Milstead: Well, I hadn't thought about that. But I do recall a personal incident, Harvey, that involved Dunbar. During Dunbar's Commissionership, I was Chief of the Cincinnati District, and I was relatively young and extremely vigorous, and we had a tremendous enforcement program at Cincinnati. There were big problems involving insanitation in the tomato industry, the corn meal industry, black walnut nut meat industry, etc., and we brought hundreds of regulatory actions. So we had an extremely active and vigorous District there, and I was constantly pushing everybody. We had an old inspector there who had

been in Food and Drug for forty years, I guess, and he was in the process of retiring when I was at Cincinnati. Well, he had been sort of loafing along, getting ready for retirement, and doing some things that irritated me very much, and I thought he wasn't doing his job. Although he was getting ready to retire, I expected him to put in his full time. We had a staff meeting one day, and I had all of the inspectors in, and we were talking over various problems, and something came up that involved this man and some job I wanted him to do. He just simply said to me: "I don't propose to do that. You know, I'm getting ready to retire. I'm taking it easy." So I became very... irritated, and I said to him, "Look as long as you're here, you're going to work. And I expect you to get off of your so and so, and you're not about to tell me that you're not going to do anything." That was before all the inspectors in a group. And I just gave him a fit. Well, the result of it was that this man wrote a letter to J. O. Clarke who was the District Chief at that time, and very seriously criticized what I had done, and said that I had embarrassed him publicly. So, Mr. Clarke (he hired me in Food and Drug) called me on the phone and said he could understand how that might have occurred and all that, but I didn't use very good judgment, and he would have to send the letter on

to Dr. Dunbar, and he wanted to let me know that Dr. Dunbar might not look kindly on that, and I said, "Well, I'm sorry about it, but that was the way I felt. So you go right ahead and send it on to Dunbar." So he did. So Dunbar wrote me a letter, and it was a very nice letter but very firm, and said that he hoped that we'd have no repeat of that performance. But before I got the letter, he called me on the phone and said that he was sending me a letter and that it was the official comment, and that's what he meant. But he said he wanted to tell me over the phone that he knew this man from a long time back and that he had often wanted to do the same thing.

Young: So that the sting was taken out.

Milstead: The sting was taken out. It illustrated that he was a very human person and something else. Based on my experience in the Food and Drug Administration, I can say this honestly: no matter what mistake you made, or almost what you did, if you were really putting forth the effort, you know, and really trying to do the right thing and trying particularly to deal with serious violations, the Commissioner might point out to you that you could have done it some other way, but never any real serious criticism and never any thought of dismissing a man or other disciplinary action for making a mistake, as long as

he was doing the best he could. There was a great spirit in Food and Drug in those days and this was one of the things that made the organization so great. There was a great era represented by Campbell, Dunbar, Crawford and Larrick. They were together so long they developed a uniform and continuing policy. And with them, the three District Directors, John L. Harvey, J. O. Clarke, and "Bill" Wharton were also a part of this era. They were a tremendous bunch of people from the standpoint of training young people. They instilled into them something that they just never lost. And I think it was their basic honesty and their great desire to enforce the law in a fair, honest way. From the day you reported...they talked at you about the Vinegar case, and the Sullivan decision and Dotterweich, and on and on. These were the guideposts to what we were doing, and you just sort of absorbed it. A tremendous experience. I've been thinking about them quite a bit lately and wondering what they would think about the organization now, what's going to happen to it in the future. The organization must grow and change with the times, but there should be some continuity in the organization. Maybe it's just the way things are but I'm afraid we've largely lost that because the men who would have normally carried on have left the organization. This

causes me to wonder about the organization and what it's going to be like in the future. Historically, FDA has always been a scientific, law enforcement agency, and, that fact permeated the whole organization. You just couldn't handle anything that wouldn't raise the question what are the scientific facts? J. O. Clarke, the old Central District Chief, was a chemist, and he was deeply interested in scientific investigations. While he was the District Director, he had a big study going on, decomposition in butter, and he directed that whole thing. Well, it showed how close they were to the problems and how interested they were in them. Harvey was very active in court cases in the Western District and Wharton, the old chief of the Eastern District was very active in the consumer education area. He developed a series of radio programs, and he was a great believer in that approach, and as a regulatory official at that time was far ahead of anybody else in the whole Food and Drug, in his relationships with industry and consumer groups. In his handling of imports he had a lot of discussion with industry, and approached the problems in this area in a cooperative way.

Young: He gave these radio talks...some of them, at any rate...in connection with the effort to get the 1938 law. But he had done it before?

Milstead: He did it before and he was very active. I think they selected him because of his interest in that type of approach and because he was good at it. Now coming to Crawford: Crawford was the most human-type of a man. He had some personal problems that greatly tempered him. I knew something about his personal problems, and I was really closer to him than most of his associates. Crawford brought me to Washington and I used to talk to him a great deal.

Young: Dr. Milstead, when we were talking, before we changed the tape, you were discussing Mr. Crawford as an administrator. I'd like you to tell me what he looked like and how he behaved when he was a Commissioner.

Milstead: Well, Crawford physically, was a medium-sized, square-built man. He was usually smoking a cigarette in a long cigarette holder; he was very thoughtful and very deliberate in his speech. He spoke softly and slowly with carefully chosen words. When I first came to Washington, Mr. Crawford always got to work very early. In fact, he was always there when I arrived and I usually got there about an hour before regular working hours. But whenever I got there, Crawford was always there, and so I think he came about 6 o'clock in the morning. He would be in his office looking over reports. He was a perfectionist and

spent a lot of time on reports, which he liked to do early in the morning.

Young: He wrote his own annual reports, didn't he? I've heard it said that he did.

Milstead: I'm not sure, but I wouldn't be surprised, because he was very particular about how he wanted things said. At that time, a lot of material that was prepared by the staff came to him for his signature. He was particular about what he signed and he would spend time early in the morning perfecting them. He became aware of the fact that I got to work very early and so did Mr. Stephens. We came down together. So Crawford said to me one time, " I notice that you get here very early. Why don't you come in and talk? Bring Steve, too." So we did, Steve and I, would go in there and visit with him early in the morning about all kinds of things; things that he was thinking about and things that we had on our minds and so we developed a very good relationship. It was a wonderful experience. And then, a little later, Larrick started coming early and he joined the group, and then later, a few others, until there was sort of a little staff meeting every morning pretty early, before anybody else came. We all grew to love Crawford and had great respect for him, because he was so kind and so thoughtful and always projecting out in the

future, you know, and always acting in the best interest of the consumer and the public...a fine public servant that I will never forget.

July 28, 1969

Young: This is a continuation of a conversation that we began almost a year ago now. Dr. Kenneth L. Milstead now of Checchi and Company in Washington, D. C., is going to continue some of the conversations that he had with me last August. I'm James Harvey Young of Emory University. Today is July 28, 1969. When we last talked, Kenny, you had said some things about Charles Crawford who was Commissioner of the Food and Drug Administration and whom you knew, and you wanted to say a few more things about him.

Milstead: Yes, Harvey. It occurred to me that because of the great interest at the present time on consumer participation in the decision-making process that it would be of interest to review briefly Mr. Crawford's great interest in that area. During his administration, it became apparent to him that the Food and Drug Administration was not obtaining feed-back from consumers on the food and drug programs. Charlie Crawford gave a great deal of thought to this question and was very anxious to develop some type of a procedure whereby the Food and Drug Administration

could obtain the opinion of consumers. He conceived what has been referred to as the Consumer Consultant Program. This was intended to place informed and carefully trained people out in the field to make contact with consumers and consumer groups and to advise the Commissioner on the attitudes and feelings of consumers about the food and drug programs. Eventually this Consumer Consultant Program was set up, and a consumer consultant was appointed in each field district office.

Young: Can you remember when the early stirrings in his mind about getting this program started might have begun? Where were you at the time?

Milstead: I was in Washington then, It was soon after I came to Washington and I think that it came about as a result of the food standards work largely in which Mr. Crawford was greatly interested, and I think he felt that the Food and Drug Administration was actually not obtaining the views of consumers on food standards.

Young: Was this in connection with the hearings that the new 1938 law required in connection with setting standards?

Milstead: Yes.

Young: Not enough consumer sentiment showed up there?

Milstead: Right. Actually at the hearings, very few, if any, consumers would appear or would comment on the

proposals. And this disturbed Mr. Crawford greatly, and the same, I think, applied to many other areas where he was anxious in some way to work out a mechanism whereby consumers could participate in the decision-making process, so that the government, the Food and Drug Administration, would have a better idea of how consumers felt about some of the regulations and labeling questions and problems of that type.

Young: Do you suppose that his contact with the women during the period that the effort was being made to get the law that became the 1938 law, and in which the women were a very important all as far as their national organization and pressure were concerned toward getting the law, do you suppose this contact with women was important in his mind at all?

Milstead: Oh, I think so, Harvey, because the League of Women Voters and the American Association of University Women and some of those groups that played an important part in the new law--and you know Crawford was sort of the architect of the new law and was in close contact with groups of that kind--no doubt influenced him or strengthened his feeling that some way we had to get closer to the consumers.

Young: I take it that these women helped get the law, but then somehow when it came to the hearings on tomato catsup, canned peaches, and so on, to get standards, these same organizations didn't come to the hearings as much as Crawford might have hoped.

Milstead: That's right, Harvey, and that's largely true today. In spite of his efforts and in spite of the fine program he worked out on the Consumer Consultant Program, I think that we'd have to say that it still has not produced the participation of consumers and consumer groups in this regulation-making procedure of Food and Drug, and for that matter, in all consumer programs at the federal level.

While I personally think the Consumer Consultant Program of Food and Drug as conceived by Crawford has contributed a great deal to the Food and Drug Administration by making their programs better known to the public and to consumer groups, I think where it has failed, and I don't know why it has failed and what to do about it, is that it has not provided the feed-back that Mr. Crawford hoped for from the women's groups and consumer groups throughout the country as to what they really think about what's going on in the Food and Drug Administration and what should go on.

Young: In some latter days, I think it has had a low priority in FDA partly because Congress more or less said

so, more or less said that money shouldn't be spent in educational endeavors, so that may be one factor.

Milstead: Yes, I'm afraid that's true, Harvey. It's another example of this complex problem of how to obtain consumer participation in the whole government-making process that's so much being talked about now in connection with the Food and Drug Administration, and Federal Trade, and other government agencies, that advocates or consumer representatives like Ralph Nader and some of the others are so greatly concerned about and are coming forward to speak for consumers. But still, Harvey, I don't believe, and I'm sure that those who knew about Crawford's views don't believe, that we yet have found the way to really reach out and obtain consumer opinion on a great many of these questions that come before the government agencies. There is still practically no participation. Seldom, I think, is there any actual consumer participation in standard-making procedure in Food and Drug. In the dietary food hearings, there are some consumer representatives there, but nothing on a scale that he anticipated.

Young: Right. One of the periods in which the broader public came to become much better acquainted with the name of the Food and Drug Administration than it had been at least since 1938, may be even more than that, came as a

result of the hearings in connection with the pharmaceutical drug industry which the late Senator Estes Kefauver held. Now, when you were in the Food and Drug Administration, I remember your telling me, it was one of your responsibilities to be the liaison man between the Food and Drug Administration and Senator Kefauver and his staff. Now I wish you would tell me the story of the day that Senator Kefauver came to the Food and Drug Administration offices.

Milstead: Well, that's a very interesting story, Harvey. As you know, the Kefauver hearings were held during Mr. Larrick's administration, and Mr. Larrick assigned me to those hearings for several months, assisting him in preparing background material and in preparing proposed testimony and doing all of the other work that was necessary in preparing him to ultimately testify before the committee. Well, early in the game, early in the considerations of the question that Kefauver was considering, the Senator made an appointment with Mr. Larrick to come over and to meet with him in Mr. Larrick's office and to bring members of his staff to discuss the whole question. At that time the sole question, as far as I recall, that was being considered was the price of prescription drugs, particularly the price of brand name drugs as contrasted to generic name drugs, and

I think the Senator's original concept was to go into that matter in great detail, on the grounds there was no difference in the quality between brand name prescription drugs and generic name drugs, and therefore, there shouldn't be any difference in the price. Mr. Larrick was aware of, through conversation with the Senator, that that was the approach or the scope of the hearings. So when he came over, he brought with him his, I believe, general counsel of the committee at that time who is now the Chairman of the Federal Trade Commission, Rand Dixon, and, as I recall, they were the only two that came. And Mr. Larrick...and I was present...and our General Counsel, Mr. Goodrich was present...and several other members of the staff, met with them to get an idea of the type of testimony or the scope of the inquiry as to the Food and Drug Administration's participation in the area that he was interested in. Incidentally, before we met, I recall very well the Senator coming down the hall with Mr. Dixon, and, as I think about it, it seems to me that he did have another person or two with him, for he had quite a little group and created quite a little commotion as he came down the hall, for he was a very impressive man and a very friendly man, and I recall as he would meet members of Food and Drug in the hall, he

would speak to them and introduce himself to them. He would say, "This is Estes Kefauver," and he came in Mr. Larrick's reception area, and he just made himself at home, introduced himself and the people with him to the girls, and visited with them, and so it was an interesting experience and interesting to see. Well, we met with them, and the Senator explained to Mr. Larrick that they were going into the question of the price of drugs and that was their interest, and the Commissioner immediately said to him, "You know the Food and Drug Administration does not have jurisdiction over the question of the price of drugs, and if that is your approach, then there is very little that the Administration can contribute in that area, because it's really not one of our responsibilities." But the Senator said, "Well, it is Food and Drug's responsibility to insure the quality and purity of drugs." Of course, that is FDA's responsibility, and it became clear that the whole basis for the hearings on the price was based on the proposition that there is no difference in the quality of prescription drugs. Well, we had done a considerable amount of work examining the Food and Drug Administration records over many years to determine whether in fact that was true. It was clear that that was not true, and therefore Mr. Larrick could not testify that generic

drugs in general were of the same quality as brand named drugs. We had tabulated a large amount of data to establish that fact beyond any question. So Mr. Larrick said to the Senator, "Well, Senator, if that is your approach, I'll have to say to you that the Food and Drug Administration will not be able to support that fundamental thesis on which your hearings will be based." Well, the Senator was greatly surprised as was Mr. Dixon, by that statement, because it completely changed the whole picture of what they were trying to establish in the hearings. So then we discussed in some detail the basis of Mr. Larrick's view, and it was clear that they could not proceed in the manner they had planned. So the result was that the hearings were held to develop legislation that would insure the quality of generic drugs and make them equal to the quality of brand named drugs. The Kefauver-Harris Amendments, resulted, which were intended to establish good manufacturing requirements for all drugs, whether they are generic or brand name, to insure the same quality of all drugs, and then the question of price could be properly evaluated. Young: Right, so that was a kind of climactic turning point in the Kefauver consideration?

Milstead: Yes, Larrick did ultimately testify and did testify as I just have said, and did introduce into the record of the Kefauver hearings all of the tabulations, all of the data, that we had accumulated, supporting the position that generic drugs were not equivalent to brand named drugs at that time. Now, looking back, I think that the fact that the hearings did take a different turn and did proceed along the line that they did, that resulted in the Kefauver-Harris Amendment, was a very desirable thing and has had and will have in the future a very fine influence on the quality of drugs, all drugs, and there should not be any difference really between the brand name and the generic product as far as the consumer is concerned from a therapeutic standpoint.

Young: Toward the very end of the period right before the bill came to be passed, there was some difference of opinion between Senator Kefauver and the Health, Education and Welfare people as to what the terms of that bill exactly should be. He was still more interested in the price angle, and patent angles as they might affect price, than HEW seemed to be. At that stage, were you involved at all in the way HEW looked at the kind of bill with the precise language it would have in it?

Milstead: No, I wasn't, Harvey. When it came to that stage, I was not involved. That was largely for the lawyers, and Mr. Larrick, I'm sure, was involved in the discussions, but I did not participate in detail on that.

Young: Right. Now, I think we could take a little time for me to ask you a little more than I did last time about two men you gave personality sketches of the administrators. I've been going through the records, and I'd like you, if you wouldn't mind, to give a personality sketch of J. O. Clarke and also one of John Harvey for me: What kind of people they were and how they operated, the same sort of thing you did in connection with the Commissioners.

Milstead: Well, J. O. Clarke was Chief of the Central District when I knew him. In fact, he appointed me in the Food and Drug Administration, and I was always very fond of him and remember him with a great deal of affection and respect. He was a chemist and came into the Food and Drug Administration, I think, at the old Savannah District as a chemist and worked on up through the Food and Drug Administration in various capacities until he was finally Chief of the old Central District, and was later brought to Washington when the Districts were abolished. Mr. Clarke was brought here as Director of Program Planning, in a new

job. Now his whole approach was scientific. He was scientifically oriented, and he was greatly interested in the application of science to food and drug law enforcement. The way he considered things and the way he evaluated problems was entirely from a scientific approach, and I think the right approach. He was really a great administrator from the standpoint particularly of the scientific problems involving Food and Drug. He had a great sense of humor and was highly respected by all the people who worked for him and was devoted to Food and Drug, and I think had great respect for the members of the industry. When he was Chief of the Central District out in Chicago, he worked very closely with industry people on some problems, particularly in the dairy field. At that time we were just getting started in the sanitation area, and in some industries like the dairy industry and the flour and corn meal industry and so on, he worked very close with them.

Young: Candy...

Milstead: Candy. The whole sanitation program started at that time. Mr. Clarke was so interested in the laboratory and in the scientific work and the development of scientific methods. He was very active in the AOAC, was a president of the AOAC, and all during the time that I knew him

up until the time he retired he always had his finger in some scientific project. He directed quite a research program in the area of decomposition in cream and butter while he was Chief of the Central District, and when I first came into Food and Drug I participated in it. So I'd say that Mr. Clarke's approach was scientific, and he stayed almost entirely on the scientific side. He was interested in the inspectional work and so on, but nothing like the scientific interest. In the legal area, he participated very little. When it got into court, he thought that was a problem for lawyers. He was interested in developing the evidence soundly on a scientific basis, then he'd let the lawyers take over.

Young: What did he look like?

Milstead: He was heavy set, crew hair cut, very Southern; he was from Georgia and was very Southern; very friendly; very fast in his movements; very active around the lab and around the office; had a great sense of humor and loved stories; and loved the people and they all loved him.

Young: Did he talk like a Southerner?

Milstead: Yes, oh, very much so, a very Southern voice, and nobody would make a mistake about the fact that he was Southern.

Young: Well, how would you compare him with John Harvey who was the Western District Chief?

Milstead: Well, John Harvey I've know better in recent years. I never worked in the Western District, but I got very well acquainted with him in Washington, because I succeeded him. When the Districts were abolished, Mr. Harvey was brought to Washington to head what was called then the Division of Litigation, and its name was later changed to the Division of Regulatory Management. And Mr. Harvey was the first director, and I succeeded him. Mr. Harvey was made the Deputy Commissioner. So I worked with him quite a bit in Washington. Mr. Harvey was always interested in the legal side. He came in as an inspector and showed great interest in the inspectional side and in the legal side of Food and Drug's work. When he was in the Western District, he actively participated in many trials and had a great interest in that area. He later became a lawyer and was admitted to the bar, and after he retired from Food and Drug has been practicing law and is at the present time, although I understand that he's thinking about retiring now. Mr. Harvey's approach was legal, and he looked at things more from a legal approach and more as lawyers would look at it, and they always used to call him and refer to him long before he had his law degree at "The

attorney, Mr. Harvey," and they used to kid him about expressing legal opinions on the law and so on, but he was greatly interested in that area.

Young: How was he as an administrator?

Milstead: Well, as I said, I never worked for him, but...

Young: I mean in Washington.

Milstead: Oh, in Washington he was respected, and I think a very capable man. He, of course, became the Deputy Commissioner and was Larrick's right hand man.

Young: If the decision had not been made to go outside the agency and bring in a man of medicine, and if the old tradition had been followed, was it not likely that he had been chosen by Mr. Larrick to be his successor? Do you think that?

Milstead: Well, I really don't know. I never heard... Larrick never commented on that question to me. In the normal course of events, as you've put it, in the old set-up of progression of the career people and so on, I don't believe there's any question that the great bulk of the career people would have liked for Mr. Harvey and hoped that Mr. Harvey would have been made the Commissioner when Mr. Larrick retired. There's no question that he had the most knowledge, the most experience, and knew more about the background and policies and history and everything of

Food and Drug than any man alive, I'm sure, at that time. Why he wasn't made Commissioner, I just don't know, Harvey. I think that many things came up at that time, and now has been shown, the career service just wasn't maintained. They were getting outside of the old promotion that we were used to.

Young: The third of the men..I just might ask if you knew him well enough to comment at the time of the old District system, in New York was Mr. Wharton.

Milstead: Well, I knew Wharton least of the three. I knew him mostly by reputation, through correspondence and what I heard, and I met him several times at conferences here in Washington, at District Directors' meetings. I used to come to Washington with Mr. Clarke when I was in his office in Chicago. So I met Mr. Wharton many times and watched him and so on, but I really don't know ...

Young: Was he more like Harvey or like Clarke?

Milstead: More like Harvey, but not as legal. I would say that Wharton was probably more interested in the consumer and the consumer approach at that time than any of the others. He developed the radio programs, as you will recall. He wrote extensively and gave many lectures and spoke a great deal to consumer groups. I think he was more of a public relations type figure...a public figure...than

either Harvey or Mr. Clarke, although both of those participated quite a bit, but Wharton was out in front in that area.

Young: Right.

Milstead: Wharton was highly respected as an administrator, and his people in the old Eastern District and many of them I knew highly respected Wharton.

Young: As you worked with Mr. Clarke in the Central District office, was there much feeling of competition among these three Districts in the eyes of themselves competing against the other Districts for Washington's favor and commendation and so on?

Milstead: There was very much, Harvey, but it was very friendly. There was a great competitive spirit among the Districts, and among the stations as they called them at that time. Mr. Clarke was a great competitor, and he generated such a spirit in the District, and Harvey was, too. I think Harvey and Mr. Clarke were more competitive than Wharton, although they competed with him, but Mr. Harvey and Mr. Clarke watched each other pretty close, about the number of legal actions and the type of legal actions and the cases they won and the personnel that they obtained, and all of them tried very hard to attract personnel from the other Districts or tried to obtain

personnel from the others. You know, they used to move the people around quite a bit, and they had meetings once a year and sometimes much more than that, at which they would swap personnel and discuss programs. There was a great competitive spirit among them.

Young: Well, you were one who very successfully climbed the ladder. Was there a sense of personal competition that you felt for getting advancements?

Milstead: Oh, very much so, Harvey. Within the old Central District, I never really felt competition from the other Districts, although it was there in a way. These District Chiefs would go down the list, I understand, Mr. Clarke later told me, and they would talk about their people, about their development, you know, what they were doing, and where they should be put. I think they wouldn't always tell all they knew, you know, because they'd be afraid one of the other District Chiefs would try to steal a man. There was great competition among the people. In the old Central District, I felt a great deal of competition, but it was wholesome, and healthy, you know, and I was trying to do the best I could and, I'm sure that all the rest of them were doing the same. The good thing about Mr. Clarke, and I of course didn't work for Wharton and Harvey, but Mr. Clarke had the reputation of being really a

little out in front on this, I mean his fairness and his objectivity with respect to his people, and promoting them on the basis of their merit. I think in the old Central District that the people almost universally respected him and respected his judgment and felt that they were treated very fair. He did promote people on merit and tried to build up his staff on that basis. There were people that said that some of the others didn't always do that.

Young: Right. Well, looking at it from Washington's point of view, going through the records, one of the surprising things perhaps is how close the Washington people, including the Commissioner himself--I'm still looking at things in Campbell's period--but certainly how closely Campbell, Crawford, Dunbar, in say, 1939, were aware of what individuals at the most isolated stations were doing. It would seem to me that they would have in their minds, on the basis of the kind of papers they looked at, quite a detailed knowledge of the strengths and perhaps weaknesses of the individual inspectors and chemists. Now, having been out in the field, were you aware that this was true of the leadership in Washington?

Milstead: Yes, it was, Harvey, very much so. They, at that time...now, of course, the organization was much

smaller..., but at that time the Commissioner himself had a remarkable insight into the people in the field and way down the line, knew them personally. They used to go out and visit the stations, spend time at the stations. But I think probably the reason for that too is because of the old District set-up. The three District Directors kept the Commissioner so advised about these matters, by meeting with him and correspondence and through other ways, that they would point up these young men that were developing and all of the things that went on in the field. I agree 100% that the Commissioner clear up through Larrick...now, Larrick began to get away from it some...but, gee, they knew every District Director and every Deputy Director and every Chief Inspector and every Chief Chemist and knew a lot about them and knew about what they were doing and their capabilities, and so on. There's no question about it.

Young: I can sense that, even with the competition, there was a strong esprit de corps, that this effort to instill an esprit de corps began even with the training program of new inspectors and new chemists. Did you all the way through have this sense of kinship with others in the agency, a sense of pride in it?

Milstead: Yes, very much so, tremendous, tremendous. Even now I feel close to a lot of the people, you know, that I worked with who are still in Food and Drug. But at that time, the whole organization, I think, felt very close--the chemists, the inspectors, all of them--there was great esprit de corps. Now, it was small, you know, and it was possible to know a lot of people, to know a large percentage of the people in Food and Drug. By being transferred, you know, and by attending meetings and things like the AOAC, you naturally got acquainted. But we had tremendous spirit. You just couldn't meet with any Food and Drug people but that almost the entire conversation was Food and Drug. The people were absorbed in the Food and Drug Administration. Completely absorbed. Those that really devoted their lives to it, once they got into it, it was their life--tremendous, really a tremendous organization. Now, maybe it's too much to expect that when it grows and gets as big as it is now--and then the problems are extremely complex now--it's too much to expect that that closeness can be maintained. The Districts are so much bigger and all of that, but some way, if you could hold on to that spirit, even when the organization gets larger, I think that you'd do a great deal more and accomplish a great deal more for a lot less money than happens if you lose the spirit, if you know what I mean.

Young: Sure. I think that that's a good tone for us to end on today, and thank you so much, Kenny, for being willing to talk again and help preserve the record of impressions about the history of the Food and Drug Administration.

Milstead: Thank you, Harvey, for the opportunity.

February 4, 1982

This is a recording in the series of FDA oral history interviews. We are interviewing today Dr. Kenneth L. Milstead a retired official of FDA at his office at Arthur A. Checchi Company, Washington, D.C.. Dr. Milstead was previously interviewed by Professor James Harvey Young, August 28, 1968 and July 28, 1969. This interview is a continuation of those previously held. Interviewers are James Harvey Young, Professor of History, Emory University and Wallace F. Janssen and Fred L. Lofsvold, Food and Drug Administration. The date is February 4, 1982.

Lofsvold: Kenny, in the earlier recordings I think you gave Harvey an excellent outline of the various positions that you held in FDA. I would like to go back just a little bit. Would you talk about your academic background before you came to the agency.

Milstead: Well, I was born on January 10, 1909, in a little town named Brashear, in the northeast part of Missouri. This was where I went to elementary school and high school. Then I went to college, at Northeast Missouri State Teachers College at Kirksville, Missouri. It's since become one of the satellite universities of the University of Missouri. I graduated from Kirksville in 1929 with a degree in Chemistry. I went from there to the University

of Cincinnati to graduate school in Chemistry and started in working toward a Ph.D in Chemistry. I was a graduate assistant there and that was during the depression and the only money we had was what I got from the graduate assistantship. But I got through and got a Ph.D, a master's degree in 1931, a Ph.D in 1933. Then I went back to Kirksville where I went undergraduate for one year while the professor of Chemistry was on sabbatical leave, and I spent that year there. Then I went to Coe College at Cedar Rapids, Iowa for one year and part of another year in, that was in 1934-1935, and I was married in the summer of 1935. I made \$1,000.00 a year when I taught at Coe. When we were married that summer the President of Coe called me in and said, "Gee, since you were married, better raise your salary." So he raised it to \$1,100.00 a year.

There was an announcement by Civil Service for Food and Drug for P-1 Chemists. And I applied and J. O. Clarke who was the Central District Director at that time came to Cedar Rapids to interview me and as a result he did offer me the job and I reported to Chicago in December of 1935. So I started work there as a junior chemist at \$2,000 a year which at that time was a fortune for me. So that was essentially my academic background. During the time that I was teaching at Kirksville and at Coe, I continued to

study. During the summers I went to the University of Chicago and the University of Iowa and listened in on graduate courses. After I came into Food and Drug I continued some academic work, particularly in the Department of Agriculture graduate school in Washington. I've always been interested in continuing to improve my knowledge not only in the scientific area, but also in the management area and I took a good many courses along that line. So, that's my academic background, Fred.

Lofsvold: Before you came to the agency had you had any particular interest in Food and Drug chemistry?

Milstead: No. I had not, Fred. I taught general courses in chemistry at both Kirksville and Coe. I don't believe I ever heard of Food and Drug until I saw that announcement for P-1 chemists. I was looking around for things all the time because there was no future at Coe. They were having a very hard time. It was a denominational school, a fine little college though. But they were having money problems and there wasn't any hope for me there. When I saw that announcement by Civil Service, I thought, "gee that sounds like an interesting possibility." So that's how I was introduced to Food and Drug chemistry.

Lofsvold: I think that was true of a great many of us around that time. We were looking for jobs, period.

Milstead: The recent TV's and everything about Roosevelt* took me back, to when I was finishing graduate school at the time that he took office in the depths of the depression. I had no idea of what I was going to do. I was getting out, finishing my Ph.D. in June and I had no job - nobody had a job.

It was discouraging after all that, this tremendous effort. And I remember Roosevelt's famous speech, you know, "nothing to fear but fear itself". It gave us all a lift and so we renewed our efforts, and my goodness, one day I got a call from my wife's father who was president of the college at Kirksville, asking me if I would be interested in coming out there for a year. I said, "would I be interested?!" So that started me on my career.

Young: When you first went to work at FDA was there a good deal of talk about the fact that Congress was considering the new law that was to become the 1938 law.

Milstead: Yes. Very soon. I'm not sure just when that occurred, but not long after I arrived in Chicago. Campbell was the commissioner at that time. Well, of course, I was

*(The television coverage of the F.D. Roosevelt centenary on January 30, 1982.)

in the lab and way down as low as you could get but, even so, I knew a lot about it. I heard Campbell when he came out and made a speech on the need for new legislation. I've forgotten to what group in Chicago, he spoke. There was a lot of interest in it on the part of Food and Drug employees. And there was Crawford who gave the big emphasis to it. But Campbell, oh I remember him so well, he was an impressive speaker, impressive man. So I remember that speech very well, and was impressed by Mr. Campbell.

Lofsvold: When you reported at Chicago, what kind of training did they give you?

Milstead: Fred, not too much. Well, Harry Garrett was the Station Chief and Homer Runkel was his assistant and they assigned me to Homer who took me back in the lab and introduced me to John Boardman who was the Chief Chemist, at that time. And John said, "Well, we'll have to get you a desk and get you something to do." So the training at that time consisted largely of assigning you to an experienced chemist who'd been there for some time. John, the chief food chemist, Chris Glycart who was the chief drug chemist would supervise you but there wasn't any formal training program. It came a while after I was there when the hiring accelerated and a good many chemists and inspectors were

hired. At that time a formal training program was started.

Lofsvold: At the time you came new people were coming in ones or perhaps twos and it wasn't really the kind of situation that would lend itself to classroom type formalized training.

Milstead: That's right. But before I got out of the lab, now I wasn't in the lab too long, I've forgotten the dates on that, but before I got out of there, they were working on an organized program.

Lofsvold: I think that was for the group that started when I did in '39 when the new law became effective and there was a big hiring across the country. That was the case I know in the Western district where I was and I think it was true of the other districts also.

Milstead: I'm sure you're right, that's when it really started.

Lofsvold: Did they give you any kind of training in the 1906 Act?

Milstead: Fred, I don't think so at that time, although we were given a copy of the law. When the group came in '39 they did have some training in the Act. They had some sessions, and although they weren't too sophisticated they did make an effort to acquaint the new people with the law and cases.

Young: There were inspectors' manuals but there weren't chemists' manuals, is that right?

Milstead: I don't believe there was anything like that when I came in, in the nature of a chemists' manual.

Lofsvold: There was the A.O.A.C. Book of Methods and the USP?

Milstead: You're right and other methods for specific products. There were two big things going on in the Chicago laboratory at that time. One was spray residue and the other was filth in foods. And the first assignment they gave me was to try to develop a method or use whatever methods we had, to determine filth in Limburger cheese. They decided...

Young: A sort of redundancy...

Milstead: I worked on that a long time but there wasn't any...

Lofsvold: In a hood, I hope.

Young: The chemists weren't broken down, some specializing in drugs, some specializing in foods?

Milstead: Yes, yes they were to a degree. They had as I said, they had a food laboratory and they had a drug laboratory now, and chemists were assigned to the laboratories. I did nothing but food analysis for a good long time but later worked on drugs.

Young: Was this because you were assigned or did your own desires have anything...

Milstead: No, I was assigned. They said you work here and I've forgotten the time period but, after a while, they said well now you ought to have some drug experience so they moved me over into the drug area. And generally that's what they did. There was no cosmetic work then, you know, there were just foods and drugs, and well, there were pesticides. I never did any work in pesticides.

The operation of the food group, was the big thing at that time. There was some work on drug analysis but it was largely compliance with the USP, and just more or less routine. And there was some analytical work on proprietary, patent medicines as we called them at that time, but it was a very crude type of a thing. The great activity there was on foods. Spray residue, my goodness, they had everybody working on spray residue.

Lofsvold: That would've been lead and arsenic?

Milstead: Lead and arsenic and using those old methods, and old digestion methods and it was a laborious operation to try and determine lead and arsenic at that time.

Lofsvold: Were fluorides in use?

Milstead: Fluorides somewhat but the methods were not very good at that time for fluorides. The food division in

Washington largely developed the methods that were used and they'd send them out and we'd try to apply them. Compared to the sophisticated methods we have now they were very crude.

Lofsvold: That was mostly apples and pears?

Milstead: Yes. But we had to digest them to apply the old colormetric method and we used our own man made colorimeters and oh they were so crude relative speaking. But we brought a lot of enforcement actions based on our analyses but I think it was just because the fruit was so loaded with lead...the levels were enough to kill anybody.

Lofsvold: Was the methodology for the filth in foods pretty well developed at that time?

Milstead: No, not well developed. It was in the developing stage. Wildman and of course Eisenberg and that group were coming on. And they had begun to develop some good methods but I think, as I recall, I was still in the lab when Wildman developed his so-called Wildman trap that was the great development in filth analysis. I believe I was still in the lab when that came along and I did do some work with it but not long.

Young: Was he in Washington or Chicago?

Milstead: He was in Washington. But the Food Division scientists came out to the field a lot. Wildman came out

to Chicago and so did others and worked in the lab and developed methods and they'd try them out there and showed the people how to use them too.

Lofsvold: Did you ever see B. J. Howard?

Milstead: No I didn't. Do you remember when he died?

Lofsvold: I think he was still living at that time but I don't remember when he left the agency.

Milstead: Gee I don't know, I'm not sure. Since I've been thinking about it I believe he did come to Chicago while I was there and I just sort of remember seeing, picturing, him sitting there at the microscope.

Lofsvold: That was about the time that, well he had developed the mold count many years before. But I think about the time you started was when we began to be able to detect worm fragments in tomatoes and I'm sure that Howard was still active with the agency at that time.

Milstead: He could very well have been. Not long though because Wildman came on and then Eisenberg. Eisenberg did most of the work on the rot fragments and Wildman did too but I think that Howard wasn't around very long.

Lofsvold: Then Wildman left and went to Cornell I believe.

Milstead: Right. And Bill Eisenberg largely took over from there and then of course I was out of lab. But then when I was the chief chemist at Cincinnati and later the

district director we had tremendous problems in the tomato industry and Eisenberg spent an awful lot of time there training the chemists in mold count work and so on. But we were getting into a much more formal training approach then.

Lofsvold: Did you ever learn to count mold?

Milstead: Yes, very much so, Fred. At Cincinnati when I was the chief chemist we had so much I did mold counting and rot fragment counting just to be familiar with it.

Young: Did you testify in court on the basis of your counting?

Milstead: No, I never did. Our people did, many of them did, I never let myself get involved to that extent. I was the boss then. We had McNall and some of those people in Cincinnati that Eisenberg trained and they were awfully good. I've thought about all of them so much. They were a great group.

Lofsvold: Were there many occasions when you were a bench chemist that you had to appear as a witness at a trial?

Milstead: No, never, Fred, never testified as a bench chemist. Later I testified when I was a district director a few times but there were no contested cases that I was involved in as a chemist.

Lofsvold: The cases you worked on never were contested?

Milstead: They were so bad... Well, those were very interesting days in the lab in Chicago though. I've thought back about it. They were dedicated people and hard working, and while their methods were crude, they accomplished a good deal. Many of the chemists that came in FDA with me progressed to top positions in FDA and I could mention O'Keefe who is here with us now. Harold came in as a chemist in Chicago and his career has been something since then. But there were many others, for example, Danny Banes who did very well that came in there during that time when I was there. So it was an active period. John Boardman who was the chief food chemist and Chris Glycart the chief drug chemist, they were outstanding in their fields and not only did excellent work themselves but were excellent teachers.

Lofsvold: About how many chemists were there at Chicago in those days? I mean, approximately.

Milstead: Oh gosh, let's see. When I came in there, Fred, I don't know maybe ten, something in that neighborhood. Then as you pointed out in, I guess it was '39 they brought in a good many and FDA was beginning to build up, but there weren't more than ten I'm sure in the whole lab at that time. I was always impressed, and I still am even today with the enormous amount of work that we turned out rela-

tively speaking, in those days. Not long ago I was looking over some of my old notes when I was in regulatory management and the number of cases and investigations that we had under way and I mean, really active with such few people directing those things it was impressive. Here among old Food and Drug people we often point out, that the appropriation was only about 10 million dollars at that time. How we did all that we did, with so little relatively speaking, is something that all those that worked in FDA at that time are proud of.

Young: Well, every case certainly accumulated a lot of paper. Now there was a lot of work involved in building up those cases.

Milstead: I have a lot of my old notes and when I look at them I'm astonished, I really am about the volume of reports and how we got all the material down on paper. We were talking about the Kefauver hearing. I was Director of Regulatory Management when Larrick said to me you know, I want you to come and work on the Kefauver amendment. My lord, the information that we put together and the background material that resulted in that change of the approach was enormous, and there were only three or four of us you know.

Young: Are your memories of when Kefauver came to Commissioner Larrick's office in the earlier tapes?

Lofsvold: There is a mention of it but it was not nearly as full as what Ken was telling us earlier before we turned the microphone on.

Young: Would you mind repeating that about when Mr. Larrick did ask you to dig up the background for when Senator Kefauver came to the office.

Milstead: Be glad to. I was then, of course in Washington was Director of the Division then known as the Division of Regulatory Management. And Larrick had asked me to work with them in his office on preparing for the Kefauver hearing.

We had information that the hearings were going to deal primarily with the question of the price of drugs. And that it was Kefauver's view that all drugs were the same quality and therefore there was no reason for the brand name products to be sold at a higher price than their generic equivalents. So we had gone through the history of the principal drug firms and a lot of the generic companies and tabulated their enforcement actions and the background which clearly showed that while there were violations of the so-called brand named manufacturers that the incidence of violation was very much less than on the

generic products. So we were prepared to really contest Kefauver's approach to that whole thing, if and when he went ahead with the hearings.

So Larrick received a call from the senator who said he wanted to come over and discuss the proposed hearings with him and so he did come over with Rand Dixon, who was then his chief counsel, to meet with Larrick. Larrick had me and Bill Goodrich with him in his office and as I was telling you before, Kefauver came down the hall and created a lot of excitement by stopping and talking to everybody and visiting. He was a very personable sort of guy. When we sat down and the Senator explained to Larrick the nature of the hearings which was that it was a question of the price of drugs and he wanted to get some legislation that would do something about the difference in prices on the theory that all the drugs were the same quality and there wasn't any reason for that. So when the Senator said that he would like for Larrick to present testimony and support this legislation Mr. Larrick said that we had looked into that matter in some detail and we were sorry that we just wouldn't be able to support him on that approach. So as I recall what happened then was that Larrick agreed to furnish the Senator with all of this background information and his views about it which we did. And the result of that

was, that the original approach was entirely abandoned and the Senator then directed his attention and hearings toward improving the quality of all the drugs which ultimately resulted in the Kefauver-Harris amendments. I think this was the real beginning of the GMP's in the drug industry and the improvement in the quality of generic drugs. So I think it's an interesting turn that the Senator took there that resulted in the legislation.

The hearings were interesting to me. Flemming was the secretary of HEW and he took a very active part in that whole proceedings and he would stay in his office till late at night, or much later than anybody else, everybody else wanted to go home. About five o'clock he'd call up Larrick and say I'm now ready to talk about what's going to happen on the testimony tomorrow or something, would you all come up. So here we all would go up to his office and sit down there and rehearse everything going on and what was going to come up the next day and so on. But he was very much involved and understood the whole thing which was something a little different having the secretary so involved.

Young: You just mentioned two names, Secretary Flemming and Senator Kefauver, and at lunch, Wally and Tilly and I were talking about this period and what a significant tran-

sition period it proved to be for the agency. Now, this was a period at the end of which, rather quickly, indeed, the dynastic system of commissionerships came to an end with George Larrick's retirement. This meant that in a sense this agency became politicized by the choice of a commissioner, probably representing the point of view of the higher administration. And several points came up that it would be interesting to have your reflections upon, since you were right there at the center of things at the time. Wally, did you not raise the question of whether it would have made any difference if George Larrick had paid more specific attention as was true of his three predecessors to grooming a specific person as a successor? And were such things as Flemming's prominent role making tremendous headlines in the cranberry case, and Kefauver's tremendous role making headlines with respect to drugs, incidents which rather brought FDA out of the quiet that it had essentially been in since Wiley quit, into headlines again? Did this not create a situation in a political city like Washington so that it became virtually inevitable that the agency would become politicized, and under the wing of the prevailing administration? You were there through these years. What are your thoughts on issues of that nature?

Milstead: Well, I think that's true, I mean the changing picture. Flemming, you will recall took a very strong role, not only in the Kefauver hearings but also in Krebiozen and in many other questions, which was I think, stronger than any other secretary and there were political problems that he got very much involved in. Of course Larrick was very much involved in them too. But the other side of the picture was that there were other people around that had been groomed to succeed Larrick. Steve, Malcolm Stephens came up through the ranks. He was an assistant commissioner and in the old days such a man would've been in line to become the commissioner, and there were probably others. Steve's the one that comes to mind at the moment.

But I think what you say is true that those people who had all that background experience could have succeeded Larrick, for example Steve, and following the previous practice would have. But Steve was not savvy politically, he could not have handled a political situation in the political sense. If he had been made the commissioner, his way of running FDA would have been the way it had been historically run, and I don't believe he could have done that. And I think Larrick saw that. I think there was a lot of talk about that at the time and there's been a lot of talk since....but I don't know, my reaction to that is

that Larrick might have been wiser than some people think; or he'd been told by the secretary that they wanted somebody from the outside.

So that's the way I react to that. I don't think there was any lack of opportunity for people in Food and Drug to have been trained in the historic sense up through the ranks, there were plenty of them around. Steve was there and there were others that would normally have been in line to have been the commissioner.

Lofsvold: Rankin, for example. Tilly? Milstead: Yes, Rankin and Tilly and others. But it was a different climate from what they were accustomed to. I don't think that those people had been trained to deal with Food and Drug matters in a political sense. They weren't trained that way. They were trained as enforcement officials, in the historic sense.

Lofsvold: Ken, kind of along the same line, I've wondered for a long time. I would agree with you completely that at the time that Larrick was to retire, there was no way that we could continue the practice of promoting from within. But I've wondered about, suppose that Larrick and Harvey had retired earlier, before we got involved with Kefauver or soon after we got involved. My concern is, did they stay too long and could some new younger man from within

the agency, have stepped in at that point before it got so big, and there was so much criticism, and been able to roll with the punch and say yes we're going to change our way of doing things and continued the practice of selecting Commissioners internally.

Milstead: Well, Fred, of course we never know. Sometimes you select a man for a position like that and he rises to the occasion and he deals with whatever situations existed there. I've always thought that Goodrich could've handled the commissioner job.

No question in my mind that he could have handled it, but, I don't know whether he was ever considered. And I think that there were others in FDA that would have made good Commissioners if they had been given the responsibility. Now I don't think Malcolm Stephens would have been happy in the position because he was too entrenched in the old philosophy. I think I knew Steve well enough and worked with him long enough to say, that he wouldn't have been able to adjust to the changing climate. On the other hand, Bill Goodrich was pretty savvy in the political area and in my opinion would have been a great commissioner. I didn't know why he wasn't selected unless it was because they thought he was too inflexible. I don't think he was.

Lofsvold: I was not in Washington, and consequently my observations were from a long way off. But it seemed to me, that in the latter days of the George Larrick commissionership, that, and I want to say on the record that I think he was a tremendous man, but I thought that there were some times when he did not decide some issues that were kind of left hanging. When Goddard came in he made a great show of making decisions on a whole lot of problems that had been staffed out long before, and were just waiting there for somebody to decide.

Milstead: I don't disagree with that Fred, but I would think that on the other hand, that George reached a point, and maybe because of his long career and so on, that some of those things I don't believe he could have decided. They were foreign to his thinking and maybe all the time he was thinking damn it I am not going to do this and he had in mind that changes were going to occur and...

Young: Was one of them the recommendation that had been made to him, which I understood that he had turned down, that he should get public health doctors in in order to review all the new drugs that had come in from 1938 on, something Goddard later did. As I understand, it had been developed as a system but Mr. Larrick just said no to it. Do you remember that?

Milstead: No I don't remember that, I don't remember that at all. It could have been. Now at that time, when Goddard came in, I was in Larrick's office. I didn't know by any means everything that was going on there but I wasn't familiar with that at all.

Young: You think maybe that's a dubious statement.

Milstead: I sort of do. I'm no admirer of Goddard but I must say that I think one thing he did, I don't know much else he did that was of much value...one thing he did was his idea, I give him credit for it, that is the DESI review. The handling of that whole situation was a good thing and a well thoughtout approach. Had Larrick thought about it? I don't think so, personally.

Lofsvold: You're speaking of getting the review done by the academic...I think this proposal that Harvey's referring to was one to actually recruit PHS physicians and pharmacists. To conduct a review ourselves.

Milstead: Well, it could've been Fred, I don't recall that.

Lofsvold: What we were told was that an internal task force studied many of the problems that were confronting the agency at the time, and it made several recommendations, one of which was this one.

Milstead: Well, that's entirely possible. The thing that Larrick did that I thought was tremendous, and Goddard forthwith destroyed was the National Advisory Committee that Harvey here was a member of. I was looking at my notes recently on that Committee and I just think that he had a great thing there. The stature of the people on that committee and what he had in mind as its function was really ahead of the times, and he foresaw what has occurred. He was seeking outside help to help him direct the agency during that, somewhat of a transition period. I think that was a tremendous committee and that he had a great idea. Goddard had no use for that committee at all and moved quickly to abolish it because it didn't fit in with his personality or anything else. Of course I think that was a big mistake.

Young: Can I pick up on one point in connection with the grooming of a successor to Larrick, as it seemed to have been done previously. You suggest that there was somebody, like Malcolm Stephens who might have been Larrick's successor under other circumstances. Was there rivalry to be heir-apparent? Was there a series of conflicting ambitions on the part of people in the administration vying for the role of heir-apparent.

Milstead: Don't think so. Not that I'm aware of. There could've been but certainly there wasn't any on Steve's part or any of the others that I knew very well. Now the one person that might've aspired was Rankin. I never knew what Rankin was thinking and what he had in mind. He may have aspired to be the commissioner. But other people like Bob Roe, who came up through the organization, I don't think so. Steve never said to me, I knew him better than almost anybody and rode with him to work every day, I don't recall he ever said or hinted or anything else that he had any ambition to be the commissioner.

Jansen: He looked forward to retiring.

Milstead: He looked forward to retiring. Now you can say, well why was that, had the administration failed to instill in him the desire to be the commissioner? Well it could be, but I think that Steve saw the changing in the political situation and it was something that he either didn't feel up to or he wasn't interested in. No question in my mind that in the old days he would have been the commissioner because it was a normal process for him to have been the commissioner. He had extensive background and training and experience would've been the logical man.

Janssen: Goodrich would have been a very, I think a great commissioner. I don't think Goodrich could have been appointed because the industry would have fought him.

Milstead: That's right. I don't know if Larrick ever thought, or if anybody else ever thought of Goodrich being the commissioner. I think what Wallace says is true and it's doubtful if he could have been. Goodrich was strong, and a forceful enforcement General Counsel. But he's flexible and adoptable as he has shown, in my opinion, by what's happened to him since he retired. Goodrich had the capacity to be a pretty big man. In his present job he deals with leaders in the food industry and I think as we all agree, he had the capacity to be the commissioner.

Lofsvold: Well, Steve did that job successfully after he retired.

Milstead: Yes, Steve preceeded Goodrich. As president of Institute of Fats and Shortenings. I think, my reaction to the basic question is that, you had at that point, a changing philosophy, an attitude toward what that job was that it was different from what we were trained to think - it was foreign to Steve's thinking, of what the commissioner ought to do. And he, I'm sure was thinking all the time that he didn't want to be involved in any political approach on the part of FDA.

Jansen: We shouldn't forget the second Citizens Advisory Committee. That report really pointed the FDA in a different direction, a radically different direction. It

really called for the agency to be more like the NIH or the PHS, than the FBI. It was very clearly a kind of a hand writing on the wall thing. I think that was the beginning of the change in philosophy about FDA - not so much within the agency. Within in the agency it was viewed with dismay and objection, but outside the agency I think a lot of people picked up the ideas of this second CAC. And certainly what happened after that when Senator Humphrey's Government Operations Subcommittee went to work on the Food and Drug Administration, they really developed an indictment that the agency was in a rut, and operated in a fuddy-duddy way, and it was ridiculous for it to be headed, by an ex-inspector when it ought to be headed by a distinguished scientist. It ought to be using computers extensively instead of doing things the way they were. I think that it was Senator Humphrey, who then was I think preparing to be a candidate for President, who really put the nails in the coffin of the old FDA.

Milstead: Yes, I don't disagree. It was all a part of the picture.

Lofsvold: Well that philosophy that Wally speaks about, was really the prevailing public health philosophy that was being taught in all the schools of public health, including the University of Michigan where a prominent member of the committee came from.

Janssen: There were several occasions when I had to object to, for example, speeches made by Public Health Service people in which they demeaned the role of "policemen". They were talking about the FDA.

Milstead: Oh sure. It used to be a subject of...

Janssen: We were not part of the public health establishment.

Milstead: When we became a part of PHS, everybody in FDA was horrified. I mean the historic people. But that all goes to what we've been discussing about who might have succeeded Larrick. The people who came into Food and Drug in our times and came up the ladder found it had to adapt their thinking to the recommendations of the Second Citizens Committee. Goodrich was a little different. He didn't come up through the service, and he's a lawyer and he was adaptable and I think he could've battled them out. But what kind of an agency it would have been, I don't know. I don't know whether, in all fairness to Bill, he could have survived in the present climate.

Lofsvold: Well, Harvey raised a question about rivalry among the people here and in the earlier interview with you, you alluded to the problems that existed, particularly with, between DRM and DFO and BFA, in who should be able to talk to the field and so on. I gathered then, from your

earlier comments that the original concept was that there would not be this kind of strict control over the field that did develop under Allan Rayfield. Was that your understanding?

Milstead: Yes it was Fred.

Lofsvold: Well, Rayfield came because Mr. Wharton retired.

Milstead: Now my understanding at that time was, that they would have regulatory management, Harvey's unit and all of the units would have full authority to deal with the field and that they would not have to go through field operations and so on. And I think when Harvey was there, that that was true. And when I came in there and Harvey moved up to the deputy commissioner that situation started to cause him a lot of trouble because Rayfield insisted that everything clear through him even in our area and it never was quite resolved. It was always a very difficult problem.

Lofsvold: I've wondered why Rayfield did feel he had to exert this close control over the field. I was in the field at the time and it made a vast change for us, in what had been the old Western District because he imposed a lot more formalized procedures of work planning and other things that we hadn't followed before. My impression was that those were things that had been done in the old Eastern District, and I wondered whether the kind of management

that he and Rankin and others established for the BFA or DFO, was the result of their having learned the business under Bill Wharton. By all reports, he was a very strong minded sort of martinet and a very authoritarian kind of manager.

Milstead: Well Fred, of course, I don't know what they said to Rayfield when they brought him in there, and what the understanding was, but my impression is that, Rayfield felt that, and probably properly so, that if he had the responsibility for the operations of the field, that he ought to have charge of them. And here I was and other regulatory managers, arguing that we ought to have a right to go directly to the field without conferring with him. And I think the reason for that was that, we really didn't want him messing around in cases and so on. It complicated the picture, but on the other hand I can see where he had a good point. And then in all fairness to him, he was sort of the beginning of the planning operation from an overall basis. And as it's developed whether it is good or bad, he was the first, I think, to plan the field operations on a national level, and to control them from Washington, because before that they were largely controlled from the districts.

Lofsvold: And that you think was maybe one of Charlie Crawford's reasons for the '48 reorganization?

Milstead: I'm sure it was. But Charlie never dealt with the conflicts that developed over the jurisdictional question. Charlie was always saying, "God can't you get along together, you know there's plenty of things to do," and he was right. Then when Harvey moved up and I came in there, it just was a problem all the time and Harvey and Larrick never really took a firm stand on it.

Young: Why was that?

Milstead: I just think they didn't want to say, but I'm not sure, or that they didn't believe that Rayfield should have charge of the field and that everybody else should go through him. Now that's actually how it came out because it came to the point where we had to really clear through there. But Larrick wouldn't issue a directive that would clarify that so the result was always uncertainty and conflict there.

Lofsvold: Is that the reason then in '64, in that reorganization why they combined what had been the Bureau of Enforcement and the Bureau of Field Administration?

Milstead: Yes, that was part of it Fred. I think it was the ultimate result of that, they may have had other things in mind, but I think the background had a lot to do with that.

Janssen: I don't think the commissioner, after Rayfield got charge of the field, I don't think the commissioner commanded the field anymore.

Milstead: That's right, not at all.

Janssen: What happened, the policy would be talked about in the staff meetings and so on, but what would actually come out through Rayfield would be Rayfield's idea on how things ought to be.

Milstead: No question about that. And as you know Fred, there was a great difference of opinion and great controversy about the way Rayfield directed the field and his personal behavior and all of that. Fundamentally, I think what Wallace says is right. He was in charge of the field, and it was understood that he was in charge.

Lofsvold: Probably the problem originated when it was not made clear at the time of the reorganization, what kind of an organization they wanted. Whether they wanted something like it turned out, or whether they wanted these as more staff people to the commissioner who spoke in his name but did not have the full authority.

Janssen: Did not the field operation continue much along the same line as it had previously rather than change with the different climate in Washington?

Lofsvold: You mean over what period?

Janssen: Well during the period after Rayfield became in charge of it. Didn't he perpetuate the old way of doing things? Start everything by making a seizure and that sort of thing?

Lofsvold: I don't think there were that many changes. The change that he brought so far as the part of the field where I was at the time on the west coast, was a great deal more regimentation of the inspectors that we did not have before. Which was good as long as it wasn't carried to extremes. But I don't think there were any great differences philosophically with what he was doing probably than what had been done before the reorganization. Certainly, it brought some order out of chaos. I'm sure that Kenny was aware that in his days in Central District and my corresponding days in the Western District that there was a differing emphasis from one District to another. Although there was a broad overall agreement among the District Chiefs and Washington on major priorities, the way they implemented them and the emphasis they put on various high priority programs were quite different.

Milstead: Oh, I agree with that Fred. In the old days when I first came in FDA and it had the old district set-up, the planning that was done was that once a year, Harvey and J. O. Clark and Wharton would come to Washington to

what was called the "district chiefs' conference". And they would sit down, down here with various people and they would plan what we were going to do for the next year. Not in any formal way, but it would be decided that the Central District was going to do this and the Western District was going to do that. And they'd go back home and write out, not in great detail, plans for the district for the year and everybody would go to work. But it wasn't any national plan as we understand today. Now what they had in mind, I think with Rayfield was to direct on a national basis the operation of the field. And now it seems to me that it has been carried to the ultimate extreme where the people in the field can hardly go to the bathroom without consulting one of the charts you know.

I was telling Fred at lunch I got ahold of one of the EDRO Field Work Plans recently, the whole national work plans. They make those available through FOI. I was looking at them on microfiche and it's absolutely amazing when you look at those, the detailed planning of the district operations now.

Young: Hour by hour.

Milstead: Hour by hour, and there's a great many people think that. Well, I was just going to say one thing more on the planning. Of course, I'm out of FDA now but from an

awful lot of remarks that I hear all the time from field people, the planning has been carried to the extreme. And it results in the destruction of what we historically thought was important - the initiative on the part of inspectors and investigators. And you don't really have that any more, they're regimented. I don't mean they're not capable, but back in our time you know we had a good deal of freedom to find out what was going on out there. Under the present system we wonder sometimes.

Young: When Mr. Rayfield was brought in and ordered to lend more structure and system to the field, it wasn't necessarily intended to be his job to determine what the priorities of action of the field were to be. That was to come from elsewhere. But did he try to assume that as well?

Milstead: Oh I think so. To a degree.

Lofsvold: To some extent, although by then the planning people, first Roe and then Shelby Gray, did have the responsibility for putting those priorities together. I think that if Allan substituted his judgment for others it was on a case by case or small area basis, not as a broad thing. I think he was a team manager. There were occasions if Kenneth had an assignment from his unit on a case that was an important one nationally and Rayfield didn't think it was as important as some other things that

were going on, in the way they transmitted it, it might then appear to the district on the other end that well, you can do this whenever you get around to it. To that extent there would be the problem. But I don't think it was a major sort of thing.

Milstead: That's where we came in real hard conflict. I thought, that in litigation in hard cases or in hard investigations, that it was regulatory managements responsibility. And that it was very unwise for us to have to clear with anybody else on whether an inspector would do this or an inspector would do that. Rayfield took the position that no no, that he didn't intend to interfere with it but he wanted to know about it. But the facts were that he did interfere, and it was a very difficult situation. While Harvey generally supported our position that we couldn't do our job by having to clear through a lot of people as to whether or not our judgment was correct, it made our life very difficult.

Lofsvold: Of course, it was difficult for the people on the receiving end in the field as to whom they were going to listen to. When you were in DRM you didn't deal with routine cases. By that time we had established a division of case guidance or some other term I think we used, that

handled the routine. Yours were only the difficult, or the precedent or the ones that were across district lines, national in scope.

Milstead: Yes and the ones that were involved in litigation you know.

Lofsvold: Even though they were involved in litigation as I remember it, you didn't really bother much about the ones that were fairly routine, the insanitation cases. If we needed expert witnesses we came to you. But otherwise you pretty much left the district to carry the ball.

Milstead: I think that's exactly right. We got involved in routine cases when we were asked to. Now on that point, I was thinking about a couple of instances of course where we got more involved than usual.

For example, the Horseradish Case. That developed into a difficult case and I think the value of regulatory management was demonstrated in a lot of ways. We were up against it in that case. There was no chemical way really to show that horseradish was adulterated with parsnips, although everybody believed it was. And we were getting ready to go to trial. That was soon after I came to Washington. Our lawyer felt that we were going to lose that case because we really had no real sound evidence. We had no inspectional evidence and the seizure was based on

microscopic examination. So we went to work on that case. What happened demonstrated the value of Regulatory Management. Infrared spectrophotometry was just coming into its own at that time.

Young: Infrared spectrophotometry?

Milstead: Infrared spectrophotometry. The FDA labs here were just starting to use it. So we all got together to discuss the case and what could be done. Our people said to the lab people, now lets see what you can do with infrared spectrophotometry on the horseradish. They didn't see any problem and went to work on it. Jonas Carol and his group was able to show that parsnips contain a volatile substance with an extremely distinctive I. R. spectrum. And by this means they were able to calculate the amount of adulterant in the horseradish. We went up to Boston and handled that case. Joe McGuire was the attorney and I went with him. I remember the case so well. At the proper time in the government's case we introduced the I. R. data and explained to the judge how it was obtained, what it showed. It was beautiful and the judge announced that he was convinced that the horseradish was adulterated, so that was the end of the case.

Young: And the trial was about 1950.

Lofsvold: Well there was a seizure trial in Boston, what, about 1952...

Milstead: Yes, soon right after I came to Washington.

Lofsvold: It would've been '51 or thereabouts. And there was a criminal case in New York on the same evidence later on.

Milstead: The reason FDA got involved was because the Army had a contract for horseradish with the firm, and we were asked to examine it for compliance with specification.

Young: But it involves innovation on the part of FDA scientists to meet a legal evidential problem?

Lofsvold: And a recognition that this kind of analytical capability was available on the part of Ken's unit, the Division of Regulatory Management.

Milstead: Right. Well, that was my point. We had some people thinking about these things all the time and that was the purpose of regulatory management in the first place. In difficult litigation, or development of cases there would be a corps of people there that would be thinking about the cases and not about other things. I think that was sound as shown by the record of success with many cases.

Krebiozen was the same thing. I take full credit for suggesting an analytical approach that resulted in the suc-

cessful outcome of that case. The facts were that when we got right down to it we didn't know what it was and we had a big meeting in I believe, Larrick's or Harvey's office of all the people involved to discuss what were we going to do about it. We were convinced that Krebiozen was a fraud but again we didn't have objective evidence of what it was. I can still visualize that meeting. After a lot of discussion I said, "Danny Banes here is the expert in all these new-fangled analytical systems that they're developing over there in the Drug Division. I suggested that he apply some of these sophisticated methods to Krebiozen and see what he gets". And so he did. The upshot of it was as you know, that we were able to show that Krebiozen was a fraud and we broke the back of the whole scheme. It was sophisticated analytical techniques that were indispensable in those cases.

Lofsvold: Well, I remember some other cases that didn't require anything that complicated, but where your unit was essential. When we were trying to control the people who were breaking out incubator rejects and selling them, it was a trade that was spread from far southeast up through New York with branches off into Kansas City and Nashville. And to keep track of all of these people who were involved in the business and they all worked together at various times, required good coordination.

Young: Birds of a feather.

Lofsvold: And I think it was only possible to do that because of Regulatory Management no one district could have handled it all alone. But with Gil Goldhammer in Ken's shop and some other people here at this end, also providing or arranging for analytical support from the micro-analysts, the micro-biologists, and the food chemists at headquarters, it was a beautiful example of the things that DRM was created to handle.

Milstead: Well, they were capable people Fred. Goldhammer and Van Smart and those people, - not many but capable and dedicated.

As I was saying I was just amazed when you look back at what was going on then and the number of cases and investigations and everything that those people were monitoring. Of course they had a lot of help from the field and so on but, we had a lot of balls in the air at one time and some of them were pretty difficult things. I don't know but my impression is that that type of investigation or monitoring, has largely disappeared. It's been diffused out into the field and when they get into a hard case now, they run around trying to determine who's going to handle it, and Fred you know better...

Lofsvold: Well, of course my knowledge is not all that recent but I think that what they're still doing is that there is an attempt to monitor this at the level of the Associate Commissioner for Compliance, in Paul Hile's office. It involves using a committee that involves the Bureau and representatives of the field districts involved. There doesn't seem to be one single place that can issue direct orders. Consequently, there's a lot of wasted motion as compared with the previous kind of an organization.

Milstead: My impression is Fred, that from what I hear that now the General Counsel, the lawyer is much more involved in directing things than being the lawyer.

Lofsvold: That was one of the things that I had wanted to explore with you - just what involvement, what were the relationships between General Counsel and DRM in the development of these difficult cases.

Milstead: Well it was tremendous, Fred. We had the closest cooperation and liaison. A lawyer would be assigned to the case, and then whoever was working on it from our office or the Scientific Division or the Bureau of Medicine would work as a team and they would meet and discuss every angle of the case - there was just tremendous cooperation there.

Lofsvold: Now did this start at the planning stage when we were deciding whether or not we were going to bring a case against, say a Krebiozen?

Milstead: Oh yes. It depended on what it was but in any serious case it would start from the very beginning. Of course, Bill Goodrich was there most of the time when I was there, and when any serious question involving a possible trial or a serious investigation, Bill would be right in on it. He would come over and bring his lawyer and they participated completely in those difficult cases as you know.

Lofsvold: Was their participation more on how we'll get it done rather than whether we're going to do it.

Milstead: Oh Fred, I would think it was more how to get it done generally speaking, unless there was some legal reason that they would say you can't do it, but generally speaking the decision had been made that we were going to do certain things.

Young: How was it made? I have the idea now that it's infinitely complex to decide to bring a legal case compared with the old days.

Milstead: You mean presently?

Young: Presently.

Milstead: Well, that's my impression too.

Young: Who did make the decision that you were going to undertake one these...

Milstead: The way that was, when I was in Regulatory Management the way we did it was that we, with the help of our staff, drew up an order of priority of very difficult cases. It was quite a long list, which we gathered from the districts and from everybody involved. And we prepared this and had some discussion of each one and the nature and significance of the violation and maybe the man-power that would be needed. And we sat down with the commissioner or the commissioner and the deputy commissioner and we said here is the list, and here is our recommendation of priority for investigation. And they said to either go or not go, or we agree or disagree in specific cases.

Young: Mostly did agree?

Milstead: Mostly did agree.

Lofsvold: But in the case of routine matters, where the policy was well understood. For instance sanitation cases after the first few years of the new law, it was well understood in the field that certain circumstances would warrant legal action. And cases of that kind were recommended to headquarters, passed through almost routinely by Ken Kirk or whoever was the reviewing officer and then sent to the United States Attorney with only I think the most

cursory examination generally by the General Counsel's office. If then a contest developed, if there was a plea of not guilty or an answer, denial to the liable so that a trial was impending, then, DRM and only then would DRM get involved.

Lofsvold: We've been talking about DRM's role being the leader and the director of centralized, large centralized investigations. Ken, wasn't there some of that done real early in your career when they had, I've heard references to a fraud school that George Larrick operated?

Milstead: Yes, that's right Fred. George, originally, I believe, was responsible for organizing what they called the fraud school. Then Walter Simmons in the old Central District set-up, sort of took that over and was the expert in fraud. And that all resulted from that court decision you know where, the Judge held that FDA must prove fraud in drug cases and then the law was amended to require the proof of fraud.

Lofsvold: The Sherley Amendment.

Milstead: The Sherley Amendment of course. Simmons became really, the expert in that area. Larrick started it or initiated the school for fraud inspectors as they called them, and then Walter Simmons took it over and conducted schools all over the country, training inspectors and

investigators in the fraud area. This specialized activity was the forerunner of Regulatory Management.

Young: You mentioned fraud inspectors as if there was a differentiation of function among inspectors. Is that so or was this just a fraud function that all inspectors might be called...

Milstead: No, that was different Harvey. There were a few investigators, inspectors, that were specially trained to make those fraud investigations and the other inspectors did not make them. Now generally speaking, I think that it was true, that the inspectors in general had very broad areas of investigation. But fraud was a specialized thing and only a few inspectors worked in that area.

Lofsvold: That entailed really extensive background investigations to find out everything you could about the prospective defendant?

Milstead: Exactly. And about his intent of course...

Young: I think of that, B and M External Remedy case where they lost the decision and then spent a whole decade of this highly specialized investigation in order to get the evidence.

Milstead: Exactly. Simmons--I've forgotten, the cases but Royal Lee I believe was one of them - worked for years trying to accumulate the necessary evidence to prove fraud.

Lofsvold: Well, the Cancer case in Detroit...

Milstead: Yes.

Young: Koch.

Milstead: Oh sure.

Lofsvold: I've seen a reference in about that same period to something called a 'flying squad'. Are you familiar with that term and what it entailed?

Milstead: Yes Fred. You mean was it in the drug area?

Lofsvold: I'm not sure.

Milstead: Well, there were several of those. There may have been one on drugs, although I don't recollect it. But there were flying cream squads, cream tasting squads back there. The problem of spoiled cream and rotten cream was tremendous. So they sent these squads of inspectors to travel throughout the cream producing areas with state inspectors to smell cream and to condemn it if it was unfit for use. They were called flying cream squads. Now there might have been one in the drug area but it doesn't register with me.

Lofsvold: Well, I think where I saw the reference is, we have a briefcase full of photographs that George Larrick took at various times throughout his career. It was turned up in Seattle, of all places, several years ago. The only thing I can guess is that perhaps Frank Clark got it from

Mrs. Larrick and carried it out there and then Frank died and everybody forgot it. But there are some photographs there of people who are identified as members of a flying squad.

Milstead: I think that was Larrick's fraud squad when he originally set it up. I'll bet Simmons is one of them. I think Larrick brought into Washington a group of special people that were trained in that fraud area and I believe you're right. I believe he called that the flying fraud squad. Then it was decentralized, in the sense that Simmons took it over.

Lofsvold: I know that George Daughters told me once about an investigation of some drug fraud that he was assigned and he followed it where ever it went. It took him all over the United States for a period of several months.

Milstead: Well that was the objective. That's what Simmons did. To have a group working in that area that could go where ever it was necessary to go.

Young: There were a few people in Regulatory Management that did that too, weren't there?

Milstead: Oh yes. Later on all of them.

Young: You'd have certain field inspectors do certain parts of the investigations but on key things you'd go right out?

Milstead: Yes, certainly. Goldhammer and Brandenburg they did extensive investigations on their own and prior to the trials and they worked on cases individually.

Lofsvold: Often with a field person, who went along to help them and also as a learning experience. It was very useful training for field people.

Milstead: When Brandenburg retired from Food and Drug he was here for a while with us. He finally decided to retire completely. But Brandenburg and Goldhammer were probably the two best investigators Food and Drug ever had in this area. They had some kind of a "sense" about fraud and how to get the evidence. They were tremendous.

Young: I was very close to Goldhammer during the period in which he was developing the evidence for the criminal trial in the Krebiozen case. And he kept me informed, and I saw that zealous, beagle-like quality in following it out.

Milstead: And sensitive to leads you know. Brandy was like that too. They were not the only ones, but all inspectors are not investigators. As a matter of fact there are relatively few who have this special sense of getting involved in these things. Well in my experience Gilbert and Brandy were great. I'm sure there were others but they were the two best ones I'd ever had anything to do with.

Brandy was like that when he came to work for us here later. Just a special aptitude. He could see through things so quickly and the meaning of them and evaluate them.

Lofsvold: In precedent setting cases, in your experience the one's that interpreted the statutes, were there many of those actually preplanned towards that end, or were they just things that we took advantage of as opportunities arose? When a routine case was contested and there was a defense raised.....

Milstead: Fred, I'd say by and large it was the latter. The number of cases where we deliberately set out to build a case to set some kind of a precedent or interpret the law, or so on I think those were few and far between. Those things just occurred in connection with cases that involved violations and in most cases were unpredictable when the action was imitated. They developed into something that became a precedent case. Now that's my feeling about that.

Lofsvold: Well that is exactly the way I felt about it but your experience was much broader than mine and I wondered if that were true. The only time that I can remember when we set out to do it deliberately was the Cardiff case on the factory inspection law and we lost it.

Milstead: That's right. Another area that comes to mind was the over the counter drug case. When we first decided to try to work in that area everybody knew that that was a very touchy area and that we were probably going to make some precedent law. I don't want to say that in some of those cases that we weren't aware of the fact that the law was not clear, and it might result in some clarification. But usually what happened was largely unexpected and unplanned.

Lofsvold: And actually, since it did take somebody willing to contest and then to appeal, we didn't have full control.

Young: As I remember when the Elixir Sulfanilamide case broke, and the Food and Drug Administration sent somebody down to Bristol, Tennessee, they sent a physician from headquarters but I think they sent an inspector from Cincinnati. Were you there then?

Milstead: I was still in Chicago in the lab when that happened. I don't know what exactly happened there but in all probability that's what occurred. I don't think any doctor from Washington would've visited any firm without an inspector with him. It was routine for inspectors to accompany people from Washington.

Young: I've read both reports that were written, they wrote, or at least the doctor wrote a report immediately and then later on he wrote a fuller report.

Lofsvold: Wasn't that inspector Billy Ford?

Young: I just don't remember, but I do have the notes. I have forgotten the name of the doctor, Klumpp perhaps.

Milstead: Klumpp was head of the Bureau of Medicine I believe, at that time.

Young: Why did you retire from FDA?

Milstead: Why I retired from Food and Drug - I really hadn't thought about retiring really. When Larrick retired then I thought, what's going to happen here, because I was very conscious of that break in the old succession and the old atmosphere. So I was concerned about that and then when they brought Goddard in I was still there as his assistant. Well, I thought I saw immediately that my tenure as an assistant to him was going to be very short because the way he operated and behaved was so foreign to what I was used to, I didn't anticipate that I would be there very long.

Young: Do you mind defining the degree or the nature of the foreignness?

Milstead: His whole approach to Food and Drug was so, I thought, was so different from Larrick's and the historic approach in the sense that he was just gung-ho from a public health type of approach. He was so dogmatic and unable to listen, really, to people. He said to me two or three

times, or indicated to me that he thought that I wasn't needed in that position and he was going to abolish the National Committee and what would I like to do. He offered me several opportunities that I wasn't interested in and I told him that.

The thing that bothered me no end was that he was very difficult with outside people and difficult with his own people. Industry people would come in there and he would do such things as set the alarm clock on them and say, "I'll give you five minutes." And he had a damn alarm clock on his desk. Several industry association people who I'd known for years would just come out of there...I had my office next to him...they'd come in and they'd say he's crazy and do you know what he did to me. Well, he did that to me. The things like that, and it wasn't just me it was, the whole set-up there was so difficult that I really, well I couldn't stay. That's what really precipitated my deciding to leave.

I always felt very sorry for Goddard and I do to this day. I hear from him every once in a while. He's running a consulting firm up in New Jersey. I thought he had great ability but there was something about his ego or something that really I think destroyed the man from being effective (now, maybe he'd deny all of that). But he had Cron in

there with him who people resented no end. Winton Rankin was trying to work with him but everybody had great doubts also about what Winton was up to. And so he created a very difficult atmosphere there which I thought was too bad because he had such a good background and great opportunity, and ideas. He had other ideas but his egotism or something just wouldn't let him operate effectively and so he didn't stay long of course.

But that's why I retired. Then there were other reasons as well. I was always interested in the public information aspect and the educational aspects of food and drug and made an awful lot of speeches. And I always thought, and I still think that that's a valuable part of effective administration of the Food and Drug Laws. Now, I don't see much of that any more...I guess the field people do make some talks...but I thought that that contributed quite a bit to understanding by the public and industry so, I was pleased about that activity, but I felt that I would not be allowed to continue it.

Lofsvold: In your mentioning Goddard do you know whether there every had been any formal management training in FDA before he came. I don't remember any. I know that soon after he came many FDA people started going to formal training courses and I wonder whether that was something he

brought in or was this something that had been thought of before and had not been done.

Milstead: Well, it probably was not as formalized.

Lofsvold: I was thinking of the theoretical side of management training, like sending people to the American Management Association courses and that sort of thing.

Milstead: I think very little before Goddard came.

Lofsvold: I didn't know of any.

Milstead: I think that's the kind of thing that Goddard was interested in. He had ideas, there is no question in my mind about that. Unfortunately I think that he was a very unpopular commissioner and didn't really see a lot his ideas materialize and mature you know because he ran in to all kinds of problems.

Young: He had a completely new form of structure for the agency and he didn't last long enough for it get set, did it?

Lofsvold: My impression was that he tried to do a number of innovative things but really the hard nuts and bolts work that needed to be done to make them work never got accomplished. He centralized the field, almost totally. But in so doing he destroyed the mechanism for getting policy information to the field and he did not replace that with any thing else.

Milstead: Well, I think that is right. He was an idea man. He would come up with all sorts of plans etc., but he wouldn't carry them through or didn't have the capacity to carry them through and ultimately just failed. He had ideas and he was a strong guy. I often wondered, just what happened to him along the way. He had so much ability, I think he does. It was a sad thing what has happened to him.

The other thing, Fred, I came in when Campbell was the commissioner and then, of course, we had Dunbar, Crawford, and Larrick and then there supporting people, people like Elliott, and Murray. They were great and dedicated people. I have thought about those men so much and their contributions and I felt that Goddard did not have a proper appreciation of their contributions.

Lofsvold: Looking back at it I get the impression that despite their enforcement stance and rather hard-nosed attitude, they were really idealists. They felt that they were doing a valuable, useful service to society and that is part of the thing that sustained them.

Milstead: Oh, I am sure of that Fred. They were all enforcement minded, but fundamentally they believed that what they were doing was absolutely essential, for the public.

The other thing that strikes me with respect to what is going on now in the Food and Drug is my impression, as to how decisions are made. Those people were decision-makers, you know. Things would come to them to handle, it didn't go to a large number of people, they wouldn't consult everybody on earth, the buck stopped there. They would make the decision but now it is fantastic, the clearance procedure for the simplest little letter or document. It is just amazing to me. Maybe it's necessary but I don't think so. Very recently I obtained a document from FDA under the Freedom of Information, a very simple thing. The routing slip showed the history of this rather simple document. There were about 15, I think, people's initials on that document. It took something like 9 months for that thing to clear from the initial writing of the document to its release. Now I just sat and looked at it and I thought, well my goodness in the old days somebody would write that thing and they might send it to a bureau director, and maybe not. More likely it would go direct to one of the commissioners he'd look it over and he'd say yes, sign it and that was it.

Young: They'd go up through the levels then to judge by the routing slips that I see in the records.

Milstead: Yes, now - a great many levels

Lofsvold: Well and laterally too.

Young: But I meant, in the cases I've looked at that it'll go from station to district and go from district to Washington and then there will be only three or four people often who initial, depending on whether the scientists had to look at it. But the thing will whip through pretty fast in the old days.

Lofsvold: I only remember one of the first district director conferences I came to, it must have been the early '60's. Harvey expressed the view to us, he said in effect, "Gentlemen, I want you to remember that the most important thing about the decision making process is that you decide."

Milstead: There has developed and maybe it's inevitable Harvey, not only in Food and Drug but throughout the government, a fear of assuming responsibility that will not allow things to move. It has to go through all of these tremendous clearance operations before somebody will sign it.

Lofsvold: It's the so-called institutional decision that spreads any future blame among a group of people.

Young: Plus the fact that all kinds of new things have to be considered, like being sure there's no unfairness, in academic life, and I'm sure it's so in government life.

The appointments are much more complex because you have to take into account that you're giving fair consideration to sex, to race, and things of that sort.

Milstead: Exactly. I'm just sure there are a great many that require that. But I am equally sure that there's hundreds of those documents don't require it. They got into this routine clearance thing instead of somebody saying, "Look, this is a bureau directors job what do we pay a bureau director for not to sit there and shuffle papers. We pay him to make decisions." I just think there comes a time when the commissioner should say, "Look, if you can't make decisions in certain areas we just have somebody that can." And stop the buck passing.

Lofsvold: If there are no other subjects or questions, should we close this off?

Young: Let's close it off. Wally Janssen, who was with us for a while, had to leave. He asked a few questions in the middle of the interview.

Lofsvold: We'll identify them in the record. Well Ken, thank you so much for sitting still again for a third interview. We greatly appreciate it and I'm sure this will be a very useful addition to our library of similar recordings.

Milstead: I appreciate very much your coming and hope that it'll be helpful.