# History

*of the*

# U. S. Food and Drug Administration

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| **Interviewee:** | Joseph P. Hile |
| **Interviewer:** | Fred L. Lofsvold<br>Robert G. Porter |
| **Date:** | August 4, 1988 |
| **Place:** | Aurora, Colorado |

# INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by Robert G. Porter, Fred L. Lofsvold and Ronald T. Ottes, retired employees of the U.S. Food and Drug Administration. The interviews are with persons, whose recollections may serve to augment the written record.

It is hoped that these narratives of things past will serve as one source along with written and pictorial source materials, for present and future researchers. The tapes and transcripts will become a part of the collection of the National Library of Medicine.

TAPE INDEX SHEET

JOSEPH P. HILE _ SECOND INTERVIEW

August 4, 1988

Interviewee: Joseph P. Hile, Retired Associate Commissioner for Regulatory Affairs, U. S. Food and Drug Administration.

Address: [redacted]

Interviewers: Robert G. Porter, Fred Lofsvold, FDA

Number of Tapes: 8 Length of Tapes: 450 Min.

| Tape No. | Time on tape | Page No. | Subject |
|---|---|---|---|
| 1-A | 0 | 1 | Commissioner Charles Edwards |
| | 3 | 2 | Reorgainzation of Field - Regionalization<br>Fred Malek<br>Ritz Committee |
| | 10 | 3 | Bureau Relationships, Reorganization problems. |
| | 13 | 4 | HEW Reglional Directors<br>Regional Food and Drug Director |
| | 21 | 7 | Field Steering Committee - other field committees |
| | 26 | 9 | Commissioner Edwards |
| 1-B | | 10 | Commissioner Edwards (cont.) |
| | This side of tape erased | | Bon Vivant investigation - food poisoning |
| | | 14 | Low acid canned foods<br>GMP's |
| | | 15 | James Grant, deputy commissioner |
| | | 16 | The General Counsel<br>Billy Goodrich<br>Peter B. Hutt |
| | | 17 | Administrative Procedures Act<br>Rule making |
| 2-A | 0 | 19 | Peter Hutt - general counsel's office |
| | 12 | 23 | Regulatory letters |
| | 19 | 25 | Richard Merrill, General Counsel regulation writing |
| | 26 | 27 | Richard Cooper, General Counsel |
| | 27 | 28 | Peter Hutt's office organization, its effect on case management and rule making |
| 2-B | 0 | 28 | Continuation of above |
| | 10 | 31 | Regulatory reform |

JOSEPH P. HILE

| Tape No. | Time on tape | Page No. | Subject |
|---|---|---|---|
| 2-B | 22 | 35 | Commissioner Schmidt |
| 3-A | 0 | 37 | Dr. Schmidt (cont.), the Policy Board, the Kennedy hearing, Schmidt's response |
| | 12 | 40 | The Canned mushroom investigation |
| | 20 | 42 | IBT investigation, clinical investigators |
| | 27 | 44 | Investigational New Drigs (IND) and New Drug Application (NDA) - regulation revision |
| | 30 | 45 | Good Laboratory Practices Regulations |
| 3-B | 0 | 45 | (continuation of above) |
| | 6 | 47 | Defense, VA, PHS drug and device inspection |
| | 12 | 49 | Sherwin Gardner, Deputy Commissioner |
| | 23 | 52 | Commissioner Donald Kennedy |
| 4-A | 0 | 55 | New drug approval, "drug lag" |
| | 29 | 62 | Food labeling, nutritional labeling |
| 4-B | 0 | 63 | (continuation of above) |
| | 8 | 65 | Kennedy as spokesman for FDA |
| | 16 | 67 | Reorganization within commissioner's office. |
| | 21 | 68 | Commissioner Jere Goyan |
| 5-A | 0 | 70 | Patricia Harris, HEW Secretary, Jere Goyan, Nancy Buc |
| | 15 | 75 | Package inserts for presc. drugs |
| | 18 | 76 | Rely tampon episode |
| | 22 | 76 | CDC, FDA interaction |
| | 29 | 78 | Formal corrective action agreement - Procter and Gamble and FDA |
| 5-B | 0 | 79 | (continuation of above) |
| | 4 | 80 | IRLG, Interagency Regulatory Liaison Group |
| | 16 | 83 | Office of Science and Technology |
| | 20 | 84 | Regulatory reform in Carter administration Operation Plain Speaking, review of regulations |
| 6-A | 0 | 87 | Carter administration policies |
| | 7 | 89 | Secretary Schweiker, Reagan acministration, delegations of authority recinded, regulatory reform |
| | 16 | 92 | "Organization Capture" |
| | 19 | 93 | Regulatory reform |
| | 27 | 95 | Infant formula episode, amendments |
| | 29 | 96 | Appointed officials, bringing them up speed on FDA policies & procedures |
| 6-B | 0 | 96 | Reagan administration and political appointees |

JOSEPH P. HILE

| Tape No. | Time on tape | Page No. | Subject |
|---|---|---|---|
| 6-B | 3 | 97 | Commissioner Arthur H. Hayes, class I recall, relations with Secretary Schweiker |
| | 14 | 100 | Clinical investigators |
| | 20 | 102 | NDA - IND rewrite |
| | 24 | 103 | Reagan administrations changes in regulation development, changes management of criminal and civil actions |
| 7-A | 0 | 105 | (continuation of above) |
| | 12 | 108 | Center for Drugs, Dr. Henry Meyer, Center for Food Safety and Applied Nutrition |
| | 16 | 109 | Center for Devised and Radiological Health |
| | 22 | 110 | Office of Regulatory Affairs combined with Office of Regional Operations |
| | 24 | 110 | Tylenol tampering episode |
| | 26 | 111 | Office of Regulatory Affairs |
| | 28 | 111 | Deputy Commissioner Dr. Mark Novitch |
| 7-B | 0 | 113 | Mark Novitch (cont.) Sherwin Gardner |
| | 4 | 114 | Ethylene dibromide fumigation of grain |
| | 8 | 115 | Commissioner Frank Young |
| | 16 | 117 | James Swanson, Regional Director |
| | 20 | 118 | Mark Novitch, Commissioner Young |
| | 24 | 119 | First Action Plan |
| 8-A | 0 | 121 | First Action Plan (cont.) |
| | 4 | 122 | Second Tylenol tampering episode |
| | 12 | 124 | Gerber baby food, glass in |
| | 16 | 125 | Commissioner Frank Young |
| | 20 | 126 | Reorganization of Regional offices |
| | 30 | 129 | Commissioner Young, his effectiveness |
| 8-B | 0 | 129 | Commissioner Young (cont.) |
| | 15 | 134 | End of interview. |

RP: This is a second interview with Joseph Paul Hile who retired on June 30, 1986 as the associate commissioner for regulatory affairs of the Food and Drug Administration. Paul is currently corporate director, regulatory affairs for Hazleton Laboratories Corporation.

The previous interview with Paul took place on October 22, 1986. The current date is August 4, 1988, and the interview is taking place in Aurora, Colorado. In addition to Paul, those present for the interview are Fred Lofsvold and Bob Porter, currently working on the history project of the Food and Drug Administration.

Paul, we covered your career and then went back and covered in more detail various events that occurred in the course of your employment with the Food and Drug Administration, and we got up to a period that was during Dr. Edwards' term as the Food and Drug commissioner. Can we pick up at about that point?

JH: Yes, I'd like to do that, Bob, because I especially enjoyed working for Charlie Edwards as commissioner, and there were several things that occurred during the time he was commissioner that I think should be recorded as part of this interview.

I touched briefly on the initiative of the department which, as Fred reminded us in our informal conversation earlier, was a government-wide initiative of the Nixon administration to bring a greater regionalization to the federal government. And you'll recall, I think both of you, that during a very short period of time we went from nine regions to eight regions and then to ten regions government-wide for what were mostly political reasons at the presidential level and the congressional level during that time.

It was a difficult time for me personally--I must be candid--because it all came at a time when Dr. Edwards had asked me to set up the new field organization. And while having to do that, which was a task of its own, the Food and Drug Administration had to deal with major initiatives that were directed toward taking federal programs that had been highly centralized and decentralize them to the regions.

There was strong resistance, and I think appropriately so, within the Food and Drug Administration to decentralizing its program. By that I mean to literally have the field structure of the Food and Drug Administration not report directly to or through a single individual that reported to the commissioner of the Food and Drug Administration, but rather to give line authority over the field to the regional directors of the then Department of Health, Education and Welfare.

I was reminded that one aspect of that was an initiative out ~~of Fred Malek's~~ office in the office of secretary where individuals were brought into Mr. Malek's office who had either special educational background in business or who had special understanding of how regional programs had been managed within the department. They began to look at the various activities within the department as a whole. There were two young men that looked particularly at the Food and Drug Administration.

It was a very difficult time because they came in with a mandate to literally decentralize to every extent possible, and of course here we were trying to centralize reporting authority within the field to a single organization that then reported to the commissioner. Those two initiatives were in direct opposition to one another. I mention it principally to just set the atmosphere in which things were occurring within the Food and Drug Administration in the early months of Dr. Edwards' administration.

Imposed upon that were some initiatives of Dr. Edwards himself. The Ritts Committee was a committee headed up by a doctor from the Mayo Clinic and staffed principally with academicians. They came into the agency to look at its science overall and then specifically at the field laboratories of the Food and Drug Administration and to provide recommendations on how the science of the agency could be strengthened.

The agency as a whole, as you'll recall, was going through a reorganization where the headquarter's bureaus were being restructured to be focused toward programs: the Bureau of Foods, the Bureau of Drugs, the Bureau of Veterinary Medicine.

FL: Paul, wasn't it about this time too that you were having a problem with the Bureau of Directors who were also seeking line authority over portions of the field force?

JH: Yes it was, Fred. When you think of all that was happening at that time, it was indeed a very difficult time. You had some new persons brought into the agency by Dr. Edwards, like ~~Henry Simmons~~, who felt very strongly that they had been brought in to establish a new initiative in the regulation of, in this instance, drugs. They had strong feelings of their own, as did some persons that they had around them, that if they had those responsibilities they needed to have authority over the field offices as well. And then there were some others within the agency who had been in the agency for some time, like Danny Banes, who shared that feeling and felt that, especially in the laboratory area, that there needed to be that close relationship. They were arguing with Dr. Edwards that the field should be divided up into a drug field force with laboratories and specialized investigators, and a food field force with specialized laboratories and investigators, as an example, all reporting to the director of the appropriate bureau. So, in the instance of drugs, they would all report in directly or through some other organizational mechanism to the director of the Bureau of Drugs.

As a consequence, there was a period of time that, as I mentioned a little earlier, was very, very demanding for me personally and for others that were working with me closely on the initiative to set up the new field organization. I had to establish myself with the field directors who had been, since 1966, reporting directly to the commissioner; had to fend off, with Dr. Edwards' help, the initiative to regionalize the programs of the Food and Drug Administration; had to be responsive to Dr. Edwards' requests for reasons why he should not respond to the suggestions of his new bureau directors to divvy up the field and have it reporting separately to the various bureaus--all of that, and to set up a new structure to manage the field, all happening at the same time. So it was really a very difficult time, and as each of

those aspects of organizational life were either taken care of or at least began to lose some of their momentum, then it made it increasingly easier for me to carry out my role as the director of the field organization.

You'll remember in our earlier interview I talked about the way Edwards asked each of the principals to submit information to him arguing the merits of different organizational structures. Finally, in one of his off-site management meetings he made the decision that there would be no change in the way the field organization was structured or in the way it reported to headquarters. There were some real knock-down-drag-outs between Edwards and the regional HEW directors as well. I mentioned briefly the one with Buck Kelly in Seattle, and I'll come back to that in a few minutes.

But there were strong regional directors, in Boston and New York particularly, that were, of course, charged with coming in and establishing under their own leadership the focus of regional departmental programs. It seemed like almost every day we were confronted with some need to respond to a regional HEW director's concern over what was or what wasn't happening in the Food and Drug Administration.

Probably one of the best examples of the head-on collision between Dr. Edwards and a regional director was the appointment of Frank Clark as the director of the Seattle office of the Food and Drug Administration. I remember vividly being called down to the department and going into the secretary's office and having Buck Kelly on the phone and the secretary and Dr. Edwards and myself there talking about who was actually going to be in charge of the Food and Drug Administration's program in Seattle and, secondly, who would that person report to.

Now ultimately the agency in its reorganization accommodated some of the regionalization concepts by establishing the position of regional Food and Drug director. Early in those months following the establishment of the regional Food and Drug director position, it was formally demonstrated on organizational charts that although there was a solid line between that regional director and the director of the

Office of Regional Operations and then to the commissioner, there was a dotted line to the regional director of HEW. Our FDA regional directors, you'll remember, Fred, had to go over and sit in the HEW directors' staff meetings, had to report on issues when matters of importance were occurring within the region as it related to FDA activities. They had to report regularly to the HEW director. You sat on committees established by regional directors of HEW.

That "lip service," if you will, that we performed during that period of time seemed to satisfy, at least outwardly, the concerns of the regional HEW directors over some involvement with and at least some control over FDA programs. I remember going up, for instance, and meeting with the regional director of HEW in New York. She was an individual who was a Democrat but in a Republican administration--very powerful politically.

FL: Bernice Bernstein.

JH: Yes, thank you. Bernice Bernstein had been in government for years and years, and as an aside, as a young woman had been involved in the Franklin D. Roosevelt administration in the writing of the Social Security legislation. A very interesting woman. I remember going up and meeting with her, recommending Cliff Shane to be the regional director there, and having to go through the list of those who had been eligible, and discussing with her how I had evaluated each one and ultimately why I had concluded that Clifford should be the regional director there. Under similar circumstances I went to Atlanta and Boston and met with the regional directors in those regions.

Over time I think the regional HEW directors began to realize that FDA was a little different kind of program and less and less was it necessary for us to accommodate their interests and their needs. I think still the regional Food and Drug directors are conscious of their obligation to keep the regional directors of the

department advised on matters so they are not embarrassed, but I don't think there is that close involvement any longer that there was early on in the early seventies.

FL: When the Public Health Service established the regional medical director program and we became a part of the Public Health Service, then in Denver, at least, where I was regional Food and Drug director, I was relieved of reporting directly to the regional director of the department and reported only to the regional medical director in the same fashion that I had been reporting to the regional director of the department. I always figured that my primary purpose was to keep them from interfering in our business. I always picked topics to report to them that emphasized the difference between the FDA and the rest of the department.

RP: It seems to me when I went to Denver you were also very happy to designate other members of your staff to attend their staff meetings. (Laughter)

FL: Not very often. I usually went myself, unless there was some important reason. I thought this was part of my job, to keep them off the backs of the people who were doing the work.

JH: I think you and your colleagues, Fred, became astute at dealing with that particular relationship and the politics of it. I think we did it very well, and I don't think there was any maliciousness about it; it's just that we had very strong feelings and, as I mentioned earlier, quite appropriately, in that the Food and Drug Administration's program continues to be materially different from almost all the other programs within the department as it relates to the importance of organizational structure, vis a vis the department. I think of others; for instance, we became, I think, good at using the regional directors in working with GSA and other government agencies where we needed the power and at least the prestige of our

department at a local level to help us solve problems that were more difficult for us to solve otherwise.

FL: Most of the regional directors of the department were politicians, and when they learned that FDA did not have large amounts of grant money to be made available to state and local agencies, as they got more into their jobs, they lost interest in what we were doing, too.

JH: Yes, that's a very important aspect of it as well, Fred. We've jumped ahead even to modern times, because we are still structured within the regional configuration, although somewhat differently from the early beginnings.

Getting back to that period of time in the early Edwards administration, you had the activities of the department and our own initiative to restructure the field organization within an office of regional operations. You'll remember that's when the establishment of the regional director position made unnecessary the deputy district director position.

FL: Yes, the regional Food and Drug director position did that.

JH: Yes, when we established the regional Food and Drug director position, then we had a number of deputy district directors who had to be placed. It was a very complex time, but I set up some committees to assist in this effort. I had a committee that helped in designing the organizational structure of the field organization, and I remember particularly that Al Hoeting was a member of that committee. That was just a committee of persons that I drew on to help think through the mechanics. I know that in the early months of that committee we began to think about work planning and how we were going to manage work planning.

Then also I established what I called the Steering Committee which had three of the new regional Food and Drug directors on it. One from the East Coast was

Weems Clevenger from New York; one from the middle part of the country was Don Healton from Chicago; and from the West Coast Frank Clark from Seattle. One reason I chose each of those persons was to get a geographical distribution and to reflect the various concerns of the different parts of the country. But each brought personal attributes to the committee as well. We met regularly, and I used them as a sounding board for the procedures and organizational structures that were evolving within the Office of Regional Operations, to make certain that there clearly was a field-management voice in the decisions that were being made at headquarters in regard to the new organization. Most often we'd meet either in New York or in Chicago to get out of the Washington area but make it convenient to the other three members.

There was a lot made of the fact that it was the Steering Committee. You'll remember, Fred, there was the famous picture of the boat with the Steering Committee in it, and then Clevenger got us each the castration tool and had Steering Committee engraved on the handle. I don't know whether you remember that or not. But I think the committee worked well--at least I felt so. I hope I wasn't deluding myself, but I think it was a good mechanism to have the field managers at least sense that they had their representative voice in what was happening.

We also set up a system of field committees that were designed to be responsive to the individual bureau needs. I worked that out with the bureau directors so we had a food committee and a drug committee and vet-med committee, as an example. Those were made up of regional and district directors principally. Occasionally we'd put on other field members if they had special experience or views to add. I'm thinking that from time to time we'd have some of our senior investigators on there or a chief inspector, whatever, to add that dimension. But they were principally the regional directors and district directors. Each one was chaired by a regional director, and they were available to the bureaus as a sounding board and as a means of feeding into the bureaus the field's concerns and attitudes and recommendations. This was true particularly in the development of regulatory

programs, that is the programs that in turn would set the goals and objectives for the field organization of FDA in each of those program areas.

They were used to a differing degree by each of the bureau directors. Probably the most effective use was by foods, I suspect, followed by vet-med, with drugs maybe down toward the bottom of the range. That was interesting because drugs was most aggressive, at first wanting to have a direct involvement in the field; and I guess when they lost that battle they lost interest. But for whatever reason, that was a mechanism of satisfying the concerns of the bureau directors that they would have no way of communicating directly with the field managers or having feedback directly from the field offices except through the Office of the Executive Director of Regional Operations.

Things were settling down reasonably well, I think, certainly by the middle of 1971. We'd established the EDRO organization and we'd established the means by which we'd interact with the regional HEW directors. By then, Bob, the planning system was at least established, and if not operational in all aspects, pretty much in place. I just remember from my own viewpoint things were settling down quite a bit.

I had an opportunity to talk to the commissioner all through the period of time that I was the EDRO in ways that other managers did not have. When the commissioner decided to go visit a field office and I went with him, then I was sitting with him on the plane all the way to wherever we were going. If we went to the West Coast we had five hours on the way out and back each; but even if it was an hour up to New York or whatever, I had the ear of the commissioner as it related to the field organization and the concerns of the field organization for that period of time. I think that worked to our advantage as well.

I established an interesting relationship with Dr. Edwards. He used to call me on Sunday mornings about 10:30 or 11:00. Had I been a regular attendee to church services, I might never have had the opportunity to have these kind of conversations with him. (Laughter) But he would call me, and we'd talk about field matters or other matters reasonably wide-ranging that related to FDA, and he would ask for my

opinion. I have no way of knowing that he wasn't making similar calls to others of his managers. But I felt good about that in that it reflected to me that he respected not only me as an individual and my opinions on agency matters that were before him, but also that I in turn reflected the field's attitudes and concerns. He was anxious to get that insight into issues as well.

As I mentioned earlier, I liked Dr. Edwards very, very much. He was an interesting man. He was not a very public man. I think he did not like the public aspect of the job of commissioner. He liked much more the role of managing the Food and Drug Administration. He delegated well; there was a good relationship between him and Sam Fine and I think of all of his managers. I was disappointed from a selfish standpoint . . .

(Interruption)

JH: . . . when he chose to go up and take the position of assistant secretary for Health. He had really only accomplished some of the things I believe he set out to accomplish. But I saw him, as I mentioned earlier, as the healer. The agency needed a time of healing, and he came in as a physician and, I think, was quite effective in that role--at least from my perspective. Perhaps he was not seen in the same way by everyone, but I certainly saw him in that regard.

One of the most important things that happened within the administration and particularly in the field during Dr. Edwards' time as commissioner was the Bon Vivant investigation. I remember Dr. Edwards and I had been in New York on a visit to the district office probably June 30 or July 1 of 1971 when, about the time we were leaving about the first of July to come back down to Washington, someone at the office ran in literally breathless to say that there had been a report that someone had died as a consequence of botulinum poisoning and as a consequence of eating canned soup. As seems always is the case, such issues arise over holiday weekends. That whole episode began over the Fourth of July weekend of 1971.

That posed some very difficult times for FDA from my point of view. I think we had become complacent within the agency over canned products, concluding that the canning industry had become so sophisticated and so capable over the years that this problem was unlikely. We hadn't had, except for home canning, concerns about botulinum toxin in canned foods for some number of years prior to that time.

FL: As I know from reading, we had a problem of serious poisonings from black olives in 1919-20. There was a great deal of study of botulism at that time that led to a lot of the time and temperature relationships used for processing in the canneries. Then there were no deaths from commercial products from that time until somewhere around 1940 when a man died from eating Liederkranz cheese, and nobody every figured out the answer to that one. The only other one then was the smoked fish and canned tuna episodes around 1960. But other than those, which were very rare instances, there had been no reason to believe that the canning industry had not solved the problem of botulinum.

JH: Well, yes, and in fact it was Washington fish in the tuna episode in the early sixties; I was at Seattle district at that time. That ultimately, I think, was attributed to a pinhole in the can, rather than a failure to process. Are you thinking of the smoked chubs?

FL: The smoked chubs and then the tuna from the West Coast.

JH: Yes, and the smoked chubs were vacuum packed in plastic as I remember, weren't they?

FL: Yes, one case; and the other case was a very large fish with heavy oil so that in the interior of the fish, the oil formed an anaerobic condition.

JH: When I say complacent, I don't only mean FDA; but I think the entire country and certainly the medical community and the industry had become complacent, because when the fellow died, the attending physician did not immediately diagnose it as botulinum toxin. It was only after the wife became ill and exhibited the same symptoms that the physician became concerned, because he had already signed the death certificate for a heart attack. Then, when the wife became ill within just a few hours after the husband died, then the physician became concerned that it was something other than the original diagnosis for the husband and began to focus on the fact that it might be botulism.

But what it meant, too, was when we were confronted with making an investigation, we really didn't have persons that were as well trained as they could have been or should have been, or as experienced, to make the investigation of the plant. As we went out and began to examine Bon Vivant's products in the marketplace, I remember we had a heck of a time with diversity among inspectors and among districts in determining what were soft swells, what were flippers, what were hard swells and that sort of thing.

There was really some period of time before we got that particular investigation structured and organized and felt comfortable with the kind of information that was coming in. Now ultimately, I don't think what I'm saying compromises at all the seriousness of the episode or the fact that the company had failed to take proper action to assure itself that its production processes were adequate to prevent the formation of botulinum toxin in their products. But I remember meeting up in Sam Fine's office with Ken Lennington, in the last months of Ken's time with the agency, and he'd been salmonella control officer in the Office of the Associate Commissioner for Compliance. We were sitting there and working through the reports that were coming in from the various district offices in regards to what they were finding and trying to reach some decisions as to how far we would extend the recall and then discussing our concern over the company's products. Of course, ultimately all of the

company's products became suspect, and all of them were taken off of the marketplace. But that was a very difficult investigation.

FL: It was an extremely time-consuming one, too, because it was different from the normal recall of products. In most recalls the company involved is interested, cooperative, and does a lot of the work of notifying consignees and so on; but in this case, as I remember, Bon Vivant did not do that, and the Food and Drug Administration had to do the whole job itself.

JH: Yes. In fact, Fred, the management was recalcitrant early on in the investigation, and then the longer the investigation went and the more clear it became that Bon Vivant was, in a sense, out of business, they walked away from it and literally left it. It was further complicated by the fact that their line was a line of specialty products. The involved product, you'll remember, was vichyssoise. They had a green turtle soup and some other, very specialized kinds of products. So, as a consequence, you didn't have shipments of maybe five hundred cases going to a Safeway distribution point. You had a mixed case of three cans of vichyssoise and two cans of something else going to every individual grocery store that had an interest in having a little bit of that kind of product on the shelf.

Literally, the investigators had to go down the road, in a sense, and stop in to every mom and pop grocery story in the country to find whether or not those products were there. They'd find two or three cans, and some of those smaller grocery stores that were privately owned, they were not very anxious to give that product away. They bought that product; they weren't about to give it away. They had money invested, and so we got to a point that our policy was if it was just so many cans, the investigator bought the cans. If it was a larger lot, then we'd seize the lot. But because of so many seizures, you remember we had a standard complaint, and it was a fill-in-the-blank complaint. Literally, we'd have twenty-five or thirty complaints filed in a single district to go out and seize one or two cases

here, one or two cases there, in order to assure ourselves that the firm's products were off the marketplace.

That episode changed FDA as it related to the way in which it was inspecting the food industry. The outgrowth of that was the critical control points concept. The outgrowth of that was the good manufacturing practices regulations (G.M.P.'s) for foods. An outgrowth of the regulations and of the critical control points were the specialized inspectors who went through the schools and learned about the processing of canned goods. And, of course, as we got deeper and deeper into those kinds of initiatives, then we found other kinds of problems, and we got into the mushroom problems of about 1973.

FL: Similar problems with low-acid, canned-food products that were insufficiently processed and were potentially hazardous.

JH: Yes.

FL: It led, ultimately, to using the section 404 of the act, with regulations to, in effect, license people who pack low-acid canned foods.

JH: That's right. My remembrance is that the idea to use that section of the act came from Tommy Austern at Covington and Burling. He at that time was counsel to National Canners.

FL: I've been told in another interview that it was his idea, but he was very put out with FDA afterwards because we made it mandatory, while he had been proposing it as a voluntary requirement.

JH: Yes, that's right. There was not a lot of harmony during that period of time.

FL: Lowrie Beacham speaks of that in his oral history interview.

JH: We learned a lot about recalls during then, although the Spice of Life episode of about 1966-67 also kind of catapulted us into our modern-time management of recalls. It also just turned us around completely in the way in which we were regulating low-acid canned foods. Then that whole concept of critical control points began to filter into other things that we were doing. Although I'm digressing a little bit, it also led the agency into the idea of having good manufacturing practices regulations in the food area where the statute was not as clear in its authorizations. So there was a lot of conflict between the industry and the agency in that regard.

Also by that time, Virgil Wodicka was the director of the Bureau of Foods, and Robert Angelotte was the director of the Office of Compliance in the Bureau of Foods, and they undertook the initiative to have, as an objective, appendices that were regulations, but they would be appendices to the umbrella food G.M.P.'s, one for every different segment of the food industry. That's why all of a sudden we began to have such important regulations as ones for the canned nut industry and some of the others that were easier ones to develop and get through. But I'd like to come back to that; it was two or three or four years later.

Let me talk about one or two other aspects of Charlie Edwards' time, and then we can move ahead. Charlie came on, as you remember I mentioned earlier, from Booz, Allen, and Hamilton, where he had been a senior management consultant. He brought some other people from Booz, Allen with him. One of those persons was Sherwin Gardner. Sherwin came in to the agency as the assistant commissioner for planning and evaluation. I always understood that Sherwin was Charlie's choice for deputy commissioner, but that Charlie was overridden by the department and by the White House, and that it was the White House, literally, that placed Jim Grant into that position, because Jim had been the executive director for the White House conference on nutrition and health. You remember Jean Mayer was the leading academician and nutritionist in that whole initiative. I understand

that Jim Grant did a good job of his role there but had, as a consequence, focused on an opportunity to become part of the Food and Drug program and saw the deputy commissioner's job as not an unreasonable one for him to assume.

There's something else I ought to mention before I leave the period of time when Charlie Edwards was commissioner that really became an important aspect of the way in which FDA conducted its business, because it was when Charlie Edwards was commissioner that Billy Goodrich retired and Peter Hutt came on as the general counsel to the commissioner. You always have to step back and reflect on the fact that the general counsel to the FDA did not report to the commissioner of the Food and Drug but reported to the general counsel of the department. Literally they were the director of the Food and Drug division of the general counsel's office of the department. But because the general counsel historically had tenures not dissimilar to the tenures of commissioners, at least in more contemporary times, there tended to be long periods of time when the same individual was the general counsel and long periods of time when the same individuals were commissioner or series of individuals who had worked closely together and knew one another and had been subordinate to one another all during that period of time from the forties, fifties, and into the middle and late sixties.

There was a personality clash, clearly, between Charlie Edwards and Billy Goodrich. I'm not going to attribute fault to either of the two, because those kinds of things happen in any organization and there would be fault on either side. It's really only that I think Charlie Edwards came on, in a sense, much as Goddard had come on board a few years earlier, with a mandate to make some changes within the Food and Drug Administration. Like it or not, the general counsel to the commissioner, by the very role that that person has in providing legal advice to the commissioner, plays an important role in program development and in program priorities within the administration. I think that there was probably a contest of wills between Billy Goodrich and Charlie Edwards in that regard, because lots of things

were changing--times were changing. Ultimately Charlie's will, principally political, prevailed, and Billy chose that time as an opportunity to retire.

I don't know the details of Peter's selection, and there probably are others who do. I candidly don't remember. If I did know, I've forgotten. Peter was, and I suspect still is, a Democrat; at least that's been my understanding throughout the years. It was interesting that he came on board as the general counsel during a Republican administration. But Peter was a champion of administrative law and came into the agency at a time when the entire federal government was moving from a period of time when precedents were established through rule-making. I guess you could look at any one organization in the government and see that it was all happening at the same time throughout government.

But clearly a growing concern on the part of the public as a whole--and I'll use that term, because within the public are different segments, varying industries and the academic community and that sort of thing--had apparently over time increasingly expressed concern over failure on the part of the government generally to fully implement the intent of the Administrative Procedures Act. This act had been passed initially in the late 1940s and provided a means by which a precedent could be established through rule-making. And that rule-making procedure provided an opportunity for people to comment on the intentions of government and influence those intentions for a good cause. There had been a study of how the government had implemented the Administrative Procedures Act that had been undertaken by the Administrative Conference of the United States. The report was issued in the late 1960s and was extremely critical of the government as a whole. It admonished all agencies to adhere more closely to the intent and letter of the Administrative Procedures Act in the process of rule-making.

It was a very good marriage in that regard, because Peter Hutt has a keen interest in administrative law and literally pushed the Food and Drug Administration into modern times in regards to implementing the full intent and spirit of the Administrative Procedures Act.

If you look at the regulations of the agency--by that I mean look at the process--you have to look at the *Federal Register* and you have to look at the proposed regulations and look at the preambles to those regulations for the period of the late 1950s, 1960s. The preambles of the regs would say that the commissioner of Food and Drugs had concluded that a certain regulatory initiative was appropriate, had looked at the matter, and had concluded that the following regulations should be promulgated. And then came the regulation.

People were asked to provide comments, and then when the final order would issue, the preamble would say the commissioner of Food and Drugs had considered all the comments and was now persuaded that the initiative of the agency was correct at the time the regulation was proposed, and so the regulation is going into effect on a certain date without change, or with only, perhaps, minor modification but without much explanation. So the preambles were a hundred words long, and I guess under Peter they became a hundred pages long. But certainly he, then, instituted the process within the agency for laying out in great detail in the preambles to the regulations in a proposal why the agency wanted to undertake the initiative, what was the science behind it, what were the problems behind it, what were the objectives of the regulation. Then, after having read the comments, comment by comment, group of comments by group of comments, he responded to them, explaining why they were accepted or why they were rejected and why ultimately the agency was taking the direction that it was taking.

Not only did Peter require that of the agency, but he also required that the agency formalize in regulation form the majority of its own administrative procedures. That was not necessarily a requirement of the Administrative Procedures Act or necessarily a strong recommendation of the report of the administration conference. It was Peter Hutt's strong feeling that the public and the industries specifically had a right to know how the agency conducted its affairs. And so beginning under Charlie Edwards and then carrying into Mac Schmidt's tenure as

commissioner, the agency and the commissioner's immediate staff literally struggled through word by word, page by page the development of the administrative procedures regulations governing our own conduct, administrative procedures on how we would implement such legislation as Freedom of Information Act and, then, procedures that led to the very detailed preambles to our own regulations.

Also, Peter saw fit to formalize, in regulation form, all of the administrative procedures that the agency had undertaken to implement certain requirements of the 1962 amendments to the act. He said if the industry is going to have to adhere to the results, the outcomes of these initiatives, then the whole process should be put into regulation form. They should have an opportunity to comment on them and have them formalized and memorialized in the code of federal regulations. So all the DESI (Drug Efficacy and Safety Investigation) procedures, all the OTC Drug Review procedures, the Generally Recognized as Safe (GRAS) Review procedures, as appropriate, were then formalized into regulation.

(Interruption)

JH: An interesting aside is that as adamant as Peter was in regards to allowing individuals outside of government to have an opportunity to influence the agency's regulations that in turn impacted upon the industry, when it came to the Administrative Procedures regulations, he concluded that the agency had the authority just to promulgate those regulations without asking for comment. And you'll remember that that was challenged in court, and the court ruled that if we were going to have them as regulations, we had to follow the procedures and provide an opportunity for comment. And so we went back through the process and offered those regulations for comment.

But he began to look at a number of things that the agency had done that he said should have greater public exposure. He began to look, for instance, at our relationship with the Association of Official Analytical Chemists (AOAC). It was

Peter's strong feeling that the AOAC should be an independent body. That began the initiative to lead away from the historic relationship that existed between the AOAC and FDA. You'll remember FDA provided office space; they provided the executive director and secretarial space. That all began to change under Peter.

He began to look at all the traditional public-health programs, like the Interstate Milk Shippers Conference and the Shellfish Shippers Conference, and concluded that all of the guidelines established at the federal level that in turn, then, were taken by the states and implemented as a means of regulating those industries, should be much more open. And so it was under Peter that, in those activities, steps were taken to change them over to become much more like the normal rule-making procedures followed in the more traditional programs of FDA.

Ultimately he didn't achieve all of those objectives, because there was strong opposition to changing the character of those traditional Public Health Services programs not only within government, but more importantly within the states and the industry itself. And so those initiatives never completely came to fruition. But as I mentioned, having seen each of the commissioners having certain impacts on the agency--I characterized Edwards as the healer--I see Peter Hutt as general counsel bringing FDA into modern times as it relates to administrative law.

Peter is a very, very strong personality, and he was no less influential in the affairs of the agency as I'm sure Billy Goodrich had been all through the years. But because he had come on board and was agreed to as the general counsel for FDA by Dr. Edwards, clearly there was a closer relationship there and greater harmony. You didn't have the problems that were extant between Billy and Charlie.

FL: Do you want to say anything about the effect on the agency from staffing and organization that came about from Peter's initiatives in this area?

JH: Yes, I think that's important, Fred, and I'm glad that you raised that. Peter reorganized his own office at that time. Also, as a consequence of having much more

complex and extensive regulations, the bureaus within FDA had to undertake initiatives to change their own structure and staff accordingly.

The general counsel's office had been principally an office of litigation. It had, in fact, a pleading section as part of its own operation. As case work came forward and was sent ultimately to the general counsel's office of the department for review before being forwarded to the U.S. Attorney's Office, all of the final paperwork, all the pleadings work, was put into the formal structure by the pleadings section within the general counsel's office. The deputy chief counsel was a very, very strong litigator, and that was Al Gottlieb. So as one thought of the general counsel's office for the department, at least from my perspective along through those years, you thought of it principally as an office in support of litigation.

Now when you look back, and if, in fact, precedence was established mainly through litigation, that's not unreasonable. Further, the commissioner of FDA had for some period of time--and here I'd have to go back a little and look at the records because it was not always thus, but at least in the periods of the sixties and into the early seventies--had been given the authority to promulgate regulations by the secretary. So as a consequence, even though regulations may well have been passed through the general counsel's office for final review, because the regulations were not all that extensive anyhow, the general counsel's office was just not structured to be responsive to this change.

What Peter did was split his office in half. Half of the office were attorneys whose principal role was litigation, and the other half of the attorneys were assigned to work with individual bureaus to assist in the development of regulations from the very beginning, when you first put pencil to paper. Because there's always a limit in government to the number of positions you have authorized, in order to release positions to Peter to hire more attorneys to act as counsel in administrative law activities, FDA agreed to pick up the pleadings activities. And those were put in to the associate commissioner for compliance's office under Robert Brandenburg. Sam Fine agreed that he would undertake doing all the final formatting and typing of all

the paperwork associated with the civil and criminal actions that were forwarded to general counsel's office for review and sign-off and forwarding to the U.S. attorney's office. That released a number of positions that Peter used to hire new attorneys, and principally they were attorneys that were assigned to work with each of the bureaus in the development of regulations.

So you see the general counsel's office and the legal mentality was involved in the development of regulations from their very inception under Peter. And that continues even today. If you had maybe two or three people writing regulations prior to this time in a bureau, with the responsibility of writing not a one-hundred-word preamble but a one-hundred-page preamble as far as the relative length is concerned, the bureaus had to staff up those offices as well. And so they began aggressive campaigns of recruiting people into those offices and establishing specific offices in each of the bureaus for the development of regulations--some more successfully than others. In each instance there were staffs of some number of consumer-safety officers whose role was to write regs.

The agency couldn't breathe a policy except that it had to be at least a candidate for regulation. We went from publishing just a few hundred pages over a year's time in the *Federal Register* to literally thousands of pages a year in the early 1970s.

As much as I admire Peter, and I really do admire Peter, and as much as it was necessary for us to change dramatically our habits in regards to how we conducted our affairs in developing regs, I think Peter kind of pushed the pendulum a little past center in that whole initiative. Because we knew that at the same time other agencies that had programs similar to ours, although they were changing their procedures quite dramatically, they never went to the extremes that FDA did. Many agencies did not formalize their own administrative procedures into regulations, as an example. And I think there are many agencies still today who have not. The procedures are formal but not in the form of regulation.

I'm talking about administrative procedures and those are all the procedures in sections 10 through 20 of the Title Twenty-one Code of Federal Regulations. Peter had an objective of formalizing our regulatory procedures. You'll remember we were to formalize the procedures for issuing regulatory letters, for taking seizure action, for recommending prosecution. Those were his objectives, and we literally began the process and have in place in chapter seven the recall procedures. But again, as I talk more a little later about the later general counsels, some of those initiatives were changed under different counsels who brought differing views in regards to the value of formalizing all of the procedures that the agency utilized in conducting its affairs.

FL: How much responsibility did Peter Hutt have in creating the idea of the regulatory letter as a substitute for formal legal action?

JH: Well, I don't think he had so much in the concept of the letter. I have to be honest; in my own experience I'd attribute that to Goddard, not from a legalistic standpoint--I don't think Goddard thought he'd do it under section 306 of the act. But you remember Goddard came on board and said, "If you've got problems with a firm's management, pick up the phone, call them in for a meeting, write them a letter." And, too, it was at that time that we backed away from using a citation for warning. Reo Duggan, you remember, wrote the policy statement in regards to how we would use citation, and that is by using it only when the agency had concluded they were ready to forward a recommendation for prosecution.

So the concept of letters had grown up during that period of time, Fred, from my point of view, from '66 into '71-72 when Peter came on board. Peter also, when he came in, was saying, "What are my attorneys working on?"

A good example. Do you remember the conversation that you and Pitt Smith and I had in your room when you and Pitt were rooming together there at the district directors' conference in Minneapolis soon after Charlie Edwards came on board?

It would have been the early summer of 1970. We were talking about enforcing the Fair Packaging and Labeling Act, and we just agreed, because there was a great concern that the agency wasn't doing anything about it, that we'd go out and do some things about it and that I would support a program of seizures.

We had support under Billy Goodrich that these were seizures--and seizures were seizures. When Peter came in to the general counsel's office and was looking at the kinds of actions we were taking and where we were focusing our attention, he saw a number of seizure actions for Fair Packaging and Labeling. He said, "Hey, from my point of view those are not high priority actions. If we're going to take action, then let's take some other kind of action and let's use the regulatory letter approach." But he said in the same breath, "But if we're going to use letters, then let's formalize the procedures, and let's focus on section 306 as the authority under which we issue letters."

So it was principally due to Peter's concern with what the general counsel's office was doing, how they were spending their time, and how, in his opinion, could they better spend their time. He felt that we were using the seizures sanction in ways that we could use other, less formal approaches to better advantage. So it was our initiative, generated in early '70 to begin to enforce the Fair Packaging and Labeling Act, that presented Peter with a basis for saying, "Let's do something other than that." But then it was also his desire to formalize that procedure that led to our formalizing the letter procedure more than it had been.

(Interruption)

JH: We got the recall procedures in place under Peter's initiative.

FL: Now those are the procedures that say to the industry, "If you choose to voluntarily recall, this is the way you should do it."

JH: Yes.

FL: They are not mandatory as far as whether they're going to recall or not.

JH: That's correct. They also go ahead and say, "And FDA will manage its affairs as it relates to a recall in the following way." It was an extension of the concept of formalizing in regulation form all of our administrative procedures, all of the different kinds of hearings that we hold and the other ways in which we manage our affairs. Even putting into regulation form the fact that persons have a right to communicate with their government. Peter wanted to say that formally, on the record. You might argue that that, in a sense, in our country is a given. But he said he wanted to have that precisely stated in regulations.

In the case of recall, because there is not statutory authority for recall in the Food, Drug and Cosmetic Act, those regulations are not only a how-to for industry if they are going to recall, but also how the FDA will conduct its own affairs if they ask a company to recall or if a company recalls on its own initiative.

We started to write regulations to try and lay out how FDA would go about decision making if we were going to issue a reg letter and under what authorities we would issue reg letters, how we would go about our decision making in reaching a decision that we would seize or prosecute and under what authorities we would seize or prosecute, how we would use publicity and under what authorities we would issue publicity. Those were tougher to write and, in my opinion, it was just as well that they were because it took us longer. And Peter will have to understand me, because the historian that he is, he may read this transcript.

When Peter left as general counsel, he was replaced by Dick Merrill. Where Peter was the administration lawyer, Dick was the academician. He came in and in my opinion brought to the general counsel's office the view of the dean of a law school. Now he didn't have less interest in administrative law or less interest in the criminal and civil sanctions, but he had a greater interest of explaining, even within

the agency itself, why it was that we had to do these kinds of things and how we could best respond to our own legal requirements imposed on us. So it was under a less aggressive administration that these drafts of the differing proposed regulatory procedures were developing. And they would come up to Dick for review, and he would look at them as the professor; and they were never quite good enough, and they'd go back.

Meanwhile, I'd become the associate commissioner for regulatory affairs (originally compliance), and although I knew what regulations were, the process of regulation development was a new responsibility for me. There was always a lot of complaining coming out of the bureaus about how tedious it was to write regulations, and that if you sent forward regulations to the general counsel's office they were never good enough. They were always rewritten and sent back, and you'd send them back again and they'd be rewritten and sent back. And ultimately the people in the bureau were saying, "Why should I even try? They never come out the way I draft them in the first place anyway."

So I said to myself, "I'm going to go through this process myself. I chose a regulation in an area I knew something about. So I took the early attempts to draft the reg letter and notice of adverse findings letter regulation. It said these are the two kinds of letters, here are the differences, here's how the agency will use them, and here's the authority under which we'll issue those letters. And I wrote the regulation, and I thought it was pretty darn good. I understood it. I had others review it, and they didn't think it was so bad, although I don't know whether they said they didn't think it was so bad because I wrote it or otherwise. But I sent it down to Dick Merrill for review. He was very gracious in his response, but it didn't come back looking anything like I had sent down. It was clearly not satisfactory in his view.

RP: Did he know you had done it personally?

JH: Yes. (Laughter) That's why he was tactful in coming back. I only give this background of intervening time because it was terribly difficult: where Peter had pushed us to write all of these regs, we then had a general counsel who felt differently. I really say this in all sincerity; I said earlier that each of the commissioners that I worked for I really admired and respected and they each brought talents and commitments to those jobs. Each was different and my relationship with each was different, but I respected them all and they were all good commissioners. The same is true of general counsels, beginning with Billy, as far as ones that I worked more closely with, and Peter and the subsequent ones. But the academic view, the need to be pristine in what came forward--you were writing a book each time you were writing a regulation as far as Dick was concerned. Dick left and then entered Rich Cooper.

Rich had come fresh from an environment of litigation. He came from a prestigious law firm in the District that had been principally in the environmental field, but he was right out of the courtroom. When he saw that we were going to try and write down and put into regulation form our thought processes as to why we would reach a conclusion to forward a prosecution case or seizure case or whatever, he said, "I don't want my hands tied in the courtroom. Our obligation is to be credible before the court, but certainly we don't want to provide the defendant with every opportunity to argue to the court, not the merits of the case, but whether we followed our procedures or not." And so all of that time and energy spent was immediately set aside. Rich Cooper said that we were not going to do that. So to everybody's relief, because many of us were no happier about it than Rich, that was the end of the initiative and the initiative was never resurrected in any way.

That's a long way of saying how dramatically Peter Hutt affected the way in which the Food and Drug Administration conducted its day-to-day affairs. Setting aside his impact on program policy, I'm just saying the impact he had on the way in which FDA day-in and day-out conducted its business . . . He was probably as

influential in agency affairs as anyone has ever been, or ever will be in the foreseeable future.

FL: In the early stage of that initiative to write criteria for various legal actions, you named me chairman of a committee of some experienced field people, two lawyers, and some experienced headquarters people who were supposed to write criteria for criminal prosecution. At the first meeting of the committee, the first order of business, we unanimously agreed that we shouldn't do it.

JH: I remember that. I had forgotten that. (Laughter)

FL: But having had the assignment, we did proceed to turn out a document. But thank goodness the succession of general counsels came around so that Rich Cooper came to the same conclusion we did, namely that if we put something down on paper there's no way we can . . .

(Interruption)

FL: . . . foresee all the contingencies that might arise in the future where we might find our hands tied by our own regulations.

JH: I had forgotten, Fred, in all honesty, that you chaired that committee. The one committee that came to my mind immediately as I was talking about that was the publicity committee under Healton. Remember how he struggled with that committee? Oh, my goodness.

FL: Peter had another impact, I believe, in the litigation area in the way that the general counsel's office organization changed from what it had been under Goodrich. At least from my perspective, it seemed that Peter turned his lawyers loose each one

to do his own thing as far as the way he wrote pleadings and things of that sort as compared with the standardized, supervised procedures that Goodrich had in place.

JH: Yes, and that's another aspect about Peter's organization of his office that's important to bring out, Fred. That was a direct result of the fact that Peter came from Covington and Burling. He structured his office to mirror the typical attorney's office in the private sector, where in fact ~~each of~~ the partners or each of the attorneys in the office had their own clients, and only under the broadest of office policies were they constrained in any way. It was their responsibility to take on the matter at hand and, using their own best talents and experience, working with that client, take the issue through to completion.

But what that meant in the general counsel's office was the litigating attorneys didn't have a single client, the Food and Drug Administration--which clearly was the way Billy Goodrich had run his office and particularly with Al Gottlieb as his deputy, a strong litigating attorney, an excellent litigating attorney. Al ruled with an iron hand all of the casework that was going on through there. They, of course, did all the pleadings under McKay in that section. That was all lost. So here I am, an attorney in Peter's office, and my client becomes either an individual district or an individual compliance officer in a bureau.

You did not have a uniformity of how pleadings were written; you didn't have a uniformity as to what was important or not important or how the evidence would be presented. And that caused a great deal of concern and unhappiness in the field offices. I just sensed, and Fred you need to add to this by all means, a frustration. I had a frustration, but my frustration was brought about by the frustrations of my colleagues in the field. We'd lost the Regulatory Procedures manual under Goddard in the "throw everything that was old out" because it wasn't any good. We'd lost the old Case Management notes under Goddard. The precedent files were lost under Goddard. But the glue that held that kind of activity together, at least as it related to how casework was forwarded, was the general counsel's office and the very strong

central control and direction of that office over how cases were developed and presented. Yes, that was a very difficult time. As you know, we struggled and struggled after Peter was gone, and we kind of began to come back under Cooper because Cooper saw more the need for this kind of guidance. By that time we were getting the Regulatory Procedures manual back in place to try and get some standard formatting for pleadings.

Meanwhile, the associate commissioner for regulatory affairs' office became increasingly influential in the structure of cases, and we became increasingly effective in dealing with the individual attorneys in arguing the way in which cases should be presented. In fairness, there were compliance officers and district directors who took advantage of that on the other side by playing to the individual attorney to get cases structured or to get cases presented in ways which they felt better and perhaps that headquarters didn't feel were appropriate.

FL: One of the adverse effects of both the change in the structure of the litigation section and its procedures and the emphasis on this regulation writing is that more and more time and effort was being put into repetitious rewriting of documents that took time away from perhaps other things that the agency should have been doing.

JH: Well, certainly that's true. The whole concept of laying out your policies through rule making first, in a sense, argues that if the industries know what the rules are to begin with and are committed to adhering to those rules, then you won't have as much litigation ensuing. If you establish the rules through litigation then, of course, from the very beginning you are out there with a greater number of civil and criminal actions as a method for establishing those rules.

I'm not arguing that it's not right for the industry to understand what the rules are. I think that is the proper way in which government should conduct its affairs. In theory the natural consequence of that would be fewer regulatory actions. But you add on to that this writing and rewriting and rewriting and rewriting, and the great

apprehension, I think, on the general counsel's office that except that you met perfection in each regulation that you could not properly defend that regulation if challenged, then a great deal of time was spent, iteration after iteration on any one regulation. It took years and years and years for some regulations ever to be completed. Some were never completed.

We're out of chronology here, but a lot of things were happening in the early 1970s that impacted ~~on FDA and the~~ way it promulgated regulations and what kinds of regulations it had and that sort of thing. Because independent of all of this, but probably if you went back far enough in time and looked as carefully as you could at what forces precipitated the Administrative Conference's review, there were forces moving to reform the way in which government conducted its affairs. In my view these were bipartisan initiatives. They were initially seen in the Congress. Initiatives like sunset legislation, as an example, freedom of information legislation, much of that growing out of Democratically controlled Congresses--this whole business of regulatory reform ultimately focused on the fact that there was probably too much regulation by government and that the regulations were frequently so complex that those persons subject to them couldn't possibly read through them and understand them and be expected to comply with them.

Here's FDA speeding headlong in a direction of being more complex, more extensive, more detailed, and everything that we did had to be at least a candidate for regulation. Meanwhile there were these forces moving along that were leading ultimately to initiatives to reduce the number of regulations. Somewhere, of course, all of this had to cross or collide. One of the best examples of this whole aspect of government and the way it conducts its affairs and how it impacted on FDA can be drawn from the initiatives undertaken as part of the agency's response to the finding of scientific fraud in the animal testing industry and clinical testing industry in developing data for presentation to FDA in support of new drug applications and that sort of thing, you know, of the mid-1970s--the bioresearch monitoring initiative.

Growing out of that initiative was a commitment on the part of FDA to write very extensive and precise regulations on how animal toxicology studies should be conducted, what the responsibilities are of the clinical investigator in clinical studies, of the sponsor of clinical studies, of the monitors of clinical studies. When you look at what has ultimately occurred--the Good Laboratory Practices regulations got out--this was in 1976 that it was undertaken, and they published a final in December 1979, two and a half years to finally get them in and out. But the ones dealing with the regulation of clinical studies never issued. If you went back to see how much time and energy was spent in writing drafts of those regulations, going up to the center director's level and/or bureau director's level, to general counsel's office, to commissioner's office, back, forward, back, up, forward. Thousands and thousands of hours. It had to be.

FL: Did it have a side effect, though, of clarifying people's thinking about these subjects?

JH: I think so, Fred. It was not all bad. Peter did the right thing; he did what had to be done and there probably was no one then or perhaps now who could have done it better. And also I talked about the pendulum being pushed way over to one side. Sometimes you have to do that. What you want to do, though, is look for the proper time to bring that pendulum back down to the mid point. Well, it just stuck over there and in a sense never got pulled back down until other things overcame that initiative.

I look at the regulation business and what happened to it generally within government and specifically within FDA from the time Peter came on board as general counsel in the early seventies to today, to this very moment, under this Republican administration. Nixon had undertaken an initiative in the executive branch with some executive orders; Mr. Ford had one; and then Mr. Carter had executive orders that focused on regulatory reform, the need to streamline the

regulation development process, to simplify the regulation process and simplify the regulations themselves. Each of those initiatives were undertaken principally as executive orders, but there are pieces of legislation: the Paperwork Reduction Act, and the act that protects the interests of small business . . . I'll tell you, the changes in the regulation development process are just tremendous in the way in which the whole thing is managed today. And not all bad.

First of all, I commented some time ago in this interview about the initiative to have appendices to regulations in the foods area. I came on as the associate commissioner in July of 1976, and I had hardly sat down in the chair that Sam had vacated when the phone started to ring and I was getting phone calls from unhappy bakers over the proposed bakery G.M.P.'s. I was forced immediately to look into that and see what it was all about. When I got into it I found out that Foods was already up to some forty-five different appendices that they envisioned being written and promulgated into regulations. Think of the repetition that would have to be inherent in that in the first place; but, secondly, to what extent do you have to tell people how to conduct their affairs? So I had already concluded by the 1977 AFDO meeting in Portland, Oregon, that that wasn't a very good thing to do, and one of the principal focuses of my speech at that time was that we were going to back away from that.

Think of that initiative. That was the way the FDA was being pushed, or at least saw that it ought to be going. And of course all of a sudden you had executive orders that were saying you can't promulgate a regulation except that you look at the economic impact. Under Mr. Carter you had to not only look at new regs, but go back and review all old regs and rewrite them if they were not clear in their language. Of course, Mr. Reagan's administration has been most effective of all in slowing down the whole process by making the internal process more bureaucratic.

So here's FDA swinging through that, and so it's no wonder, in a way, that you had by the late seventies tremendous regulations. By tremendous I mean in size: detailed, step-by-step kind of regulations directed at certain segments of the

regulated industry, hundreds and hundreds of pages long that had gone through rewrite after rewrite after rewrite. Then, all of a sudden, there was an initiative to begin to reduce the frequency of the promulgation of regulations. Other kinds of factors affected some of the regulations; you had a couple of commissioners who had been clinicians, which contributed to it as well. You'd say, "Enough! We're just flat out not going to publish these." So lots of resources were spent there. But there were other things like that, too, Fred. And we need to move along.

FL: Plus, of course, the problem that nobody ever addressed, that once you had the regulations written you were then responsible for revising them if there were technological or other reasons to change them, and that would be a never-ending task.

JH: Yes, and another thing that was a concern to a lot of us in the early seventies--but Peter felt strongly that our concerns were not well founded--we had concerns that if we wrote a lot of very detailed regulations focusing on very specialized aspects of the industries we regulated, that there would be every expectation by the public that we would have to be out there enforcing them--expectations by the Congress, as an example, or at least by the industry itself. And when we weren't, there would be expressions of concern and complaints. Peter's position was that for the most part people are willing to adhere to the rules if they know what the rules are. And so it was to the advantage of the agency, and ultimately to the consumer, to put those rules into place, even if you did not have the resources to actively and aggressively have programs enforcing all of them, because the majority of the industry would comply by nature. If they knew what the rules were they would comply with the rules.

I'm sure that's the case; I think the majority would have complied. The problem is the agency never got flack over what the majority of the industry was doing; they got flack over what individual companies or small segments of the

industry were doing or not doing, and flack over special-interest concerns on the part of the Congress particularly if we were not enforcing certain regulations that were on the books. And so I really think in the long term, although I suffered under the process a lot of the agonies and frustrations of Mr. Reagan's programs of regulatory reform, the long-term objectives and the way he went about it was more effective than any of those of Mr. Nixon, Ford, or Carter. I think in longer term that it was the right thing to do. We've already got eight or nine volumes of the CFR now, thirteen or fourteen hundred pages of regulations. And you have to say to yourself, "Are all of those necessary to make sure that the products we regulate are safe, effective, properly labeled and all those kinds of things?"

FL: Of course the other side of that argument that if you put regulations out, the majority will comply with them is that yes, they may, at least to begin with. But laws or regulations on the books that are not enforced soon are ignored.

JH: That's true also. The 55-mile speed limit, I think, is the best example of that. I think there are a lot of persons that didn't agree entirely with Peter's position on that. Clearly it's important to have regulations in place in very, very key issues; but we had really gone too far afield. As we think back through the seventies, there was a lot of time spent on initiatives that some felt were not very good uses of our time and resources.

After Dr. Edwards, then Dr. Schmidt came on board. He came into an organization where, under Edwards' leadership, the senior managers had begun to meet together, were drawn together periodically for staff meetings--by that I mean special staff meetings--to deal with specialized issues. Schmidt formalized that process and established the so-called Policy Board. I mean, it was Schmidt or someone close to him that coined the term Policy Board. He pushed it to the extreme. Talk about writing regs, we were literally going through regs page by page

by page as the Policy Board. All the administrative procedures regs we literally went through page by page by page.

But it was interesting: Edwards had initiated an organization that clearly could foster an independence of action among the various parts of the agency--by that, I mean, we have a commissioner saying to an individual, "You come in, be the director of the center," or at that time, the Bureau of Drugs, "and I want you to be the chief ~~drug~~ enforcement official of the Food and Drug Administration." What's that going to say to a person? A person's going to come in and say, "I'm the chief drug enforcement person in the Food and Drug Administration," right? "Now I'm not foods, and I'm not vet-med, and I'm not anything else. I'm drugs, and I really don't care about anything else. My focus is there and my concern is there." If you have that kind of an organization, it fosters an independence of thought.

You also had at that time individuals with rather diverse backgrounds. You had Virgil Wodicka from industry; Henry Simmons from the consulting industry. You had Hank Meyer in biologics from the traditional Public Health Service, but from the research community; he was a researcher. He had some very important findings of his own that he could take credit for in the area of biologics. You had John Vilforth out of the Public Health Service mode in the area of radiological health. You had Van Houweling principally out of industry. You had me as a career Food and Drugger. You had Sam Fine as a career Food and Drugger. Really everything was there for us to go our own ways.

Of course, for me in that time in the field having to deal with each one of those bureaus just really further emphasized the diversity of those individuals in their organizations. As much as we all moaned and groaned over having to sit around that table as the Policy Board, with Peter taking us word for word through the administrative procedural regulations, we learned to know one another and understand one another, and in a sense those regs gave us something to . . . We kind of banded together to try and overcome some of the kinds of things that were being done in

those regs. (Laughter) So in a sense it was a mechanism, to the extent that growing out of that was a group of persons who were willing to sit down and . . .

(Interruption)

JH: . . . tackle agency problems, and even though sometimes begrudgingly, commit to initiatives that were not necessarily ones that fostered their own organization's interest. I did see, in the time that Dr. Schmidt was commissioner, a coming together of the senior staff of the agency and a willingness to deal with agency issues as an agency, and I think to the betterment, ultimately, of the agency.

FL: It also gave the commissioner a tool to make sure that all of the centers or bureaus were headed in the direction he wanted the agency to go.

JH: Yes, absolutely. Mac Schmidt, I think, kind of missed his calling. He could have been probably the most outstanding stand-up comic that we've had in the country for many years. But that sense of humor carried over into those very difficult times. And under his leadership and management the policy board became an effective mechanism for managing the affairs of the agency.

Later in his term it was probably well that it had, because he became so personally involved, so personally concerned about the allegations of wrongdoing and mismanagement in drugs that grew out of Senator Ted Kennedy's hearings of 1974-75. He took those allegations personally. Mac Schmidt's an interesting man. He was commissioner, and as commissioner he literally personified in one individual the entire administration. An insult on the administration was a personal insult upon him. And there were charges of improprieties made by Senator Kennedy regarding the review of new drug applications on the one hand, not adequate review; or on the other hand greater influence by industry than there should have been, in whether or not a drug was approved; allegations of incompetence in the management--all of

those allegations. I remember that when they were brought out, I was sitting there at the hearing table along with the commissioner and along with others at the time . . .

But Dr. Schmidt didn't say, as I believe he should have and could have, "Mr. Chairman, if you don't know him, I want to introduce to you my principal management official on my staff, the associate commissioner for management and operations, Gerry Meyer. I am charging him today to undertake an inquiry into the allegations that have been made, and to come back to me within a certain reasonable time; I will tell you what those times are. I will share his findings and recommendations with you, and I will discuss them with you before I take any action." Then gone back to the agency, turned it over to Gerry, and said, "Get in there and find out what's happening." The interesting thing is, later Gerry got in there to find out what was happening ten years later.

But instead, Mac took all that on himself, and then said, "Gosh, what can I do? I've got to have somebody outside help me." So he went to the department, and you remember the secretary's committee was established. They came in and began to look at the agency. And Mac closeted himself literally; we lost him for a year or more as commissioner, effectively, in my opinion, while he personally wrote a response to many of those allegations. And you'll remember the response was several hundred pages printed. I hope one of those is in our historical archives, but otherwise, it was only him saying, "You charged me personally, and I have to personally respond to those allegations."

RP: Did his response go to the Congress?

JH: Oh, yes. Yes. Ultimately it was drafted and prepared formally as a response to the Congress. Those were difficult times as well.

I kind of got carried away in regards to why it was important that the policy board had learned to know one another and become an effective team in managing,

but it's because when Dr. Schmidt turned his attention to these allegations and therefore was not prepared to be involved in the day-to-day management of the agency, the Policy Board could move ahead and when necessary act as a body to conduct the affairs of the agency. They understood what the commissioner's policies were and what his expectations were, and we had learned to know one another, and we literally could move. And under Sherwin Gardner's leadership as deputy, we could effectively manage the organization. And the fact that Schmidt was not there, so to speak, day in and day out, really I don't think was ever necessarily realized except by those of us that reported directly to him and realized that he was closeted and so heavily involved in personally developing the response to the charges made about the agency's conduct of the new drug review process.

When Dr. Schmidt came on board as commissioner, many of the things that Dr. Edwards had put into place continued and were further strengthened under his leadership. But Mac was an entirely different kind of person than Charlie was and managed in an entirely different fashion as well. He was the first of the contemporary commissioners that came on board from the academic community, and came on board, it was later learned, under a two-year leave of absence. Of course, that immediately meant in his own thinking, in his own planning, that he would be there for two years to complete whatever initiatives he felt were appropriate for his term in office. This was significant later, and I'll make a comment about it in a few minutes.

But he was less disposed as commissioner to delegate authorities, and as a consequence the relationship, as an example, that had existed between Charlie Edwards and Sam Fine, where Sam would come to the commissioner, discuss a new regulatory initiative, a proposed regulation, or a final regulation as far as that's concerned, that Sam felt ought to be signed, met the agency's needs, established good policy . . . Sam would provide the commissioner with a very solid, thorough briefing. But frequently, then, Charlie, in lieu of reading the entire document, would sign it based on Sam's recommendation.

Mac would not do that. Mac instead would take the document and read the entire document, and in that reading was disposed to do a great deal of editorializing in it. By that I mean not so much word change as phrasing and punctuation and that sort of thing. As an example, when he left, one of the gifts he got was a whole jar full of commas (Laughter), because he frequently disagreed with the drafters, even after some considerable review, as to how the sentence or paragraph should be structured, and would insert additional commas and that sort of thing.

What it meant, though, was that a process that was rather lengthy and laborious already became even more so, because when you put a comparatively large document into the commissioner's office, directly into his immediate office, and then he had to look for time to read through it, and was not disposed to accept it in its structure, but rather to read it solely for substance, it would take quite a long time for those documents to turn around and come back out.

There was some frustration, then, as a consequence, on the part of those persons immediately below him and in the chain of regulation development, over how long it took for him to review those documents. And there were some instances where the issues were particularly controversial where I think Mac had some considerable difficulty coming to grips with just what was the most proper course of action. Kind of a wide range of kinds of issues. Remember the initiative to regulate the dumping of waste on the railroad tracks from passenger cars? That whole initiative took place during Dr. Schmidt's tour. Another was the iron in bread issue over the further fortification of bread with iron and whether or not that was an appropriate course of action.

I remember from the field standpoint, one of the things that occurred during Dr. Schmidt's tour, and a matter in which he took considerable interest and gave considerable support to the field, was the mushroom investigation. It was in a sense a follow-on to the Bon Vivant episode, and the greater interest in and involvement of the agency in the regulation of low-acid canned foods. As you'll remember, after having encountered a number of the small canners of mushrooms--and there were

some forty, forty-five of them clustered principally in Pennsylvania and Ohio, along in that area, and mostly all small--and on the basis of inspection finding a number that were not operating under good manufacturing practices, and finding a number of cans in the marketplace that exhibited inadequate processing, we became increasingly concerned over the quality of mushrooms generally in the marketplace. Then we began to look at all those coming in from Taiwan, as an example, as to whether or not they were adequately processed. And you'll recall that we undertook an initiative to examine all of the mushrooms then on the marketplace.

You recall the warehouse survey? That was no little task. It took special support from the commissioner in order to undertake that initiative. But he was highly supportive of it. And it seems to me in looking back at that episode, short of on the one hand requiring that all of the product come back off the marketplace, there was really no other alternative except to go out and see what it was like, and pass judgment on its quality, and decide whether those lots could remain there or not, or satisfy yourself through examination of additional lots that recalls should be undertaken.

That was a very, very difficult project because the firms were small and because they had not really been extensively regulated by FDA. They really didn't know how to react. And I remember any number of meetings with representatives of their small trade association, or with just groups of them that would come down to meet with us, they just didn't know what they had to do to get themselves into compliance. Then once they learned, they didn't have the capital to undertake the initiatives that had to be undertaken. Some were quite recalcitrant, on the other hand, and concluded that they had been canning mushrooms for an awfully long time without the benefit of FDA's oversight or involvement, and there was no reason why they should change now. We ultimately had to take regulatory action against several of them on several occasions before they either changed their procedures to be in compliance or decided to get out of the business.

But perhaps the thing that overshadowed any of the other matters that were going on at that time, particularly from the field standpoint, that occurred during Dr. Schmidt's term was the IBT episode, and that is the finding of the production of fraudulent scientific data by firms that were conducting animal safety tests, toxicology tests. I can't remember what IBT stands for now, but IBT was the big operation in Chicago. You'll remember there were some side aspects of that. Some of the investigators involved, both from headquarters and the field, were highly critical of the way in which the agency was conducting the investigation, and felt that we were not being aggressive enough perhaps. Although I don't know what more we could have done.

But they saw fit to bring to the attention of some of our critics on the Hill that things in their view were not being conducted in a way in which they felt they ought to be. There was a young inspector at the Chicago district and a toxicologist from headquarters who were particularly critical of the agency. Their complaints particularly to Mr. Ted Kennedy and members of his staff resulted in some several very, very difficult and acrimonious hearings before Senator Kennedy's oversight committee, in which these investigators described in great detail the inadequacies they were finding in these studies: dead rats that continued to have weights attributed to them or visible findings attributed to them weeks after they had died and that sort of thing.

The agency was criticized, I believe, unduly, because, after all, that was a dimension of science and of the industry that there had been no indication of wrongdoing, and in a sense, was always viewed as one step away, at least from my perspective, from the traditional regulatory responsibilities of the agency, notwithstanding the fact that those data ultimately appeared in new drug applications and food additive petitions, color additive petitions. The petitions were being submitted by responsible firms, that were regularly inspected, with certifications to the adequacy of those data. But the findings of wrongdoings in several of the firms led to considerable criticism of the agency in the way it conducted its affairs for having not

anticipated this kind of a problem and begun a much more aggressive program of inspection.

Ultimately, some good came of all of the badgering and belaboring of the agency by the Congress in this matter in that a special appropriation was passed to provide the agency with additional resources, both manpower and dollar resources, to undertake a much more extensive program of regular, frequent regulation of those firms that were in the business of producing scientific data that would ultimately be presented to the agency in support of a new product approval petition. It didn't make any difference whether those activities were taking place in the sponsoring firms themselves or in contract firms. The Congress expected that the agency would extend its regulation to all of them.

When the agency received those resources, it was concluded that the initiatives that should be undertaken should be undertaken as an agency, and there shouldn't be specialized good-laboratory-practices regulations for foods, and specialized good-laboratory-practices regulations for drugs, and so forth. And to the extent that clinicians should be regulated, it really didn't make any difference whether they were studying drugs or devices, as an example, or for that matter, animal drugs. The conduct of those studies should all be done under generally accepted, good clinical practices or good laboratory practices. So we established early in 1976 an agency-wide committee to begin the process of developing the regulations and the regulatory programs necessary to implement a new bioresearch monitoring initiative. And that included considering what were the responsibilities in each of the areas, dividing among the various bureaus their share of the new resources, those to be given to the field offices, and the recruitment efforts undertaken to recruit the new staff.

That was an interesting and challenging project, and it was initiated under Sam Fine's office. So that when Sam Fine retired at the end of June 1976, and Mac asked me to assume the responsibilities of that position, going into the new position of associate commissioner for compliance, as it was then know, it was one of the first major responsibilities I undertook: to manage the bioresearch monitoring project.

As I mentioned earlier today, really the good-laboratory-practices initiative was the only major initiative that came to fruition. The other initiatives to establish good clinical practices, ultimately the principles that were the most significant of all the number that were considered, were melted into the IND and NDA rewrites that were published.

FL: That's the revision of the regulations on investigational new drugs and new drug applications?

JH: Yes. I need to be more specific there, because what they became known as around the agency were the IND and NDA rewrites. Rewrite was really correct; they were written and rewritten and rewritten and rewritten, and then rewritten again. But basically they were a rewrite of existing regulations. And when the final regulations were published, both for the new drug approval regs and the investigation of new drug application regs, they did embody a number of the principles of good clinical practice that would have otherwise been part of any new individual regulations.

FL: That whole program was somewhat controversial since we were regulating a section of the industry that was not previously used to having been regulated.

JH: Absolutely, yes. Our authority was challenged early on. There was not unanimity within the agency itself as to whether or not we should be regulating science, and to what extent the regulation of science would interfere in the development of new products.

A good illustration of the differences of opinion that existed within the agency itself was that we ultimately concluded that, to the extent that the agency undertook studies on its own that would result in developing data that would either be used by the agency to counter applications submitted by the industry or to take initiatives to

withdraw approval of already approved drugs or food additives, that those studies should be conducted under good-laboratory practices as well. If they were animal studies, as an example. There was considerable resistance to that concept by some segments of the agency, particularly those segments of the agency whose activities through the years had bordered heavily on research themselves. As an example, the biologics program.

Furthermore, there ~~was great concern~~ over extending the regulatory concept to the academic community and considerable argument that we ought to have two levels of regulation, one that applied to industry--that is, those firms who made a business out of this kind of study--as contrasted to the university setting where, I guess, arguably their principal business was to educate, and it was only through grants and all to support other research initiatives that they were at all conducting these kinds of studies for the regulated industry. Ultimately, the arguments from within the agency in that regard did not prevail, and I think quite appropriately so, because clearly the universities were in the business of gaining funds through that mechanism, and there was no reason in the world they should not comply with the same requirements as any other laboratory conducting those kinds of businesses.

But there was another aspect of it: we really didn't know what constituted good practice, and we had to rely heavily on the industry to help us in that regard. Once it was clear to the industry they couldn't avoid regulation, then they concluded that if they were going to be regulated, then it was in their best interest that they step forward and assist us. There was at that time a trade association, National Association of Life Sciences, NALSI.

(Interruption)

JH: It was a trade association made up principally of contract laboratories, and had been established in the late 1960s, early 1970s as a means of bringing pressure on the NIH to direct some of its grant funds away from universities to the private

sector. But it had been in place, then, when this whole thing occurred. And the officers of that association stepped forward and were quite helpful in educating FDA as to what went on in those kinds of laboratory settings and assisting the agency in deciding what constituted good practice, or at least what constituted existing practice so that the agency could consider the extent to which their investigational findings in those labs that had been producing data fraudulently, how those ought to be changed or further monitored or regulated to prevent that kind of thing from occurring again.

RP: Did the National Institutes of Health have any input into our regulation?

JH: Not directly, but they had had for some several years a program of auditing laboratories that were candidates for grants. And they had, and still have, a set of criteria for the proper management of those kinds of laboratories. Now, the requirements were not nearly as extensive as what ultimately became the Good Laboratory Practices Regulations, but they focused, especially, as an example, on the care and treatment of animals, the adequacy of training of those persons who would be responsible for the conduct of studies; but the program was carried out in the concept of peer review. So the NIH would draw on persons from within the academic community to form teams to in turn go out and inspect and audit other universities. The agency in all honesty had some concern over how effective a program of that kind might be.

Meanwhile, there grew up an independent, nonprofit organization that certified laboratories for their ability to adequately manage and care for the animals themselves. And that particular organization and their program is still extant. But those regs, although the GLPs speak to the proper care and treatment of animals, those programs were more closely associated with the programs of the Department of Agriculture under the Animal Welfare Act.

But we did set up a working committee with the NIH, and met with them regularly and shared with them our drafts and asked for their input during the whole initiative. Because clearly we didn't want to come out with requirements that were in contradiction with what they had required along through the years. But there was some talk about whether or not the kind of program that the NIH had might substitute for or be the kind of program that we'd implement. Ultimately, of course, we opted for the more traditional FDA approach, and the whole concept of good laboratory practices really mimicked the concept of good manufacturing practices that grew out of the 1962 drug amendments. We chose the once-every-two-year cycle, and structured them along the same general format.

I think another interesting initiative that really was focused on principally during Dr. Schmidt's time--and it doesn't involve Dr. Schmidt so much as it just took place at that time--was the initiative to streamline the processes used by the federal government to purchase drugs, medical devices, and foods. What was occurring at that time was the Department of Defense, which purchased a lot of drugs and medical devices, had its own program. It had its own organization that developed standards for the products. It had its own organization that elicited and evaluated bids on contracts. As part of that organization they had inspectors that went out and inspected the companies that submitted the bids. In fact, in some instances, where the companies routinely got bids so that they were producing drugs for the Department of Defense regularly, they placed resident inspectors in those plants. The Public Health Service in their hospital system at that time was a large purchaser of drugs and medical devices, as is the Veterans Administration. Each of them had their own programs and their own inspectors, and a lot of their own standards.

The Office of Management and Budget asked the question, "If every day these same firms are producing drugs that are being sold broadly to the general public without any adverse effect, and those firms are being regulated by the Food and Drug Administration, why should that regulation not be sufficient to assure the Department of Defense and VA and Public Health Service that those products are

as satisfactory for their needs?" So they undertook a specific initiative to over time transfer the responsibilities for the inspection of competing firms for bids to the Food and Drug Administration, and the acceptance of products manufactured under contracts to the Food and Drug Administration.

That was a very traumatic time, not so much for FDA, but for the Department of Defense, VA, and the Public Health Service. The Public Health Service gave up the initiative rather easily, and I don't know whether that was because they concluded it was a pain in the neck for them and they were just as glad to get rid of it, or because they were part of the department and they were persuaded by the secretary and assistant secretary for Health that that was the proper thing to do.

But the Department of Defense and VA gave up that responsibility very, very grudgingly. It took a great deal of politicking on the part of FDA to move that whole program into FDA. There was a great deal of resistance, and that took the form of allegations on the part of the persons in those programs at DOD and VA, particularly DOD, that FDA's program was not an adequate program. Of course, some of the allegations, then, that arose--one as a consequence as I mentioned of the IBT episode, some of the concerns over the adequacy in the new drug approval process in the Bureau of Drugs--didn't add anything to FDA's ability to defend their capability to take on those initiatives. But OMB looked past all of those allegations and criticisms and said, "Look, if there are shortcomings at FDA, that's one thing. Let's correct those, but it still argues that there should be only one organization." So we worked very closely with OMB to achieve that.

There was some concern within the agency itself as to where that function should be placed, and ultimately it was placed, again, in the associate commissioner for compliance's office--Sam Fine's office--I think to satisfy on the one hand the concerns of the EDRO organization who thought they ought to have the responsibility, and the then Bureau of Devices who thought they ought to have the responsibility. So they said, "Well, it ought to be in one place only; therefore, we'll put it in the commissioner's office."

We had to learn to do some things as a consequence of it, because, although basically the argument put forward by OMB was correct that if we were satisfied that those drugs were satisfactory for general distribution they ought to be satisfactory for use in government hospitals and for defense, there were some special needs, especially in the Department of Defense for stability and packaging and that sort of thing. And there are just the requirements of the purchase system in the federal government. There are certain criteria, whether you're buying rubber bands or drugs. We had to set up procedures to satisfy those procedures as far as certifying the products that, first of all, competitors were capable of meeting the requirements of the proposed contract, and then once a company got the contract, satisfying the government that the products being delivered met the contract specifications.

I think we did a good job of that, and of course that program for drugs and devices is still in place. But I think it over time has become increasingly more routine, and increasingly the day-in-and-day-out activities of FDA in regards to assuring quality of drugs and devices has taken the place for any specialized procedures set up to meet Defense Department and Veterans Administration requirements.

One of the longest periods of time, at least in my experience, between commissioners occurred between the time Dr. Schmidt left and the time that Dr. Donald Kennedy came on board. That was principally because, I suspect, an election took place during that period of time, and there was a change of parties in the White House. So it was clear that there would be a general change of persons such as the commissioner effective the next January at the time of the inauguration of Mr. Carter. The importance of that is that I want to talk a little bit about the person that was deputy commissioner at the time and acted as commissioner during that period. That person was Sherwin Gardner.

Sherwin was an engineer by training, and had been a senior consultant at Booz, Allen & Hamilton at the time Charlie Edwards was appointed commissioner. Although Charlie never said so openly, the stories around the hall were at the time

Charlie came on board that Sherwin would have been his choice as deputy commissioner, but that the White House and the department played an active role in the selection of the deputy commissioner, and Jim Grant received that appointment.

Meanwhile, Charlie brought Sherwin in to be the assistant commissioner for planning and evaluation. And Sherwin did a very good job in that position. Maybe too good a job sometimes, as I think back, Bob, because remember he was adamant as to what was a staff role and what was a line role. You and I would get frustrated occasionally over the opportunities we thought that he might have as the assistant commissioner for planning and evaluation to assist the EDRO organization in dealing with the bureaus in the planning process. He was reluctant to step in and assume a more authoritative role because he was, after all, staff and not line.

RP: But he did bring kind of a solid and more methodical, and really more intelligent, approach to our planning, I think. I worked with him quite closely during the period he had that job, and I found that he was easy to work with and sensible.

JH: Absolutely.

RP: And you don't always find people in that business very sensible.

JH: Well, perhaps not very pragmatic. I agree with you whole-heartedly. A great deal of pragmatism is necessary in planning, especially in government, I think we all agree. There had not necessarily been that pragmatism in that particular office, at least beginning with the appointment of Ed Turk in 1966 under Dr. Goddard. Sherwin did bring a great deal of stability and substance to that job; and within his own realm, where it was important that he did make decisions, he would make decisions. They were good ones and based on thoughtful analysis of alternatives.

This is all important because what I'm leading to, and Bob's comments add to, is that within a year of Jim Grant's appointment, he accepted an opportunity to go with CPC International and left the agency; and Charlie took that opportunity to appoint Sherwin as the deputy commissioner.

They made a good team, because literally overnight, in a sense, Sherwin--and the reason I emphasized his strong feelings about roles--became line. He took off the staff hat and put ~~on the line hat, and~~ took over the job of deputy commissioner and the role of assisting the commissioner in the day-to-day management of the organization. He did a very good job, and you could rely on Sherwin to make decisions. That was one of the great things that I felt about Sherwin and continue to feel about him. That was not always true about some of the commissioners or other people within the agency. You didn't always necessarily agree with his decisions, but that was not as important as the fact that a decision was made and you knew what you had to do in order to carry out those decisions. And the agency went forward.

Well, Sherwin, then, acted as commissioner the brief time between Edwards and Schmidt, but that was, in my remembrance, not a very long period of time. But after Schmidt left, and before Don Kennedy came on board, because you had a change of governments, was a longer period of time, and Sherwin was acting commissioner and did a very, very good job.

As far as the agency was concerned, its whole operations didn't skip a beat after Schmidt left and when Sherwin assumed the reins. The fact is, as I had mentioned earlier, those last number of months of Dr. Schmidt's tenure as commissioner--and he went back and got special dispensation from the university to spend an additional year; so he was commissioner for three years . . . And that third year he was so heavily involved in responding to the Senate's criticisms--that is, Schmidt was--that Sherwin literally was doing a great deal of the day-to-day management, and he just kept on doing that during that period or time when he was acting commissioner. He did it very well. When Don Kennedy came in as

commissioner as part of the Carter administration, he had real distrust, I think inherent, of the bureaucracy first, and of political appointees second, or those who had been appointed by political appointees. At the time, the commissioner had become a Schedule C, but I don't think at that time yet the deputy was Schedule C. Had it been, Sherwin would have had to tender his resignation, and it would have been accepted, and he would have been out.

FL: Schedule C are those government employees who are political appointees?

JH: Yes, political employees serving at the pleasure of the president. Even though there were a number of changes when Kennedy came on board, particularly in the persons that were in Kennedy's inner circle, he did not change the deputy commissioner; he saw in Sherwin the solid kind of support that anyone new coming into that position should have.

(Interruption)

RP: This is a continuation of the recorded interview with Joseph P. Hile. The date is August 5, 1988. Paul, if you just want to go right ahead from where you were last night, that would be great.

JH: I had been talking last night about Sherwin Gardner. Really I wanted just to introduce Sherwin into our discussion because he was, in my opinion, one of the best deputy commissioners that we had during that period of time. I want to come back to Sherwin again later in our discussions today. But let me begin to talk about the period of time that Don Kennedy was commissioner and some of the kinds of things that occurred during that period.

You'll both remember that Mr. Carter came into the presidency running, at least in my view, on a very strong anti-federal-government platform. As he came into

the White House, he brought in around him a number of persons who had not had extensive experience at Washington-level politics. That same approach was used by many of his appointees, including Dr. Kennedy. When Dr. Kennedy came into the position of commissioner, he brought with him an apparent concern--and I'm reluctant to use the word "distrust," but perhaps there's not a better term for the present time--of the persons who had been in positions of responsibility within the federal government and within the Food and Drug Administration prior to the Carter administration. Although he did not make major changes in the senior staff of the agency, he did bring into his immediate office several persons of his own selection who brought, from our perspective, the same general perceptions that carried through the Carter administration as a whole. I'd be less than candid if I didn't say that there was some concern on the part of many of us as to what that change might bring.

It brought a number of changes, some reflective of the broader goals of the administration, and others that were, I think, typical of the way in which Dr. Kennedy managed his own affairs and his own office. By that I mean, you'll recall that this was the post-Nixon era; there was still a major concern over the possibility of wrongdoing within government. And of course, for FDA that frequently translates into too cozy a relationship with the industries that we regulate. So one of the early initiatives of Dr. Kennedy was to establish some announced, formalized policies on how the Food and Drug Administration would interact with the regulated industries. They were much, much more conservative--not in a political sense, but in the sense of allowing for interaction between government and industry--than had been the policies leading up to that time. I don't want to convey in any way that FDA in my opinion was ever an organization, at least in contemporary times, that was overly friendly with and involved itself more extensively with industry than it should in carrying out its responsibilities.

But certainly there was interaction between FDA and firms, particularly in the new product development area. That was, I think, the principal focus of Dr. Kennedy's new initiatives. There was a great deal more formalization about the

process. Much of the initiative required the reduction of every contact to writing. There was an effort to expand the requirement that contacts be made part of the public calendar of the agency. Just an entire atmosphere of aloofness. And for some persons, whose whole program initiative was in a sense to enhance industry relationships, not necessarily directly with individual firms, but through trade associations and professional associations, really were caught in the middle. They didn't know whether to continue those kinds of activities--as an example, the Food and Drug Law Institute, or the Proprietary Association, or the PMA or GMA--or whether to step back and be as aloof as the individual reviewers and individual compliance officers were being required to be under the new policies.

That whole kind of an atmosphere prevailed for some number of months in the agency, and it seemed to me that perhaps if not purposely on the part of Dr. Kennedy, the outcome was that some of us who had been intimately involved in the decision-making of the agency and in the inner circles of the commissioner's office found ourselves kind of standing outside in the hallway, being asked to come in under some circumstances but not necessarily others. That may not be a fair characterization of Dr. Kennedy's viewpoint, but clearly many who had been around a while sensed that in those early months particularly.

Dr. Kennedy was an interesting person. He was an excellent scientist and I think a very capable man in the management of science. Certainly that's been reflective in his responsibilities following his tenure as commissioner. He also was a person who was anxious to learn the business early on and in its full dimension. He would take every opportunity possible to gain an insight into the legal side of the business as well, and frequently would go down to the lunch room in the basement of the Parklawn Building, where many of us were eating at that time, before the cafeteria gained such a bad reputation, and would have his lunch in the cafeteria there and sit with the attorneys from the general counsel's office. He would talk with them about the law and talk about the issues to gain an insight into their viewpoint on matters.

(Interruption)

JH: Dr. Kennedy appointed as a special assistant to him within his own immediate office, an attorney from the general counsel's office so that he, I believe, could have available to him regularly the kinds of insights and the kinds of reactions to issues that he gained through his luncheon meetings. The first person to fill that position was a young man named Stuart Pape. Stuart was ~~a bright~~ young ~~attorney~~ who had been assigned to work with the Bureau of Foods on foods issues, and as a consequence had opportunity to work directly with Dr. Kennedy early in the commissioner's tenure in the office by virtue of the nitrate-nitrite episodes and the saccharin issues.

The interesting thing is that all subsequent commissioners have continued to have a position similar to that filled by an attorney from the general counsel's office. Although one might have concluded that it would raise concerns between the general counsel's office and the commissioner's office, by virtue I think of the commissioner's counseling with the chief counsel and selecting someone that was not only satisfactory to the commissioner but also the general counsel, the relationship between the commissioner's office and general counsel's office was not compromised.

A number of things occurred in addition to this initiative during the Kennedy administration. It seems to me in looking back over that period of time from 1966 forward that Dr. Kennedy brought into that position a much closer personal relationship between himself and the secretary than had existed before. It might be that I had not necessarily observed that, and that clearly could have been the case; but on the other hand, in subsequent administrations I had opportunity to see that close relationship and participate in activities that involved the secretary. But there was from the very beginning a very close personal relationship, at least apparently, in day-to-day business relationship between Dr. Kennedy and Secretary Califano. I am not implying a personal friendship, but I am talking about a business kind of personal relationship.

It was clear, I believe, that there was a decision made that there would be some very special kinds of initiatives undertaken as part of this new administration to demonstrate their commitment to furthering and strengthening the Food and Drug program. One of those initiatives that they selected was to work with Senator Ted Kennedy and his committee to develop proposed amendments to the drug sections of the Food, Drug, and Cosmetic Act.

In a sense, I see this as an extension of the criticisms that had been raised about the agency's handling of the new drug approval process during 1975-1976 when Dr. Schmidt was commissioner. I mentioned only briefly the fact that Dr. Schmidt had recommended, as a means of assisting the FDA in solving those problems, the establishment by the secretary of a review committee to look at the agency, to look at how the new drug approval process had been managed, to make recommendations about that process as to how it could be improved. The Congress undertook some similar kinds of initiatives and had some committees looking at the process as well. Growing out of both of those initiatives were concerns over, not only problems associated with industry-FDA relationships in the new drug approval process, but also whether or not the process was being responsive to the public health needs of the general public.

By that I mean that for the first time, really, there began to emerge the major criticisms of FDA for contributing to what has become known as "drug lag." The argument was that there was great support on the one hand for thorough, complete review of new drug applications and a need for a complete objective evaluation by the agency not influenced at all by too close an interaction between the agency and the petitioner. There also had to be a process in place that would assure as timely a review as possible, and approval of those applications that merited approval as quickly as possible, to assure that new therapies reached the marketplace. There was some very strong criticisms raised by both the committee that reported to the secretary and the committee that reported to the oversight committees in Congress.

As a consequence, Mr. Kennedy saw from his standpoint an opportunity to propose some amendments to the Food, Drug, and Cosmetic Act. And because there was harmony at least politically between the Congress and the administration at that time, Mr. Califano and Dr. Kennedy seized upon that opportunity as well to provide from the administration's standpoint legislation that they believed was reasonable and appropriate to streamline on the one hand the new drug approval process, and on the ~~other hand strengt~~hen those processes that had been seen as inadequate, in Mr. Kennedy's eyes, in protecting the public's interest.

A major initiative, then, was undertaken within the FDA itself to draft specific language to be forwarded as an administration legislative initiative to the Congress to amend the Food, Drug, and Cosmetic Act, the drug sections of the act. Dr. Kennedy brought into his office for this initiative a young attorney by the name of Bill Vodera. Bill had been active, to the extent necessary and appropriate, in drug affairs, similar as I mentioned earlier to Stu Pape. He had been assigned to the Bureau of Drugs and had been quite open and vocal about his feelings in regards to the opportunity to improve the process and to streamline and update those sections of the act. I think those kinds of attitudes probably emerged and became known to the commissioner in the course of his luncheon meetings with the attorneys from the general counsel's office.

Bill became the principal architect of the specific language and it reflected, I'm certain, the personal views of Dr. Kennedy, personal views of Mr. Califano, and others who were close to the commissioner and who had been appointed into the commissioner's office, when he assumed the role as commissioner.

FL: That is, from outside FDA.

JH: Yes, thanks Fred. From outside FDA. What occurred as a consequence is that emerging from this team of writers, which was, from our viewpoint, within the commissioner's office, was any number of drafts of language for the various parts of

the legislative proposal. These were given to the other offices: given to the Bureau of Drugs, given to the general counsel's office, given to the associate commissioner for medical affairs, associate commissioner for regulatory affairs, to the EDRO organization, all in form for comment--and, just an aside, with very short turnaround time. So that when that initiative was undertaken within the agency, in all of the involved offices there were literally hundreds of person hours applied on a very crash basis to receive the drafts, respond to the drafts, make suggestions as to how the language might be modified.

The principal focus was to try to streamline the new drug approval process on the one hand and allow for a more timely review leading to earlier introduction into the marketplace of safe and effective and valuable new therapies, while on the other hand not allowing for any compromise of safety or efficacy as a consequence of that streamlining. That's not an easy task, and at least from the viewpoint of some, those are not necessarily compatible objectives.

But many of the concepts that arose during that initiative, although never becoming law, were later used in the drafting of the revision of procedures in the new drug approval regulations. I'm not sure it's useful to go into all of the concepts that were embodied in that legislation right now. My hopes are that copies of that legislative initiative are available.

For the first time you had emerging opportunities for greater flexibility in the conduct of clinical trials, greater flexibility in deciding the amount of data that would come before the agency routinely for review, and suggestions on how the NDA itself would be structured to facilitate review. All of these kinds of ideas, as I say, later emerged as part of the rewrite of the regulations.

So one can conclude that perhaps the whole initiative was not in vain, but it was a terribly, terribly costly initiative at the time. And whether or not the timing was as critical as everyone concluded it was or not, I don't know. It was very, very demanding, and all of us that were not participating in the initial drafting came away feeling as though we were being dragged along by the process, that we really didn't

have adequate time to think through and respond to the suggested changes. In all candor, many of us felt that the policies that were emerging as part of this new initiative had been decided upon beforehand and were being written into legislative language, and the opportunity for comment was only pro forma. Whether that was true or not, I don't know. But that was the perception that most all of us had that were on the outside of that initiative.

FL: That is, the people who had had experience in administering the drug sections before.

JH: Yes. That included persons like John Jennings, M.D., who had held senior positions in the Bureau of Drugs and had been the director of the Bureau of Drugs and at that time was the associate commissioner for medical affairs. I don't think it's unfair to characterize John's feelings in that regard. They certainly were my feelings, and I feel confident they were the feelings of my colleagues in the EDRO organization at the time. Things were moving just too rapidly and you did not see, necessarily, the changes, that were being suggested as a consequence of the review, incorporated into the final language of the legislative proposal. And you did not necessarily have feedback as to why your suggestions were not being accepted. We were not unmindful of the time frame that had been set by the administration to develop this legislative initiative on the one hand, but on the other hand there was not a good rapport or feedback or relationship between the drafters on the one hand and the reviewers on the other.

Let me just make a few specific comments about the legislative initiative, even though we could spend an entire session talking about the particulars of it. It did propose new administrative procedures on the part of the agency on the registration of firms, and on the registration of drugs. These were paperwork initiatives that would have been a real burden to FDA to maintain. They were a reflection of the

Carter administration's reaction to the allegations made earlier of interaction and relationships that existed between the industry and FDA.

This effort was once seen as an opportunity to focus on and improve the new drug approval procedures. If it had stayed within that very narrow confine, it would have been all right, but they began to expand it well beyond that. We got into big discussions over whether or not we should attempt to exclude or refine, or attempt to be much more definitive about the Homeopathic Pharmacopeia. Although we can step back and be amused about that a little bit, that particular issue took hours and hours of debate and discussion. One issue was what would happen politically if we wrote out recognition of the Homeopathic Pharmacopeia. On the other hand, should we attempt to build into the legislation language that would require the pharmacopeia to be more regularly updated, to be more reflective of homeopathic medicines of today? There was considerable debate over that issue alone.

Also they began to get into the business of administrative sanctions. The concern was over removing from the marketplace an approved drug and removing an approval. They got into a lot of discussion over imminent hazard and the procedures; a lot of discussion over recall. Legislation to change the administrative process had been coming forward from the Congress from time to time after the Park case in the early seventies which had confirmed the strict criminal liability doctrine inherent in the Food, Drug, and Cosmetic Act. These legislative initiatives were attempts to compromise the strict criminal liability doctrine as a trade-off for providing FDA with greater administrative powers to levy fines, to administratively require recall and those kinds of enforcement sanctions. The drug legislation developed by the administration included some of these kinds of trade-offs.

Ultimately, as you two will recall, as part of this process there was a hearing held at the Parklawn Building by Mr. Kennedy--this was later in the process--at which representatives of the agency had an opportunity to testify about various sections of this new legislative initiative. A number of the reviewers in the bureau testified in opposition to initiatives that they saw would have limited the amount of data that

came to them for review as a part of streamlining the process and making the initial NDA submission less voluminous. A group of regional Food and Drug directors testified in regards to their strong opposition to the compromise of the strict criminal liability doctrine.

FL: Maurice Kinslow, the regional Food and Drug director at Atlanta, testified representing all the other directors.

JH: The legislation finally went forward, but not as a strongly, aggressively supported legislative initiative of the administration, because meanwhile, Mr. Kennedy was developing his own piece of legislation. He was being provided all along, to the best of my knowledge, with knowledge and acquiescence of the administration with draft language that was being prepared in the agency. Although the legislation was acted upon and passed by the Senate, there was no action or consideration of it in the House, and the whole initiative died away. One has to speculate upon the amount of true support and interest that really existed within the Congress for such an initiative outside Mr. Kennedy's own personal interest as chairman of our oversight committee in the Senate.

As I mentioned, however, a lot of the concepts for streamlining the new drug approval process were not lost and ultimately gained what I'll characterize as bipartisan support within the Food and Drug Administration at the commissioner office level. Meanwhile, the agency continued to be criticized seriously over contributing to drug lag. There were those within the industry and those within the Congress that had very strong feelings that the process as originally designed in the legislation, or at least the way in which it was being administered by the agency, contributed to the delay of useful, valuable new therapies reaching the public here in the United States. Those were very serious allegations, and subsequent commissioners to Dr. Kennedy saw them as serious allegations and attempted to be responsive to those criticisms.

I don't think I'll go into greater detail about this now except that it comes up later, I think, in initiatives taken by Dr. Hayes and Dr. Young. But I want to emphasize that it was seized upon as a major challenge, focused on as a major initiative, and a tremendous amount of the agency's resource was put into this particular effort. I'm not sure that there was a great deal of planning and thoughtful consideration beforehand as much as "Here we are; it's appropriate for us to have some major new initiatives. What can some of those be that are particularly visible on behalf of this administration?" I don't want to seem overly critical; it's just that there was a tremendous adverse impact on the agency as a whole.

A second initiative undertaken by Dr. Kennedy was one to finalize the food-labeling program undertaken in the early 1970s as a consequence of the White House Conference on Nutrition and Health. FDA had started a number of actions in the early 1970s that led to nutritional labeling as an example, but the whole process had kind of bogged down. It was a victim in a sense of the approaches I discussed earlier when I was discussing how Peter Hutt had moved the agency to an agency where all its policy initiatives were candidates for regulation making, where almost overnight massive new regulation development processes were undertaken. As you looked at the regulatory initiatives of the Bureau of Foods, you saw a number of individual labeling proposals to assist consumers, at least in the view of the administration, in buying foods so they could be assured of more balanced and nutritional diets. Those had been started with proposals, but there was never any action taken to finalize them. There were probably fifteen or twenty, if we were to go back and count them.

The Carter administration itself had very strong commitments to furthering initiatives that they felt contributed to the consumer's interest. Those were meritorious, and I don't mean to imply otherwise. They had appointed, as an example, one of the USDA assistant secretaries to oversee this activity.

(Interruption)

JH: They had appointed Carol Tucker Foreman to the position, and Mrs. Foreman was an outspoken advocate of consumer interests. As a consequence, Dr. Kennedy joined Mrs. Foreman, the Federal Trade Commission, and the Food Safety and Inspection Service in the Department of Agriculture to undertake a three-agency effort to finalize this major initiative to change the food-labeling requirements of the federal government. It involved some very controversial initiatives that were begun at that time, ~~like cholesterol labeling~~, fat labeling, concern over sugar and its contribution, whether it contributed to or detracted from good nutrition. It also involved net weight requirements.

You'll remember there had been major litigation brought by the state of California against Rath Packing Co., ultimately joined by the Department of Agriculture, over the net weight of packaged bacon. Without going into detail on the Rath case, finally because of the preemptive language of the Meat Inspection Act, the state's position did not prevail. The state was very, very unhappy over the policies of the federal government, and particularly in that instance the Food, Safety, and Inspection Service that provided for a certain amount of moisture at the time of packaging but did not require that the moisture level persist through the entire retail merchandising period. And so when the product was purchased, the package could weigh considerably less than, say, one pound. There was concern over whether the amount of moisture and the amount of loss of moisture was reasonable or not.

Well, we in FDA had a number of informal policies on products like flour. We were willing to accept the fact that flour under normal milling conditions would have a certain amount of moisture, and then if it was marketed in Arizona as compared to New York, the amount of moisture loss would be different, and the net weight could be considerably less at the time of the sale. We did not object if at the time of packaging the amount of moisture was reasonable and the moisture loss could be accounted for by normal exposure conditions of marketing.

So we not only looked back with an attempt to update and finalize the number of nutritional kinds of initiatives that had been started in the early seventies,

but had been languishing because of their scientific complexities, but also undertook some new initiatives to try and resolve food-labeling issues that had been raised in the intervening time, as a consequence, in this instance, of action taken by the state of California.

One of the approaches that was decided upon so that the administration could clearly argue that its policies reflected the concern of the public was to conduct a number of public meetings across the country in which these issues were discussed. So a joint effort was undertaken to schedule these public meetings, to advertise that the meetings were going to be held, to get information out beforehand to organizations that were known to have interest, to hold these meetings, to record the proceedings, and then to have available those proceedings as inputs into the rule making.

The initiative was no less complex than the one to amend the drug provisions of the act. And just as that effort became so wide-ranging, as to encompass such a wide number of issues beyond just improving the new drug approval procedures, that in a sense it just died of its own weight. This whole initiative came to a grinding halt, again, because of its own weight.

Had they looked at one or two of the most significant kinds of issues--let's say cholesterol labeling--and undertaken an initiative to solve the scientific issues attendant to that, and finalized a regulation that provided the public with greater insight into the merits of a product and its contribution to a reduction of cholesterol intake or whatever, they might well have been able to achieve that. But as you look back, very little was achieved, and the important regulations such as cholesterol labeling are still within the process, and the entire net weight issue, as an example, finally just died. They found it's a much more complex issue than they believed.

The reason these initiatives were as wide-ranging as they were to begin with, and ultimately failed and collapsed of their own weight, was a reflection of what in my opinion was a characteristic of the Carter administration in its totality, and that was they were so strongly in support of a major change in the way in which the

federal government did its business, that they felt that the only way that could come about was to bring persons in who were never tainted by having been part of the federal government system. And so they had a bunch of people who knew nothing about the federal process, knew nothing about the technical aspects of what they were dealing with. So from the very beginning it was doomed to failure.

We were busy during those first number of months in the Kennedy administration doing a great deal of work intended to amend the drug provisions of the act and complete the labeling initiatives undertaken by the FDA in the early 1970s to improve food labeling. But the way in which it was attacked, there was a great flurry of paperwork to support commitment to change and a commitment to achieve the goals. But in the end, nothing much came of either of those initiatives.

As I look at the Kennedy administration, that is the Donald Kennedy administration as commissioner, certain things emerged as a real benefit, but none of those point back to the two major initiatives that were not only the commissioner's initiatives but were the administration's FDA initiatives. For the first time, one could see a very close relationship between the administration and the commissioner, and between the secretary and the commissioner.

Kennedy has been perhaps the most eloquent spokesman for the Food and Drug Administration that the agency has had, at least in contemporary times. Persons who knew George Larrick well--and Fred, you can please interject here--but knew him when he was at his prime as commissioner of the Food and Drug Administration, attribute to him great abilities in his working with the Congress and his ability to convey the concerns of and the objectives of the Food and Drug Administration. He was very, very effective in interacting with the Congress. But in more contemporary times, and I'll say beginning with Goddard and ending through now, with Dr. Young, of all of those commissioners, ones that I knew best in my own career, Kennedy was the most eloquent and most effective spokesman. I have to credit him for that. He did the agency a great deal of good in his ability to represent

the agency's interests before the Congress, before the public generally, before the executive branch--a very, very eloquent and effective spokesman.

Let me expand on the contribution that his eloquence made, because a person can be an eloquent speaker but not necessarily contribute to the welfare of an organization like FDA. Again we have to go back to what had occurred to the agency in the middle seventies, the allegations that there were relationships occurring ~~within the new~~ drug approval process between the reviewers and the industry. Things were occurring where the public did not understand, did not know why new drugs were being approved, did not have an insight into the way in which the agency conducted its affairs. And notwithstanding Peter Hutt's initiative to open up the agency by virtue of having all of our procedures codified in the CFR and those kinds of things, those allegations were made. And, of course, the Carter administration as a whole came in with a goal to open up government. And some of the kinds of wider, broader federal activities in the area of paperwork control and that sort of thing occurred in Mr. Carter's administration.

But Dr. Kennedy undertook an initiative to explain to the public what our concerns were: segments of the public such as the consumers, the medical profession, others whose day-to-day lives are impacted upon by the activities of FDA. It was during this period of time when the summary basis of approval was really put into effect in the new drug approval and new device approval procedures, where there is on the public record at the time a new drug is approved a written summary of the basis on which the agency reached a decision that the drug should be approved.

Many of those kinds of things didn't exist before. And Dr. Kennedy was very, very effective. He was very, very effective in conveying the problems of the agency, the concerns of the agency, the objectives of the agency to the segments of the public. He contributed effectively to opening up the agency to scrutiny, to providing mechanisms by which decisions within the agency could be made public. There was an initiative on the part of the commissioner of the Food and Drug Administration

to convey regularly what the agency was doing and why they were doing it, and to assure all of these various segments of the public that their interests would be considered in the activities of the administration.

A couple other things occurred during Dr. Kennedy's term as commissioner. He undertook a study principally of the commissioner's office, with the goal of streamlining and improving that activity as well. And there were some changes recommended by a committee that he appointed ~~that certain program~~ activities be reassigned within the office of commissioner.

I raise this principally in that here again the way in which that was managed was a reflection of the concern of the Carter administration and its appointees over how the federal government had been conducting its affairs. They were concerned over the extent to which those who had been conducting the activities could be embraced and brought into initiatives for change. In this instance, the commissioner appointed a committee composed principally of persons who were not long-term FDA employees to look at the office of commissioner, and to evaluate what the activities of the various offices within that organizational structure were doing, and to make recommendations for change. This was all done pretty much in secret. You knew they were out there; you knew what their objectives were; but you had no sense of what their conclusions were or what their recommendations were going to be until the conclusions were announced and the commissioner's decisions announced.

Ultimately none of the changes were overly dramatic; none of them were unreasonable. But again it was a situation where those of us who had been part of the decision-making process within the commissioner's office felt kind of an exclusion from what was happening. Here again, I'm not personalizing this to Dr. Kennedy as much as I'm reflecting it as an extension of the Carter administration. But notwithstanding that, I don't think it contributed to a feeling of strong support or commitment on the part of a lot of people to what was going on and the changes that were being suggested.

As an example in my own office, the recommendation was that the title be changed from the Office of Compliance and the association commissioner for compliance to the Office of Regulatory Affairs and the associate commissioner for regulatory affairs. The recommendation to transfer to the EDRO the program that I mentioned earlier to manage the interaction between the Defense Department, the Veterans Administration, and the Public Health Service hospitals and other government agencies and departments that were buying drugs ~~and devices--it should~~ not have been part of the commissioner's office. No one can really argue that.

The freedom of information activity, which had been part of the Office of Compliance, and by the way a real pain in my side because I couldn't seem to gain any support for expanding the staff there, was transferred to the associate commissioner for public affairs office. I, in all candor, was not reluctant to see it go.

Another recommendation was that the hearing clerk's office be transferred from the Office of Compliance to the Office of Management and Operations. The hearing clerk's office was the office in which all of the regulations were put on public display, and all of the petitions coming to the agency were put on display. Literally, it is a function of rule making; it is a function of policy making. And in my opinion, it didn't make any sense to transfer that to the Office of Management and Operations. And really I never did understand, and it was never explained why that recommendation was made and those changes implemented.

I guess I just want to emphasize that, again, this was a reflection of what I'll attribute more broadly to the Carter administration, of excluding from some of the decision making, particularly as it related to how the federal government conducted its affairs, those who had been intimately involved in conducting the government's business prior to the time Mr. Carter was elected as president. I don't want to overemphasize this; it's just that I can't avoid reflecting how, at least in my own opinion, it impacted on the way in which things were carried out within FDA itself.

Dr. Kennedy left about two years after his appointment. Again, he was from the academic community and his original leave of absence was probably about two

years. So he began to look at opportunities for him to return to the academic field as the two-year term began to draw to a close. For those of us who know the federal system, you could attribute the failure of those two major earlier initiatives that I characterized to the two-year term of Dr. Kennedy, because the kinds of things he undertook clearly could not have been completed in two years. They were much longer-term initiatives.

Here ~~again, though, after~~ Dr. Kennedy left and before a permanent commissioner was appointed, Sherwin Gardner, as deputy, assumed the role of acting commissioner. In this instance, Sherwin had been acting commissioner between Charlie Edwards and Mac Schmidt, and between Mac Schmidt and Don Kennedy, and now was again acting commissioner between Don Kennedy and a new appointee. From my own viewpoint, here's a person who had been very, very effective in managing the affairs of the agency on several occasions, his capabilities were proven, and yet apparently he had not been actively considered for the position. It appeared to me he actively campaigned, in this instance, for the position of commissioner. And in my own opinion, he would have made a very good commissioner. Perhaps unhappily, he didn't have some of the academic qualifications that had begun to emerge for the commissioner of Food and Drug--that is a doctorate in a scientific field, either a Ph.D. or an M.D. And perhaps that is now seen as a very important criterion for the position of commissioner of Food and Drugs.

But whatever the reason, during that period of time, the agency performed very effectively in my opinion. Nobody in an acting capacity ever feels comfortable in undertaking major initiatives during that period of time, but certainly the agency continued to quite effectively conduct its affairs. But ultimately Sherwin was not selected, and I think that contributed to his decision to leave the agency.

The person who was selected and came into the office was Jere Goyan. Where Dr. Kennedy had been a Ph.D. in the biological sciences, Dr. Goyan had a Ph.D. in pharmacy. He had come in from holding the position of dean of the school of pharmacy at the University of California at San Francisco. Dr. Goyan came into

the position about nine months before the election. And anyone coming into the position like the commissioner's job, a politically appointed position, that close to an election runs some risk as to whether or not the position will be long term.

I never talked with Jere in regards to what his own personal feelings were about coming into the position at that time. Later I had extensive conversations with Frank Young about his coming in much closer to election time and gained an insight into his personal views. But I really can't contribute in this interview to what Jere Goyan's attitudes were in that regard, except that at the breakfast that we had honoring him at the time he left the job of commissioner, at the end of January of 1981, he quoted someone--and it was not his own phrase; he didn't say that it was; but I thought it was very clever and quite appropriate for him--that he was one of the few people that had both come into the job of commissioner and left the job "fired with enthusiasm."

I think he was fired with enthusiasm, but the Goyan term as commissioner was an interesting one. Because about the same time that Dr. Kennedy left as commissioner, Rich Cooper left as general counsel, and Joe Califano left as secretary. So at that time, you had a change in secretary from Mr. Califano to Mrs. Patricia Harris, and you had an appointment of a new general counsel, Jody Bernstein, for the department. You also had a new Food and Drug counsel appointed, and that was Nancy Buc.

(Interruption)

JH: Patricia Harris was confirmed as secretary before Jere Goyan came on as commissioner, so she was in place as secretary. And Jody Bernstein and Nancy Buc also were appointed to their positions, I believe, before Jere Goyan came on board.

Now, there was an interesting relationship, clearly--and not an inappropriate one--between Mrs. Harris and Jody Bernstein. Mrs. Harris was an attorney, as I remember; and Jody Bernstein, of course, as general counsel, an attorney; and Nancy

Buc, an attorney--all bringing to their positions, I believe, strong opinions about how the FDA should be managed, not only as attorneys. I want to be very careful here, because I don't intend to convey anything chauvinistic at all, because I think my own reputation in furthering the interests of women in the Food and Drug Administration, particularly, will speak for itself in that regard. But clearly, I think, they brought to those positions the viewpoint of women in those jobs, and that's not inappropriate. But it was kind of all of a sudden, as it related to the Food and Drug Administration, an interesting set of circumstances.

I believe I can summarize that period of time that Jere was commissioner as a period of time when the general counsel to the commissioner, in this instance Nancy Buc, played a greater role in the program affairs of the Food and Drug Administration than even Peter Hutt did during his tenure as general counsel, and certainly greater than Dick Merrill, Rich Cooper, or subsequently, Tom Scarlett. I don't know whether that was by design from the very beginning of Mrs. Harris's time as secretary, but I believe that it at least grew over time in regards to how Mrs. Harris viewed the Food and Drug Administration. I have to look back, and I've looked back subsequently, and tried to pick out little bits and pieces as to how that might have occurred or how there might have been signals in that regard.

As an example, before Dr. Goyan came on board as commissioner but after Mrs. Harris came on board as secretary, I was sitting at my desk one day. And I don't even remember now the case that was involved, and it's not so important as what occurred is important. The phone rang and it was my secretary. She said, "Secretary Harris is on the phone." Well, it turned out that Sherwin was out of the office, and because he was acting as commissioner, there was not a deputy. The next person down was the associate commissioner for regulatory affairs, and so I got the call.

I took the call, and I introduced myself to Secretary Harris and what my position was and that Sherwin was out of the office, and asked her how I could help her. She was very, very unhappy about and distressed over the fact that the Food

and Drug Administration had made the decision to appeal an adverse decision at the district-court level to the circuit-court level. So I explained the fact that those kinds of initiatives were undertaken only on the approval of our chief counsel, that the chief counsel was literally a member of her general counsel's office, and that the agency had routinely and regularly looked at that kind of interaction and that kind of approval as a reflection of a concurrence on the part of the secretary's office. Although that procedure might not be one that she felt comfortable with, it was not a situation where the agency was taking an initiative on its own without an involvement with, or at least an understanding, that the secretary's office had had an involvement in that decision.

Well, she was very gracious about it, but it was clear to me that she was not very happy about it either. And I think, as I look back then on what happened subsequently, that decision making was heavily influenced by Mrs. Harris and her view of her role as secretary and, I think, her very strong feelings about herself as an attorney, as well as the importance of the law in the affairs of the department and FDA specifically. Through that period of time when Dr. Goyan was commissioner, there was great concern and a lot of conversation within the confines of one's own office. Everyone liked Dr. Goyan; everybody respected him as commissioner--that is, those that worked with him day in and day out--and had no reason to believe he was not and could not have been a good commissioner. But it was clear to us, working day in and day out on the affairs of the agency, that the true decision makers on FDA policy during that period of time were Mrs. Harris, Jody Bernstein, and Nancy Buc.

Now, I guess one has to step back and say, "If the secretary of the department wants to conduct the affairs of the department in that way, that's her prerogative." And I'm not arguing that it was wrong. But it was an interesting set of circumstances, because by virtue of my position as the association commissioner of regulatory affairs, I dealt regularly with Nancy as the chief counsel. I had, and continue to have, I believe, a very good relationship with Nancy. I have the highest regard for her as

an attorney, and I believe she was a very effective general counsel. She brought to that general counsel's office a perspective that had not been there before, notwithstanding the quality and capability of the other counsels.

But it was clear in the day-to-day affairs of the agency that Nancy carried greater weight on Food and Drug matters, not only legal but program policy, with the secretary than did Dr. Goyan. One has to know that that was a frustration for Jere, but he bore it well and never allowed it to be openly reflected in the way in which he conducted the day-to-day affairs of the agency.

Soon after Jere came on board, Dave Link, who was director of the Bureau of Devices at that time, was terribly, terribly distressed with how the general counsel's office was interjecting itself in the affairs of the bureau and the day-to-day way in which the bureau was conducting its activities. Of course, to those of us who had been in the administration a long time and knowing that the agency was in the third year of implementing the device amendments, a major new initiative, it was not necessarily surprising. But it was a great frustration to Dave, and he saw an opportunity to bring that frustration to the attention of a new commissioner. We talked about what happened to me in 1970 with Dr. Edwards and the bureau directors. That happens, I suspect, in all organizations with a changeover in leadership, and a person sees that opportunity to bring their personal issues to the attention of the new leadership with the hope of some change.

So I sat in with a meeting of Dr. Goyan, Dave Link, Nancy Buc, and myself to discuss the role of the general counsel's office. It was not much of a discussion. Nancy laid out what the role would be, and the meeting ended rather quickly. And that happened early in Dr. Goyan's term, and it probably was a signal, now read in retrospect, of what the period of time would be. But over that time, periodically I would get calls from the secretary's office when Mrs. Harris, Jody Bernstein, and Nancy together were talking about issues that related to the Food and Drug Administration. And I would receive a call in regards to my opinion or my attitudes or some history of how the agency had dealt with those issues in the past.

Let me come back to Jere and some of the things that did happen during that period of time.

FL: This situation, though, is vastly different from what had existed immediately before, when Don Kennedy had these direct contacts with the secretary.

JH: Absolutely.

FL: And bypassed the assistant secretary for Health and any other intervening persons.

JH: Yes, in direct contrast. I just want to close this particular little segment and then come back to some things that occurred during Jere's tenure as commissioner, and then kind of what led to some of the early months of the Reagan administration. I don't think that I'm compromising any confidential conversation here, but after the Republicans were in power and Secretary Schweiker had retracted some of the delegations of authority that had been in place to the commissioner of Food and Drug for some fifteen or twenty years, Nancy told me something that happened when Mr. Schweiker came down, after the election but before the inauguration, and sat with Mrs. Harris to talk about the department and the various programs within the department. At that time, Mrs. Harris suggested that one of the things that Mr. Schweiker would want to do is to gain greater direct control as secretary over the day-to-day activities of the Food and Drug Administration.

That's coming from Nancy, who was a confidante to Mrs. Harris on Food and Drug matters. I have no reason to believe that that did not occur. I'm convinced that, had Mr. Carter been reelected as president and Mrs. Harris then continued as secretary, what happened in the early months of the Reagan administration, as it specifically impacted on FDA, to retract some of the delegations of authority to the commissioner, would have occurred anyhow; because over that period of time, Mrs.

Harris, as secretary, from her point of view, saw the kinds of things that occurred in the Food and Drug Administration, the political importance and significance and visibility of things that happened in the administration, and I think just concluded she wanted to have greater involvement in those affairs. So, in my opinion, what occurred later would have occurred whether Mr. Carter was elected president or Mr. Reagan was elected president.

Dr. Goyan continued ~~several initiatives~~ undertaken by Dr. Kennedy as commissioner that were an outgrowth of the actions to provide greater insight to the general public and to the consumer about what the agency was doing, and to provide greater understanding about the products that we regulated. One of those was to provide patient package information for prescription legend drugs. That initiative had been undertaken, the proposal published, while Dr. Kennedy was commissioner. There was a great flurry of activity to complete that regulation and similar kinds of initiatives in the period of time that Dr. Goyan was the commissioner.

This was especially true following the election, when it became clear that the Carter administration would not be returned to power, then we really struggled to finalize those major regulations. You gentlemen recall how long it would take the agency to complete a regulation even under the best of circumstances. So most all of those major FDA regs that the Carter administration wanted to finalize and publish before they left power were finished and published in final form in the early days of January 1981. All of them then had an implementation date, 30 days or 60 days or 120 days after publication.

And, as an aside, that offered the Reagan administration an opportunity to jump in and interrupt those regs. I may come back to that later. As I look back and I remember Jere Goyan's tenure as commissioner, there are two or three things that emerge. One of them was the major effort on the part of the agency to finalize some of the key regulation initiatives before they left office, to publish the majority of them before the inauguration, and then, what happened to this effort subsequently when Mr. Reagan and the Republican administration came into power.

A couple more things I want to talk about briefly. One was a regulatory enforcement initiative that occurred during that period of time. That was the Rely tampon episode. I want to raise it only as it reflected a couple different kinds of reactions on the part of the agency, and the fact that it involved the Centers for Disease Control. The initial indictment of the Rely tampon came from work done by several states and evaluated by the Centers for Disease Control, and that complicated, as far as I'm concerned, considerably, the first few days or weeks of the FDA's ability to come to grips with the problem. The epidemiological data that began to be compiled to reflect the fact that there was a problem or a potential problem there had grown out of the relationship that the CDC has with state health offices. Then an assessment of those data resulted in a conclusion that there's a problem that needs to be brought to the attention of health officers throughout the country. And then the issue was complicated by CDC's desire to undertake that initiative and their frequent failure to remember that the Food and Drug Administration has the responsibility to regulate those kinds of products.

And so the first time that FDA might be aware of these kinds of issues would be a day or so before, even the day, that their morbidity and mortality report, their MMWR, their weekly report, would issue. And that's pretty much what occurred in this instance. The whole episode was dropped into FDA's lap by the CDC. Of course, the Congress and the public generally and the company began to look at FDA and our response because the tampon is a medical device under the device amendment; it had been classified as a medical device.

Whether or not the relationship between the CDC and FDA will ever be resolved, short of making a determination to put one or the other in and under the responsibilities of the other, I don't know. This was the subject of conversations that Charlie Edwards and I had on several occasions in the early 1970s about the desirability of putting the Centers for Disease Control within the Food and Drug Administration, because we saw it as the only way to effectively assure a coordination between the two organizations.

But to focus briefly on the CDC aspect, you had the CDC taking the initiative to call tampon manufacturers into their offices in Atlanta without involving the Food and Drug Administration, without inviting the Food and Drug Administration. Having found out about it, we had people there at the CDC who were left outside in the hallway while they had started their meetings. So, having to overcome that, we had to go around through the assistant secretary for Health's office to attempt to interject ourselves into those kinds of relationships. You had the CDC wanting to regularly put out information about the hazards and dangers that they saw associated with the Rely tampon specifically and, perhaps, other tampons generally, again without the involvement of the Food and Drug Administration.

Another problem is that many of the scientists at CDC, except for the career persons who hold the principal managerial positions, are persons who come into the Public Health Service, into the corps, for a period of a couple years or so as a career opportunity to get experience as they look to their longer-term goals, maybe in academe or at the state level or whatever. But they're persons who have more of the publish-or-perish kind of scientific attitude that you find in the academic community, or at least that you find outside of the regulatory community. So all of a sudden we were confronted with these young scientists who were assigned to manage the project within the CDC who were now reluctant to share data with us after having raised the allegations--data that they were wanting to protect and keep as part of a basis for a scientific article that they then wanted published in such journals as *The New England Journal of Medicine*. And, of course, *The New England Journal* has a very strict policy about not publishing articles where the information has been made generally, publicly available prior to the time of publication. So I'll tell you, it caused no little bit of unhappiness and difficulty between the Food and Drug Administration and the CDC.

There were several very, very acrimonious telephone conversations between Nancy Buc, as an example, on the one end, and some of the CDC division directors

on the other, about their obligation to release to FDA the data needed in order to undertake an appropriate regulatory response and carry out their responsibilities.

To digress a little bit, it has ever been thus between CDC and FDA. It doesn't occur frequently, but when it does, it's a most distressing and difficult issue to overcome. It occurred in the second Abbott large volume parenteral episode, and that was early in Edwards' tenure. And that's what raised his hackles over the way in which CDC was conducting its affairs. And it would occur periodically when the CDC would be the focal point for reports of injuries or possibly deaths that at least on limited investigation were attributed to foodstuffs, and particularly if they believed it was botulinum toxin poisoning. They'd come out with a news release in regards to the episode and always named the product they thought had caused the problem. I remember the Stokely green bean episode of the early seventies was the same kind of a matter. I don't want to belabor it here because it's a little out of context, but clearly, when you talk about interaction between segments of the Public Health Service, there's very little in the way of positive interaction, in my view, between the Centers for Disease Control and the Food and Drug Administration.

But going back to the Rely tampon problem, here was a new concern, a different kind of concern, for FDA to deal with. Nancy Buc, as chief counsel, took the initiative to work within the device amendments--the notification requirements, as an example, the compensation requirements of those amendments--and utilized her own experience when she was an attorney at the Federal Trade Commission to develop an approach they frequently use. I'll characterize that as an administrative injunctive kind of approach, to sit in with the representatives of Procter and Gamble and literally devise a formalized, voluntary, administrative corrective-action plan--lurking behind it, the compensation requirements, the notification requirements of the amendments--a plan into which Procter and Gamble and the Food and Drug Administration would enter in a formal sense.

Both Procter and Gamble and the FDA would both be signatories to that particular agreement. We wrote into it commitments for newspaper advertisements,

for television advertisements, for means by which individuals could send back in to Procter and Gamble unused tampons, and a process to make certain that the commitments Procter and Gamble Company had agreed to were effective, that the message was being heard by the women of the country, and that they understood that they posed a threat to their health and that they should return the unused tampons.

(Interruption)

JH: That was a very interesting initiative. It was probably, as you look back at FDA's own experience in the other kinds of products that it regulates, unique in a number of different ways in that all of the basis for the action was epidemiological data, retrospective data. There was no way to test the product itself as you could most all the other products that we regulated for the kinds of public health dangers that might be inherent in those products. And you had a product that had been sent directly into millions of households in the United States as free samples as a marketing initiative to begin with.

So in contrast to the normal procedures of a product coming into the market, going into normal retail outlets and that sort of thing, none of our experience in dealing with those kinds of recalls applied directly. So we had to take that experience, modify it with the experience that Nancy had had in the Federal Trade Commission, and come up with a regulatory solution.

And I think that that particular agreement, if it's not in our historical archives, clearly ought to be as a unique approach to regulation. I'm not sure of the extent to which that kind of approach might be used again. We burned some long midnight oil, and I have to say that the representatives of the Procter and Gamble Company conducted themselves in the most professional and positive way in coming to grips with this problem. I don't want to imply that they were not anxious to make certain that the data were as complete as possible and that there was reason to believe that the injuries of toxic-shock syndrome could be directly attributed to the Rely tampon.

But as the whole procedure moved through the process, they acted in a most responsible way, and the agreement was unique in its character.

Briefly, let me talk about an entirely new kind of program that was undertaken in the Carter administration initially when Dr. Kennedy was commissioner and then carried through while Dr. Goyan was commissioner, but was not long-lived. One of the concerns raised by those program managers who came into government as part of the Carter administration was a concern that agencies that had similar kinds of regulatory responsibilities and who relied frequently on the same general kinds of scientific data to reach regulatory decisions were not coordinating their activities to the extent that was appropriate or that might ultimately reflect the best possible use of federal resources to protect the consumer's interest or the general public's interest. In that regard, as an example, the extent to which the scientists of the various agencies were using scientific data to project risk of exposure, the kinds of risk assessments that they were making, and their decisions whether or not regulatory action should be taken to remove a product from the marketplace or restrict exposure to the product.

So the administration took steps to put together what was characterized as the Interagency Regulatory Liaison Group; it became known as the IRLG. And the first steps were to get the administrators of the various programs together. So the administrator of the EPA, the commissioner of the Food and Drug Administration, the administrator of the Occupational Safety and Health Administration, the appropriate assistant secretaries from the Department of Agriculture, as an example, who had responsibility for their meat and poultry safety inspection programs, came together and concluded that they should establish a group, an extraorganizational initiative--by that I mean outside of the normal organizational structure of the executive branch of government--formalize that relationship into an organization that met regularly, dealt regularly with these issues and, ultimately, would be responsible for policies, policies reflecting the joint agreement of the various agencies that participated in the IRLG.

As this whole initiative moved along, it began to go beyond the initial focus, that is, the scientific basis for action, to looking at how these agencies, in the normal conduct of their day-to-day programs could become more efficient in identifying problems for resolution.

Of course, OSHA makes inspections of industrial plant sites; the USDA makes inspections of selected industrial plant sites; EPA makes inspections; as does FDA. So one of the initiatives that went beyond the science aspect was one to take advantage of an OSHA inspector in a plant making an inspection under the authorities of OSHA for compliance with the basic statutes and regulations of OSHA, to look for violations of the Food, Drug, and Cosmetic Act. Or an FDA inspector to look for violations of the OSHA regulations or of EPA regulations. And there was to be a regular structure. They went as far as to detail training programs for FDA inspectors into the other activities and vice versa. There were reporting mechanisms established. There were formal contacts raised.

Well, as one can imagine, the industry itself began to become increasingly concerned over what this was growing into. One might argue early on that there was merit in having some unification of government policy on risk assessment, so that a firm that was involved in the use of a given compound, either in the production of food or a drug or a cosmetic but also maybe using a pesticide in their environment that contained the same ingredients, might not be confronted with varying attitudes as to whether or not certain amounts posed a hazard. Or if it was used in the production of a food--if FDA had reached the conclusion that certain levels were safe in food but OSHA had an entirely different attitude in regards to the amount of that in the workplace environment in that food plant, particularly if they were conflicting.

Early on, I think industry saw some merit in it. But as soon as they began to see the possibility, as an example, of an FDA inspector authorized to be in the plant under very specific terms of the Food, Drug, and Cosmetic Act, with certain limitations to those authorities (which the industry is very cognizant of and uses to their own advantage--from their point of view--to limit the extent to which

government interferes in their matters), they were not too happy to see the FDA inspector saying, "Oh, by the way, I think you're violating OSHA here," and notifying OSHA.

So issues over the legal authority of the various representatives to conduct those kinds of affairs under the enabling legislation began to be raised by the industry itself. Also, the whole burden of having this extra cost outside the normal, authorization structure, either by statute or otherwise--to set up this organization now called the IRLG that met regularly, had offices, had people assigned to those kinds of activities . . . If you were responsible for an operation in FDA, then you were asked to devote part of your offices, part of your dollars, and part of your manpower resource to the IRLG activities. Meanwhile, people in the Congress who did not necessarily support this initiative began to raise concern over the use of authorized funds. You know, "Hey, the Congress authorized the Food and Drug Administration to use these funds to administer the Food, Drug, and Cosmetic Act and related acts, not to administer other legislation or whatever."

There was a program and there was a momentum behind it, however, that was very, very hard to step in front of. And again, in the Carter administration, if you raised any concern over it as an old-line Food and Drugger, as an example, you were seen as reflecting the old-line bureaucracy, the federal government positions of the past which this administration was attempting to overcome. So you did your darndest to further those initiatives and try to make them work. I participated in any number of committee meetings with my counterparts in OSHA and USDA and EPA, principally, FTC, others, in an attempt to come to grips with these matters and develop procedures by which the initiatives could be implemented.

But here again, not unlike some of the other initiatives I've already talked about, this was a major undertaking, and clearly, then, without the Carter administration being returned to power four years later, that whole initiative finally collapsed. There was some considerable discussion in the early weeks of the Reagan administration over the merits of the initiative and to what extent should any of the activity be

perpetuated. And there was some support for the concepts of the IRLG. As I mentioned, having a broader administration position--in this I mean the executive branch having a policy on risk assessment, on the kinds of scientific data that are necessary to reach decisions, on whether a compound poses a public health risk or not. There's a great deal of merit in having those kinds of policies go beyond any one agency.

So the final decision of the Reagan administration, as I understood it, was that the IRLG approach would be abandoned, seen as not only extraorganizational but, by now, extralegal, and there was a formal decision on the part of the White House to abandon that. But the advantages of having executive-branch-wide scientific policies was recognized, and that responsibility was assigned to the Office of Science and Technology in the office of the president. And subsequently, OSTP issued a policy document in regards to risk assessment, the kinds of data that are accepted and recognized as adequate to demonstrate risk, what levels of protection would seem reasonable.

That document was ultimately published under the Reagan administration, and FDA played a major role in that, in that the committee that was appointed within OSTP to consider the whole matter and to develop a statement of policy that then embodied each of the agencies' own approaches, was chaired by Ron Hart, who was the director of--and continues to be the director of--the National Center of Toxicological Research within the Food and Drug Administration, located at Jefferson, Arkansas.

Later, before I left the agency, I participated to some considerable degree in developing FDA's policy in regards to how FDA would regulate the products of biotechnology. In this instance, although each of the agencies involved ultimately took some different kinds of approaches one from the other, there was a single document published under the umbrella of the Office of Science and Technology Policy that announced a government-wide policy document on the regulation of the products of biotechnology. So the whole IRLG concept, as a concept as initially seen

by its founding fathers in the Carter Administration, was dissolved and abandoned. Some of the concepts that had merit were adopted, interestingly enough, by a very different administration and implemented in a different way.

Let me raise one additional example indicative of the way in which the Carter Administration came in and began to implement initiatives that were reflective of its commitment to change the federal government system, and how that, then, impacted on the Food and Drug Administration, and what ~~the outcomes~~ of those were. I mentioned earlier in this particular interview the whole initiative that became known as regulatory reform and that I saw it as a bipartisan initiative that had its genesis in a Democratically controlled Congress. As you read the history of regulatory reform, you see a number of very aggressive Democratic Congressmen taking initiatives to effect legislation, imposing sunset requirements, and that sort of thing.

It became an initiative of the Nixon administration. Mr. Ford had an executive order and Mr. Carter, then, issued executive orders implementing programs leading to a simplification of the manner in which government interacted with the public as a whole and to limit new regulation initiatives to the extent that they went beyond certain thresholds, principally regarding cost to individuals or segments of the public.

Another of the initiatives that the Carter administration undertook was to review all, literally all, government wide, all of the regulations that were currently then on the books to determine whether or not they were written in a way that could be understood by the average person on the street. I don't remember the exact catch phrase that they used, something like "operation plain speaking" or something of that nature. All of the agencies were required, under very tight time frames, to first, review all of their existing regulations, categorize them as to whether or not they were ones that could be rewritten or needed to be rewritten, and set up priorities to begin the process of rewriting those regulations.

Now, for FDA, that meant a review of about 1,300 pages of regulations, and the leadership for that fell, quite appropriately, into my office. As an office, we had

the responsibility for managing the regulations as they came forward for final consideration, either by the commissioner for signature at that time or for my signature on behalf of the commissioner.

So we undertook the review, and there was a person in the department's general counsel office who was designated as responsible for coordinating this activity in the department, and she held regular meetings and required regular reports on progress. Now, we decided there were a number of our regulations that we characterized as monographs, and that they were very technical in their character and really could not be rewritten to meet the objectives of this initiative because they were, as an example, like an antibiotic monograph or a food additive monograph, a standard of identity for these kinds of products, and did not lend themselves to lay language. Of course, there were an awful lot of regulations that could lend themselves to lay language: all the good manufacturing practices regulations; all of the administrative procedures, such as new drug approval, food additive petition, submission of the GRAS, Generally Recognized as Safe, affirmation petition. All of these kinds of regulations could lend themselves to this kind of an initiative.

We even, in FDA, began to look at some regs like the food standard regs promulgated under Section 401 of the act as candidates for rewriting. What one has to reflect on, however, is a rewriting of the language can only be achieved, ultimately, through the formal notice and comment process. So you would have to rewrite the regulation, propose the rewritten regulation as an amendment, ask for comment under the Administrative Procedures Act processes, react to those comments, and than publish a final order. So to achieve the goals of this, although admirable, as maybe all of us, as taxpayers, would like to have seen the IRS regulations rewritten in a way that they were more understandable, the process itself posed an impossible task, really. But you were not allowed to raise the possibility of it being impossible; you had to respond and do your very best to lay out a program that was designed to achieve that end.

We really began to rewrite some regulations. In fact, down in Foods, working with persons like Brad Rosenthal, they hired some ex-FDAers that had been leading scientists in the Bureau of Foods through the years. They knew the foods program in FDA, and they knew the food standards program. And they hired them to begin rewriting some of the food standards initiatives.

Again, stepping back and thinking about the administrative process, the majority of the regulations issued by FDA are under the authorities of 701(a) of the act, which relates to the informal rule-making procedure of the Administrative Procedures Act. But the informal procedure is very formal. "Informal" is that agency proposes, asks for comment, reaches a decision, issues a final regulation, and then that regulation is challengeable at the district court level.

Section 701(e) of the Food, Drug, and Cosmetic Act provides authority for the promulgation of regulations under the formal rule-making procedures of the Administrative Procedures Act, and 401 happens to be one of those, as does the food and color additives and several other sections of the act. And in that instance, you propose, you receive comments, you finalize and offer an opportunity for an administrative hearing. If you reflect back on the peanut butter standards and a few others of our era, it was that administrative hearing process that went on forever that is part of the formal rule-making procedure.

So one could speculate that, in attempting to rewrite the food standards regulations, which, although initially, I believe, were put into place in good faith by the Congress as a means of assuring the public as a whole that certain foodstuffs could be relied upon as providing nourishment--standardized bread, as an example, or standardized flour--over the years, I think, they've become more a protection of trade or constraint of trade. That's a personal opinion. So one could speculate there would be a great deal of opposition by the industry to modifying them all, and you would get a number of requests for administrative hearings.

I raise this in saying the objectives of this initiative to rewrite all of the existing regulations of the federal government in a very short schedule was an

impossible task. And collectively, and in summary, and reflecting some of the informal conversation that the three of us have had during periodic breaks in this particular interview session, for FDA to have the initiative to focus on rewriting the FDA procedures and amending the Food, Drug, and Cosmetic Act as it relates to Section 505, all of sudden expanded to include many, many more sections of the drug sections of the act, the food initiatives and the food labeling initiatives, to take on the whole world of food labeling instead of, perhaps, focusing on one or two very important initiatives was mind boggling.

(Interruption)

JH: The IRLG initiative, which was government wide, and, of course, this project to rewrite the regulations in plain language, for the federal government, I think, reflected the naivete of the Carter administration as to how the federal system worked. Not arguing the merits of the initiatives of that administration to come in and change those procedures, but I think it's a reflection of the fact that they attempted to do so without having anyone on their team that really understood how the federal system works.

And when you took that attitude and that approach from the White House and then put it into FDA, you had, at least initially, Dr. Kennedy as commissioner of Food and Drugs utilizing as his most intimate confidants persons that he brought into the agency from outside who didn't understand the program and had little or no experience in the federal government. And he excluded, at least from my point of view, a number of us who understood the system and could have contributed effectively. If he had taken time early on to test the water, to sense and look to the attitudes of the career Food and Drug employees, especially those individuals within the commissioner's office, I think he could have seen that we would have turned-to to help implement that administration's policies. But they were reluctant to do that.

I think, in summary, one, they uniformly bit off more than they could chew, because they didn't understand the process and set expectations well beyond what they could have achieved; and, two, they didn't bring into the process early on, to help design and plan those initiatives, people who understood how the process worked. And, unhappily, good ideas, *good* ideas, frequently fell by the wayside because there was no way in the world that the expectations could have been fulfilled.

I want to digress and speak to something that emerged just now in this recent break, that's reflective of my comments about the Carter administration and how it ran its campaign against the federal system. Mr. Reagan did the same thing, and so the presidential election of 1980 left the career government employee, at least as I represented the career government employee and the colleagues that I had at that time who were career government employees, with some considerable concern as to what their role was and where they stood in this whole business of our government. Both the Democrats and the Republicans, and particularly the Democrats, had been strong supporters of the federal employee through the years. I do remember comments by persons who had viewed, in the early Eisenhower administration, Mr. Nelson A. Rockefeller as being a real supporter of FDA and the strengthening of the FDA as a consequence of the First Citizens Advisory Committee report and recommendation. So I don't want to say it's always the Republicans or always the Democrats.

But here you had neither the Republicans nor Democrats attributing anything of value to the historic federal system or to the career government employee. Those were very, very difficult times and they carried over and were perpetuated in a number of ways, those feelings, especially in the early years of the Reagan administration.

I don't believe, however, that those frustrations or agonies impacted directly on or adversely on how the employees of the Food and Drug Administration carried

out their responsibilities. I really believe that the commitment of the employees to do the very best job they could to protect the interests of the consumer, as good soldiers, and to carry out the policies of the administration in power at the time . . . I don't think that obligation was compromised in any way. But notwithstanding that, there was a great deal of concern, personal concern, and talk in the halls about how both the Republicans and the Democrats had somehow abandoned the career government employee.

The Republicans came in with a bang into power in 1981. It was an interesting time. Within a very short period of time, from the standpoint of FDA, we knew there would be a major change in the way we conducted our affairs. This was because Secretary Schweiker undertook an initiative to rescind certain of the delegations of authority that had been in place for the commissioner of Food and Drug, which focused principally on the authorities of the commissioner to promulgate regulations. The new administration also stayed the effective date of a number of previous administration's initiatives, for instance, the patient package insert regulations that were promulgated in the last days of the Carter administration and which had not yet gone into effect. They took an initiative to stay those regulations with a view to reviewing them under the regulatory reform policies of the new administration. And the administration began to put in place regulatory procedures that for the first time really had the potential to effect the rate at which new regulations were developed and promulgated.

All of the initiatives of the previous administrations--Nixon, Ford, and Carter-gave a lot of lip service to regulatory reform. As an example, the initiative to rewrite all of the regulations within the Carter administration. Beginning with Mr. Nixon, there were mandates that regulatory initiatives had to be reviewed as to the cost that those initiatives would impose upon the segment of the public to which they were directed. None of them really had an impact of slowing down the rate at which regulations were developed and published for comment and finalized.

Now, the process itself was never a rapid process, just by its nature. But FDA, as an example, kept churning out regulations along through that period of time, even though the executive orders were in place. You developed them to meet your own objectives, but still meet the requirements of the executive order. And if the commissioner of Food and Drugs had the authority to promulgate regulations, that was the final level; there was no further review except at the initiative of the commissioner himself. So there was no reason for the process to by slowed down, at least as it related to FDA.

But the first step, which was to rescind certain of those authorities and require that the regulations be signed by the secretary--to which, of course, the authority is really delegated in the Food, Drug, and Cosmetic Act itself--and the second step of the Reagan administration procedure whereby the Office of Management and Budget would be included in the review process, in a sense, turned the bureaucracy in on itself. So to the extent one would argue that the procedure for developing and promulgating regulations was a very bureaucratic process and laborious by its very nature to begin with, the Reagan administration very effectively just extended and made more complex that bureaucratic procedure. By its very nature, this slowed down the rate at which new regulatory initiatives were undertaken by publication of a proposal in the *Federal Register.*

Under the former procedure, a regulation was developed by FDA, reviewed by the general counsel of FDA (which was an extension of the secretary's office--that satisfied the commissioner that the secretary's office had an involvement in its development) signed and put into effect in final order all by the commissioner. All of a sudden, regulations not only had to go through all of the initial developmental process, developed, drafted in the agency, go through the commissioner's office, be reviewed by the general counsel's office; but then they also had to go to the assistant secretary for Health's office, where they were reviewed by an office that was

established for that sole purpose, and commented on. And FDA had to react to questions and concerns raised by that level.

Then they went to the department level, where they were reviewed by an office established for that very purpose in the office of the executive secretariat of the department. And you had to be responsive to all the concerns raised by that office. And then finally they went forward to the Office of Management and Budget, where ~~they were~~ reviewed by an office which was expanded to accommodate the review of all of these regulations government wide. You had to be responsive to all of the questions and concerns that they raised. You can imagine those drafts going back and forth, being commented on and sent back for reaction to comments, rewritten, redrafted, sent back through to be assured that we were responsive to the concerns and the change agreements we had, and then go to the next level. You don't need to be an expert in administrative process to understand why that was an effective way of delaying and reducing the number of regulations published throughout the federal government and by FDA specifically.

So if you had the figures in hand, you would find that the number of pages in the *Federal Register* that the FDA paid for--because you have to pay the National Archives each year for the number of pages that they printed for you in the *Federal Register*--were dramatically reduced. Where we were previously paying for some thousands of pages, that number was reduced to hundreds of pages almost overnight. Giving credit where credit's due, the Reagan administration came in and found an effective procedure for accomplishing what the previous three administrations had argued was their objective, but really had no effect in changing the conduct of the executive branch of government.

FL: A highly inefficient way of accomplishing that, though.

JH: Well, perhaps, but effective. And so, you know, one might consider a more efficient way and develop it, but it might have taken longer to develop and put in place. This one could be put into effect very quickly. "You can't sign them anymore, Commissioner. You've got to send them to me." And, of course, the president's saying, and as I understand he said to his cabinet, "I want you to go in and gain control of your departments." Now, I began to hear in the Carter administration and even more so in the early months of the Reagan administration the term "organizational capture." That phrase was a phrase that was applied to political appointees who, by the very fact that they were political appointees, came into the executive branch of government with the expectations and intentions that they would implement the policies of the elected official, but that ultimately did not do so because they were "captured" by the organizations that they headed.

As a consequence, instead of the elected officials capturing the bureaucracy, used in its most positive sense--because I hold some very strong opinions about the value of what I think is the fourth part of this government--instead of the elected officials capturing that part of government and turning it to achieve the goals that were described in the platform of that particular party at the time they were elected, the reverse happened. Instead these officials were captured by the bureaucratic part of the executive branch of government, and the objectives and policies and attitudes of that part of our government were perpetuated and not changed.

The interesting thing is that probably as much as any program in government, I think the Food and Drug Administration has the ability to capture someone. Otherwise, the three of us might not have spent as many years in the program. You two gentlemen might not have continued to devote time and energy in FDA's interests after retirement. I certainly would not hold the FDA in the high regard that I do. I would not represent the interests of the FDA and the position of FDA in the way I do to my clients now in my new position if I were not, in a sense, captured by the Food and Drug Administration and its programs. That's the great thing that I

think emerges from all of the initiatives we're taking to put together the history of the agency. Somehow the agency captures the people that become a part of it.

Again digressing somewhat, when you talk to these individuals that we've talked about so far that have come in as commissioner, the one thing--after they're gone--that they always look back on and talk about is that they became "Food and Druggers." Jere Goyan talks about having become a Food and Drugger in thirteen months. And when they talk about, having been the commissioner, what is so particularly outstanding to them, is that they were captured by the agency.

Now, I digressed a little bit, and I'm not sure I remember where I was when I started this, but there was a great deal of concern, in the Reagan administration, particularly, over agency capture. And the cabinet officials and the appointed officials in the independent agencies were told by the president, I understand, that they had the responsibility of moving in and taking control of their departments. So you attributed to those instructions the initiative on the part of Secretary Schweiker to withdraw authorities from his own appointee, Arthur Hull Hayes. You can almost hear him saying, "Gee, Arthur Hull Hayes is my man in FDA; can I not expect him to perform as I want him to perform?" They had great, great apprehensions over agency capture. They seemed to think that the only way they could really assure themselves that that wouldn't ever happen to their own appointee was to draw that authority back and involve themselves.

So you first attributed Schweiker's initiative to rescind much of the delegation of authority to the commissioner of Food and Drugs, particularly in the area of promulgating regulations, to the new Republican administration. But as I mentioned earlier, my conversations with Nancy Buc following the inauguration--and she was out of and away from the administration--was that Mrs. Harris had concluded that she could only really gain control over the Food and Drug Administration to the extent that she felt it was appropriate and necessary to do so by rescinding some of the authorities. I believe that would have happened under any circumstance, as far as FDA is concerned.

So there were major changes, and Mr. Reagan initiated these new procedures through executive orders, and those executive orders required regulation development plans. You had to say what initiatives you were going to undertake, how long it would take you to complete the certain segments. You had to explain on the record why they were necessary, what would be the goals of those initiatives, put those into short- and long-range regulation plans. Those plans went forward. They were reviewed at the various levels, ultimately by OMB, and the Office of Management and Budget published government-wide plans for what the government intended to do in the way of developing and finalizing new regulations over the next six months, over the next year.

Of course, that process slowed the development as well because, first of all, if we intended at FDA to begin to develop a regulation, no pencil to paper yet, you had to say, "I intend to develop it, and here's why and what I hope to achieve." And, of course, if then it's reviewed at the assistant secretary's level and the department level and OMB level, and they come back and say, "Is it really necessary? What are you going to achieve?" Then that was another means of beginning to interrupt the regulation development process.

Now, ultimately, regulations that were really absolutely necessary were never completely prevented from publication. And when it was important to move aggressively, the Reagan administration, although they ran against the bureaucracy, were much more astute, I think, in bringing in their intimate advisors, persons who understood the procedure, were politically astute enough not to interrupt those important regulations.

For instance, at the first tampering incident, where we used a very rarely used section of the Administrative Procedures Act to promulgate in final form, without opportunity for comment, the tampering regs, there was no interruption of that. On the other hand, you could get very, very frustrated over going through this whole process in developing a regulation that either you had to develop under law or,

clearly, politically you know ought to be developed, and having to go through all this, jump all through these hoops . . .

A good example of the latter was the regulations that we were required to publish under the infant formula amendments to the act. Now, I didn't even mention the infant formula episode in Dr. Goyan's term as commissioner. I guess that's just reflective of the fact that . . . As I think back at my own career, a career I shared with ~~you two gentlemen~~ for a period of time and many others, it's hard to focus in a few hours that we sit together on what was important and happened to the agency, all of the things that happened. Jere Goyan walked in as commissioner of Food and Drug about September, I'll say, for example, about September first or second. And on about September fifth or sixth, we had a hearing before Mr. Henry Waxman and his committee on the infant formula episode. Again this was one of those episodes where the whole matter began to emerge through data coming to CDC. CDC then went out and sat down with Syntex and excluded us from that meeting, believe it or not.

But, be that as it may, Jere probably would have been better off had he sent Sherwin, because Sherwin had been acting commissioner during the course of that whole matter, and me and the others who had been involved. And I think that the committee would have accepted that. "Mr. Chairman, I've been here three, four days. I really can't contribute. You can be assured that I'll find out what's happening. By the way, I'm a Democrat." But be that as it may, he went there. And poor Jere, there he was in one of the most, oh, acrimonious hearings, one of those where you're the last ones on and some of the ones that preceded you were the families of children who were injured, who had their children in arms. You know, it was one of those kinds of hearings. So poor Jere had his baptism in fire.

But meanwhile, of course, Congress passed the amendments to the act providing the FDA with more authority to regulate infant formulas. Also, as part of that legislation, a requirement to promulgate certain regulations early on as it related to the recall of infant formulas, certain requirements. And all those regulations were

ones that were under development and began to flow down to the department for review. I remember getting into long discussions with these persons who were coming in and beginning to implement these new initiatives to begin to restrict the number of regulations going out, whether or not the word "recall" ought to be in red, ought to be in bold figures. Why did it need to be there on the envelope at all and all of those kinds of things.

You had to begin to educate, not only newly appointed officials at the FDA level but all the way along, on some of the most basic kinds of activities that the agency involved itself in. You had to discuss the experience that the agency had gained through fifty years of recall activity going back to the black olive instances of around 1920, and also more contemporary experience, beginning with the first Abbott episode in 1965-66. You had to go back and go through all of that to justify why you'd have the word "recall" on the envelope at all, and then why it needed to be in red as contrasted to black. Because I think one of the concerns was that it would make it that much more expensive, and their concern was what was the expense that these regulations would impose and not the fact that the administration would look good to the public generally by moving through reasonable regulations that the industry would accept. The industry's going to put red on there anyhow, for product liability reasons, as far as I'm concerned. But you really had to suffer through, and I mean suffer through, all of those procedures.

(Interruption)

JH: As an aside, to give the people later reading this some insight into our frustration, all of us that are familiar with organizational structure recognize that sometimes persons who are part of long-standing organizations are unhappy with and covet the authorities of others. It began to emerge that there were career departmental employees who for years had not been very happy with the fact that FDA could promulgate its own regulations and no one else in the department could.

They seized on this initiative and said, "It's about time." So you not only had to deal with the political appointees who brought in the attitudes of the new administration--and you knew they would--but you had to deal with those persons who were career government employees who now had an opportunity to step forward and assume greater authorities and, by golly, began to influence and control the activities of FDA from the department level where before they had been estopped from doing that.

So I mentioned the fact that you had all of those plans to go forward to OMB. Then, all of those plans had to be managed at the department level as well. I was regularly going downtown, or members of my staff were, to meet with departmental representatives to go over the plans for each of our agencies in the way of new regulatory initiatives. A very, very effective way; although, perhaps, laborious and crude, it was effective. Occasionally, when matters came along and needed to be moved through quickly, you could see that they were politically astute and would do that. But otherwise, at every turn, challenge; at every turn, explanation; at every turn, the possibility of rewrite and restructure. For an organization that had for some number of years pretty much had things its own way, it was really a traumatic change. And that trauma extended down all the way into the agency.

I'd like to return in a few minutes to procedures that the Reagan administration put into place to begin to have greater influence over the activities of the organizations within the various departments, and particularly in this instance FDA. But let me talk a little bit about Dr. Hayes as commissioner, at least his early months. Particularly I want to focus on something that I raised earlier, beginning with Don Kennedy, and that's the relationship that existed between Don Kennedy and Joseph Califano as secretary, a direct relationship that bypassed any intervening organizational structure, like the assistant secretary's level, in contrast to the kind of nonrelationship, or the opposite of that in a sense, that existed between Mrs. Harris and Jere Goyan.

There was a very, very positive--I mean very positive--relationship, from my point of view, between Art Hayes and Secretary Schweiker, and that manifested itself

in a number of different ways in a very wide variety of FDA affairs. To give you a good example would be when we would, as an agency, became involved in a critical recall situation, a Class 1 recall situation. As you know, those almost always occurred on a Friday afternoon at 4:30 (and I have my own beliefs why that occurs). At the time it comes forward to the commissioner's office to be signed off, all of a sudden you're confronted with having to worry about a press release and how to involve the commissioner ~~as appropriate and that~~ sort of thing. You wind up sitting around a table at about 7:30, 8:00, 9:00, maybe, in the evening, going through the final stages of getting everything in place to implement a recall.

One of the kinds of issues that always arose was whether or not the agency would be most effective in protecting the interests of the consumer by going out onto the press with the announcement of a Class 1 recall at 10:00 in the evening, having missed the opportunity maybe even for the morning papers and for the evening news and maybe even for the late news, or holding it until very early the next day to get all that. You know, get the next edition of the paper or get it onto the morning news or whatever, TV.

Those kinds of issues would arise, and we'd agonize over them because they were very important. And, of course, too, depending on when you release the information, the commissioner always would have an obligation to let the secretary's office know, at least, what was happening so that the secretary would not be caught unaware of some important issue of that kind.

After we'd go all through it and we'd have reached certain points where we thought we had concluded the approach we were going to use on one of these recalls, Art would get up and he'd motion to me, and the two of us would go into his office and he'd call the secretary. It didn't make any difference when it was. He'd call him through the White House switchboard, and you can do that and it's the way to get hold of persons like that at off hours. You don't just pick up and call them at home; you get them through the White House switchboard.

Art would place the call; pretty soon, Schweiker would come on and he'd say, "Mr. Secretary, I want to brief you on a recall action that we've been contemplating here. It's Class 1. Here are the details. If you want us to fill in some of the particulars in it . . ." We'd talk to him a little bit about it, and then Dr. Hayes would say, "Now, in regards to this issue or this issue, these are the alternatives we considered. This is where we've come out, Mr. Secretary, and this is the way we feel we want to handle it." Schweiker would discuss it with us and might say, "Well, you know, gentlemen, in my opinion, I think maybe you don't want to go tonight or, maybe, you don't want to wait until next morning." So the secretary would involve himself directly in the issue.

Here we were, talking to the secretary on operational matters where this was not done under earlier circumstances, with other commissioners. Previously I was not involved in that kind of a relationship existing between the commissioner and the secretary, although certainly I was involved directly in Class 1 recall issues all along, because they had to come to my office for final sign off.

FL: Class 1 being the highest classification that involves hazards to health?

JH: Yes, the highest priority, most often involving a press release either agreed to by FDA and issued by the firm or a press release issued by the agency itself. It had the highest priority in follow up on the part of the agency to assure that the product was coming off the marketplace.

I use that as an illustration of that close working relationship. Then over time, I realized that as things came along that Commissioner Hayes thought the secretary ought to be involved in or be aware of, it was more than just a notification; it was an opportunity to discuss it directly with the secretary and involve him in the decision making.

In that regard, when Mr. Schweiker left and Mrs. Heckler came on as secretary, that kind of relationship did not exist between Secretary Heckler and Art

Hayes as commissioner. I think that had a major impact on the feeling Art Hayes had about the job and how he felt he could best perform within the job. I'm not saying either of the two approaches is better than the other; each reflects the personality of the individual, particularly in the secretary's office, because there are intervening levels of organization. So it's not as if Mrs. Heckler just, in a sense, said, "We're not going to talk together anymore even though you report to me," because technically the commissioner reports to the assistant secretary and in turn to the secretary. But I think there was an obvious--and I can understand--feeling of loss on the part of Art Hayes in being able to seek directly the involvement of the secretary in matters of the Food and Drug Administration that he felt were important and that FDA could profit from that kind of involvement.

FL: Had Dr. Hayes and Secretary Schweiker had any kind of . . . Did they know each other before they came to the government?

JH: They may have, Fred. I don't know that for sure. They were both from Pennsylvania. And, you know, Art was from a very influential and reasonably wealthy family, active in Republican politics; so it would not have been surprising that there would have been some relationship there. But it never came out that there was that kind of relationship before. One only assumes that, in the interviews that took place leading to Dr. Hayes' appointment, that relationship grew and prospered. But it was an interesting situation. It was the only time, even subsequently, that such a direct involvement existed on matters, to the best of my knowledge. I didn't participate in them, at least, between Dr. Young and the secretary's office . . . That is, the secretary him- or herself.

Art Hayes came into the job from the academic community where he had held a senior position in the school of medicine at Penn State University at Hershey. He had been a clinical investigator and had also had within his department clinical investigators. So he came into the job with some very strong feelings about how the

Food and Drug Administration ought to regulate clinicians. That manifested itself early on, soon after he came on board. Our program of inspecting clinicians ordinarily was not too different from our inspecting anyone. Not infrequently, they were unannounced. We recognized that we might not get to the clinician right away, but we could begin to talk to nurses or administrators who dealt with the clinician and, particularly, if we were conducting a "for cause" investigation.

We had undertaken to ~~make an inspection~~ of a clinician somewhere; I don't even remember now where it was. But the clinician was not very happy about having an FDA "gumshoe" walking into the front door unannounced; and so he contacted Dr. Hayes in some fashion. I think he picked up the phone and called, because Dr. Hayes picked up the phone and called me up. I got Ernie Brisson up to the office with me, and we began to explain to him our program and the policies of our program. The outcome of that whole discussion was that we changed the process appreciably and went to an approach where the investigation of clinical investigators, except where we had real reason to suspect fraud and had reason to believe that records might be destroyed, there would be written notification and confirmation of an inspection beforehand to assure the clinician when we were coming and the circumstances under which we were coming and what we were looking for.

Now, I'm not saying this in the way of a criticism of the commissioner. I'm just saying Art Hayes brought into the position of commissioner for the first time, at least after the bioresearch monitoring program was undertaken in the mid-seventies, the attitudes of someone who had been a clinical investigator. And I need to add to that that Dr. Young had also been a clinical investigator and had within his department persons who were clinical investigators and had very strong views in regards to how clinical investigators should be regulated, and they paralleled reasonably closely those of Dr. Hayes.

I raise it now in that you'll remember that, beginning in the mid-seventies with the problems that IBT and some attendant kinds of concerns over the integrity of data coming to FDA, we undertook the bioresearch monitoring project that had as

part of the initiative the clinical investigators sponsor monitor regulations, or at least the development of much more detailed regulations. Those had been moving along, written, rewritten, written, rewritten, partly because of the changes in personnel responsible for managing the program along and the slowness of the review process. But clearly, once the whole issue of regulating that segment of drug development came up before the commissioner, the agency was not going to undertake an initiative that would impose extensive, detailed regulatory requirements on clinical investigators.

So the agency began to step back from that regulatory approach. They never said this in so many words as part of all of this business of planning for regulations and all. But ultimately, the solution on behalf of this administration and two commissioners who had very, very strong feelings about FDA's regulation of clinical investigators was not that they should be free of regulation, but rather was directed toward the extent to which they should be regulated and how that regulation was structured. The results of that were to take from those initiatives the few most important regulatory requirements--and these were regulations that in draft form were several hundred pages long--and build them into the rewriting of the new drug approval regulations and the investigational new drug application regulations.

Also, the initiative that was undertaken in the Don Kennedy administration to develop the proposed legislation to amend the drug sections of the act, those portions that dealt with the new drug approval process and were responsive to the criticisms of the process standing in the way of new therapies coming to the marketplace were still sitting there. Those were picked up and teased out of all that work and became the basis for the rewrite of the NDA and IND regulations.

It is interesting to see that what began to happen in Dr. Schmidt's time as commissioner continued to be matters of concern: the allegations of improprieties; ineffective management of the process; arguments that the process was laborious and should be streamlined. All of these had been raised by the critics of the agency in 1974, 1975, into 1976--the IBT issues and related issues in regards to the credibility

of data coming forward from studies done in support of new drug applications; moving into the bioresearch monitoring program and its objectives moving into the drafting of legislative changes; continuing to respond to allegations of drug lag, all continued from one Republican administration to another, through a Democratic administration and into, now, a conservative Republican administration.

Finally, all the efforts came to light--to the extent that any of the ideas were accepted for change--in those two regulations, the NDA rewrite and the IND rewrite. All of that effort wended its way through ten years or more of any number of changes: Schmidt, Gardner, Kennedy, Gardner, Goyan, Novitch, Hayes, Novitch, Young (Laughter), and the various secretaries and all, and the presidents and all. I didn't mention the general counsels that changed during that period of time. If you sit down and read those two regulations, sum and substance, that was the end result of all of that bioresearch initiative, except for some specific regs like GLPs and the patient protection regs that deal with institutional review boards and informed consent. Lots of effort, more person, days, hours, years, than you could even hope to capture, in all of those initiatives through the years.

There are a couple of other aspects of the time when Art Hayes was commissioner that I'd like to touch upon. One I'd like to go back to just pick up a little bit is the initiative of the Reagan administration to interrupt and impose additional procedures into the regulation development process as a means of achieving their longer-range goals of slowing the rate at which the government promulgated new regulations. In the same way, they looked to influence other procedures within the government, and for FDA one of those procedures was the way in which civil and criminal actions were managed and forwarded to the U.S. attorney's office.

Now, for the most part, you will remember in the middle 1970s all of the cases brought by the Food and Drug Administration went though a procedure where the recommendations were initiated at the district office and came forward for review at the appropriate headquarters offices of FDA--depending on whether it was food

or drugs or whatever. Then they came, at least in later years, to the Office of Regulatory Affairs for review on agency policy and for the pleadings work, going back to that office accepting that responsibility from general counsel's office several years ago. Then those recommendations would go to the FDA's general counsel's office in the department for final review, and the cases would be actually forwarded by the department to the U.S. attorney's office over the signature of the general counsel.

That was a reasonably laborious path for regulatory actions. We had tried over the years to streamline that process to where seizure cases that dealt with very routine kinds of matters would go directly from the district office to the general counsel's office and then out to the U.S. attorney's office. For injunctions, where speed was of importance, we even for a while tried to hand carry those in, as you remember, to headquarters, walked them through the process, then would be reviewed finally by the general counsel's office and sent on to the U.S. attorney.

Now, this entire process was complicated somewhat with the reorganization of the general counsel's office by Peter Hutt. I mentioned this earlier in our discussion where Peter reorganized his office to be more representative of a private sector law office than the more traditional government general counsel's office, and certainly different from the one that was managed by Billy Goodrich. Well, the subsequent general counsels kept the organizational structure implemented by Peter--and that meant that the concept of that office operating like a private-sector office: here a case would come forward, be assigned to an attorney; then it was that attorney's concept of how best to manage that case and how to structure the case before it was given to the general counsel for final review and sign off. That organizational concept and approach itself sometimes added to the amount of time that was necessary for a case to go through the procedures just because there would be differences of opinion between the district office, the bureau/center or the Office of Regulatory Affairs and the general counsel as to how best present the case that would be signed off and sent to the U.S. attorney.

Well, in the early months of the Reagan administration, the administration took steps to include in that particular process the Department of Justice. Now, we would regularly go to the Department of Justice in cases that were really major precedent-setting cases where we might need assistance in getting the case filed, managing the case, whatever. Particularly if there was an adverse ruling at the district court level or even at the circuit court level, we would have to come back and gain their support for appeal.

(Interruption)

JH: But previously in the day-to-day routine forwarding of cases, the Justice Department was seldom, if ever, involved. Now, we were supposed to, after the case had been reviewed at the department level by our own general counsel's office and was ready for forwarding, forward it to the U.S. attorney's through the Consumer Affairs Division of the Department of Justice. So you had now an additional attorney assigned before it ever got to the U.S. attorney's office, and that attorney, we realized after this procedure got underway, would have ideas as to how best to present the case and, ultimately, would be responsible for dealing with the U.S. attorney's office on managing the case.

So where, in the past, you'd have most often an assistant U.S. attorney that had the case for filing and managing at the local level who would look to the district compliance officer and the FDA's general counsel's attorney as assisting and supporting the development of the case, now you add another attorney who's out of the Justice Department. And, of course, add the fact that there's frequently not a lot of love lost between the U.S. attorney's office and the Justice Department. You added another complication in the casework of the agency being accepted, filed, and pursued to completion.

When this was first proposed, interestingly enough, where previously FDA within the department had been smarting and struggling over a greater involvement

of the Secretary of HHS involvement in FDA affairs, now you had the Department of HHS, in the guise of the general counsel's office, beginning to smart under the prospects of having the Justice Department becoming involved in their affairs.

Soon after this was proposed, a delegation consisting of the department's chief counsel at the time, Juan del Real, Jeff Springer, who was acting chief counsel at the time, Arthur Levine, who continues to be deputy chief counsel for litigation of the Food and Drug Division within the department, Dr. Hayes, and I all went over to the Justice Department and met with the appropriate officials there.

Now, I really have to step back a minute and think about who those three persons were. Clearly they represented the assistant attorney general level and the office director and the division director within the appropriate division. Dr. Hayes and our own department's general counsel argued very, very strongly in opposition to this initiative. But they were overruled; and although we reached some agreements on the more simple seizure cases, otherwise all casework routinely began to go through the Justice Department for filing. That offered an opportunity not only just to add additional views and additional attitudes over the merits of cases, but also added that much greater opportunity for the political views of the administration to be reflected in whether casework was filed.

Now, I don't know as I can ever point in that whole time that this was occurring to where a case was turned down for political purposes, so I think in fairness I never saw that aggressively, actively, take place. But certainly it did slow down the cases. It provided an opportunity for the cases to be rewritten, the legal basis for the cases to be redirected. And we know from our own experience that that can reflect a political view as to the extent to which precedent can be established through the mechanism of casework. Because if you drop certain charges or you don't pursue certain charges under given sections of the act, then you're not going to have established precedent in that regard.

The unhappy thing is that about the time this was all occurring we had a couple of cases that came forward that had been languishing around through the

whole procedure within the FDA itself. And so they were old, they were close to the statute running, and it just provided an opportunity for the Justice Department to argue that their involvement might have hastened decision making, might have provided the agency and the department with even greater opportunity to move aggressively to reach decision and send cases forward. It's unhappy that that occurred at that time, but it turned out that we were our own worst enemy right at that moment in time by virtue of having some of these older cases going forward for consideration for filing. In a couple instances we were within a couple months of the statute running.

FL: The statute of limitations?

JH: The statute of limitations, yes. So that meant it had taken us four years, ten months from the time that the violation occurred to make a decision that we'd forward the thing to the Justice Department, which would have required rapid review and filing in order to make it under the five-year wire.

It was just another instance where time and energy and effort had to be then turned to developing procedures whereby this review process could take place. This involved not only procedures in the Washington area, but we had to establish procedures at the district office level where, all of a sudden, compliance officers at the district office, who'd been working with U.S. attorneys' offices and working with attorneys out of our own general counsel's office, would find themselves working with attorneys out of the Department of Justice.

The administration achieved some of its longer-term objectives. I'm not arguing that they wanted to necessarily slow down the rate at which people were prosecuted who deserved to be prosecuted, but certainly it allowed the administration to have greater involvement and extend their control over the executive branch of government. And I'm confident that FDA was not singled out for that kind of action. FDA was just reflective of what was occurring throughout government.

A couple of other things to talk about. Soon after Dr. Hayes became commissioner, Dr. Richard Crout left as director of the Bureau of Drugs. Dr. Hayes undertook an initiative to find a director--without a lot of success. Now, over the years I can understand why good qualified scientists who are outstanding in their field--for instance, as a physician--may not be attracted to the position. Salaries are not nearly in government what they are in the private sector. You don't have to put up with some of the nonsense of the bureaucracy and certainly of the Congress as it relates to your managing those kinds of activities. But for whatever reason, Art was having a heck of a time finding someone to come in and take that position.

Finally, the solution was to ask Hank Meyer to not only head up the Bureau of Biologics but also head up the Bureau of Drugs and combine the two activities. The story is that Hank said he'd be pleased to do that except there needed to be some increase in the prestige of the organization within the agency and some benefit for him to assume the responsibility for managing two major offices. One of the suggestions he made was that they establish, within the Food and Drug Administration, the National Center for Drugs and Biologics. And there for a while they were calling it the National Center for Drugs and Biologics.

For drugs that wasn't so bad, but then--and this is just an aside--once the one organization within the agency assumed that title, then the other bureaus also wanted it. They said, "Hey, wait a minute. We're doing the same kind of work. If we're going to change and be more like, say, the Centers for Disease Control and have centers--for instance, the national institute has institutes--then we need to have centers and we need to have a national center for foods." But, of course, that began to tread on the toes of the Department of Agriculture, which also regulates foods. Apparently, some opposition to having a national center for foods was raised. So then they backed down to where they had a Center for Food Safety and, it turned out, Applied Nutrition. And they had to back away from their commitment to Hank for a National Center for Drugs, and they just characterized it as a center. It's an interesting little bit of politics within the executive branch and just an interesting

aside as to what was important for persons when they were thinking about assuming additional responsibilities. And that's not surprising.

But the interesting thing, that was only the first of several organizational changes that came about under Art Hayes. And in that instance, the first step was taken because Art literally had to begin to look within the agency itself for the competent, capable leadership that he needed to run the old Bureau of Drugs. He found that, in his view, in Hank Meyer.

FL: Who was already directing the Bureau of Biologics.

JH: And doing, I think, a very good job of it. Now, it turned out that the two programs are somewhat different one from the other, and it didn't work out. Those of us that had been around a while realized that they were considerably different in their background and history and attitude toward how industry ought to be regulated. It was a shotgun marriage, and now Dr. Young has seen fit to tease those two apart again, and you have two separate centers. But at the time, it was the only thing to do; it was the right thing to do.

Falling soon on the heels of that, the commissioner was confronted with a vacancy in the old Bureau of Devices, and he was no more successful in looking for and attracting someone to come in to take over that bureau as he had been in the case of Drugs. So again, he looked within and looked to John Villforth, who was the Director of the Bureau of Radiological Health and had been, I think, again, quite an effective manager in that program, to take over the two programs and combine them into a single organization. Therefore, you had the Center for Devices and Radiological Health.

I think that's worked out quite well. There's a much closer relationship between those two programs and the scientific expertise required; and, to some extent, even though their backgrounds were clearly different one from the other, the overall attitudes toward regulation and interaction with the regulated industries are

much more compatible than had been the old, traditional Bureau of Drugs approach to regulating drugs and the Bureau of Biologics approach to regulating biologics.

That set Dr. Hayes to looking to whether or not some other organizational changes might be appropriate, and he made some other decisions in that regard as well. One of them was to combine the Office of Regulatory Affairs with the Office of Regional Operations so that the field offices of the agency would, at least in the view of the rest of the agency, have a more direct line of reporting to the commissioner and be in a position to, at least in Dr. Hayes's view, influence agency policy more effectively when it was appropriate that they do so than they could by being a peer group to the centers.

Now, part of the reasoning behind Dr. Hayes's view is I think he was heavily influenced by a major investigational effort that took place early in his tenure as commissioner, and that was the first Tylenol tampering episode. As you will recall, that occurred late in the fall of 1982 and was perhaps one of the most difficult and challenging regulatory problems the agency had ever had to deal with. The Tylenol matter can, and probably has been, the subject of more writing in recent years than any other single event, and I don't think it's necessary or appropriate to go into a lot of detail here in regards to that initiative. But certainly some things evolved from it that I think are important, from my perspective, to put on the record as to what I think the agency achieved in that whole initiative.

We were very, very effective in dealing with the individual issues at hand, following up with all of the "me, too" tamperings that took place. We contributed directly and, I think, effectively to the task force that was established in Chicago under the direction of the state attorney general in the state of Illinois to pursue the criminal investigation. We were timely in considering what kinds of actions could be taken to attempt to preclude that kind of tampering occurring again and getting the tamper-resistant packaging regulation on the books as a final regulation. We reacted well to all of the initiatives at the state and local level where local politicians were concerned that the federal government might not move rapidly enough to protect

their citizenry, and to overcome that and to prevent a deluge of individual regulations. We did all of those things, but to me, the most important achievement of that whole initiative was the fact that the agency was able to preserve the integrity of the over-the-counter drug and the food distribution system in the United States.

Had the agency not been able to preserve that and assure the public that those products were safe, that this was an isolated incidence and, it was reasonable to believe, would not, could not, should not occur again, we might find our entire marketing system changing dramatically. And certainly all drugs could go back behind the counter, many foods could go back behind the counter, and we would have had a dramatic change in the way this country perceives its food and over-the-counter drug supply. And to me, the major accomplishment of the agency was to assure the public of the integrity of the OTC drug and the food supply in the United States.

But again, that whole initiative just made it clear to Art Hayes that he wanted closer, more direct opportunity to interact with the field and for the field organization to influence agency affairs. He thought that could best be achieved by elevating it to the office of commissioner level. He proposed a change to Secretary Heckler in, I think, late July, early August of 1983. By the end of August, he was gone. He had accepted an opportunity to become dean of a medical school. It was important for him to assume that role before the fall term, and within a very short time, he was gone. So that recommendation was at the secretary's office, but the secretary concluded that she could not act upon it without a permanent commissioner in place.

Meanwhile, Dr. Hayes had, when he first approved the concept, asked that I implement the concept in an informal way, and that took place as early as April of 1983. So that informal organization continued to be in place all during the time between April of 1983 and July of 1984, when Dr. Young accepted the position to come in as commissioner.

Let me take a few minutes to talk about Mark Novitch. And it's important that I talk about Mark, just as it was that I talked a little about Sherwin Gardner,

because of the circumstances that brought them into the job of deputy commissioner and then their opportunity to act as commissioner. You'll remember I talked about the period between Dr. Kennedy and Dr. Goyan when, for about the third time, Sherwin was asked to act as commissioner and he quite actively and aggressively sought the position at that time and could have done the job quite easily. But he was not selected, and I think that was influential in his making a decision to make a change.

Dr. Goyan, as a nonphysician, I think, looked especially to candidates, then, to replace Sherwin as deputy commissioner who would bring that particular experience and that particular educational background into the commissioner's office. And I think that that's not unreasonable. He focused on Mark who had, by that time, become the associate commissioner for medical affairs in the agency, as a principal candidate for the job.

Mark saw himself as a career government employee. He'd been in government, by that time, for about ten years or so and had started his career at the department level. He'd been actively involved in a number of departmental initiatives. He was one of the principal architects of the so-called Maximum Allowable Cost, MAC, regulations. He'd been working with Ted Cooper before Ted became the assistant secretary for Health and Ted was in the department. And you remember there was the Cooper Committee that looked at the need for device legislation in 1973, '74, along in there. The Cooper Committee report was widely quoted as influencing to some considerable degree the device amendments, and in being persuasive that it was time for those kinds of amendments to be passed. And Mark had had an involvement there, so he'd been involved in public health kinds of issues within the department for some time and then had come into FDA.

I learned to know Mark best first when he was John Jennings's deputy when John was the associate commissioner for medical affairs for a while under Dr. Kennedy. John left government during that time, and that was when Mark assumed the role of associate commissioner. Although an entirely different kind of person

from Sherwin in the way in which he managed the office and interacted with the staff, he was no less effective in his approach to the job as deputy commissioner. His ability to perform as commissioner, again, was reflected in those periods of time when Dr. Goyan left with the change of administration and Dr. Hayes came into the job several months later, and again between the time Dr. Hayes left and Dr. Young came on board.

(Interruption)

JH: In contrast to Sherwin, though, where Sherwin was acting a couple of times before he ultimately became more aggressive in seeking the job, Mark was open and aggressively sought the position of commissioner in that period of time between Dr. Hayes and the appointment of Dr. Young. I think he was probably much more openly aggressive and sought more openly support for his candidacy for the position than Sherwin had.

As a consequence, when Dr. Young was selected to come in as commissioner, it was not surprising that Mark would elect to leave government. In both instances, it's a shame that that had to occur in that both Sherwin and Mark were very, very effective as deputy; both demonstrated their ability to act as commissioner and be quite effective in that role as well; both provided a continuity between administrations of individual commissioners or between changes in the executive branch of government itself. And that was very helpful to the agency, provided a stability to the commissioner's office that it might not have otherwise been able to maintain. It's just very important that, as I have opportunity to talk about the principal leadership of FDA as embodied by the commissioner, I also have an opportunity to particularly talk about two of the persons that I had an opportunity to work with as deputy commissioners. Sherwin Gardner and Mark Novitch as deputy commissioners were very effective and were well received and viewed by the agency as a whole in that job. What a good job they did.

When Art Hayes left, Mark said, "Look, we're going to demonstrate that we're able to manage this organization and manage it effectively, and we're not going to skip a beat in the initiatives that this administration has undertaken and in our handling matters in a timely and appropriate way." Mark was conscious of the fact that here it was August of 1983 and the elections were just a year away. The expectation was not very strong that the administration could find someone from outside to ~~come in and accept~~ the position in what might be a very short-term appointment. We were not unmindful of that. To Mark's everlasting credit, notwithstanding his own ambitions, he did not allow the agency to falter or to slow or to in any way respond adversely to the fact that, just within a year and a few weeks of the upcoming election, Dr. Hayes had decided to leave the agency. He did a very effective job of managing; it was a privilege to work with him as acting commissioner.

Mark Novitch was very effective in dealing with the public and the press and the Congress. He could be very strong in that position because during his tenure as acting commissioner, several issues arose, one of them the issue that was originally precipitated by EPA in their concern raised in the pesticide used for the fumigation of grain, ethylene dibromide. Clearly, with a Democratic house, the activity of the executive branch, which was Republican, was not viewed as being particularly progressive and effective. And in my opinion, it was not, at least to the extent it was EPA's principal role here. They were, I think, quite inept overall in the management of this matter, and FDA just got swept into it by virtue of regulating the tolerances that were set by EPA.

But notwithstanding that, we were brought before a joint committee of Representative Weiss of New York and Representative Synar from Oklahoma who chaired one of the agricultural committees. Really an acrimonious hearing, but, boy, I was so proud of Mark. Not an easy role, not an easy task as an acting commissioner. He did a very effective job of representing the agency and defending the agency in a most difficult setting. I guess you can see that I liked him personally as well as

having a high regard for him professionally. I enjoyed my relationship with him very much.

We were all kind of surprised, then, when in the middle of July of 1984, it was announced that they had identified someone to come in as commissioner and to come in from outside of government. And none of us would have been surprised had the administration selected someone that was already within government, somewhere else within the department ~~or elsewhere within~~ government, to take the job of commissioner. And there were a number of names being bandied around of persons who could have clearly come in and been qualified for the job. We were also not necessarily surprised when Mark did not get the job, because I think Mark is a Democrat, and this administration has been more conscious of political affiliation than anyone up until this time.

So it wasn't surprising, but it was surprising that Frank Young accepted the position of commissioner with just--what?--July, August, September, October, four months before the election, and certainly with the expectation that within a few months later he would be confronted with having to tender his resignation if Mr. Reagan was not reelected. I think Frank accepting the position reflected two things. I think Frank was ready to make a change from where he had been. He had been in the position of Dean of the School of Medicine and Dentistry at the University of Rochester for several years. He had, I think, been at least reportedly quite effective in turning around that particular department. I think he was looking for an opportunity to do something different.

Furthermore, I think he had a sincere desire to become involved in public affairs, and I use that term "affairs" as contrasted to public service. Now, public service is a way in which you become involved in public affairs, but one does not necessarily always follow the other. I think had Frank had an opportunity to become directly involved in influencing public affairs in a political setting other than becoming a member of the administration and assuming a public servant's role, he would have been attracted to that and been, I think, quite effective there as well.

But this offered him an opportunity to get involved in public affairs and to make a change.

I reach this conclusion not on things that he told me at the time he came on board but on the basis of conversations I had with him when I decided to retire myself and my discussions with him about my need to assume new and different challenges and responsibilities. And that all didn't come necessarily from my conversations with him, because I talked with Lee Ann, his wife, at that time as well. I'm just convinced that Frank was ready to do something different and willing to take the chance that it would not work out, because, coming from academe, not unlike Schmidt, Don Kennedy, Goyan, and Hayes, he had retreat rights back to the university. Now, some had retreat rights back to, say, a tenured chair, as an example. But my understanding was that Frank had to give up retreat rights to the dean job, and that's not surprising. You know, you don't want necessarily to have your dean's chair empty for a couple of years or more. But he did have, and maybe still has, retreat rights to the university. So he wouldn't have been out of a job, so to speak. And a third aspect of this, he was convinced, in his own mind, because he is a very strong supporter of the administration, that Mr. Reagan would be elected to a second term. So all those put together: he came in and assumed his new responsibilities just within months of the election.

I think in my own experience, Frank Young is probably the most politically oriented commissioner that I worked with of those commissioners that were political appointees, starting with Charlie Edwards. Now, I don't mean that in any sense in a derogatory way. I just think that he came in more of a politician as well as a physician, as well as an administrator, than his predecessors. I believe that his capabilities in that kind of a role have been demonstrated over the intervening months. And, quite frankly, in balance, to the benefit of the agency rather than to its detriment in this particular administration.

We didn't necessarily feel that way early on, some of us. We didn't know Frank. We sensed a political dimension to him that we had not encountered before

and, in all candor, it made some of us a little apprehensive, because we didn't know what that might ultimately result in. Frank is a dynamic person. He has greater energies than perhaps almost anybody I've ever encountered. He has capabilities to read and absorb, and become involved in and learn the things he had to learn. He was better at that or as good at that as anybody I ever knew in that particular job.

By chance more than anything, just by chance, the first day he came to the agency, ~~not to stay but just~~ to come in and say, "Look, I'm Frank Young. I want to meet several of you. I'll be back in several weeks" . . . That day there was a meeting where a number of us were together out at the Ramada. Jim Swanson was one of those persons that was in that meeting. I don't even remember now exactly what that meeting was about. I don't remember whether it was an RFDD, Regional Food and Drug Director, meeting or a meeting of compliance officers or whatever, and Jim was part of that. I remember I established the situation where RFDDs, or district directors, had a direct involvement with the compliance branch chiefs' group or with the chiefs of the investigations branch and so forth. I think it was a meeting of one of those groups and that Jim was in as part of that.

But I was called on the phone and told that the new commissioner was there and he was taking a few minutes just to meet the members of the policy board, and could I come over and meet with him briefly. Of course, I said I would and could. But I took Jim with me. So he met, not only me for the first time that day, but also Jim, and he had an opportunity in that meeting to understand right away that there was a field organization to FDA and that we had regional Food and Drug directors, and we talked about that as much as we talked about anything else in that particular first meeting.

It lasted, oh, thirty, forty-five minutes. But Jim, of course, in his gracious way, said, "Look, Dr. Young, one of the first things that I'd like to have you do is consider to come out to a field office right away." Well, that clicked in Frank's mind, and he decided that before he came on permanently, he would spend a day at a regional and/or district office. So he let me know that. And we looked at what we could

achieve in a day, concluded we'd take him to Chicago because he could get into Chicago out of Rochester with comparative ease. He'd have an opportunity to meet and talk to a regional director and people on a regional staff, meet and talk to people at a district staff level, see one of our newer laboratories, but also go to a region in which there was more than one district.

So we had the district directors come in: John Feldman from Minneapolis, Jim Simmonds from Cincinnati, and Al Hoeting from Detroit. Mary Ellis was there at Chicago. So he had an opportunity in one day to kind of get a broad feel of what goes on in the field offices. I think it was very effective and very beneficial to us later--when I say "us," to the field part of the Office of Regulatory Affairs--that Jim was there at the time to meet him the first time, plant the seed that he needed to get out to the field offices, and then, that he chose to do that even before he came on full-time.

He asked for some briefing material as well on each of the organizations, and we prepared a very thoughtful briefing document on the Office of Regulatory Affairs, both its headquarters and responsibilities of the field. And as part of that, we raised the issue of Dr. Hayes having recommended to Secretary Heckler the establishment of the new organization but that it was still before her and had not been acted upon. So that was one of the first issues that I talked to him about. He made a commitment for a timely decision but would not act upon it until he had an opportunity to get better acquainted in the agency and a better sense of the reasons behind the recommendation. He was true to his word in that regard and, within just a couple months of coming on board full-time, made the recommendation to the secretary that she approve that reorganization, which she did.

When Frank came on, Mark, then, was candid with him, said that he would stay long enough to make sure that Frank got his feet on the ground and understood what the job was and was comfortable that he could manage the job of commissioner on a day-to-day basis, but then that he, Mark, intended to leave government. Frank told me frequently that he tried to persuade Mark not to leave, and I think that's

true. Anyone coming in and inquiring about Mark's effectiveness, I think, could have concluded that it would have been to their advantage to keep him in the job. But I don't think that was possible, just would not have been possible.

I think even if Mark had opted to stay, I'm not sure it would have been a good marriage and lasted. They were quite different, one from the other. They were both M.D.s and other issues might have come up. When you've got one M.D. and one that isn't, then you don't have the potential of a strong difference of opinion within the office. Although that did not arise between Art Hayes and Mark, it might have between Frank Young and Mark in that they were quite different in their attitudes about the job and what the objectives of the job ought to be.

Frank, then, decided to bring someone in to the position from outside of government. He brought a person in that he knew, had learned to know, in the capacity of a management consultant that he had drawn on when he was trying to make major changes in the way in which the University of Rochester managed its teaching hospital program, and that was a fellow by the name of John Norris. John came on board, then, as deputy within about six, eight months after Frank Young came on board, because I don't think Mark stayed around more than two or three months. Then John was at the agency for a while in a consulting capacity. They made an arrangement for John to be there as a consultant, and then he assumed the full-time responsibilities as quickly as the paperwork could be processed.

Frank Young, like his predecessors, especially beginning with Don Kennedy, looked to what might emerge as some major program initiatives that could be seen as initiatives for that commissioner. As an example, Art Hayes--we didn't talk about this at all--took on as a major initiative concerns over sodium in foods. In contrast, Frank Young took on an initiative to look, not at program matters, not drugs, not foods, not food labeling or whatever, but he took on operational issues. He asked the question, "How can the operational procedures of the Food and Drug Administration be improved?" And as a consequence, he undertook the initiative that became the First Action Plan.

Now, there were some politics there and some pizazz there. The objective of the First Action Plan was to prepare the Food and Drug Administration for the twenty-first century. Those of us that were having a hard time dealing with the next day (Laughter), especially confronted with some kind of a politically difficult issue of the moment--a hearing or whatever--we had even some problems going to the end of the month. But that was catchy, and he presented that as an initiative to Secretary Heckler. It was accepted by her, and with some considerable fanfare.

So early on, he began to hold meetings of the policy board and began to discuss with us this concept of an action plan. He was looking to us to identify the areas of greatest importance to the agency, now and for the future, that could benefit from specific identification for improvement. He was looking for issues for which specific action items could be identified with periodic steps--develop the plan, the objectives, time frames, commitments, and end results, and be measured, each of us in part, by whether we achieved those goals.

Early in this effort there was, again, some apprehension. Preparing the agency for the twenty-first century. Let's identify some of these issues and begin to work on them. Some that emerged were ones that maybe had surfaced time and time again through the last fifteen years or more and not had anything much accomplished as a consequence of it. But again, I have to be candid that the idea caught on; it caught on within the agency itself. People began to see opportunity to influence or change things that they thought ought to be changed, and so, ultimately, I sensed some considerable commitment on the part of the agency as a whole to the action plan and to completing and fulfilling the objectives of the action plan. People were willing to set aside some of the Hollywood nature of the initiative as being acceptable and understandable if, in fact, the process allowed for a positive impact on how those several issues of the action plan were dealt with.

(Interruption)

FL: How would you evaluate the action plan as compared with earlier attempts by FDA to establish long-range plans, such as the five-year plans of the 1960s?

JH: I would evaluate it as being a much more effective way of approaching the problems of the agency and have to reach that conclusion by saying that it was an entirely different kind of plan. It was not a plan that was designed to project what should the agency be doing in five years, what it should be doing in ten years. It turned out to be, having identified the kinds of things the agency will have to be dealing with in five or ten or fifteen years, what are the first steps the agency has to take to begin to deal with those issues today?

Now, the buzz words "Prepare for the twenty-first century" could have just as easily said, "Prepare to take the first steps in turn to prepare for the twenty-first century," because, ultimately, after I left the agency two years ago, there was a second action plan, and now there's a third action plan. The whole concept of using this approach to kind of tease out of five-year plans, to tease out of two-year strategic plans, even to tease out of annual budgets, specific kinds of issues that need to be dealt with and given visibility and make commitments to individual tasks has, I think, been proven to be a reasonably effective way for the agency to deal with those things.

The earlier five-year plans or the longer-range strategies would raise these issues. I think of the go-aways of the 1970s that became popular, where the policy board would go to an off-site for a day or two and begin to focus on what were the long-range concerns. Well, we went through the exercise in that period of time in good faith, and those issues would be raised, and then we'd all just go back to work. That's all there was to it. That's one of the principal reasons I really strongly opposed the off-sites, because nothing ever happened as a consequence of them short of raising issues that the management of the agency ought to be dealing with. But there was no transition, no means of saying, "Okay, having identified this, how do we start to deal with it?" Because then you would come away from the off-sites and then get involved in the shorter-term planning and the annual budgeting. And, you know,

that's really where the rubber hit the road as far as that particular cycle of planning was concerned, and you lost sight of these other issues.

Young reached into that process--because you've still got the long-term planning, the strategic planning, the annual budgeting--and said, "Okay, what are these issues that I can pull out of there and bring together under an umbrella that I can put a little pizazz to it, get people to commit to it whatever their motivation, and actually begin to see some change?" I think it was very effective. All of us didn't necessarily believe it would be when we'd first gotten started, but I think it was an effective tool.

Now, whether it would continue to be effective, I don't know. And I earlier said that a change of administration might change things and the agency lose its momentum. You have to be careful that this kind of a process itself doesn't become routine and trite and lose its effectiveness. So any new commissioner coming in would be confronted with having to design new ways of assuring that the process continued. Not to belabor it, but I saw it as quite effective but different, an addition to rather than a substitute for these other planning initiatives.

Something that I have to raise as a programmatic issue that arose during my time with Dr. Young as commissioner was the second Tylenol tampering episode. Again, there's probably enough available on the record in regard to the specifics of the incidents themselves. But here again, the agency was confronted with having to assure the public that they could go down to the drugstore, or the supermarket, or could stop at the 7-Eleven, and continue to buy over-the-counter drugs and foods without major concern; that these tamperings were anomalies, that they were narrowly focused, that they were situations that did not extend to the entire food supply or the entire OTC drug supply.

To the everlasting credit of the agency as a whole and to its leadership--entirely different this time, as far as the commissioner and deputy commissioner are concerned--the agency was very effective in that regard. In both instances, the commissioner stepped forward, the deputy commissioner stepped forward, as

spokesmen for the agency, effective spokesmen, particularly the commissioner in the second instance and both the commissioner and deputy commissioner in the first instance. In this case, I think a physician talking not only as commissioner but as a physician saying to the public, "Look, these are problems, but we're doing something about it. And if you do the following things, you can feel confident that this is not going to reach you and we're going to deal with it effectively." Earlier, Dr. Hayes and Dr. Novitch both played ~~that role, both very~~ effectively. Secondly, Dr. Young did it very effectively. It fell to John Norris only occasionally, and, probably, again, because you wanted the doctor image there.

But it was interesting. I talked about Frank Young and his energies. They seemed to be endless during those episodes. We were working in the Office of Regulatory Affairs at the field level and at headquarters; we were on duty twenty-four hours a day. We were literally in the offices up to midnight, 1:00, and 2:00 in the morning, back in those offices at 6:00, 7:00 in the morning; duty officers on duty in between, either in the office or within immediate reach by phone. It was just like the first time around, only more so. Tylenol started; Gerber's baby food followed with glass; "me, too" incidents with cookies, the Girl Scout cookie episode all over again. All of those kinds of things. It was a most, most difficult set of circumstances. And maybe sometime, if you ever want to come back, I'll talk more about those particular investigations, particularly the second one.

There were aspects of the second one that did not evolve from the first one. I think we were much more effective in dealing with the Federal Bureau of Investigation, as an example, during the second Tylenol episode. I think we were much more effective in dealing with the firms themselves the second time around than we were the first. Now, maybe you'd say, "Well, you learned something from the first one." But I'm not so sure. We did learn some things, obviously. Clearly, we strengthened some of our recall procedures and some of the other kinds of things as a consequence of the first one, but those are not experiences necessarily that you dwell on. During the course of them, you always say, "What we really need is to step

away from this, step back, and after it's all over, say 'What did we do? Let's have an analysis of what we did.'" But I guess by the time it's over, you're so exhausted, mentally and physically, it never happens.

Meanwhile, everything else is going on just at the same pace and you've got to catch up, but you never really do an analysis. I don't know whether you attribute that to the fact that you get back to business as usual and you have to deal with business as usual or whether ~~that's all of it, or~~ part of it is that you just don't want to go back and revisit because it was such a difficult thing to deal with. But somehow, I just think in the second go-round we did a much better job, much more effective job as an agency. Not the field offices as individuals, not the centers as individuals. They were as effective the first time around and the second. They were major regulatory initiatives, and they did good jobs both times. But I just had a better feeling that the whole thing was better managed overall the second time around.

I think we were bolder in taking strong positions. I felt very strongly that, as an example, Gerber needed to be protected against a surge of pressure to get them to recall all their baby foods off the marketplace. Early on, J and J, Johnson and Johnson, had decided to pull all the Tylenol off the market; they were not going to go through what they went through the first time around. I respect them for that. I don't see that necessarily they had an alternative. It was a different situation for them.

Every shred of evidence pointed to the fact that what was being encountered in the way of glass particles in Gerber's baby food initially was not tampering and would have been accepted under any other circumstances as the very rare, occasional circumstance of any product packed in glass, and that the American public had become accustomed to encountering. But because we were involved in the Tylenol matter and because of the fear and the whole atmosphere of the moment, right away, a little, tiny bit of glass was attributed to tampering. Then later, I mean, they were encountering pieces of glass an inch square. And there was no way in the world that

kind of glass could have gone through Gerber's process, flat out did not go through it, the way in which they were being encountered.

Now, there were circumstances in which glass could be found in Gerber's products, and we never denied that. But the kind of glass we were encountering clearly could not have been attributed to that. We got smart, too. We began to realize that glass has its "fingerprints," and you can analyze glass and tell where it came from; so we began to use Libby. The Libby Glass Company worked with us very effectively, and then we learned that the FBI laboratory can also analyze glass quite effectively. And we were determining on the record that the glass being found in these jars was not the same glass that was used in making the jars.

Even within the agency itself, from the Center for Food Safety, there was some waffling that maybe the best way to deal with this is just require all these products to come off the marketplace. I was adamant in my own feeling; I was adamant in my arguments to the commissioner. I was very pleased that he accepted my point of view in this instance. And we were not pushed into having Gerber call everything off the market. We were prepared to do it if it proved it had to be done, but we just resisted that.

And we resisted other recalls if we didn't think it was necessary for them to take place. Now, a lot took place because the companies themselves concluded that they would do that. We respected that, and once they made that decision we worked with them; but we argued strongly that it was not the agency concluding that the product was hazardous but rather a decision on the part of the company, in the public interest, to take the products off the market. But we had to really struggle along. We had to be very astute and careful in what we said and how we said it. We had to work very carefully with Gerber to make sure that they didn't undertake to say things in what we thought might be the wrong way or, at least, do more harm than good.

I kind of got away from the point I wanted to make. Frank Young's energies, Frank Young's interests in individual matters, clearly were reflected in this as well,

because he went well beyond what he normally would have had to do as commissioner, even to be effective as a spokesman for the agency, in involving himself in the intricacies of the investigation. He became the principal contact between the agency and the senior management of the firms. It became the commissioner of Food and Drug talking with the chief executive of J and J or the commissioner of Food and Drug talking with the president and chief executive of Gerber. He became the principal spokesman between the agency and the coroner's offices in instances where the coroner's offices became involved because there were deaths attributed to tampered-with products.

He wanted to play an active role in that regard; he did play an active role in that regard. And he would remain at the agency to be briefed on what was occurring up until 11:30, 12:00, 1:00 at night. Then we'd wrap things up to the extent we could, because even the tamperers, I guess, go to bed. Most all of us would go home and go to bed. But then I would get a call at 5:30 in the morning from Dick Swanson in the Division of Emergency and Epidemiological Operations. Dick Swanson would call me saying, "Here's what I heard since we parted company at 1:00 or 2:00 in the morning." Or, "Where we were last night is where we are now." I would call the commissioner at no later than about 6:00 in the morning and give him a report on what had occurred between our last briefing of him, say, at midnight or whatever, and 6:00 in the morning. He was then prepared to be responsive to, or even take the initiative to report on behalf of the agency to the press as to what had occurred, if he felt that was the proper thing to do. So he literally, as commissioner of Food and Drugs, was an active, integral part of the investigation.

Another aspect of my working with Frank Young as commissioner that I'd like to discuss, at least briefly, is the fact that under the Reagan administration the field organization of FDA was able to implement a concept that it had had in mind for some long period of time, and that is a reduction in the number of regional Food and Drug director positions. A complete discussion of the regionalization of FDA would have to include a realization that it really didn't make an awful lot of sense

for FDA to have to adopt the regional configuration of the government, especially those regions in which the Department of Health, Education, and Welfare and, later, Health and Human Services, was assigned; because those are principally political structures and boundaries and do not necessarily reflect at all either commercial routes or areas of crop production or industrial areas or whatever that are the kinds of factors that more clearly affect the Food and Drug program.

What you wound up with, as an example, was that Kansas City and Seattle and Denver were regional offices in one district, so you had an artificial separation of regional office and district office. In contrast, in some regions, like Chicago or Atlanta, you'd have more than one district and it made a little more sense; at least organizationally it made a little more sense. But all through those years, FDA kept looking for an opportunity to step back from the ten-regional concept to see if they couldn't still fulfill the objectives of a regionalization of program but not have the artificial structure of ten regions.

The Reagan administration provided an opportunity for this to be looked at anew when they directed all of the various departments to look at the regional office configuration within their department and see whether or not there could be a consolidation or change of that regional structure as a means of finding economies in government. So we were directed, in that sense, within the department, to begin to look at how that could be achieved.

At the same time, some things were happening in the field office structure from the standpoint of staffing that would facilitate those kinds of changes, in that we were beginning to realize some vacancies or expect some vacancies at the regional Food and Drug director level. It allowed, with good planning, an opportunity to take advantage of those kinds of vacancies to, over time, to implement a program of a reduced number of regions. So we were pleased in the Office of Regulatory Affairs to look again at some configurations that reduced the number of regions, and concluded on the basis of that initiative that we could move quite conveniently from ten regions to six regions without major disruption of our own

program and still work within any regional configuration imposed upon us by the government as a whole, because we maintained regional offices in the principal major cities of the country, like New York, Atlanta, Chicago, Dallas, and San Francisco.

Ultimately, the White House backed away from that initiative for political reasons. And as you look back through the years--and as I mentioned, they were political boundaries to begin with--it was not surprising that the political pressures and commitments of an administration would result in their not taking those kinds of actions.

But FDA was ready to move, and being ready to move, and with the full commitment of the commissioner, Dr. Young, was able to take advantage of that. With vacancies at the regional Food and Drug director position in New York, Chicago, Denver, and Seattle, he proposed to the secretary in lieu of filling those positions that we implement the program of reducing the number of regional directors and put regional Food and Drug directors into place in a reduced number of regions. Now, some of this took place after I left the agency, so I'm not privy to the exact steps that were taken. But I know that just before I left, the FDA was ready to move to reduce the number of regions and had a good, solid plan for doing so.

Well, let me come back to that. I was going to talk about laboratories. But I probably ought to talk about laboratories later, because that was really one of my great frustrations: facilities, and laboratories specifically.

I would like to urge that Suzanne White, the FDA historian, take steps to preserve some of that paperwork that represents the thought process that the Office of Regulatory Affairs went through. This should include the various regional configurations they considered, the basis on which they reached their judgment, the recommendations that went forward. A copy of that document ought to be put into the archives. I doubt, however, if the documents, that reflected the way in which we considered the organization, to begin with, and then thought about reducing the

number of regions even in the 1975-76 time, are still around and captured. I think those are important documents.

RP: I have some of them because I played a part on both occasions, but they're certainly not the whole thing.

JH: I don't want to spend too much time on it. I think it's too late to go back, in some instances. But clearly, from now on, we need to learn lessons from the past.

Another thing I want to talk yet about Dr. Young as commissioner, and it relates to the political dimension of him, because I believe it's played a major role in it, and that is his effectiveness in protecting resources of the agency and gaining new resources for the agency at a time when the government was reducing its size. I believe there was really bipartisan support for reducing the expenditures in government. Clearly that was visible in the actions of the Congress in the early months of the Reagan administration and, subsequently, the strong initiatives on the part of the administration to reduce expenditures, particularly in the domestic programs. Dr. Young has gone to bat, and quite effectively, to protect the resources of the agency and to, in fact, in a number of instances, gain resources.

(Interruption)

JH: Now, he's not been able, and I suspect no one would be able, to return the agency to its size at its peak; but certainly at a time of reducing resources everywhere within government, for a commissioner within a program as small as FDA, even though it's quite visible, to protect that resource and to, in fact, add to it over time, I think, is a major accomplishment.

In my conversations with people like Jerry Meyer, he and I saw Frank Young as the most effective spokesman for the agency in regards to resources as any commissioner, at least in contemporary time, and I think at least all of those

beginning with Goddard. Because the major resource allocations to the agency in the early seventies and mid seventies were not as a consequence of agency initiatives, but as the result of outside reviews of the agency's activities, criticisms of the agency's activities, and initiatives principally on the part of Congress to give us additional resources. An extension of that is that I think much needs to be . . . How can I best say this?

Dr. Young's effectiveness is a combination of his own personal capabilities in the job and the fact that by chance, perhaps as much as anything, and his commitment to the program, he's been able to stay in the job for four years and will be, even with a change in administration, commissioner of Food and Drug for four and a half years. And that's longer than any other commissioner since George P. Larrick. And when you consider a period of time of twenty-two years--from 1966 to 1988--when the average term for commissioner was probably between eighteen and twenty-four months, and then a turnover, it has to tell you some things.

One thing it tells you is that the Food and Drug Administration is a terribly strong organization. It's not a new organization; it's been around for seventy-five, eighty years. It's a program by its very nature, as we were talking earlier, that attracts people that are committed to the program, and a large part of its staffing are career employees. There's been a stability, again, to the credit of the commissioners who had opportunities to change some of the organization that I think contributes to that stability, and that's the field. All of those things, and many more, I'm sure, contribute to a strength of the agency.

But eventually, I think that might have been worn down and compromised if periodically there wasn't an opportunity to step back and draw your breath. The fact that Frank Young has been commissioner for four, and will be commissioner for at least four and a half years, has allowed the agency to step back and draw its breath, and, I think, will contribute to the strength and stability of FDA in the future.

Each commissioner has brought his own attributes, his own attitudes, his own personality to the job. Each has been a good person, a good commissioner in his

way. Frank Young has been no less committed to the job, no less effective in the job, and because of his effectiveness in individual ways, particularly, and being in that position for that period of time, I see that as a major contribution that he has made as commissioner, because he could have left earlier and did not.

Part of his strength lies in his political astuteness, his political dimension, his willingness to interact with the Office of Management and Budget, with the department, his willingness to interact with the Congress, and he aggressively will interact with the Congress. He is proactive in that regard where many others, even though they were political appointees and even though the Congress was of the same political party, they were reactive in their involvement with the Congress. Frank Young's been very proactive in that regard. And, as an extension of that, he has been actively engaged almost from the moment that he came on board in beginning to build a constituency for the Food and Drug Administration outside of the Congress and outside of the government.

The fact is, one of the problems that the FDA has had through the years is it has no constituency. We used to jokingly say that if everybody was unhappy with you, you were thinking you were doing reasonably well because nobody was happy. But even then, when the chips were down and you needed someone to step forward and defend you, there wasn't anybody there. You were all by yourself. And you'd look around at some of your sister organizations even within the department, especially somebody like the NIH that has and had a great constituency in the Congress, in the private sector, and in a sense could hardly ever do any wrong. You felt that FDA was singularly disadvantaged as a consequence of not having that kind of support.

Now, certainly, we can't ever have the same kind of support that the NIH will have. But Frank Young went out and aggressively began to talk to the industry, particularly through its trade associations, to say, "You know deep down inside, you understand down deep inside, that the FDA's not going to go away; regulation of your product is not going to go away; and your industries profit most by having a

strong, effective, scientifically and otherwise capable Food and Drug Administration. Except and unless you begin to step forward and talk about that and emphasize that in your contacts with the administration and your contacts with the Congress and your public pronouncements, you're not going to have that. Because the FDA will, along with a lot of other programs, particularly in the foreseeable future, begin to feel the impact of the economy measures in government."

He began to do things that I think other commissioners were almost afraid to do because of what might result in the way of criticisms. I mean, when you have a Dr. Kennedy coming in and saying, "Don't talk to the industry except you put it on the record. Don't do these things except you have major exposure of what you're doing, for fear of allegation of wrongdoing . . . " Frank said, "I'm going to risk that criticism, and I'm going to go out and establish a constituency." I think he's been reasonably effective in beginning that process. If he is not to be commissioner beyond next January, then I would hope that the commissioner that comes in behind him has the intestinal fortitude to continue that procedure. I think that cannot hurt the agency if properly managed and certainly can do nothing but help it.

Let me talk about an interesting experience that I had that was not an experience in FDA but relates to my current position as a member of Hazleton Laboratories Corporation. Each year at the Society of Toxicology annual meeting, Hazleton sponsors a by-invitation-only breakfast. It's a nice event and quite well attended. Each year they have a speaker at the breakfast that brings a special message of general interest to persons attending that scientific meeting. Two years ago, we had Senator Hatch of Utah, and he made a very interesting presentation. But more importantly, this last time we had Jerry Mossinghoff, who is the president of the Pharmaceutical Manufacturers of America trade association, PMA. Jerry made a presentation that was a combination of the economic well-being of the drug industry of the United States today and of the programs of the PMA. As part of his presentation, he used slides.

The latter part of the presentation was the effectiveness and the activities of the PMA, and he put a slide up there on which he had listed the eight or ten most important achievements of this past year. Among those were the support for the Food and Drug Administration's budget. Now, in my opinion, that would not have happened in years past. But here is the PMA publicly saying, "We're prepared to support the budget of the Food and Drug Administration."

Now, they had their own reasons as well. I mean, there's concern over user fees. User fees used to come up regularly as a way in which the revenues could be generated at the federal level, and FDA was asked to respond to user fees. But this administration, more than any other, has been aggressive in implementing new-user fee programs. The new drug approval process has been a prime target for that, and the pharmaceutical industry has not been very happy about that. But, you know, let's face it: politics is a give-and-take kind of business, and we're not going to be surprised that our constituency would want to have some benefit for their support of the agency other than just being good guys. But the fact is that that constituency is beginning to develop. And I know that other trade associations, like the National Food Processors, GMA, and others were actively involved in supporting the agency's budget proposals, both within the administration and on the Hill.

I support that kind of initiative. I think it can be done without compromising the political integrity of the agency. And, in fact, I look back at my own experience through those years as a senior official of FDA, standing out there naked, all by yourself, nobody coming to your defense, and you're saying, "Too bad we don't have a constituency." I hope that the initiative continues and that it would be broadened to include a much wider range of membership.

Frank Young would like very much to continue to be the commissioner, even with a change of administration. He's very open about that, and I think is probably actively campaigning to remain as commissioner if Mr. Bush is elected as president. I think that's interesting as well, and I would wish him good luck. My own opinion is that if Mr. Dukakis is elected as president, he doesn't have a snowball's chance in

the hot place of staying in the job just because of the way our government works. He will be required to submit his resignation as the new administration comes in, and there's no reason in the world to believe that a Democratic administration under the leadership of Mr. Dukakis would keep a person like Frank Young in as commissioner. He has greater expectations of staying, probably, under Mr. Bush's administration. But here again, it depends on how many commitments and all that Mr. Bush has as a consequence of his running for ~~the~~ presidency.

But you know that, I think, also brings a stability to the agency, a feeling on the part of the rank and file that here's a person that does enjoy the job, has been reasonably effective in the job, as effective as any one of the commissioners of recent times, and wants to stay and sees it as a challenging job and not just something that you come in, spend eighteen, twenty-four months or whatever, and then move on to some other challenge. So to that extent, Frank Young is different from the others that I've talked about the last two days.

RP: Thank you, Paul. It is getting late, and I think this might make a good stopping place for us. This is true, particularly since you have already been kind enough to agree to another interview at a later date. This ends the interview.