

History

of the

U. S. Food and Drug Administration

Interviewee: Alexander M. Schmidt

Interviewer: James Harvey Young,
Robert G. Porter

Date: 8-9 March 1985

Place: Chicago, Illinois

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.

Editor's Note

Dr. Alexander M. Schmidt passed away on 28 January 1991, before he could do a final review of this transcript. The FDA History Office acknowledges Dr. Schmidt's wife, Patricia W. Schmidt, for her assistance in the editing. Also, the reader should be aware that this transcript follows as closely as possible the guidelines of *The Chicago Manual of Style*, 13th edition; references to names and terms are capitalized (or not) accordingly.

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(If retired, title of last FDA position)

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BP: This recording is one in the series of oral history interviews with former Food and Drug Administration employees. Today we are interviewing Dr. Alexander Schmidt, now Vice-Chancellor for Health Affairs of the University of Illinois Health Sciences Center, and former Commissioner of the Food and Drug Administration. Present in addition to Dr. Schmidt, are James Harvey Young of Emory University and Robert G. Porter of the Food and Drug Administration. The date is March 8, 1985. The interview is taking place in Dr. Schmidt's office in Chicago, Illinois.

JY: Dr. Schmidt, in these interviews we like to begin with some autobiography. Would you please start at the beginning of your life and carry it up to the time that you were chosen as commissioner?

AS: Well, that is a long question. I was born in Jamestown, North Dakota on January 26, 1930. My father was with the J. C. Penney Company and had requested to go to North Dakota to work because my mother was from a little town named Bottineau, North Dakota, up on the Canadian border. She wanted to be closer to her home than Chicago, where my parents had been living shortly after they were married. My father was from Chicago and went to Northwestern and they met at Northwestern University, and started out married life here. Chicago was a bit much for my mother, so they went up to Jamestown, North Dakota, a town of 2,000 people. My father lived through the dust bowl and drought in North Dakota, but requested of the Penney company a little more water, so he was sent to Scottsbluff, Nebraska, which is in an irrigated valley not depending on rainfall for the

crops. So, we lived in Scottsbluff, Nebraska for a while and then Ogden, Utah, which I really considered my home since high school.

Northwestern was the family school. I went to undergraduate college at Northwestern University. The intent was to follow the path of some of my relatives and go to Northwestern Medical School, but several different factors entered into my going to Utah University College of Medicine instead of Northwestern.

JY: Had you thought of being a physician before you went to college?

AS: Well, yes. My lifelong hero was my maternal grandfather, who was a physician, and knew Sir William Osler and was really a great man in many respects. He was a practitioner of medicine in Bottineau, North Dakota. He took care of many people throughout southern Manitoba and northern North Dakota. He was kind of my role model in many respects.

It was either human medicine or veterinary medicine. Almost up to the time I went to medical school, I didn't know whether I would be going to medical school or vet school because I grew up with animals and loved animals. I was kind of intellectually drawn to medical school and emotionally drawn to vet school. Finally, I think my parents and other friends sort of pressured me in the direction of medical school saying that my talents, such as they might be, might be better occupied in human medicine than in animal medicine. I've never been certain whether that was absolutely correct, but as it turned out I went to medical school.

At the time I was deciding where to go to medical school, I think the main factor was that I missed the West and missed the mountains and missed my animals. I had one or more horses that I missed. I preferred the lifestyle of the West, and the idea of living and working in downtown Chicago, which I now do, didn't really thrill me at that time.

The second thing was that Utah had just started up and had got going what was a first-class medical school with superb people. Rocky Miller, who was president of Northwestern University, and Richard Young, who was dean of Northwestern University Medical School, had both been at Utah. As a matter of fact, Rocky Miller recruited Young, who was dean at Utah, to come here to be dean at Northwestern. There was always a fairly strong connection between Utah and Northwestern in a lot of different ways. Richard Young suggested that Utah might be a good place for me to go.

So I did go to University of Utah Medical School, and to this day have been grateful for that opportunity because it was a marvelous place to get an education. The quality of the people that were there then was spectacularly good. Classes were very small. Some of my closest friends were department heads and faculty of that school.

JY: Who had the most influence upon you, would you guess?

AS: Well, that's easy to say. The head of the Department of Medicine, Max Wintrobe, the great hematologist, had a great influence over everybody who came into contact with that school. Most certainly me. I worked with Hans Hecht in cardiology at times when I was in

medical school. Then, of course, I went into cardiology and trained with Hans Hecht in the Department of Medicine.

The summer between my second and third year, I worked with Lou Goodman in the Department of Pharmacology. One of my close friends through all of these years has been Lou Goodman. I think, obviously, he's one of the great pharmacologists of the country and one of the authors of *Goodman and Gillman*, the standard textbook in the field.

Lou Goodman and Hans Hecht and Max Wintrobe—I think those were the three people with the greatest influence. But there were others there, Horace Davenport of the ABC, of acid-base chemistry. Horace was head of physiology. And Tom Doherty, the lymphocyte man, was head of anatomy.

So many of the people there were first rate. The intellectual excitement and stimulation of that place in those days, I've never seen any other place I have been. I think it's gone from Utah now, too. In those early days in Utah, Max Wintrobe would invite the Department of Medicine and some students to his home for Thanksgiving dinner. Can you imagine a thing like that, given the numbers in departments of medicine today? The way we were able to get to know those people was really something very special. Certainly my interests were formed very much in that medical school.

It was a small school and a lot of the people were from Hopkins. I suppose there was much about Hopkins at Utah in those days. Phil Price, the head of surgery, Max Wintrobe, and George Cartwright, who later was head of medicine there—all these people were at Hopkins.

JY: You stayed on?

AS: The idea was that the cream of the crop, so to speak, stayed at Utah. To be invited to be a straight medicine intern at Utah for the Utah student was better than going to Harvard or Stanford or anyplace else. Max first invited me to be one of his straight medicine interns, and then one of his residents in medicine. As I looked at the other opportunities, other places to live in the country, or other places to train, I really couldn't think of another place I would rather live in those days. I was convinced then, and am still convinced, that the training I got there was as good as anyplace I could have gone.

So, with a two-year period out in the Army in the middle of my training, I was at Utah for my whole formative career in medical school--a straight medicine internship, a residency in internal medicine, and then a two-year public health research fellowship in cardiology with Hans Hecht.

JY: Did the Army experience have any relevance that you can think of to your later commissionership?

AS: Not a hell of a lot. I think I learned something about administration in the Army. How both to do it and not to do it. My Army experience was in Germany, first as a surgeon with a field artillery battalion for approximately half the time and then as a C.O. of a thirty-two-bed station hospital.

The second half of my time, what I tried to do there was to practice good medicine. I think probably the most important thing that happened to me there was that I had a patient, a young woman, with anemia, and I did the standard University of Utah anemia workup and still didn't know what the cause of the anemia was. So, I sent her and the workup I'd done up to Frankfurt to the 97th General Hospital. She came back that night in tears because I had reassured her that if she went up to the big hospital in Frankfurt, they would take care of her and find out what was wrong. She really wasn't feeling too well. She went up there to whatever receiving part of the hospital it was, and they looked at the workup I'd done with the little lab I'd set up in my little hospital. They told her that I'd done more than they knew how to do and that it was ridiculous for her to be in that hospital and to go back and let me take care of her because I obviously knew more hematology than they did. Well, most people out of Utah knew more hematology than most people.

The next day I was called up to Frankfurt and interviewed. They wanted to transfer me to Frankfurt to be the Usura area hematologist. But since I'd moved too quickly or something, I couldn't do that. So, I ended up being hematologist to the Army in Europe from my little hospital in Darmstadt. I really spent that time trying to take very good care of the many people that I had responsibility for.

As far as the Food and Drug Administration went . . . Well, I never thought of this before, but I did have a couple of veterinarians that were under my administrative control who did meat inspections and food inspections. I remember once, I had to settle a dispute between a veterinarian of mine who said that a semi-trailer truckload of hamburger was good and the mess officer who said it was rotten. A semi-trailer truckload of hamburger was

worth a lot of money. The mess officer wouldn't serve it because he said it was putrid. The veterinarian said it had just aged a little bit and was fine and to serve it. I had to . . .

JY: Play Solomon.

AS: Well, they opened the back of that truck, and this awful odor came out and it was all brown on top and this water ran out of the back of the truck. I turned to the veterinarian. He said, "It's all right, captain. It's just a little watery." So, he fried up some hamburgers and he ate one and he wanted me to eat one. I finally decided I had to support my veterinarian, so I ate one of the hamburgers. Actually, it tasted pretty good. So, I declared the meat all right, and it was served. Fortunately, nobody got anything.

But, in reality, there was nothing in that experience that would have given me any particular interest in or expertise, either, in the matters that fall within FDA's purview.

JY: How were you chosen to go to the National Institutes of Health?

AS: You mean the first time I went to Washington?

JY: The Division of Regional Medical Programs.

AS: Okay. After I finished my cardiology fellowship, Hans Hecht and Max Wintrobe both asked me to stay on and be on the faculty at Utah. And once again, it was a small

faculty even when I joined it. I considered that a great honor to be asked by Wintrobe to be a member of his department, and I was delighted to stay. So stay I did. Hans Hecht left Utah and went to the University of Chicago and wanted me to go with him. I looked at the University of Chicago and decided to stay in cardiology at Utah and got more and more involved.

One year Hans was on a sabbatical in Europe, and I was sort of acting head of Cardiology. We did a number of things, including getting involved early in a program called regional medical programs, which some people called the heart disease, cancer, and stroke program that grew out of a report by Michael DeBakey that called for regional centers for heart disease, cancer, and stroke. This became transmuted in wending its way through Congress into the regional medical programs. But a very large part of it was cardiology. At Utah we wrote one of the first grants and we were one of the first regional medical programs established. It was really a highly successful effort.

JY: So that that really was, in a sense, financed by NIH, but it was done in Utah.

AS: Well, the Regional Medical Program was a national program. It was started in Jim Shannon's office in the National Institutes of Health. Bob Marston, who later had a series of jobs, including being director of NIH and, most recently, president of the University of Florida, was brought into Jim Shannon's office by Jim to run this national program. The intermountain area was one of the regional medical programs. Many others across the

country were formed so that finally all parts of the country fell under one or another regional medical program.

Bob Marston asked me to come to Washington in the early days of that program and help get it started. So, I took a leave of absence from Utah and went to Washington in 1966 and spent a little over a year and a half with RMP in Washington.

I think there was one other factor, and that is that while in Utah, I had been selected to be a Markle scholar in medicine. The Markle program has since been stopped by the Markle Foundation--it's gone into other areas. But at that time the Markle program was very important to academic medicine. It gave relatively large awards to young faculty. It was a process of identifying young faculty who, in the view of the Markle Foundation, were capable of doing things that were good for academic medicine.

The reason that was important is that if you look today at a roster of Markle scholars, you will find major figures in American medicine in the past twenty years. Bob Marston was a Markle scholar. The dean of Harvard Medical School is a Markle scholar. John Cooper, the long-term president of the AAMC, is a Markle scholar. Surgeon generals have been Markle scholars.

I was president of my class of Markle scholars and was involved in most of the meetings over a several-year period and got to know all of these people. Some of them were truly the leaders of American medicine, in and out of government. So, I was invited to come to Washington, essentially, by a couple of Markle scholars. The initial conversation I had was around the table at an annual Markle meeting, where I was sitting with Jim Shannon and the then surgeon general and Bob Marston and others, talking about RMP and what we

were doing in Utah. Within days I got a call that said, "You've got to come and help us do this."

RMP was a very prominent program in those days. Lyndon Johnson and others were watching the program with personal interest. And I was assigned by Jim Shannon to the White House for a number of weeks while I was there, so I was able to meet people, including the president and his staff and others and worked directly in the White House. I had a temporary office, right in the East Wing of the White House, so that I got to know people.

JY: That was really building all kinds of bridges of importance.

AS: Well, that's right. It was learning things and getting to know people, and learning how things worked and learning how to get things done. Particularly, it was fun to talk to Lyndon Johnson, which I had the opportunity to do briefly on a couple of occasions about how to get things done in government and so on.

And it was fun. There were good people in the White House. I remember that there was one presentation that I was at that was made by a young lawyer from the Defense Department. Lyndon Johnson took a liking to him and had him brought into the White House. His name was Califano and he was at the beginning of his career.

So, you meet people and you establish some kind of a reputation for yourself and you stick in some people's minds. In particular, if you're a Republican working in a Democratic

administration, you stick in people's minds. There's always a lot of teasing and so on going on.

JY: How were you invited here, then, the first time?

AS: Well, my intent was to spend up to two years with the regional medical programs in Washington and then go back to Utah. But another very important figure in American medical education, if not American medicine, was a man by the name of George Miller. And George was here at the University of Illinois directing the Office of Research and Medical Education. George started what is now commonplace in American medical education, that is, formal offices of research and medical education. He was very well known. He was on the review committee for the regional medical programs. RMP was set up much like NIH institutes because it was in Jim Shannon's office, so it was natural that RMP take the shape of one of the institutes of health.

So, we had a National Advisory Council. We had study sections. As I recall, George was on the study section, and I got to know him well, and he got to know me. The University of Illinois was beginning a major revision of its medical education program. It was really almost a total redo of the organization and of the curriculum and so on. The college was contemplating, essentially, doubling its size, setting up programs in Rockford, Illinois; Peoria, Illinois; Urbana Champaign on the other campus, greatly expanding its activities and launching a huge building program. You're sitting in the middle of the largest

medical center in the country right now. They were planning a total redo of curriculum, as I said.

They needed somebody to come and do that: to plan that and to oversee it and to carry it out. So George said, "Come to Illinois and meet the chancellor and meet some people and just talk to them and see if you'd be interested in coming to Illinois, because it's going to be a very exciting place in the next five to ten years." So, I came here. I'll never forget walking the first time on this campus with these huge gothic buildings. It was almost like walking down a canyon. Here outside my window, the buildings . . . To come from Utah, where in medical school we were in wooden barracks from the old Fort Douglas, and to see what there was here in the richness and the amount of state funds coming in here, I couldn't get over it. The opportunity that they offered me was something I just couldn't turn down.

JY: The chance to create.

AS: Well, there were resources that were here. And there were resources in the city of Chicago. I'm fond of telling people that a lot of what you hear about Chicago is true. It may have been a little more true when Mayor Daley was alive than is true now, but it was a city that worked in many respects. Of course, there are some of the unfortunate aspects of the city that slowly are being addressed, that have to do with the poor and minorities and so on. But let's talk just for a moment about what the university was trying to do and how we were trying to do it. It was a city that you could get things done in. At any time I could

pick up the phone and get to Mayor Daley. And if we had a good idea, he'd say, "That's a good idea, let's do it." And then you could do it.

The state of Illinois, by and large through the years, has supported in hard money this institution very well. When I came here, as one example, nobody, no faculty person could be in a tenure track position unless there was a hard line in the state budget for that person. And, in essence, the faculty were a hundred percent supported by hard monies appropriated by the state. In Utah we could stay there as long as we supported ourselves. The luxury of not having to worry about where your salary was coming from was a big change to me.

JY: Not having to write grant applications all the time.

AS: Yes. Now, you know, there's a good side and a bad side to that. The bad side to that was Utah had a hell of a lot more research going on than was going on here.

BP: What year did you come here?

AS: Well, I was with RMP in Washington in '66 and '67. I moved here near Thanksgiving. So, I came here Thanksgiving of '68. Under, of course, the chancellor and the dean, I was called the executive associate dean of the College of Medicine. My responsibility, literally, was to be dean in the absence of the dean. To be kind of number two. But my principle responsibility was to plan what was referred to as the reorganization and expansion of the College of Medicine. And I did that, essentially, full time, and was very pleased that

when we finished the job of planning--we being the faculty committees I set up and so on--and took it to the executive committee of the college, it was voted as approved almost unanimously. One person voted no, and everybody was so surprised that this individual was asked why he voted no. He said, "Because something this important should never be unanimous." But this was against the background of an earlier attempt to reorganize and expand the college having been voted down by the faculty. And when I first came, the institution was hostile to the idea of doubling its size and setting up regional programs.

When we did then reorganize, I became dean of what was the old College of Medicine here in Chicago. I forget exactly when I became dean; I think early 1970. From then until I did go to FDA, which was mid '73, those three-plus years I was dean of the medical school here in Chicago.

JY: Just a kind of personal question: Did you know Harry Dowling before you came here?

AS: No, I did not. And actually, I didn't know him when I came here either, because he was on a leave. Nicholas Cotsonas, who came from Georgetown with Harry Dowling when he came here, who is now the editor of *Diseases of the Month*, was acting head of Medicine. I didn't meet Harry until he came back from his sabbatical, which was some number of months after I came.

I was familiar with his name, though, having been in internal medicine and academic medicine, but Harry didn't figure in all of this until 1973 really.

JY: Then how was it that when 1973 came you were chosen? What were the dynamics underlying that important step?

AS: Well, I'm not sure I know. I've read interviews of other commissioners and most commissioners get asked, with varying degrees of surprise in the voice, the question, "How did you ever end up being commissioner?"

JY: I hope I didn't have that tone.

AS: I've been asked that question, and I've always said I don't know, which, if I were forced to a short answer, would be the most truthful short answer. I really don't know very much about it.

But I do know the following: one is that I knew a lot of people in Washington. I knew a lot of people in Washington because I was a Markle scholar and there are a lot of them in Washington, and I knew all the Markle scholars, or a great number of them.

Secondly, I had been in Washington for a year and a half and had been in a very visible program in a very visible way in Jim Shannon's office and Bob Marston's office. Bob and I and a couple of others planned the reorganization of the Public Health Service that was presented to Phil Lee and Lyndon Johnson. Bob Marston was superb at taking me where he went. And Jim Shannon, they were both interested in young people. They would say, "We're going over to the White House; why don't you come," and things like that.

So, if I count my heroes, I've given you my grandfather. I named Max Wintrobe, Hans Hecht, Lou Goodman. Then I got to Bob Marston and Jim Shannon, because they really taught me a tremendous amount. In a year and a half I learned a fantastic amount from those two guys by watching them and listening to them. Bob and I used to fall into a conversation sometimes at 5:00 and we would just keep talking until 9:00 about whatever issue. And he would give me that kind of time to teach me.

Then, after I came to Illinois, Illinois was prominent in medical education circles because of George Miller, Harry Dowling, and George Jackson, the people that were here. And I was doing a number of things in Washington. I stayed involved with RMP. I was chairman of their study section. And after I had been away from programming an appropriate period of time, I was doing things with the AAMC, so that I knew a number of people.

JY: Had your research in any way been related particularly to the kinds of things that the Food and Drug Administration was concerned with?

AS: No. First of all, my research career has not been one of the more exciting aspects of my life. When I first started out in cardiology, I was doing some research, but I fell into the category of faculty that, because of interest and because I could write and because I was a little bit of a showman, I think, I was given a lot of teaching to do. I also was the principal, clinical cardiologist. The research I did was largely in the cath lab and with pulmonary physiology and the interaction between pulmonary and cardiovascular physiology. But the

research was not a major part of my career. After Hans Hecht left Utah, I very quickly became an administrator, as you said earlier, by having to fund myself and others. I wrote a good part of the RMP grant, which is a very large grant.

And then I was one of the people working with the people in Washington, even when I was back at Utah, to formulate a program that became known as cardiovascular research and training centers. There were three or four of us, people around the country, who talked the Heart Institute into starting this new program. And then, of course, I wrote a grant for that. And it was funded, so I became director of the Cardiovascular Research and Training Center at Utah. It was very heavily an administrative job, and actually led to my being appointed as a dean in charge of planning of the Utah Medical School.

So, I was into planning, administration, and management very early in my career, much to Max Wintrobe's dismay. He used to call me in and chew me out and say I would never amount to anything because I was spending too much of my time doing things that wouldn't advance my career. And I'd say, "But Dr. Wintrobe, you asked me to do those things." And he would say, "Well, that's because you're so good at it." And I'd say, "Well, quit asking me." And he'd say, "Well, I can't." And I'd say, "Well, then quit chewing me out." And he'd say, "I can't." It really was one of the reasons that I left, in a sense, to go to RMP, because I was better at making arrangements of things. I liked to look at a problem and arrange people, events, dollars, and space or whatever it is, so that the goal could be accomplished. In RMP it was arranging the country, getting the country organized to do things with the advances of medicine.

JY: So that your reputation for these things, you think, is obviously an important factor in your choice to do that kind of thing at FDA?

AS: Well, yes. I was not thought of because I was a superb scientist. That would be clear to me and, I think, everybody else. I think I have a pretty good feeling for science and what it is and what is necessary to science, and I've actually done some writing on that. I think I've done enough investigation to have a feel for it. Yet, if I was known for anything, it was being a manager, not being a scientist. I was known for being a teacher and not a scientist. I was known for someone who could write well and speak reasonably well in public, but not as a scientist.

JY: Who approached you from the Food and Drug Administration? How were you approached?

AS: None of the above. You have to remember, now, that this was the beginning of Nixon's second term. And you have to remember that toward the end of his first term, he asked for a lot of people's resignations and he turned over a lot of the cabinet. And, as you see now with Reagan, the Nixon administration wanted a certain kind of appointment. One of the things I think that was going on is that they were literally looking for Republicans, or moderates. They weren't looking for spendthrift liberals--that's for sure. I probably had, over the years, maybe someplace between twelve and twenty people tell me that they were

the one that suggested me to the White House. John Cooper said that. There were just many, many people who said that.

And then the other thing was, at that time, management was considered important. Nixon was one of the many presidents who said he wanted to try to manage the bureaucracy. All presidents have said that; few have done it. But Nixon was interested in management talents, and I think the people who were looking at FDA believed that management was important--management skills were important at that stage of FDA's evolution.

I was sitting in my office here as dean of the medical school one morning when my secretary came in and said, in effect, "There's some nut on the phone who says he's calling from the White House." So I really don't think she thought it was for real. So I picked up the phone. The first contact was with the chief headhunter at the White House. I was recruited by the White House, not FDA and not the department, although I know that before I was brought in, I had been discussed with Cap Weinberger and Charlie Edwards.

JY: Edwards was still in FDA?

AS: Edwards was just sort of in between when I first showed up. He was still at FDA when I first visited.

JY: Was he briefly the associate secretary for health or whatever it was called within the department before he left?

AS: Charlie was commissioner of FDA. Then Cap Weinberger asked him to become assistant secretary for health, which opened up FDA. NIH was open at the same time, and they were looking to fill, simultaneously, both NIH and FDA.

In my initial conversations with the White House, the conversation was about both NIH and FDA. They were looking at me to see if I was fit, I guess, for anything, or NIH or FDA. And I very quickly said to them the same thing I just said to you, and that is that my main credentials and accomplishments to that date had not been in science. And NIH needed a leader from science more than I was. And our conversations led fairly quickly to FDA and its need for a commissioner. Parenthetically, they finally got Bob Stone to head NIH. He was, in many respects, similar to me in that he was dean of a medical school and more a manager than a scientist.

So, in a way, I think I fit what the administration was looking for, and that was a Republican person from the academic field who had some management skills and might be able to manage FDA.

JY: Did you have any conversations before you accepted the position, or afterwards, in which you were given any kind of instructions as to what the White House or the department had in mind for you to do besides being a good manager? Any policy counsel you were given?

AS: Well, the first time I went into Washington to talk, I spent the entire day in the White House and did not meet Secretary Weinberger or Charlie Edwards or anybody else. That

was just a general set of interviews with the White House staff on what they were trying to accomplish and what kinds of people they were looking for and what they were trying to do, and to get acquainted and sizing up and all that kind of stuff.

JY: It was more general level policy than it was things particular . . .

AS: Very, very much so. They were giving me their view of NIH and their view of health and their view of the needs for health and national health insurance and their views of HEW and how it was run and testing me and asking me questions. You know, some of the questions were a little off-the-wall and were a little startling to me. I mean, you know, I'm dean of a medical school and a good kid from the Midwest who grew up in Utah, and all of a sudden I'm talking to the likes of Ehrlichman and Haldeman and so on,

JY: What kind of off-the-wall questions do you mean? Do you remember an example?

AS: Well, just things asking about management philosophy. There was only one question that I thought was bizarre that had to do, for instance, with what would you do if you want something done and people refuse to follow the order or some such thing like that. But for the most part, it was very general. I suppose there were four or five hours worth of meeting people and chatting. And a lot of it was about fishing and mountains and the West and California. A lot of those guys are from California. So, a lot of it was just talking about the West.

Well, I came back here and promptly forgot about it, but within a week I got a call, "Would I come back and have some serious talks?" So, I went back. And again, I started in the White House, spent about an hour in the White House, was driven up to HEW and then spent about an hour, hour and a half, with Cap Weinberger, which for Cap Weinberger is a long time because, you know, he's a very efficient person with his time, and you cover a lot of territory in a short period of time. And then he introduced me to Charlie Edwards. I can't remember if I had known Charlie before. If I had met him before, I didn't know him well. Then I spent time with Charlie and then I spent time with Peter Hutt, and those were the people I met on the second visit.

JY: How would you characterize them? Did you rather think of yourself as being quite similar in ideas to Dr. Edwards, so that your going into FDA was kind of a continuation of policy that had existed or was this in any way a break?

AS: I think I'm a very different style of person than Charlie Edwards. There are many differences in our outlook and on some things, certainly, our administrative styles are different. But we were similar in other ways. I think Charlie had a very good sense of what the organization was when he took it over and what the organization was when he was leaving it and what the organization needed. I was able to get that fairly quickly from Charlie.

One of the things I did then, following that talking to people, was testing what Charlie said and seeing if it was right or wrong and correcting it or making adjustments until finally I could evolve my own feeling of the agency and where it was and what it needed.

I think Charlie was fairly accurate. Peter's approach was different. From what Peter and then-bureau directors and others I talked to said, I was able to build a more complete picture that all seemed pretty much to fit.

JY: Can you sketch in the broad outlines of that picture? What did the agency need as you came to sum it up at the beginning of your commissionership?

AS: Well, to start with my conclusion, what it seemed to me was that the agency needed some settling down. It had undergone a tremendous amount of change. That was something I was very familiar with. I haven't talked about some of the things I've done or studied as I learned administration, but certainly change in organizations and how it's accomplished and what change does to an organization is something I was very interested in and had studied and saw. Remember, also, that I came to Illinois here to change it in very dramatic ways. And planning change and accomplishing change in the least traumatic way was something I was interested in.

I think with FDA, starting with Goddard, things began to change. I think that Goddard sort of signaled the modern era for FDA. I don't think Goddard was the modern era. I think he was almost sounding a warning trumpet or something for the agency. He was a big change in administrative style for the agency and the country, for that matter . . .

I think that Goddard began an era of change and of buffeting and of difficulty with FDA that went on then for a decade. Goddard didn't last long. Nobody lasted long. As a matter of fact, my tenure as commissioner of FDA is longer than anybody in modern history.

JY: Anybody since Larrick, yes.

AS: For whatever that means. But Goddard was followed by Herb Ley, who I think held the shortest tenure of anybody in modern times. The whole cranberry business and all of that really shook the agency.

There were questions about its efficiency, and about its management, about its organization; there were all kinds of questions. Studies had started at FDA. Charlie Edwards was really brought in to change FDA. That's why he was hired. Remember, Charlie came to FDA from Booz, Allen, Hamilton, a management consulting firm. And he brought with him Sherwin Gardner, or recruited Sherwin from Booz, Allen. And Sherwin came out of management. Sherwin was not a health professional. Sherwin was an engineer who was a management engineering consultant for Booz, Allen.

Charlie was brought in, in a sense, to bring the agency up to the speed necessary in the 1970s. And Charlie did that.

JY: How would you characterize, quickly, the ways that he did it, to bring it up to the seventies? What main things?

AS: Well, he reorganized it. He set up a different way for it to do business. And he brought in a bunch of new people--very good people, indeed. So that, particularly in the drugs area, there had been dramatic changes in the organization of the bureau. Well, Charlie just picked up the agency and gave it a good shake and then set it on its feet and said, "All right. Go." And then about that time he left.

And what I saw was an agency that had just been picked up and given a good shake. In a sense, its teeth were still rattling a little bit. In many respects the hard work had been done. The job that I saw to do then was to make the organization that was there work, because it had not been given a good try yet.

So, I saw an organization with good people. Virgil Wodicka in the Bureau of Foods was first rate, and he had a very good staff. Taylor Quinn just retired a week ago. The people of Taylor's calibre . . . Howard Roberts and so on . . . That bureau had excellent people in it.

And the Bureau of Drugs--Henry Simmons was director and then Charlie took Henry downtown. But I was able to appoint Dick Crout, who was on board, and had been recruited by Charlie.

Sherwin Gardner was there; John Jennings was there; Mark Novitch was there: many of the people who had been very important to the agency and still are. Hank Meyer was there. John Villforth, a superb administrator, was there.

So, my job wasn't to go in and reorganize. My job was not to go in and recruit a whole bunch of people. Charlie had done both of those things. My job was one that I thought I was particularly suited to do, which was to make it work, to manage it, to make

people feel good about what they were doing and to have it run efficiently and effectively and do some of the things then that had been promised in terms of making the organization work. Some of it you can do and some of it you can't do.

JY: Of course the environment in which an agency operates keeps changing, too.

AS: That's the understatement of the year, because when I first went to the White House, while Watergate had occurred, it wasn't there yet. And, of course, there were several major events that impacted one way or another on the agency while I was there, that I didn't expect when I walked in.

One was the set of Kennedy hearings on the drug approval process, which some people will always associate with me and my time at FDA, and kind of think of that era with regard to the Kennedy hearings. They were certainly prominent with regard to newspapers and so on, and were one of the more prominent parts of my administration of the agency, although far and away from being the most important. But then the whole Watergate thing, the dissolution of the executive branch of the government, which happened right before my eyes. Max Wintrobe and Bob Marston and others, Cap Weinberger, were very good to me and spent a lot of time with me. As Watergate began to unfold and come to an end with the president resigning, Cap--who was close to Nixon--suffered through that and I was able to see that. None of that was expected when I went to Washington.

JY: How did that affect your plans? Did the break-up of the Nixon administration make administering FDA more difficult?

AS: In a few minor areas it made it more difficult, but largely it made it easier.

One thing that I think is important is that when Charlie Edwards was there and when I was there, the commissioner had delegated to him the authority to run the agency and make decisions. That has changed dramatically to this day.

But one of the things I was concerned about when I went there was that I'd be commissioner of Food and Drugs and I'd be able to run the agency. I talked to the people at the White House and I talked to Cap Weinberger and sort of made a deal. And that was that I would keep Cap and the White House informed of anything they needed to be or should be informed of so they wouldn't be surprised and they wouldn't get hit on the back of the head with a wet fish or whatever, and I would run the agency well. And in return for that, they would leave me alone.

And that's the way we operated, and I was very firm in turning back any approach to the agency, either from downtown or, on one or two occasions from the White House or one or two occasions from the OMB, when they made a move that might "usurp" our prerogatives. You know, the FDA is a proud and distinguished agency and in those days was very proud of its independence. It knew what it was doing, it knew how to do it, and it wanted to be left alone to do it. It was made very clear to me by the professionals in the agency that one of my jobs, by God, was to be sure that it stayed that way. And one of the things I did,

even on a couple of occasions, was to say, "Look, you want to be commissioner, you be commissioner. You don't need me; I'll go home."

JY: Do you want to be more specific about an example of an occasion?

AS: Well, I just read about it, as a matter of fact. I was reading about somebody writing about somebody going after Dick Crout once and wanting to fire Dick Crout.

JY: Where did you read this?

AS: Well, I'd have to stop and think. It pointed out that I'd said, "Well, you can fire Dick Crout if you'd fire me first." And that was the end of that.

On one occasion Jerry Meyer came into my office and said that he'd just received a telephone call from the secretary's office, you know, somebody "downtown" was the word used, and it was some ridiculous thing. It was truly a dumb thing, to use Sherwin Gardner's favorite word for such things. "That's dumb," Sherwin would say. And that was dumb.

So, in a jocular mood I used a phrase that's kind of crude that I picked up in the Army. But I was really irritated. I said, "Jerry, just tell them to pound sand up their ass." And Jerry looked at me and he said, "Now really, what should I say?" And Sherwin says, "You heard him." So, Jerry laughed and went out of the office. Sherwin and I fell back to talking about what we were talking about. About half an hour later, Jerry Meyer came back in, kind of red in the face and laughing. And he said, "Well, I took care of it." And I said,

"You took care of what?" And he said, "What I told you about earlier." And I said, "Oh, what did you tell them?" He said, "I told them just what you said. I told them to pound sand up their ass." And he laughed. And I said, "You didn't." And he said, "Yes, I did." I said, "What did they say?" They said, "Oh." That's all they said.

Well, we never heard anything more. As a matter of fact it was probably two or three months before we even heard from downtown again, which was fine.

What I like to do is be given a job, understand the job, feel comfortable that I have the tools, then be left alone. We had several advantages. One was Charlie Edwards was, in effect, my immediate boss. And Charlie knew the FDA and he knew what needed to be done, and he felt comfortable with what I was doing and how I was doing it. Charlie and I spent a lot of time together so that our communication was good. When I needed to see Cap, it was no problem with Charlie, and Charlie and I went or I went by myself. The secretary was very supportive. There is an advantage to being a member of the party in power. The White House left me alone. I was Republican. I come from a Republican family. My father was well known in Republican circles. He had known the famous senator from Illinois here for many years who was still alive the first time I went to Washington, and I knew him.

BP: Dirksen?

JY: Dirksen.

AS: Ev Dirksen. Ev took me to a party once, and that doesn't hurt.

JY: Then they were preoccupied, too?

AS: Well, then the White House just sort of fell apart. I made peace with the OMB very early on. Again, I used weapons that I found had been very handy for me all my life, which is humor, and a little entertainment, a little showmanship, and so on. And early on I went to OMB and we did a show for them that they never forgot. I knew the guy who ran OMB. His girl and my girl were classmates in school and we lived near each other. And OMB was pleasant, if you can believe that. If you look back at the whole time I was at FDA, you will never find reference, the whole time I was there, you will never find reference to the White House or the OMB. It was almost as if they did not exist. And I literally had total authority over the agency and what it did and regulations and decision making and so on. There was one exception, one major exception. And that's when I needed help and asked for help and got help.

JY: What was that?

AS: That was with the Kennedy hearings.

JY: Yes.

AS: The one area where the secretary stood beside me and, in effect, took over was when things were not going well with the whole Kennedy business. I had done my own investigation of the agency, which was not a mistake, but which was insufficient to the cause. It was necessary for the secretary to do something to change what was becoming a more and more difficult situation. So, the secretary set up a panel that was run by Norm Dorson. It was the result of a conversation between Ted Kennedy, the secretary, and myself in the Senate hearing chamber. During a recess, I went over to Ted Kennedy, whom I knew personally. Personally we are on the best of terms. He recessed the hearing and he wiggled his finger at me and I walked over and he said, "Mack, what are we gonna do?" The secretary was at that hearing at my request. I needed some muscle. He wiggled his finger at the secretary, who came over, and he said, "What are we gonna do?" And in about fifteen or twenty minutes we'd agreed that the secretary would establish another panel to investigate the charges that had been brought by the FDA employees, and so on.

Other than that particular thing, everything that I did, I did. Everything the agency did, including some things like banning the red dye number . . .

JY: Ten?

AS: Number two. That thing was a big deal then. All the controversy and everything that happened was within FDA. Now it's in the secretary's office.

JY: Did you have the feeling that you, in a sense, inherited the dissidents, as they came to be called? And was it just sort of bad fate that their protest came after you arrived, or did you take this personally?

AS: Well, first of all, most of the dissidents were there and had been there and had been dissidents for a long time.

JY: That's what I meant by inherit, yes.

AS: I inherited that situation. Any person who became commissioner of food and drugs when I became commissioner of food and drugs would have been at the same hearing in the same way that I was. Whether they would have handled it the way I handled it and so on is open to question. But John Nester was going to say that come hell or high water. And Kennedy and Larry Horowitz were going to have that hearing. So, it was just my bad luck, if you want to look at it that way, to have it happen to a brand new commissioner. I didn't know a goddamn thing about either what was going to happen or how it was going to happen until it happened. And neither did anybody else. This was a plot. This was a planned ambush of Peter Hutt and myself.

JY: So, the general account of it that you were absolutely surprised, that really is true, when you went to that hearing?

AS: I had no inkling. I went prepared to talk about the drug approval process. And I got ambushed, pure and simple. I was in a state of shock. Again, here is a little country boy, comes in and gets subjected to a beating up like that at the hands of a senator of the United States, and so on. It took me a little while to glue myself back together after that.

I only got mad, really angry, once. That is when I thought Ted Kennedy really overreached and said some things that really ticked me off. I thought he was getting awful close to wondering about my integrity. And I'm not sure that he was exactly the individual to question my integrity, which has never been questioned. That's too much. So, at the end of the hearing, I went charging up, but he ducked out the back and was gone. In that building there are special elevators for the senators that the common man can't get on, so I had to take another public elevator. By the time I got to his office, he was just disappearing in his office and I yelled at him. You know, I was really angry. I was about ready to do bodily harm. And he turned around and he saw me and he said, "Oh, Mack. I wanted to ask you about Saturday." Art Buchwald and I were going to be judges at Ethel's animal-kid day on Saturday, or something like that. And then he stopped and he said, "Are you mad?" I said, "Yes, I'm mad." So, then he gave me a little lecture about taking things personally and so we talked it through.

After the initial shock of it, that was the only time I really got angry, got personally involved in it. Otherwise it was just a royal pain in the ass.

JY: You settled down and used a lot of patience and spent a tremendous amount of time studying the thing.

AS: It burned agency resources; it wasted a lot of time. What really was kind of bad about it was that almost everybody knew that a lot of it was crap. It was a charade, and a lot of people knew it was a charade. But yet you had to go through with it. I didn't know, when I first heard these things whether they were true or not, and right there at that very first hearing, I said, "I'm shocked at what I'm hearing; I will investigate it." I mean what else is the head of an agency going to say?

In retrospect, I should have investigated it myself, but probably earlier, and I should have had some other independent verification of either my study or another study. At home hanging on my wall someplace I have the original of Herblock. When I said I was going to do this myself, Herblock drew a cartoon that really pissed me off. Here I am in the *Washington Post* stamping myself okay. I should have anticipated that, but the counsel I was getting said, "No, you should do it. Be firm and be in charge of your agency and do it." What they didn't tell me was that once I did it, it would be thrown out as not being believable because I had done it.

To this day, however, it stands as an accurate assessment. Nobody there said I was wrong. It was just that it was not persuasive. So Norm Dorson comes out and, in essence, verified my findings.

I gave a talk last week in Washington on congressional hearings. After all this time, it was sort of interesting. In that talk I pointed out what bad hearings like these can do to an agency.

JY: Do you think we could get a copy of the text?

AS: Sure. But I pointed out there are really four bad things. And I was thinking of the Kennedy hearings. I think that four bad things came out of that set of hearings.

One was the sheer waste of my time and other people's time. You know, Dick Crout and I and Peter Hutt and Bill Vodra and Sherwin, important people--at least important to the agency--spent days and days and weeks of time responding to all of this. We could have otherwise been approving new drugs and so on. It affects the morale of the people in the agency without any question. It undermines the authority of the managers of the agency.

Having said that, yet that was by far and away not one of the more important things that happened while I was there.

JY: Right. At the same time there was this criticism, which in a sense some of the consumers groups were also making of the agency, that there was not enough caution within the agency about approving new drugs. There came from the industry side a continuation of the drug lag critique of the agency, so that the agency was getting it in publication from two polarized sides. Do you want to talk about how you view, in retrospect, that matter? One of the things that you were doing and that you were speaking about, publicly, was looking at the agency from the point of view of its machinery of approving NDAs. And you were doing various things to expedite that machinery, as I look at the things that I've seen. As you look back at that whole drug lag debate from this perspective, do you want to say anything about that with relationship to your commissionership?

AS: Well, there's an old saying in FDA that if you're being criticized just about equally from opposite sides of a question, you're probably about where you ought to be. And, you know, there's a little bit of wisdom to that saying.

My feeling about the drug lag was, first, to discover what the agency was saying about it. Henry Simmons had done a piece when he was there that, in effect, denied that there was a drug lag. And Charlie denied there was a drug lag. I said, "Well, what are we saying about that?" And everybody said, "Well, we're saying there isn't one." And I said, "Well is there one?" And I noticed some eyes flickering around the table. And, in talking to Dick Crout about this subject, it appeared to me that the United States had a fairly rigorous drug approval process, and that we did demand things that a number of other countries did not demand, and that that was more time-consuming. We did take longer than some countries to approve some drugs. And some other countries took longer than we did to approve some drugs. At that time, it depended in part on where the pre-clinical work was done, where the clinical studies were done, what data--FDA was then not accepting foreign data. A lot of drug companies were starting their drugs out in Europe because it was easier to do clinical studies there than in the U.S., and they were registering drugs first in other countries before they even submitted an NDA in the U.S.

And, as I looked at all of this stuff, it became apparent to me that we should quit denying that there was a drug lag. Because, first of all, like any term, the term itself gets you into trouble. It's a negative term.

I can give you an example from here. A week ago there was an issue that had to do with somebody named Tom Beckham. Tom is a fine fellow and a close friend, and it had

nothing to do with Tom. The issue didn't have a name. So, I was thinking one night as I was driving home how I was going to address this issue the next day. In a major meeting with university officials, I called the issue the Beckham problem. It was a problem that had to be solved, in good part, for Tom Beckham. By giving it the name "the Beckham problem," that was picked up immediately and everybody started talking about it as the Beckham problem. Within a relatively short time, it got solved, and it was a two-year-old problem. Because people hadn't been thinking of it as a problem. When I gave it the name of the Beckham problem, everybody laughed loud and long, started to call it the Beckham problem; it got labeled as a problem and therefore something to be solved.

You call something a drug lag, you got one. It's got a name, so it must exist. So, that was really stupid. So, if you go back and look, you will see that Dick Crout, in a speech that I consulted with him on, for the first time said, "We have a marvelous system here. Some other countries don't do what we do and you're going to pay a price for that, and that price is in time and in dollars." And we started to say that.

Further, since we've mentioned John Nester, it is simply a fact that the cardiovascular division--and remember I'm a cardiologist and had worked with Lou Goodman and I did know something about at least cardiovascular pharmacology--that division hadn't approved anything in year after year after year. There was not a slowness because of caution, but there was a drug lag in the cardiovascular field, and Dick Crout admitted that in public.

So, we changed the tune of the agency. In a way, the drug lag issue has totally disappeared. It started to disappear in 1974 because we started to treat it, in my view, much

more honestly than it had been treated before. And also the agency did a number of things that responded to the valid criticism. I said, "Look, what are the valid criticisms?"

Well, one is that we spend a lot of time treating drugs alike, and drugs are not alike. You know there are some drugs that are just "me too" drugs. They are copies of other drugs that present no therapeutic advantage. There are other brand new chemical entities that might be lifesaving where there is nothing else available. If you don't distinguish and differentiate between those two, you know, that's ridiculous.

JY: That was one of your innovations. Kind of a fast track for . . .

AS: The fast track and the labeling of the fast track came later. I wish I had been smart enough to label what we were doing. But we did begin paying attention to the distinctions between drug entities. And the way we did that was by classifying them as important new chemical entities, or me too's, or by advantages, and so on. But labeling is important. And I've got to hand it to whoever it was--I think it was Don Kennedy, during his time at . . . Dick Crout was still there. But saying we have the fast track and then putting one drug through it and getting one drug through in six months: that single thing did more to do away with the drug lag than anything else over a decade before that.

The other side of it was Ralph Nader saying we were sold out to industry and in bed with industry and approving unsafe drugs. I remember one meeting I laughed and said, "Is it possible, somehow or other, very, very slowly to approve a set of very, very bad drugs? Because if I put together all of the charges, you've got an agency that takes forever to

approve a very, very bad drug. Is that what we're doing?" Everybody laughed. Up to that point, we'd been saying we were being charged with opposite sins, and I was able to put it together in one big sin, which everyone recognized as being ridiculous.

JY: Did you ever converse personally with Nader about these problems?

AS: Oh sure. I got to know Ralph Nader well, and Sidney Wolf well, and a lot of congressmen and senators and people downtown. I became good friends with Morton Mintz. You know, I enjoy people and I like people and I like most everyone I dealt with. I also disagree with a lot of people. But I enjoy them and like them. You know, Ralph Nader is a very likable chap. You can disagree with his thesis that all American industry is dishonest, but you can like him as an individual and a person. And I got to know him and Sidney.

As a matter of fact, one very funny remembrance that I don't think I ever told anybody because I sort of promised Ralph I wouldn't, was one time when we were appearing together in a panel. When it was over and we were standing in back of the podium, I said, "You know, I have to go down to FOB-8. Do you want a ride?" And he said, "Yeah, I'd love a ride." So, we went out and got in my car, which was a government car. I did a lot of work in it, and I would have a briefcase open by my side and I would sit sideways to work. I didn't like the seat belts and I finally got tired of them. So, I told the driver to take the back seat out, just drop the seat belts down to the floor, so I wouldn't be sitting on them.

Well, we got in the car. Ralph sat down and I told the driver where to go and the car took off at a fairly rapid clip, and Ralph was feeling around for the seat belt and he couldn't find any. So, he figured they were shoved down in between the bottom of the back cushion and the seat. So, he turned around and knelt down on the seat and had his fingers slipped in that crevice. We were kind of careening down the road, and I finally said, "Ralph, would you please turn around and sit down. You're gonna get killed." Here he was riding backwards down the street on his hands and knees in an unstable state looking for those damn seat belts.

I think the drug lag issue started to fade about midway through my tenure, and I think now it's essentially gone.

JY: Industry is trying to work for a law related to simplifying the new drug development, new drug process, though, isn't it?

AS: Well, just recently the final draft of the NDA re-write came out and the industry doesn't like some of that because it isn't as simple as some of the industry wants. I think that industry would like a much simpler process. It's interesting, I don't think that many of the drug companies would be able to do much less than they are now doing, FDA or no. It's just the case now that we can do so many different things and should do so many different things that are difficult and time consuming and expensive in order to know whether a drug is safe and effective.

With the product liability situation the way it is today, any company left on its own devices without FDA would probably end up doing more than they are doing now and be as slow or slower, because to a degree FDA offers drug companies a protection. When FDA sets standards, and those standards are followed, and FDA says they are followed well, if FDA approves the drug for marketing, like it or not, in a sense that is a sample of government approval. If FDA went away and a company had a new chemical entity they wanted to market, what would happen in that company would be that the lawyers in that company would decide when it could be marketed. And those lawyers would be protecting the financial interest of the company against what now are becoming ridiculous product liability lawsuits and awards by judges and juries. There's a national competition going on right now among courts and judges and juries about who can give out the largest sum of money.

You pick up any story about a major award and it'll say it was the second largest award. You'd think it was the high jump. The largest award. There's a contest going on. And lawyers would protect their companies from that. They would make them do more, I swear to God, than FDA is now doing, because FDA protects the companies against certain claims. I think the thoughtful people and the good companies are content with knowing that if they've got an important new drug, FDA can get it through in the eighteen months and will. And otherwise, you know, let the contest go on.

JY: The fact that a great many new chemical entities have come along from new experiments, including new basic science to draw on, has also probably had something to do with lessening the industry pressure, hasn't it?

AS: I think FDA has been doing a better job in the last ten years than they had been doing eight years previous to that. I mean, like it or not, breaking up that cardiovascular division did accomplish something.

JY: Did you do that? Or was that done later? I didn't remember that.

AS: Part of it was done when I was with the agency, in that some individuals were transferred and so on. I didn't know all of the history and I was fairly new at the agency. What I remember was that Dick Crout and probably John Jennings and maybe one or two others laid before me a reorganization plan and said, "We're having problems, and we're going to make these transfers and do these things." I said, "Great, it sounds good to me." And here I think your point is valid in that nobody said, "Oh, by the way, one of them is John Nester and let me tell you a little bit about John Nester." I didn't know who the hell John Nester was, prior to the hearing. But prior to the hearing I did know there were some transfers going on, and I wasn't smart enough or skilled enough or knowledgeable enough, whatever it was, to do what I would do now and have done ever since. That is to say, "Tell me a little bit about who these people are and is there anything hidden?" You've got to learn stuff like that, and I hadn't learned that by that time.

It is true that I knew that some transfers were being made. But who it was and how they were being made and the reasons and so on, I did not know about prior to the Kennedy hearings. We keep coming back to that because it's interesting, but it really isn't important.

JY: You wanted, for the Food and Drug Administration, more scientists. And coming from academia, you suggested that there ought to be a campus atmosphere--you had Beltsville in mind. You thought that there should be an opportunity for the scientists to engage in fundamental research. Commissioner Young still occupies the same office that you occupied in Rockville, and there isn't a Beltsville.

AS: Well, there's a Beltsville.

JY: Beginning.

AS: Well, the first part of that is almost done, or done.

JY: Well, do you want to talk about the scientific competence of the agency? Your evaluation and what lay behind your making these suggestions?

AS: Well, again, I'll reference another piece I wrote. I was asked by the Food and Drug Law Institute last December at their annual education conference, the big one, to give a talk on science and the Food and Drug Act. I did a piece on that that kind of expresses my views. And again, I can give you a copy of that. I put down what I thought in that paper. In essence, what I said and what I would say is that I went to FDA believing that the rigorous application of good science would make less controversial and better the decisions

that FDA had to make in many areas. Much to my dismay, what I learned was that, by and large, that was not true.

JY: Why not? Can you explain that?

AS: Well, because most people who instigate the controversy or fight with FDA don't understand science or what science is or the limitations of science or when science leaves off and something else begins. That something else is really politics. The principle reason is that there is not a rigorous differentiation of science and politics.

You see, I often have explained this by saying that if you take an experiment, it begins with posing a question that nature can answer for you. It's usually in the form of a hypothesis that's going to be tested. Then you set up conditions that will provide data that will allow you to answer that question. Then you conduct the experiment. And then you get the data and you analyze the data. And from those data you say with what probability under what conditions is such-and-such truth or false. Now there science ends.

But in FDA there are two more questions. One is what does the experiment mean? What do the data show? That's still science. But then, the next question everybody asks is, well then what does that mean generally to the human condition? Now that's interpreting something. That is clearly going beyond science, because science can't answer that.

But then the last question is, what should we do about it? And that has nothing to do with science. That's regulation or that's public policy.

JY: And it's got to be black and white, yes or no.

AS: That's right. Science is always wrong. I quoted George Bernard Shaw in my paper and said that science is always wrong; it never answers a question without asking twenty more. Science is not absolute. The most you can say in science is that, under a certain set of conditions, the probabilities are something. That's all you can say in science. There is no absolute in science. The problem is that the Food and Drug Act seems to require absolutes that are not present in science.

Ralph Nader and Sidney Wolf are very black and white people, and science is shades of grey. So that when I would try to apply science and do that, it wouldn't help because the difficulties weren't really with the science. The difficulties weren't really with the interpretation of the data. Because I would get, no matter what area it was--you know, saccharin, cyclamates, or red dye number two or four or whatever it was--I would get the scientists out. Sometimes I reviewed data myself, or sometimes I met myself with advisory committees. We'd almost always come to, these data mean this. But then you say, "All right, but what does that mean to the human condition?" And it would just fall apart at that point. We would be able to agree that what the experiment showed was that so many mice got so many tumors of a certain kind. Now, to make that jump to what that means to the human condition and to make another jump as to what the means with regard to a product, that's where the difference lay; that's where the controversies always lay. And that is not subject to science.

So I was bitterly disappointed, in a sense, that my rigorous application of good science did not really help with many of the difficulties that had to do with science. They

were difficulties that had to do with the absence of public policy, the presence of a bad piece of legislation, and so on.

JY: Regulation has to be categorical, and then, politically speaking, somebody's bound to be offended.

AS: Sure.

JY: I took out of *Food Chemical News* a quotation from Dr. Edwards that he gave late last month, in which he was addressing this kind of problem. And he said, "Nonetheless, it should be FDA that should have the flexibility to make these decisions. Then if the courts wanted to overrule them, all right; but these weren't the kinds of problems that you could correct by legislation. That was more unscientific than letting FDA be flexible."

AS: I think Charlie said that it ought to be left to FDA because they were best suited to make these judgments, and I strongly agree with that. It should not be elevated to the secretary's office, where it became highly political. And I agree with that. I have talked directly with Secretary Heckler about re-delegating to the agency some of the authority that ought, rightfully, to belong to the agency and the people in the agency.

(Interruption)

JY: This is James Harvey Young of Emory University. Robert Porter and I are in Chicago in the office of Alexander M. Schmidt, former commissioner of the Food and Drug Administration, continuing to visit with him about his experiences in that office.

I think it might be good for the record to indicate that you haven't left your interest behind coming back into academia, but have done a number of things to keep up with the problems, especially the drug problems of the agency and to give your services in ways that might actually continue to help in policy formation. Would you just repeat some of those things for the record?

AS: There is an old saying among FDAers: Once an FDAer, always an FDAer. And I've certainly found that to be true. I've done a number of things that have sort of kept me up to speed. I think more in the drug area, obviously, than other areas.

One is, I get FDA's news clips, which have proved very helpful to me, because they cover things like the articles that appear in magazine sections of the *New York Times* or *Washington Post*. And they clip from the *Wall Street Journal*, and the *Times*, and the *Post*, and other major papers so I can follow the stories and the issues and get a sense of the political background of things. Of course, I subscribe to the *Food Chemical News*, which probably, of that sort of publication, is the most useful long-run in FDA issues, because the *Food Chemical News* is pretty sound and unbiased coverage of FDA issues.

JY: I'd appreciate your evaluation of the current pink sheet (*F-D-C Reports*).

AS: Well, I think the pink sheet was, in some ways, better when Wally Werbel was alive and doing it because he had such a deep interest in FDA and its activities, and he was eminently a fair person and was highly indignant when FDA suffered. His reporting was a little more political than it is now. I think that the pink sheet now is a more staid reporting of facts sort of thing that doesn't give you the music of what's going on nearly as well as Wally did--Wally Senior.

JY: It doesn't seem to me to show what's happening inside the agency as well as it did in his day.

AS: No, it does not. Wally, Ray Gallant, and people like that have a lot of friends in the agency who will sit and chat with them and give them the straight story, and I don't think that the current people at the pink sheet have that intimate relationship with old-line FDAers. Then, unfortunately in many respects, a lot of the old-line FDAers are retiring or leaving for one reason or another. So things change.

But I read the pink sheet and the blue sheet. And just in the course of things, the *Food and Drug Letter*, and so on.

There also is a group of people that would include Charlie Edwards and Sherwin Gardner and Peter Hutt and Dick Merrill, Dick Crout, Lou Lasagna and myself and a few others--a group of people who stay in touch. I talk to Peter Hutt every few weeks on the telephone or in person. And we tend to gather at seminars and meetings of various kinds and be on panels together. And I've stayed active in that sort of thing. I've been a director

of the Food and Drug Law Institute and a frequent speaker at the annual session, which probably is one of the more important FDA meetings. That gathers just about everybody at least once a year. I've spoken at that meeting more times than I haven't in the last ten years. I've been asked by Congress to do things, by the Proprietary Association to do things. In the university here we have a very active international program. When I was at FDA, I made a lot of contacts in different countries around the world, and then in my university role here, I also have activities associated with WHO and so on. These things kind of tend to come together so that when I go to Japan, which I've done a number of times, I tend to do both sorts of things: university activities and then consulting with governments or universities about regulatory public policy sorts of things.

Just this last year, for example, I made a trip. I was in Japan for a week on drug issues and then went to China on university business and sort of combined the two.

So, in many respects, I've kept up more than I thought I would've, and I think more than some others. Don Kennedy, for example, does some things, but he is so incredibly busy as president of Stanford that he hasn't enjoyed, probably, the time that I have had to keep up with FDA sorts of things.

JY: You mentioned Peter Hutt. The kind of impression that I have is that he was a terribly important figure in a rather major shift that occurred. To wit, the nature of regulation within the agency. The lessening of court actions and the rise of the regulatory letter and the recall as techniques of regulation, seemed to me to be more related to him, in

his position as general counsel, than to anybody else. Is this so? What did you think of him and his generating ideas while he was a very pivotal figure in the general counsel's office?

AS: Well, I think it's a little more complicated than that. A lot of people tend to oversimplify, I think, what was going on. The most simple way of putting it is that the agency with Billy Goodrich, as general counsel, and Sam Fine being an important person, and so on, was a cop agency. It was an enforcement agency. It enforced the law, and that was about it.

Now going back to some of the things I said earlier about the agency changing. The things that you mentioned are results of the change, but not the change. Charlie Edwards was brought in to change the agency. The cyclamate fiasco really shook HEW, shook FDA; it shook the establishment.

JY: Do you mean to say it was a fiasco because the wrong decision was made?

AS: Well, it was a fiasco for several reasons. Now I was not there, but I've talked to a lot of people about what happened, because it very clearly was a turning point in the life of FDA. And if I boil it all down to a pungent sauce and say, "What have I got left?," what it is is that the agency was faced with a modern kind of problem for the first time. The agency now is fairly sophisticated with dealing with residues of pesticides and so on, but that was sort of a first. The agency did not know what to do. And it floundered around. It thought of declaring peaches, or whatever it was, a drug for a while. Some really weird things that

just demonstrated to everybody that FDA didn't know how to handle this. The commissioner didn't know how to handle it, and the secretary didn't. The thing became politicized. Of course, Finch, who was then secretary and lost this job over this and a few other things, also didn't know what to do. In a sense, the thing was bungled.

I believe that it shook people's confidence in FDA, and it made a lot of people take a look at FDA and say, "What kind of a beast is it and how should it behave and what should it be doing?" Charlie was brought in to move the agency into the twentieth century, so to speak. He was brought in to institute good management in the agency, put in modern people, modern science into the agency. In essence, to revamp the thing and to bring it into the modern world.

Now, one of the things that was an important question for the agency was, is the agency, by nature, an enforcement agency? Should everybody be wearing a badge and carrying a gun and putting people in jail? It's the old railroad question, what business are you in? If you're in the business of running railroads, in forty years you end up with Amtrak. If you're in the business of transportation, the railroads could be in the airline business, and all of that. And the question for FDA is, what business were they in? And Charlie asked that question. And the answer was not, we're in the business of putting people in jail. The answer to the question of what business is FDA in is, it's a public safety agency. It's insuring safe and effective products on the market. It's not like the FTC; it's not economic regulation. What it is to assure safe and effective drugs, safe and nutritious, clean food supply, and so on.

Now, the question then becomes, what is the most effective, efficient way of insuring safe and effective products. And Charlie's answer was, and a lot of people's answer was, that there were ways other than sticking people in jail. Education, for example. Voluntary compliance with guidelines and with standards, for example. An enlightened, educated society doesn't need to be stuck in jail to do certain things.

Charlie revamped the administration of the agency and was looking for more effective ways of accomplishing the business of the agency, which was to ensure safe and effective products. Charlie brought Peter Hutt into the agency because Peter was a superb expert in administrative law and was capable of doing what Charlie and others, and subsequently I, felt were good things to do. So that the lessening of the putting people in jail--and the increase of the education and the administrative remedies--was a deliberate policy that found in Peter Hutt a superb executor, if you like, of that policy.

The most important thing that happened at FDA while I was there was that I sensed what Charlie and Peter and others thought should be done at the agency and had started to do: the OTC Review, the re-write of all the administrative regulations of the agency, the revamping of the administration and management of the agency. Charlie had set a course and had initiated a number of things. It was clear to me that my job, since I agreed with the directions that they were going was to then take the FDA ship across the sea.

What I think I did of significance to the agency was, number one, to establish the policy board and to have it work; number two, to work with Peter and give Peter the rein and support and, from time to time, the instruction and so on to have him and his enthusiastic and talented colleagues in the counsel's office do what they did to revamp the admin-

istration of the agency. Third, I think that my management style for that agency at that time was a happy style. I've had many people, in and outside the agency, describe things that they will remember all of their lives. That had to do with a more collegial style. I've been both accused of and told and complimented concerning the fact that I ran the agency the way those people conceived a university should be run--that is, in a truly collegial style, which is what the policy board was. That was management by consensus of the people who ran the organization, and they loved it.

Somebody, Jake Barkdoll, described it to me once by saying, "When you came . . ." You know, Charlie was a get-it-done type. He was a centralizer and he ran things tightly out of his office. He used personal assistants, and he liked to set up task forces reporting to him. That was a very effective way to change the agency and to shake it up and to get things started. But it was a difficult thing to have over the long haul, because it excluded important people in the agency. And he said, "When you came, there were all kinds of people leaning up against the door with their ear pressed to the door trying to hear what was going on in the inner sanctum. You came and opened the door, and we all tumbled into the room and were embarrassed and surprised and didn't know how to behave. You taught us how to behave with the policy board and we were able then to get going and do the things that we did." These included the colossal changes of the administrative regulations and the re-looking at all of the ways we coerced industry into doing what they should do.

The medical device area, of course, had been a big mess and there had been several attempts at getting medical device legislation written and through. Again, largely due to Peter's superb administrative talents, but also due to the contributions of Paul Rogers and his

staff and others, and in the face of all of the changes we were making in the internal workings of FDA, we also got the medical device legislation through, which was, you know, a very large task.

I view these things as the major accomplishments of the agency while I was there. It was in this realm, and to this day, the agency is still working, including the policy board, in the way that I set it up to work, which was not the way Charlie was working it.

JY: That clarifies a lot, also makes me think of a dozen subsidiary questions. One, once I argued before the policy board that what had happened applied to reputable industry, but the ending of the cops-and-robbers approach didn't apply so well to hard-core quackery, which was growing. Using the cops-and-robbers approach toward hard-core quackery might be required in order to stop the new wave, since, on the whole, not too much had been done during the decade of the seventies with regard to that since these other problems were requiring attention and energy. That related, to some extent, to Laetrile, which began to grow during your period.

Crout said, at one point, that it was growing so fast that it was really a jeopardy to the agency and he'd almost rather have Congress pass a law, if the pressure got high enough, to exempt Laetrile. Sort of what they did with saccharin--if that were necessary to save the agency in its basic mission against the kind of retrogressive legislation across the board that might have come in the wake of Laetrile as, in a sense, it did come with that other bill of 1976, the vitamin amendments.

Can you take what I've just said and comment on it?

AS: Well, I would make several comments. One is that quackery is something that will always be with us, number one. I remember once quoting H. L. Mencken, who said that quacks should be left alone, that they provided a valuable service by ridding the world of people without good sense. I was being facetious, but I was also telling some of the people in the agency who wanted to devote immense resources of the agency to stamping out quackery, that, in my judgment, what the agency needed to do was to use judgment. If there was something that obviously should be stamped out, then the agency should stamp it out, but not try to eradicate quackery. I kind of took an Old Testament view toward that subject, that it will always be with us and the agency would be foolish to devote more than a reasonable amount to quackery. Yet, while I was there, we kept going after some of the more gross violators in the health food business. We took a number of actions in that area. The Q-Meter . . . Well, we were after the Rodales and some of the more fraudulent aspects of the health food industry.

JY: You were sued, actually, by the trade association.

AS: Oh yes. Some of the black boxes with bells and whistles that flashed, we went after.

JY: Do you think that the old-fashioned court action criminal procedures were sometimes needed in that area, because of the recalcitrance of the quacks? You couldn't persuade them to be good boys by the more gentle regulatory approaches.

AS: Well, I'll remind you that, much more when I was there than now, there were the Sam Fines and others of the agency who not only reminded me, but persuaded me of the importance of the iron fist in the educator's glove. And there is a criminal statute and there are criminals. I had no problem at all with putting people in jail who belonged there. I had a lot of trouble, though, with the way the agency was approaching some of its routine things, which was, to a degree, a little too much like the bullying cop and not like the educator. But I'll remind you that we sent material having to do with Searle pharmaceutical to justice for evaluation for criminal prosecution of people at Searle. We were not reluctant to use the firm approach where it was warranted.

The problem with quackery is that there is just too much of it to go against all of it. You could burn every dollar of the agency's resources going against quackery and not eradicate quackery, because it relates to a very basic human need, which is for hope. The reason that quackery still exists is exactly that, that no one ever wants to be without hope. So that if someone is told that they have cancer and there is not an effective treatment, people will seek for anything that stands any chance, however remote, of helping them. And bang, you're into Laetrile and you're into Krebiozen. And remember that the University of Illinois was the home of Krebiozen, and Pat Ward and I know a lot about that.

The issue isn't so much quackery, in a sense, as it is, did the agency turn soft? Did the agency quit enforcing the law? Some hard-liners viewed attempts at educating industry, attempts at the voluntary compliance programs, viewed FDA's having industry itself set standards as being a sell-out to industry, as being soft on industry. I heartily disagreed with that.

JY: Just one more on the quackery front. You said, at the time that the vitamin amendments were being considered, that if they'd pass, it would be a godsend to quackery or produce a heyday to quackery, or some such thing. I've got a quotation from you on that somewhere. And yet, those bills did pass. The pressure from the health food interest was sufficient to get those bills passed, which did, rather drastically, reduce the agency's authority to police the vitamin and food supplement marketplace. You fought that hard, but that was one that you just got beat on, because of the great deluge of material that the health food interests were able to bring to bear upon the Congress.

AS: You're right, we lost that one. And, in retrospect, I think, probably, it was a loser from the beginning. It was not pressure from the health food industry that beat us; it was pressure from the American people. Now, you can say that's a different way of saying the same thing. But it really isn't. I think we could have beat the health food industry. The most damaging single thing there was was that somebody in the health food industry put out, in flyers, that we were trying to take the vitamins and minerals away from the American people and make them prescription drugs. Now, nothing was further from the truth, and the whole thing was just asinine and ridiculous. But that got around. I believe this to be true--I was told this and it's in print--that Congress got more mail on the vitamin issue than on any other subject, including Watergate. People were more excited about their vitamins and minerals and the possibility of losing them than they were about the cover-up in the White House.

So, you're quite right, we lost that. I think of that once in a while when I see both the ads for and the poisonings from the mega vitamin dosage that's still going on.

JY: Right. In connection with the educational approach, both within industry and with regard to the medical profession and with regard to the broader public, there were certain initiatives that, it seems to me, you yourself had a great role in. Some of which didn't come off in the long run. For example, there was a concept of the national prescription drug compendium, which I took it that you may have been quite in favor of. Am I right about that?

AS: Yes. I think so.

JY: And then the patient package inserts as a way of reaching the public and educating them better to handle their prescription drugs. Both of those seemed to be rather strong initiatives. And yet, in the long run, at least up to this point, neither has come through. The compendium, as run by government, hasn't come through. There are only a couple or three things that have patient package inserts. And a program of enlarging that under FDA auspices was eventually thwarted. I was interested in your reaction to that.

AS: You know, you've got to be skillful, again, about change and about accomplishing some things, and I think that Jere Goyan kind of blew the patient package insert business. What I intended to do with that was, on a drug-by-drug basis, where it was obvious that they

were good, to do it. Take, for example, insulin: there's always been a patient package insert, in effect. It's needed and it didn't bother anybody.

With the oral contraceptives, that was a lovely one. As a cardiologist, I thought it'd be neat to have one on digitalis. I think there are probably more patients across the country in trouble with digitalis, either because they're overdosed or underdosed with digitalis, than any other drug used by internists, with the possible exception of Valium or something like that, or antibiotics, which aren't cardiovascular drugs.

But I think if the agency had bided its time and selected drugs one by one when a problem arose or when a problem could clearly be demonstrated and could say, "Well now, here's an example of where we need a patient package insert." *Forget the name, package insert.* If the name became a problem, just say here's where the patient and physician and pharmacist need to share more information. You know, there's a half a dozen ways of skinning a cat.

There are people in Washington and people in agencies and a new commissioner will come in and they say, "Well, you've got sixty days to make your name." They dangle other people in front of you. And they say, "Well, look at Goddard. Nobody will ever forget Goddard, now You don't want anybody to ever forget you, and you've got to do something." And there's a pressure, you know. Whether Goyan decided upon the patient package inserts because he was a pharmacist . . . I don't know. But all of a sudden the agency had too big a program, doing too much at once without a good reason to do it. And the pharmaceutical industry creamed them. FDA made a mistake by underestimating the costs of the total program. We're talking about \$200 million of costs at one point. And the

pharmaceutical industry calculated the costs at \$2 billion. I mean the spread was between a couple hundred million and \$2.5 billion or something like that. And the day I saw that, I said to myself, "The program is dead." I was not personally in favor of every drug having a package insert. The country would be littered with little white pieces of paper. That would be ridiculous.

JY: You knew that there were certain drugs that the patient did need to know more about than he was getting.

AS: And that remains true today.

JY: And you wanted to edge into it as these major areas of education surfaced.

AS: Sure. In a sense, you see, the FDA lost the patient package insert thing for the same reason I lost the vitamin mineral thing. And that is that the regulatory scheme that Peter and others came up with, I was uneasy with, because it seemed to me we were trying to do much--"bang."

JY: You mean the regulations.

AS: With the regulation of vitamin and mineral supplements and so on. We lost it because it was too much, too soon, all at once.

JY: That is making the set formulas that everybody had to follow.

AS: With vitamins and minerals we tried to revamp the entire use of food supplements. What we did is we define vitamins and minerals in three classes, and the three classes were: a very small use, a sort of food fortification; then supplemental use; and then drug use. And it was the drug use one that killed us, because that's what allowed people to say we were going to make them prescription drugs. All we were going to do is say you can buy them in your local gas station, but they aren't going to be called food supplements. We want you to know that that's a therapeutic level. And mega doses had to be labeled as drugs, because that's what they were.

So, that was too much all at once. Jere Goyan and the agency in putting out a massive patient package insert program were just doing too much all at once. It was too big a bolus for anybody to swallow, and they choked and that killed the program.

Now, the compendium which you mention, that's going to come. That's just a matter of time. How it's going to come is over that tube over there. You're already seeing a move with automated, updated telecommunications sorts of data bases. That's a data base in today's parlance, and I think there will be that kind of a data base available to all physicians by computer and . . .

JY: From FDA?

AS: I don't know where from. It could be FDA; it could be from the National Formulary; it could be anybody. Could be PMA. It doesn't matter who does it. But I think, clearly, at some point that's going to come.

JY: That was part of the debate at the time. There were those in FDA who had the feeling that it needed to be FDA to be, as it were, Simon pure.

AS: Well, I didn't agree with that. And, of course, if you're head of an agency, you've got to be at the head of the agency. If you aren't at the head of the agency, you aren't heading it. You can't be standing here and all your troops are over there.

That is why I always come back to change, because one of the things that I tried to do was to change the agency in such a way that I could stay at its head. The strict constructionists, the old timers, the cops in the agency, knew what their useful tools were. And there aren't very many. It's like the carpenter, in the old days, had a very good saw and he took very good care of his saw, because that was one of his most valuable tools, and there weren't very many.

And FDA had the labeling regulations and, of all of the tools FDA has, one of the most valuable is the labeling regs. The use of those regs became a very fine art. And the people who were sophisticated and good enough to understand the use of the labeling regs, fended off any challenge to the agency's authority to declare what was a proper or an improper label. The compendium issue for a large segment of FDA was that FDA, if it gave

up its authority to label, would be giving up the whole ship. Giving to some outside, even quasi-governmental group . . .

JY: Or USP.

AS: USP, whoever. To give up to them the authority to label--which in effect was what the compendium was, it was stating what the labeling was of the drug--would be giving away the ship. Now that was a hard one to counter. It wouldn't have bothered me. I would have run the risk and thought there were other ways of maintaining your authority over labeling, but I won't argue that . . . Since we didn't conduct the experiment, we'll never know.

But we controlled a lot of stuff, including advertising and journals and meetings and educational seminars that took place on ships in the Caribbean. I mean, we did an awful lot of regulating in the name of labeling and controlling labels. What people could or could not say about a drug in what kind of a setting. You see, all that came under that labeling authority. That was what brought down the compendium, in my day, was the labeling question.

JY: Another area of rapid change that had already begun and that was reaching high tide while you were commissioner, was that pair of things that had been generated by the 1962 law: the DESI Review, and then the OTC Review, which you've mentioned, which I think while you were commissioner, had led to its first file report.

AS: The antacid. Someday, if I live long enough and I do what I intend to do, I'm going to write some things. And I think among the funniest things--it would be more fascinating than Pat Ward's Krebiozen, "Belling the Cat"--would be to write one on Alka-Seltzer. You know, this became a national controversy that was entered into by the *New England Journal of Medicine*. And, Franz Inglefinger, you see, was editor of the *New England Journal* and was chairman of that panel and was just funny as a crutch about the whole thing. I know things that, in a sense, nobody else knows about that, and what Franz did and didn't do, and what people were saying about that . . .

JY: That would be a great story. I hope you will.

AS: Someday I intend to write that down. In a way we pushed the antacid panel first because I thought it would be non-controversial and the easiest one to bring to fruition--forgetting about Alka-Seltzer . . .

JY: With its double ingredient.

AS: I mean, my consumption of Alka-Seltzer shot way up during that episode, because I took it because it was a nice way to take aspirin. And both Franz Inglefinger and I used Alka-Seltzer because we both felt that it was a great way to take aspirin. And there it was in the antacid panel. And, of course, aspirin is a lousy way to take an antacid, so we got caught in the horns of that dilemma.

JY: How do you think that the concept of the committees worked out? That's another one of the ventures, it seems to me, which you accepted and strengthened--the use of the advisory committees, kind of across the board in FDA. And here's an example of such committees in use.

AS: Well, both the DESI Review and the OTC Review were ongoing when I became commissioner. The DESI Review had been long standing and is still going on. It's coming rapidly now to a conclusion after all these years. And my views on the DESI Review were that, by the time I really got involved in it, which is probably the last couple of years I was there, in all candor, it was sort of boring. The exciting phases of the program were over and the agency was bogged down in extremely difficult and tedious working through of issues that just took a long time. Nobody understood the complexity of the DESI Review when it got going or the amount of work and time it would take to go through the hearings or the denial of hearings, and get the data that were necessary. Nobody anticipated the number of challenges by the drug industry. I was just sort of grateful to escape major problems with the DESI Review while I was there.

For me, the OTC Review was much more fun because it had just gotten off the ground and was just starting. Here was this thing and the question was, what was it and how do you bring it up and make it work well? It went awfully well, I think, while I was there. The panels that we established were very, very good. They were the best people in the country, or sometimes even from Europe. They did awfully good work.

And the thing was a lot of fun. I was very sorry to see it slow down after I left, in the sense that it was neglected. Recently, there have even been some questions as to whether it should be abandoned without being finished.

JY: Really?

AS: And I think that would be a horrific mistake for a lot of reasons.

Basically, the regulatory scheme is a good one. A little more difficult than we had anticipated, but the central issue from day one of the OTC Review--that got very prominent within the agency while I was still there, and has been with the OTC Review to this day--is, who owns it? Where does it belong in the agency? What kind of an activity is it?

Now, I said earlier that Charlie Edwards was a centralizer and somebody who liked to do things out of his office and to have task forces. That way he was sure he could direct it and get it done. So, what I found was an office in my office, and Gary Yingling was in charge of that when I went there. Later Bob Pinkow and others got involved in that and, in essence, they worked for the commissioner. And the Bureau of Drugs was dead-set against that and fought that the whole time.

JY: The structure.

AS: The structure. There was a lot of tension within the agency about the placement of the OTC program because early on it got a lot of resources and it was sexy and exciting. Dick Crout resented very deeply that that program was not in the Bureau of Drugs.

Now, Charlie's theory was that the only way to get the goddamn thing going, and so on, was do it out of his office, because if he gave it to the Bureau of Drugs to do, they would never do it. It would get caught up in bureaucracy, and the Bureau of Drugs had more important things to do. Charlie was right. I left that structure in place until, toward the end of my tenure as commissioner, I moved it into the bureau. And the reason I moved it into the bureau was that it was far enough along that it started to have to be legitimate. If you were going to regulate that huge class of drugs then with monographs and so on, and if you were going to make switches between prescription and OTC drugs, and if this was going to become a regular part of the program, it could not be a special pet of the commissioner's.

So I told Dick Crout, "All right, I'm going to put it in the Bureau of Drugs and you can have it, but I want it to be a special activity in the Bureau of Drugs, and the instant that thing starts to slow down, I'm going to pull it out again." And I had a kind of a personal contract with Dick Crout and we agreed and shook hands and I put it in the Bureau of Drugs. And it was all right until I left. When I left and quit protecting the program personally, it started to slow down. It was not a high priority in the Bureau of Drugs, and I think that that was the major reason that it . . .

And then the new commissioners would come in and it wasn't sitting there right in front of them, and it became, then, to later commissioners like the DESI Review was to me.

JY: Right.

AS: Kind of boring.

JY: Right. I see that. Two questions: One, what was your own personal view of a point that was much disputed, and I'm not sure is settled yet, about whether the labeling claims for the different classes of OTC drugs should be rigorously fixed by FDA and literally followed by industry, as against greater flexibility for claims and synonyms that industry could come up with?

And the second questions is, why do you think that the OTC Review seemed to generate a movement of drugs from prescription to non-prescription status that seems to be rolling on today?

AS: Well, with regard to the second question, the reason the switch issue came up was because there were good people on the panel. Again, you see, the question was not a cop-type question. The question of the OTC Review was, what products under what conditions ought to be freely available to the American people?

The way the panels were set up, I think, was clever because the panels were set up almost by disease grouping or by disease category. They were functional panels by problem areas--antacids or hemorrhoids or skin conditions or gastrointestinal conditions or sleep. You know, what kinds of products should be freely available to the American people to help them sleep?

If you've got a group of good people sitting there thinking about this, one of the first things they'll think of is Benadryl or an antihistamine, and say, "Well, that is safer and more effective than some of this garbage that's on the market now." If what you want is a safe and effective thing, you're going to look over the range of things you know makes people drowsy. And some people get drowsy with antihistamines.

JY: So, these were specialists reaching scientific judgments.

AS: Sure. And I think that the switch issue fell, normally and naturally, out of the OTC Review, and I thought it was one of the beneficial by-products, in the sense of the need to regulate that large class of drugs and their ingredients. Then, of course, the fact that there were too many drug products to review--so we chose to review active ingredients--drove people in that same way, because if you are looking at molecules then you think of other molecules. And you say, "Well, you know, what I use this for all the time is X." And somebody would say, "Well, that's a prescription drug." Somebody else would say, "Well, should it be a prescription drug?"

The best example of this was the switch of hydrocortisone cream to OTC status, the ointment. This has been studied by economists and by physicians and by all sorts of people, and everybody agrees that that was just a very happy thing to do, because it made available to people, and readily available, an extremely useful, important, safe, effective way to treat a lot of skin conditions. It cut health care costs and all sorts of things. And there are, I think, many others that could be switched.

So, the switch issue was a neat thing that came out of the OTC Review. I forgot what your first question was.

JY: It had to do with your own judgment about the therapeutic claims in the labeling of these products.

AS: The matter was decided, in a sense, on the wrong issues. The real problem there was that FDA did not control the advertising of OTC drugs. It's interesting, but I think it's a fact, that if FDA had controlled the advertising of OTC drugs, that issue never would have surfaced.

JY: But they lost that battle in 1938.

AS: The real problem there was an interagency rivalry between FDA and the FTC. And the FDA does not trust the FTC--never has, never will. If you want evidence of that, I can give it to you from the last month.

JY: Tell me.

AS: Kellogg's health claims on their cereal. FDA thought that was a problem. In the face of FDA's saying, "I think we have problems with that," the FTC people said, "We think it's great." And that made FDA mad as hell.

You're seeing the same squabble now. The FDA is highly indignant that the FTC is making statements about what can and cannot be a health claim. That's FDA's turf.

JY: Because the whole food market is out there waiting to do this kind of thing.

AS: But we're back to what I said a little while ago. Remember I said that if you want to stir FDA up, do something that might challenge its labeling authority. And the FDA does control labeling of therapeutic products. Anything that you make a health claim for is FDA's.

So here's Kellogg's saying their cereal will help prevent cancer because of the fiber in it. This is a health claim that belongs to FDA, and FTC is moving in on that. With the OTC drugs, FDA was afraid that if it did not take the strict constructionist's view of labeling, the FTC would screw it all up. FDA didn't want the OTC Review threatened by some stupid things coming out of the FTC.

Now, this was presented to me and I thought about it. And where I came down on it was, well, there's nothing wrong with starting out tough and then loosening up.

But, to tell you the truth, I thought then and think now that the issue was a little bit dumb, because it is simply a fact that there is a vernacular in our language and it communicates, and there's nothing the matter with using that. And FDA would have allowed the vernacular if FDA, at the same time, could control the excesses in advertising that were sure to follow that loosening up. Because there's no question that the drug companies and advertising agencies would have taken that quickly to the limit.

JY: Sure.

AS: And that's what FDA was worried about.

JY: That's not really resolved either, is it?

AS: No. And the reason it isn't, I've just told you, which is that, if anything, the Kellogg breakfast cereal business will make it harder to resolve the OTC thing. One way of resolving it, I suppose, is to give OTC drug advertising to FDA. I was asked once if I wanted it passed by Congress, when I was there, and I said no. And I didn't.

JY: It seems to me that the FTC, historically, has wavered much much more than FDA has, historically, about the intent of its mission.

AS: Oh sure.

JY: And about the rigor of its enforcement.

AS: Oh absolutely. You can just look in the last decade. They were practically abolished at one point.

JY: Exactly. Right. Well, that's great. Now another thing I would appreciate your commenting upon . . .

AS: Well let me, before you go on . . .

JY: Excuse me.

AS: You brought up something that I've been trying to work in, and you gave me the opportunity, and that is the advisory committee business.

JY: Right.

AS: You're quite right that coming into the agency, we said earlier, that I was interested in the application of science in the agency. You looked around the agency, and there were some very good people in it, but it was obvious that you couldn't have one of everything in the agency. We had to have the world's best science brought to the decision-making of the agency, and the logical way to do that was through advisory committees. Remember also that I had spent time at NIH and I'd worked in Jim Shannon's office. I'd been chairman of a study section for regional medical programs, and most people in the academy are well familiar with councils and study sections and advisory committees, so it was not very mysterious why I really seized on the advisory committee structure, which again had been started by Charlie Edwards. I give Charlie just immense credit for setting things up so that

when I went into the agency, what I did was put meat on the bones that Charlie had already strung together as a skeleton. That was true also for the advisory committees. I made more of them and made some of them better, and I worked with them more than Charlie had had time to do. But I thought that that was a very important part of the agency.

Again, one of the things I've done since I left the agency, is object vigorously when there were challenges to FDA's advisory committees. I talked personally to secretaries and others as I've done with Secretary Heckler, Secretary Schweiker, and others.

JY: Have there been challenges?

AS: Oh sure. Because when you go in and cut the federal budget, OMB always goes after advisory committees, including some of the NIH committees.

JY: And you knew how, from academia, how to find the experts to go on the advisory committees. Did you play a pretty direct role when lots of these were set up in actual picking?

AS: It was fascinating to me that very good people accepted; the people that you might expect to turn FDA down as being not in the direct line of science, or because the people were too busy with NIH. We would call the best people in the world, and they'd say, "Gee, I'd love to." And we did not have to do a lot of arm-twisting when we were setting up the committees to get the best people there were.

I did three things, I think. One is that when we were going to appoint somebody, I would suggest names and look at the list and approve the list and say, "That's my list." Because then when it went downtown, people knew that I was grouchy, and if they knew that was my list, there was no political interference with the establishment of those advisory committees while I was there. I don't think I was ever given a single person to be on the advisory committees.

And, since I've left, at times some very bad, or if not bad, inappropriate, people have been given to FDA by the department or OMB or the White House. And that sort of thing, if somebody had tried that when I was there, I would have quit.

JY: Here is where the independence of the commissioner, you believe, is just an absolute must.

AS: Absolutely critical.

JY: Yes, right.

AS: Ordinarily Dick Crout or somebody in the Bureau of Drugs would call people for the Bureau of Drugs committee. I said, "If I can help you recruit somebody, let me know." But I did not call a lot of people or twist a lot of arms to get people to come on to the advisory committees, because they were pleased to do that.

I've talked to a lot of people since about that. For example, right now the head of dermatology here and our transplant surgeon, Olga Jonasson--she is one of the leading academic surgeons in the country--agreed to serve on the hemorrhoid panel. And I said to her once, you know, "Olga, why in the world would you . . ." And she said, "It's important. I have hemorrhoids." It was fun.

JY: Yes, right. Well I understand that, even from personal experience. It's not only an honor, but it truly can be a major service to the whole public.

AS: I'll say two more things. One is I want to refer to the Fountain hearings on the use of advisory committees. If you want to know my views on that, refer to hearings that the Fountain subcommittee held on FDA's use of advisory committees. That's a full reporting of problems other people had with FDA's use of advisory committees. And my defense and arguments against people's concerns, the concerns being that FDA was not doing its job, that FDA was a cop and you couldn't appoint somebody and all that sort of stuff.

The other thing is that the only time FDA advisory committees and my interaction with them wasn't fun had to do with the Dalkon Shield controversy--what was an extremely difficult and messy situation that goes on to this day. One of the problems was that I had two different advisory committees claiming--at one point three advisory committees--all offering me conflicting advice. And that was difficult.

JY: Were these OTC committees or were these ad hoc?

AS: Well, that was the problem, you see. We had an OTC committee, we had a device committee, and we had in the Bureau of Drugs a contraceptive committee. And then on some of the committees were some very aggressive--sometimes even loud-mouthed--people who wanted to climb up on the top of the hill and shout about it and were not statesmen. The whole thing was a pain in the ass. Serious. But handling it was a pain in the ass.

The other thing I want to be sure to mention, that again was started by Charlie but was an infant that I brought along and took a lot of personal interest in, was the National Center for Toxicological Research in Pine Bluff, Arkansas. The reason that comes to mind now is because it had an advisory committee that was also a pain in the ass, because of some of the people that were on it, and the way they behaved.

But the NCTR was a good effort and was important and was another thing that sort of came along during my tenure. You know, that, and the idea of a campus in Beltsville, and some of these other things are still going and are coming slowly to fruition. I take a quiet pleasure in watching those developments.

JY: In connection with prescription drugs, another thing that still continues relates to the problems of getting the drugs on the market and then what happens. And you suggested making pre-marketing power for drugs easier, which relates to something we talked about yesterday. Partly by providing for more intense post-marketing evaluation and easier removal than the law, up to that point, allowed of drugs from the market when their problems fell short of the severe and imminent hazard standard that the law included. Can you talk about that, both as seen at the time and from your present perspective?

AS: In trying to explain this once, I fell on the use of an equation which was very useful pointing out that there was a relationship between the information that you had to have about a drug, and when you got it, and what you could do about it.

If, after a drug were put on the market, FDA could not discover what it needed to know about the drug, and, once discovering that necessary knowledge, couldn't do anything about it, then what happened was that FDA tried to find out everything it needed to know about that drug before it went on the market.

If the person who put his stamp of approval on that drug and allowed it to go to market didn't want to run a risk of being heavily criticized, if, after use of that drug for a period of time in a lot of people, it turned out the drug had a severe side-effect that you couldn't know until it had been used in two thousand people over a two-year period, then that person would want that drug used in two thousand people over a two-year period before it was approved for marketing. It was obvious to me that the drug lag issue, in my terms, was an issue of how much did you have to know about that drug before it went on the market. And if the answer to that was everything, then we were on a course toward never approving any drug as the ultimate way of protecting the public against drugs. So I said, "Look, we need to know this sort of stuff about a drug: what happens to people who take it over a long period of time; are there rarely occurring but very serious side effects that occur only once in five thousands people or once in two thousand people or even once in a thousand people?"

If, after the drug went on the market, we could do post-marketing studies, Phase IV studies, and if we could take a regulatory action short of declaring it an imminent hazard, the

drug approval process, in a sense then, could extend through the first few years of its being marketed, we could obviously let the drug on the market quicker than we do now.

So, I set up an equation that had sort of what you needed to know pre-market and what you needed to know post-marketing and set it all equal to a constant. And obviously, then, if one value changed the other value changed in the equation. Then there came a very useful way of demonstrating this that was picked up by Lou Lasagna and others and has appeared many times in articles and so on.

The fact of the matter is, though, that essentially nothing has happened.

JY: Why has . . .

AS: In the face of it being so logical.

JY: What's the reason? Why has FDA had such trouble getting feedback from real experience? Adequate feedback.

AS: Oh, I've thought about that a lot and I've talked about that and testified on that subject. What I conclude is that there are so many reasons that it's hard even to list them all. You start with the nature of our society. We're a free society. We are not a regimented society. We don't have the same habits or mores as some other countries where they have good post-marketing surveillance. We don't like to follow rules. If the federal

government set up a rule for the American physician that he had to do something, he'd say, "Stick it, I won't do it." So that's one reason.

The second reason is, just look at the lawsuits and the malpractice and so on. No physician, who is now paying \$100,000 a year for malpractice coverage, is going to start reporting adverse reactions in his patients because of drugs that he prescribed for them. He'll get sued and his malpractice insurance will be \$150,000. So, our litigious society is another reason. So that's the second reason.

Third reason is that basically drug companies don't want it. They feel that the front-end of the process is so expensive and so long and what will happen is that you are going to add Phase IV, that will be additive. It will not replace anything on the front end. Ralph Nader won't permit, the agency, the *Washington Post* won't permit, Morton Mintz won't permit the agency to ease off on the front end in exchange for something on the back end of the approval process. The pharmaceutical industry opposes it vigorously because they don't trust the agency and they feel it will just be additive. So that's the third reason.

Fourth reason is, it's expensive. Costs money to do that. A good post-market surveillance system for this nation, which is very large, heterogeneous and so on, would be expensive. We are not a little homogeneous country that can do this sort of thing well. We're a big sprawling set of kids that don't behave ourselves. So, there are just so many reasons, that I am very pessimistic that we are ever going to really have a good post-market surveillance system.

Again, you're into the patient package insert problem. Another reason is that, if you're a drug company and you want to kill it, the best thing to do is to keep talking about

doing it for all drugs at a cost of \$180 billion a year or whatever they're going to come up with. What the agency needs to do is what Peter Hutt and I would have done, and that's to say to a drug company, "We will approve this if you will do that. We want a Phase IV study."

JY: There's some of that going on.

AS: That's right. And I would've done it just the way I did patient package inserts. And then, in three or four or five years, you would've had it, and nobody would have seen it coming, and it would be accepted and the agency would have backed off on the front end quietly, and bingo, it's done, and nobody really knows it.

That, by the way, is one of the prices the agency pays for the tenure of commissioners being one to two years. With the exception of Charlie and me, you had one- to two-year commissioners since Larrick.

JY: That's right.

AS: And that's crummy continuity.

JY: That's one of the great watersheds that needs to be explained and analyzed.

AS: Not only that, but the second most important office in the agency, which is general counsel, has become politicized and has been turning over. Right now, since I'm speaking this for history, I'll say that I was in Washington on Monday and learned two things. Since today is--what's today?--March 9, 1985, I'll say that my prediction is that the current commissioner, who's been there only a few months, is going to be taken out of that job within a week or two or three and the general counsel is going to be fired. Now, the deputy just left; Taylor Quinn just retired. I've talked to other people in the agency who are very discouraged and are going to take early retirement, and I think that the current department is doing grievous harm to the agency. But Heckler needs an assistant secretary for health, and Young is an easy choice. And I think that, if she can, she's going to pull Young up into that office and then who is running FDA? Mark Novitch is gone. You've got Paul Hile who, in essence, will be running the agency.

JY: And under the circumstances in Washington, it will be hard to select and get the kind of person that is needed.

AS: Well, you've got a two-year period that you could do something, because things won't fall apart until everybody starts campaigning, which will be about a year and a half before the next election. So, if Young stayed in there and was a good person and all, he could do a lot in the next two years. The next two years would be a time you could get something done. The first year of a new administration is hard; the last year of any

administration is hard. The second and third years of a stable administration are when you can get something done.

JY: Moving right along and shifting gears here, in a speech that you made at Tulane in 1975, where you looked ahead to 1985, the current year . . .

AS: Geez, I'd have to get that out; I've forgotten.

JY: I've got a copy with me, would you like to have a copy? I'd like to keep it.

AS: I've probably got it in my files someplace.

JY: Okay. You seemed to be countering threats that the Food and Drug Administration was going to be splintered, that was your word, broken up. What did you have in mind? It was rather vague in the speech. Do you remember what you had in mind about the threats?

AS: I remember that speech and I think that was because I was not as mature as commissioner as I was when I left the agency. You have to remember that that was against the backdrop of the Kennedy hearings. And what was going on at that time made me feel a little less secure than I would in the same circumstance today, knowing what I now know. But at the time, some people were talking about the agency being restructured because of its lack of effectiveness and it had "sold out to industry," and all that crap was floating around. And

there were some people who were saying, "Well, maybe the agency has too much to do and it should be broken up." And the other thing is that the Department of Agriculture has always been after the food part of FDA. And so there were some people in agriculture, who were taking advantage of the attacks being made on FDA at that time to say, "Well, give us . . ." and so on.

And what I was doing was sort of saying to people that FDA wasn't about to be broken up; "Knock it off" sort of thing.

JY: It was a defend-the-turf kind of speech.

AS: Yes. Yes.

JY: Right.

AS: But the friends of FDA were concerned. You know, a lot of people who don't track this, even as closely as I do now, were concerned for FDA and would say to me, "I read someplace that FDA is going to be broken up." So, I was just answering that question.

JY: Fending that off. It wasn't nearly the real problem, I think, at your period as it had been some years before.

AS: Yes, well that's a recurring theme.

JY: Right.

AS: Well, what you hear now is whether all food shouldn't come to FDA. One of the features of the reorganization of FDA into centers is that--and the clever aspect, I suppose of a center for food safety--is that people would say, "Well, gee, we have a center. We ought to group things together with that." So, the way things are going now, I think if a switch were made, it would be a switch from agriculture to FDA. Some of the reasons are just as stupid as going the other way, and that is that agriculture has "sold out to industry" or that the department isn't being kind to farmers nowadays and let's punish them and that sort of thing.

JY: Right. Nutrition policy has been one of those amorphous things spread around, about which there's been a lot of debate. Where should it mainly be centered?

AS: Right. Yes. That's another dumb issue. My response to anything like that is, quit arguing about it and do it and then it'll be done. Quit arguing about patient package inserts; just do a couple. Quit arguing about the drug compendium; do it. Quit arguing about . . . you know, do it. It's more fun, less work, and easier all the way around to argue than it is to do something. And I see that every day here in the university. People would much rather stand in the halls and gossip than get to work.

JY: Yes. The people in a bureau aren't much different from faculty members on a campus in ways like that, I imagine.

But one other thing that I noticed in going through the annual reports for your years as commissioner, might be grouped under the heading, "Danger in the Products that the Agency Regulated." There were issues that came up, some of which we mentioned in connection with the artificial sweeteners: saccharin is still a problem; aspartame was approved in July 1974 with some debate still; there was a crisis over mushrooms; there was a minor crisis involving a couple of antibiotics; DES as a residue in meat kept being mentioned; there was the ozone crisis; food additives continued occasionally to be attacked. (One instance involved the alleged impact on hyperactive children.) So here is a kind of conglomeration of things. Probably during any period you could go and look and find these sorts of things. Do you want to say anything about this matter of dangers coming along day by day, now here now there?

AS: I think if you plotted it on a piece of paper, you'd start it at the left-hand end with cranberries, at least in the modern era, and get a big blip with cyclamate, but what you'd find is a concentration in that period that I was there. I picture the world forming with a kind of a fog first and gradually getting denser and denser and then suddenly you've got a planet, or over a few billion years you've got a planet. I could see on the television screen a kind of a fog of issues sort of coalescing and becoming more concrete during that period, where you had a sharper definition of what you were talking about, and how you handled it and so on. And that was a product of a number of things coming together. One was science and technology, which really were being applied at that period. Another was that the agency itself was better prepared to engage the issues and discuss them. The products of a lot of

consumer activism were becoming apparent. Nader and Sidney Wolf were at the height of their powers. They've been on the downhill side the last eight to ten years. All of those things came together.

I think, that while we still have issues coming along, I think, probably, the number and intensity of discussions during that period was greater than it's been since or greater than it will be. People learned by that, and that was an early formative period in the issues. You know, it was learned that some friends could turn against you. I could add to that list, one biggie was the Dalkon Shield. Another one was the oral contraceptive.

I used to laugh and joke, in a sense, about the Friday afternoon crisis because what would happen in the rhythm of the agency is that inspectors would go out Monday and Tuesday, and analyze Wednesday, and discover a problem Thursday, and boot it up to headquarters on Friday. Then they'd go home for the weekend and we would have this dead cat that came in over the wire sitting in front of us. The agency would look at it Friday morning, and it would arrive in my office Friday afternoon at 2:00--and there went the weekend. That was true for mushrooms and it was true for all sorts of things.

It was a very intense period of examination of issues.

JY: Did you develop a system?

AS: Well, yes. First of all, we developed a system for getting Friday night dinners brought in.

We also developed a number of other things. This was a period where we established the Science Advisory Board. It gets back to this common thread that runs through this discussion, and that is the application of science to FDA issues. The advisory committees were one approach; Peter and I and others, Dick Merrill when he came, spent a lot of time discussing the basic concept of the science court. And what the Science Advisory Board was, was our version of the science court. We established that, and my intent was to use it for the several purposes of sharpening issues, defining issues, educating people about issues in a neutral forum with the world's best people, and then providing advices to the interpretation of science that could allow the regulators to answer that last question I mentioned yesterday, which is "What do you do about it?"

JY: Does the concept of a science court have precedents in history? Or was this a kind of creation that you yourselves were forming?

AS: Well, the concept has been around for some time. I haven't done the research to know where the concept of a science court came from. The science court is to be found more in literature than in real life. However, I think there are real-life precedents and one of them is to be found in the World Court. Scientific issues are decided by the World Court. It will set up panelists to decide scientific issues and scientific disputes, largely among industries.

For instance, I was once asked by the World Court to be one of the judges in a dispute between two pharmaceutical houses on a matter of the application of science. And that comes close to being one version of a science court.

JY: But you thought of this as a useful internal mechanism for all these things that were coming from every direction.

AS: Yes. It's only been used twice by the agency, and I think if I'd stayed with the agency, it would have been used a lot and refined and made useful. As it is, it's still not thought of by a lot of people as being all that important and useful, in part because both times it's been used there have been some problems with it.

JY: What were the occasions?

AS: Well, most recently it was used for aspartame. I was going to use it for aspartame, and it finally got used for aspartame. The court's verdict was overturned by the commissioner, I think properly so. But that didn't help it exactly.

It was used for aspartame and it was used for something else that escapes me at the moment, but I'll think of it.

JY: Right. In connection with these crisis issues that came on Friday afternoon, I thought of a question that Fred Lofsvold wanted us to ask, and that had to do with your interface

with the press. Did you do things in connection with the agency in relationship to its general approach toward structure and attitude toward the press, point one? Second point, your own relationship with members of the press. You mentioned you knew Mintz and so on. Did you often go on television or hold key interviews in connection with some of these crises or more fundamental things?

AS: Well, it's a sad truism that the best preparation for being commissioner of food and drugs is to be commissioner of food and drugs. I think when I left the agency, I was much better prepared for the job than I was when I arrived. Were I to do it again, as I said recently in a speech, a thought far more disturbing to me than anybody else, I would try to do a much better job with the press than I did my first couple of years. Coming out of the academy, I viewed dealing with the press not as important as managing the agency, and straightening out the administration, and doing the other things we've been talking about that I felt were important. I know now that dealing with the press was far more important than I thought early on in my administration. Jack Walden, who is first rate, did look after me in that aspect relatively well. I think I was more reluctant to do some of the things he was suggesting than I should have been.

I did go on the offensive after the Kennedy hearings to defend the agency, and that included things like being on *Face the Nation*, and the *Today Show*, but I didn't do enough of it. Today I would do more of it. It is a bully pulpit and I didn't use it enough.

I said earlier that I like people and I am generally fascinated by people and like to get to know them, and I did that. I did several things. One is, I went down to the *Washington*

Post and met the editor and publisher and the editorial writers. I got so I could call up Colman McCarthy or other people. I got to know Colman. I went down and sat with Morton Mintz one day and discovered what made him tick. You know, you have somebody like Morton Mintz, there's a reason that he's like he is. I wanted to discover what that reason was. He turns out to be a very open and honest guy who had a family tragedy that one of his own kids had involving drugs. That led him to become interested in and finally outraged by what went on in the drug area. Once I understood that and once he understood me, we got along fine. In a sense, he treated me better because he understood who I was and what I was trying to do. He ended up being one of my questioners on *Face the Nation* once, for example.

I got to know Lesley Stahl reasonably well and enjoyed knowing her. FDA was such an easy target and there were so many issues—you just enumerated some of them, and there were many more. We were just grist for everybody's mill, and grind they did. Again, there was nothing really personal in it. I was attacked personally only by a few people, and only by one that really was offending me; and she didn't understand me or what I was saying and misinterpreted it.

JY: Who was that?

AS: She gave me a bad, really a lousy interview someplace. That was a woman who wrote for the *Washington Post*, and I'm even blocking her name right now. I felt badly

about that because, in a way, I gave a bad interview and she misinterpreted it. That was just generally a bad scene.

By and large, I would give myself a C or a C+ on what I did and how I did it. I think I could do much better now.

JY: Here's a chapter in what every young commissioner ought to know. A book that, in retrospect, you might write. Are there other chapters?

AS: Well, the problem with that job is that unless you are an old Washington hand, you go into it quite naive and you *don't know things you should know*. My maturing took a huge step a few weeks after that first Kennedy hearing. I didn't know what in the hell was going on or what in the hell was happening to me. And somebody, whose name I won't mention, said, "Let me do you a favor. I want you to spend some time with Clark Clifford." So, this individual called up Clark, and I don't know to this day whether Clark was paid for this or not--I kind of think he was not--but I got a call from this person who said, "Call Clark Clifford. He's expecting a call from you." So I called Clark Clifford and we made an appointment in Clark's office at 2:00 in the afternoon or something like that.

So I went down and, you know, he had this lovely office. Clark Clifford is a lovely man and a very imposing person. I went in the office and introduced myself, and we chatted, and he said, "Well, tell me. I understand you're having a little difficulty. Tell me about it." So, Clark is an awfully good listener; I got wound up and *I delivered myself* finally. I started out just saying, "Well . . ." and so on, but I really got into it and ended

up talking about twenty minutes. And I noticed as I was really getting wound up, he was . . . A little smile was playing around the corners of his mouth, and finally he just couldn't contain himself. He started to laugh. And he laughed and laughed. And he said, "Oh, you are really marvelous. My, what you have to learn." And we ended up spending hours together that day.

Then, subsequently, at other times I would consult with him because he was a master at the Washington scene, and what the meaning of things were, and how you should respond, and what you should do. And I didn't know a lot of that when I went to FDA.

JY: And this was very useful?

AS: Oh yes.

JY: Practical.

AS: Yes, I think Clark Clifford sort of glued me back together, in a sense, after that onslaught of the Kennedy hearing. And I really didn't know. I was confused. I didn't know what was going on. And he told me what was going on.

I think of three people who really helped me quite a bit. This'll sound funny, but one of them was Clark Clifford and the other was his Republican counterpart who was another lawyer who worked for Eisenhower and was always, you know, on the "in" in the Republican administration. And Clark Clifford was more on the "in" in the Democratic administra-

tion, although they were both important no matter what happened in Washington. I'm blocking the name of the Republican lawyer. He's sort of the Republican Clark Clifford and I just can't think of his name right now. And the third person was Art Buchwald, because Art understood Washington just as well as the other two, but had this marvelous ability of saying things in a funny way and in an amusing way, but yet struck right to the heart of it. I used all three of these individuals. I'd pick up the phone and call them and ask them what the hell was going on, or what this meant, or what I should do, or would this be wise to do. And I learned from those people.

Cap Weinberger, obviously, was somebody else who knew the Washington scene, but was a little less useful in the sense of explaining things to me. Cap knew, but he wasn't quite as good a teacher as Clark Clifford.

Of course, one of the characteristics of my tenure was that every time I turned around, somebody would be gone. Just stop and think about it for a minute. I was there for three and a half plus years. And I worked for two secretaries and three under-secretaries and, I think, three assistant secretaries, two presidents and three vice presidents. It is true that, of the people at the cabinet level or agency level or White House level, only Arthur Burns and I were left of the entire administration, at the time I left. I was once with him at a party, and we compared notes. You know, the president, the vice president, all cabinet officers had turned over at least once during that three and a half years, so that, in a sense, it was kind of hard to cultivate people.

Consider the minority leader in the House. When I went there, I called on him. He was important to the medical device legislation; he was important to my working in the

House, particularly since it was a Republican administration. And I got to know him and we started to work together. He was very concerned about one of his kids who was going to Logan, Utah, and I knew about Utah State. And then I turn around and he's gone. And that's Gerry Ford; he's vice president. Well, that's kind of slick. But, nevertheless, he was gone. Then suddenly he's president. That element made it difficult.

In a way, it was not a stable environment for learning what I should have learned, because the teachers kept going away, and the scene kept changing.

JY: And your set lines of communication that you'd established had to be done all over again. Did you automatically talk to the secretary every so often and personally bring before him the major concerns?

AS: Yes. I came into contact with the secretary at regular staff meetings. You see the assistant secretaries were Charlie Edwards and then Ted Cooper. They were both friends of mine. They both trusted me. Both of them felt that if there was something important coming out of FDA that the secretary should hear . . . I had free and direct access to the secretary. Then you have to know who the secretaries are, because Cap and I became reasonably friendly. He was kind enough to take my wife and me and my kids with him to Camp David and stuff like that. We became friends. I understood Cap and what he wanted and gave it to him, and he developed a trust in me. No matter where he was or what he was doing, if I called, he'd immediately come to the phone. I never wasted his time, and he appreciated that.

Then the next secretary was David Matthews, whom I had known. He was president of the University of Alabama and was an academic. I mean, he was really academic. To tell you the truth, the longest conversation I had with him was one time we spent hours talking about Greek poetry, about which he knew a tremendous amount. He knew nothing about FDA or FDA matters and didn't really want to be bothered. So I kept him informed of things that were going to be in the newspapers and be big issues. By then, Ted Cooper was assistant secretary, and Ted and I were good friends. And Ted understood about FDA because he had worked with FDA for years, from the Heart Institute, and so on, on the medical device legislation. And he was instrumental in getting that. And he trusted me and left me alone.

But the subject we are discussing is sort of the greening of Schmidt, and where I could have done better. And I think that I could have done . . . If I did it again, I'd make the same mistakes, if they were mistakes. Because what the agency needed was attention to its internal matters. As I said before, Charlie had really shaken the place up and it needed settling down, and I'm a good settler-downer. I'm less good than Charlie at massaging Congressmen and pressing the flesh and scanning cocktail parties for the right person to talk to. I'm not too good at that right now. I will go to a banquet like last night. Charlie Edwards, if he went to the banquet last night, would be talking to me but scanning the room for somebody he needed to see or ought to see or should see.

What I liked to do was find somebody fascinating, go over in the corner and spend the evening getting to know them. That doesn't help you a hell of a lot to survive as a commissioner of FDA. It's interesting that I have left, though, with good and deep and

friendships for instance--with Morton Mintz. Believe it or not, I've had to do with some serious things with Morton Mintz just in the last few weeks. Also there are other people in Washington who are deep and good friends.

JY: I get the impression you feel a very loyal and dedicated alumnus, that you feel you're still serving the agency in a whole host of ways. Not necessarily because it's the agency, as such, but because of the commitment to the kinds of problems in society that it was and is involved in.

AS: Yes. I think that's right. Once an FDAer, always an FDAer. I think Charlie feels that way, but he's in California. But, as you pointed out, he did make a speech just a week or two ago. That's certainly true of Peter Hutt, who is extremely active--in part, because that's also his vocation.

JY: All kinds of historical, but also present interpretive articles come out in that journal which I get of the Food and Drug Law Institute that must be helpful to the agency. Although sometimes what it is is an ongoing debate.

AS: Yes.

JY: Right. Well, I'm just kind of checking. We've alluded to the antibiotic residue in animal feeds and the implications for human health. That was one of the dangers. Is there

any more about that particular thing which continues that you feel you'd like to say something about?

AS: Well, that's a difficult issue. It's a classic example of what I was talking about before: where there's science, which takes you so far, but then there are a couple of other questions that aren't science. Science right now has not provided any great help in answering the questions about antibiotic resistance. What seems to be true is that England banned the use in animal feed of antibiotics that were useful in human therapy, but that hasn't lessened their incidence of resistance in bacteria. And the use in this country hasn't seemed to increase it. What there is, is a theoretical possibility that has not been proved yet. Whether that's good enough for the agency to act on, I don't know.

To tell you the truth, if I were commissioner right now, I don't know where I'd come down on that. At the time, we were proceeding to get rid of them.

JY: Yes.

AS: And I can't tell you how sophisticated I was at that time in terms of this sort of issue. But we were told by Congress to get more data, and that's been the consistent response of Congress to the agency. That's not all bad; that's not stupid to say, "Here's an important issue and it ought to be studied." I think what we've learned is that studying it is harder than most people thought. The answer to it is going to be like the answer to the non-nutritive sweeteners, and that is to find alternatives that will be better. The sweetener

issue is going to be resolved by a lot of sweeteners coming along eventually, although more slowly than I would have thought. I think the ultimate answer to the antibiotics in animal feed will be molecular biology and genetic engineering--or else some other kind of growth promoter, whether it's growth hormone or a variant of that. Something will come along.

JY: One other particular area that I had written down. There was a good deal of pressure through your term for improving both the good manufacturing procedures and the good laboratory procedures. Involved in that were problems of the integrity of clinical investigators. Any personal involvement in that that might be on the record?

AS: Well, this grew out of the agency's own work. We had a unit that was looking at the integrity of the data and the studies that we were using. This was in Frances Kelsey's shop. They turned up some stuff that didn't look right that had to do with studies that had been reported by Searle. Once we discovered that, then we launched a thorough going investigation of Searle, and, like a lot of things, it led to Searle's contract labs and then, finally, to a broader survey. And the agency would have gone ahead and we would have done what we did in any case. It wouldn't have become such a well-known matter had it not been for the fact that for most of the time I was there and sometime before I was there, Ted Kennedy had in the agency a full-time investigator.

JY: You mean he just asked to plant him in the agency?

AS: He assigned him to the agency. His name was Walter Sheridan. He was a former, if my memory serves me right . . . He had been with the FBI. He had been an employee of Bobby Kennedy's. Bobby Kennedy had used him to nail Jimmy Hoffa. Walter Sheridan was one of those people intensely loyal to the Kennedy family and the Kennedys, and when Bobby was killed, Ted picked him up. He was a first-rate investigator, and Ted assigned him to the FDA. He was full time in the FDA. He walked the halls of FDA and he talked to people, and he had full congressional authority to pick up any piece of paper. There was nothing that could be kept from Walter Sheridan, and he was an investigator. He knew more than I knew what was going on in the agency, without any question. Because that was what his job was.

So he picked this up, and we had a set of hearings on the integrity of the investigative process that led to, finally, recommendations from us to the Justice Department to prosecute certain individuals in Searle. That led, eventually, to a massive shake-up in Searle. Particularly when management of Searle changed and Don Rumsfeld went in: he cleaned house at Searle. It resulted in the prosecution and conviction of people in some contract labs. And it resulted in the establishment of the good laboratory practice regulations and a work force to police universities and contract labs and pharmaceutical houses, in the conduct of their animal and clinical experimentation. The need for this program was discovered and it was established while I was there.

I remember one hearing, Kennedy asked me how much it would take to police the effort. As I remember, I said \$16.5 million, which is what we'd calculated for staff and so

on, and he said, "You got it." Within about two weeks we had \$16.5 million and set that program up.

You know, if you read the hearings, I made some statements that are still sort of reverberating around. The most recent I've seen my statements quoted was in *Common Cause Magazine*. They did a very large piece on aspartame, within the last month or two or three, calling for the removal of aspartame and investigation and so on. The lady that wrote that article went back to those hearings, the Kennedy hearings of Searle, and was using some of my statements about sloppy research and all that kind of stuff. Sort of taking some of it out of context, and since Searle was also involved in aspartame, saying at that time their research was . . . and so on. It's still bouncing around though.

JY: But this was still a major trouble-shooting job that you had to confront.

AS: No question about it. But again, I think the agency did very well with it.

You know, some other things had come along that are major that the agency handled well; one was Walter Sheridan and Kennedy's turning it into another circus.

JY: Right.

AS: Another bit of theatre, as you'll read in the paper. Did you pick up the paper?

BP: Oh yes, I did. And thank you.

AS: Do me a favor, as long as I'm spending all this time. Read my paper on hearings, and then drop me a note and tell me what you think of it.

JY: All right. Bob will xerox it and get it to me.

BP: Yes, I will.

JY: There are kind of close-out questions. Let me mention all of them and we can take them up in what seems to be the right order. We talked about the circumstances that surrounded your going into the commissionership. I'd like to know the circumstances about your leaving it and coming back here. Fred wanted us to ask what were your most important accomplishments and what were your biggest disappointments. And maybe we can deduce that, but it might be interesting just to have a first blush response to the question. Is there anything you want to put on the record that we haven't touched on? And particularly judgments of people and policy that we might have a special section on if you want to be really frank and candid and perhaps block the record for some time. You've been very outgoing, I think. But I don't think there's very much that you said that you'd want to block. And then what is the outlook, as you see it, for the future of FDA? There are elements of all of these that are inherent in what you've said, and I think this has been an excellent interview.

BP: Could I just add here if, in case, you do wish to say some things that you want to block. The way we handle that is that I personally type it up. And there are only two copies made. One goes to you and one's put in a sealed envelope to the National Library of Medicine with the date for opening. That's our practice.

AS: Yes.

JY: Jim Goddard. I did a lot of interviews right after he got out of the office, and he sealed the whole thing--because it was sort of hard to detach, where he felt he was extra candid from the rest of it--for fifteen years, I think. And next Thursday it comes to open up.

AS: Well, you look at it and probably wonder why it was sealed.

JY: Exactly. That's right.

AS: No, I don't . . . I don't think there's anything in me that I would say about anybody . . . If there's anything in me that I would have to say about somebody that would have to be sealed, it would have been something I would have said to them, because it would be so important.

The whole business of FDA. When I was thinking about going to Washington, I talked to a number of people. And somebody said, "If you're going to do that, be sure you

go on leave from your university." Now, I was dean of a medical school, and I was perfectly happy, and this came out of the blue. I wasn't seeking a job in Washington. And I don't think there was anybody more surprised than I, that I was called into the White House and asked if I would be interested in taking a look at FDA.

I can't remember who suggested it, but I did ask the university for a leave of absence. Now, you get leaves from a university for a year. This was not a sabbatical. This was a leave without pay, and that's usually for a year. On occasion it gets extended for two years. But that's it.

I went to Washington. I was talking not too long after I had been there to Henry Kissinger, and we were joking about something. He was in hot water for something at the moment. And he said, "Well, I can always go back to school." Then he said to me, "Are you on leave?" And I said, "Yes." And he said, "Don't ever let that go, because someday you'll need it." And as it worked out, this university was kinder to me than Harvard was to Henry, because it finally ended up that he couldn't go back.

So, my intent was to be there during that four years and then come back to the university. All along that was my intent. So, as the time wound down, I spent August in Montana, my place in Montana. I often would stop here in Chicago to see my friends or my wife's parents or whatnot. My wife's parents live in River Forest. So we were here once a year, or I was here for a speech or something and would talk to the people at the university. They said, "When are you coming back?" And I said, "Well, I hope the Board of Trustees will extend my leave so I can finish out, and then I'll come back." So, I'm very grateful to

the university's Board of Trustees that extended my leave of absence so that I could come back.

But my plan always was to come back. Then in August of 1976 with the election in November, I came back and talked seriously with Joe Begando, who was sitting in this office at the time. And I said, "Are you going to have something for me to do? Is there some way I can be useful to the university?" And he said, "Absolutely yes, we want you to do this and come back." And I said, "Fine, I'm coming." So, then I went back and I hadn't talked to anybody about this. And I wondered, "Well, now what am I going to do because I'm going to leave, and how do I leave gracefully and stay friends with everybody." One thing I've observed about institutions is that, by and large, when people leave an institution, the institution stops liking them for some reason or other. It's hard to leave gracefully.

I don't even remember what happened. I think it was announced by the university here a little prematurely. I don't remember how it got out. But I remember a lot of people said, "Boy, you're really stupid, you know, because you could stay and you should stay. The agency needs continuity, and you know Gerry Ford and he's going to get re-elected." Remember that Gerry Ford did not have a full term, and a lot of people felt that he should have a full term, and he had the advantage of the incumbency and so on and so on. And they said, "You know, you should at least wait and find out how the election is going to turn out and then quit." But my plan always had been and was to come back to the university. Also, I said to my wife early on that Jimmy Carter was a populist, and this was a good time for populists to run and I thought he would probably win. Well, as it turned out, as I was

leaving Washington everybody said to me, "How come you were so smart?" But that was just simply my plan and what I intended to do.

My father was puzzled, because he thought I should take any number of offers that were being made to me by industry. He felt I could have a secure financial future if I took one of a number of fairly attractive offers from industry. I tried to explain to him that I belonged in a university, and that was my life, and I was going to go back to it.

And that's all there is to that.

JY: That was that. You left actually when?

AS: Well, I said yesterday, when we first started to talk, that I always seemed to be moving to Chicago at Thanksgiving.

JY: Thanksgiving. So that the election had taken place, but you had set up ahead of time and predicted exactly when you'd go . . .

AS: Oh yes. It was knowing that I was coming back to the University of Illinois in September, I think September.

JY: So that, rather through it all, you kept thinking of yourself as an academic . . .

AS: Sure.

JY: And you thought of this as a deviation from your main thing for your own interest and the public service?

AS: Well, no. First of all, I don't like your word "deviation." If you study that word a little bit, it's not quite right.

JY: I don't mean devious.

AS: I've never been devious or deviant. You see, you have to go back to my Markle business. Markle scholars were people who became deans and administrators, department heads, division heads. They were people who ended up interested in the broader picture than just strictly the research laboratory. Some people would head toward a Nobel prize, others might head down the Markle scholar path, but they weren't the same path.

A Markle scholar named Bill Mayer, whose path and mine, in a way, have been similar, and several others felt that it was important for people in the academy to be familiar with Washington and how it worked in Washington agencies, and that the experience of being in Washington was extremely valuable.

Now, you see, I mentioned Bob Marston who'd been dean in Mississippi and went to Washington then back to Florida, the University of Florida. Bill Mayer was at RMP and went back to the University of Missouri. I was at Utah and went into RMP and came back to Illinois. John Gronville was with us in Washington and came back to be dean of the Michigan Medical School. I could go on and on and on and give you Markle scholars,

which is really a club of people who were deans of medical schools and went to Washington and then back to the academy. I viewed leaving the university and going to FDA as not a deviation at all, but something that was good to do. It was good for me; it was good for the university. One hoped it would be good for the government and FDA, as an example of an exchange between the academy and government. Henry Kissinger, John Kennedy's use of people from Harvard; the exchange of individuals . . .

And then, one thing we've done here is bring government people to the university for six months or one or two years and then back to government. And the Markle Foundation . . . Bill Mayer and I and a couple of others tried to get the Markle Foundation to do something like the White House fellows program. So that I viewed this as a natural progression of my career.

JY: Right. It was education in the sense of Henry Adams.

AS: Sure. Now I'm involved a little bit in industry. What I get to do is a lot of fun. And that is I get to view my world of interests from the vantage point of the academy, from government, and a little bit from industry, so I get a broader perspective, and that's of value to me.

JY: Of course. There wasn't anything of boredom bringing you back; you were still as interested day-by-day in the kinds of challenges FDA had?

AS: Sure. I could have been happy staying at FDA. When I've seen some of the things that happened, in a sense, I regretted leaving because, by God, I wouldn't have allowed some of the things that have happened to happen. Chances are that I would have gotten fired, maybe, but . . .

JY: What's a good example?

AS: Well, I told the story yesterday of fending off the department . . . FDA matters sometimes are sexy and are attractive to politicians. You can see that in hearings and the people lined up to hold hearings on FDA matters. Certainly people in the secretary's office would salivate over the press coverage FDA got.

Starting with Schweiker--well, starting before that. I got along beautifully with Cap Weinberger and with David Matthews as secretaries. When the secretary's press officers would lean on Jack Walden, I would call up the secretary and say, "Call those idiots off." And he would.

Which reminds me of another thing we haven't mentioned that took place while I was there, and that was the whole swine flu business.

JY: I did have that down.

AS: Which was another fascinating episode. Now, there's something I might lock up. The reason that popped into my mind was because that was one time when the department

wanted to move in on Jack Walden on swine flu; he saw that as something getting a lot of press coverage, and I was smart enough to tell him to give it away, because I was very uneasy about the whole swine flu business, and, frankly, didn't want any part of it. FDA came out unscathed, you'll notice, on the swine flu thing, and that was because I distanced the agency from it, because I just didn't like the smell of it from the start.

But starting with Kennedy and Califano, Don Kennedy and Califano did not have the relationship that I had with Cap Weinberger and David Matthews. That was the point I started on. There were no difficulties with the secretary's office when I was there. With Charlie Edwards, who had been at the agency; and Ted Cooper, who knew all about it (and we were good friends, the three of us); and Cap and David Matthews. It literally was sweet and light. If an idiot downtown started to do something with the agency, I'd say something rude or call the secretary or Charlie. Charlie wouldn't brook any interference with me or FDA.

But with Califano, he started to speak for FDA. And Schweiker started to pull back the authorities. And under Schweiker, there began to be stripped away from the commissioner the delegations that allowed him to run the agency. That has accelerated and has been increased with Heckler and now with OMB, to the point now where the commissioner can't run the agency. I think that that's bad for the American people; I think it's bad for the agency; I think it's bad government, because, as Charlie said (we pointed out yesterday), you get it up there and it gets politicized. And I said that in talks, including a number I've given just on this subject.

I think that the agency should be established as an independent agency by law, with the commissioner approved by Senate confirmation. I think the commissioner ought to be protected from politics to the extent of that kind of appointment. I think the agency ought to be left in HHS, but be independently chartered by legislation. And I think that the delegation thereby, then, of the authority to the commissioner would be by law, and that would solve an awful lot of problems.

Now I tried to do that, by the way. We had the bill all prepared. We'd got to the point where the administration was going to support it, when all my friends were there. Then I forget what happened, but the thing fell apart, and we couldn't get it through.

JY: Since there's been slippage, do you think the outlook for that kind of an FDA in the future is very good? Can the agency win back the sort of independence that you think . . .

AS: Well, the way things are going now, if my predictions are true (that is, that Frank Young goes up and leaves the agency), or if people start bailing out and the agency gets into trouble, then you'll be back to the cycle of, well, maybe it should be broken up, or all that stuff.

What I would do, at that point, is get on the horn and call all of the former commissioners and gather a group together to try to do just what I'm talking about. And that might be an opportunity to do it.

JY: So, the alumni may have an opportunity to try to save the college.

AS: Well, maybe I can get Reagan to do me a favor as he leaves and set the agency up or do something. But, I mean, Margaret Heckler is not the right person to be making these judgments.

JY: Right.

JY: And her background is quite alien to this, too.

AS: Sure. Whoever listens to this tape will hear my clock.

JY: Right.

AS: Chiming in the background and know the passage of the hours.

JY: Yes, time marches on. Do you think that, inherent in the kind of emphasis that you gave as we've talked about these things, we've got enough about the answer to Fred's question, what you would deem your most important contributions and your biggest disappointments?

AS: Well, my biggest disappointment, I suppose, would be the time I wasted with the commissioner's investigation and the commissioner's report, and just a set of really wasteful hearings--some of them downright dishonest. I tried--in the speech you have there on

hearings where I described hearings as theatre--I was being sort of nice in calling them theatre. Some of them were just offensive, because they were intellectually dishonest, and they were set-ups, and they were intellectually sleazy. I just resented and was offended by having to spend my time with that sort of garbage. You can say, "Well, that's show biz," or you can say, "That's politics," or you can say, "That's Larry Horowitz." You can say whatever you want, but the net result was that the agency, to a degree, took a beating; I took a beating.

You know, if I go down as the commissioner that was there during the Kennedy hearings, that'll be too bad, because what that will mean is that the very real accomplishments of the agency are obscured by a heap of garbage. And I'll come back and haunt Ted Kennedy, or I'll do something to gain my just historical desserts.

But, I think the record will show, and I think the things that you have talked about will show, that a tremendous amount was accomplished during that time.

JY: Particularly effectuating some of the changes that Dr. Edwards adumbrated, or initially pointed to.

AS: Yes. I just . . . You know, I pay immense amount of credit to the individuals that I've been talking about and some that I haven't mentioned. I was really privileged and honored to be able to come into an agency at that particular point and work with the people who were there and the things that had been initiated.

I think that, of the things that I enjoyed most--I think the Policy Board would be one thing I point to that I'll take great pleasure in, because it was a success. It was effective, and it's continued. It's not been as effective since Young is there, because his style, apparently, is a little more like Charlie's. Charlie would not have used the Policy Board, or he didn't set it up. He wouldn't have conceived of it, because that isn't the way he operated. Once I set it up and it worked, though, I knew it would keep going, because the Policy Board wouldn't let it stop. And, indeed, that's the way it's been.

JY: Who else that you haven't mention might you like to give credit to?

AS: Well, I mentioned people generally through the agency. I think that John Jennings was an old pro and was very helpful and was a good teacher. Mark Novitch . . . An interesting story that only he and I know is that he really got tired of being under John Jennings and chafed in his position. He and I talked and I urged him to be patient; but he was impatient, and he left the agency. I told him when he left that he was making a mistake and he shouldn't do that, but if that's what he wanted to do, I'd help him. I also told him he could come back.

Well, as it turned out, I was right, and he did make a mistake; but he, in a sense, was embarrassed and didn't want to come back. I waited until I figured it was about time that he was maybe wishing to be back in the agency. We got together and I brought him back in the agency, which was good for both Mark and the agency because, obviously, he's been one of the most important people in the agency in the last few years.

JY: Yes. And if there's turmoil now, his being gone will be one of the tough things.

AS: I made a few good appointments. One of them was Kay Hamric, my administrative secretary, who was one of the more effective employees of the government, I think.

I was responsible for the appointment of the first woman director of an NIH institute. The director was looking for a director for the National Institute of General Medical Sciences. I suggested Ruth Kirschstein, whom I had appointed as an associate commissioner for science.

I steered her over to NIH, thereby losing a valuable person, but helping her become the first woman institute director. I'm pleased with some people things.

I'm pleased that people were happy and had fun while I was there. I'm pleased that people looked forward to the meetings, because they were never quite sure what would happen or how I'd behave or what I'd say. We had a good time together and we became good friends.

JY: There was a congeniality.

AS: Jake Barkdoll, a marvelous person. You know, I was told that FDA was one of the two best-run agencies in federal government when I was there, and I think it's true. The morale was good in spite of the Kennedy hearings. Jake Barkdoll and that planning staff was excellent. Jerry Meyer was a superb administrator and so on. There were just a lot of good people for whom I feel--and always will--a great deal of affection. It's funny that people

refer to my time there now to me frequently. Maybe they are just doing it to make me feel good, but they're calling it "the good old days."

When you were there, I don't think a lot of people would have said this is going to be a time when it was "the good old days." But it was "the good old days," because after I left, the proud, old agency, the independent, fiercely independent, proud agency began to change away from that. And it is not that now. Ask Taylor Quinn. You can't do anything without OMB's permission right now, and the agency is going to get in trouble because of that. Margaret Heckler should get in trouble; but the agency will get in trouble.

People think back then to some of the meetings where we were . . . I made that Policy Board sit and go over Peter Hutt's re-write of the regulations, so that they would know them and understand them and understand what they meant; understand what they would then have to do in their bureaus. People think back to that now and think that was great fun.

JY: Two names. Does a second chance bring to mind the Republican counterpart of Clifford? And there was the girl from the *Washington Post* and the unfortunate interview.

AS: I think it was Judy Randall, but I'm not sure. Judy Randall's name springs to mind. The Republican lawyer was Bryce Harlow.

JY: Bob, do you have any questions?

BP: I don't think so. It's been fascinating.

JY: It really has been. It's been meaty and precise.

BP: There's time on the tape to make some kind of a closing statement if you desire.

AS: I hope to continue to be involved in FDA things, and kind of be helpful where I can, but try to work when I can, to restore some of the authorities to the commissioner. I'm really concerned the way things are going with the agency right now.

I guess you could say, "Well, you're concerned because there's been change," and so on, but I'm not the only one that's concerned. Everybody I've talked to has been concerned, and that's not been the case before.

We mentioned the swine flu thing, and I'll just say that, because I knew Gerry Ford and talked to him, I'll say that was a fascinating business; because the president of the United States was had. I saw it happen. I know exactly what happened and why it happened. I knew it was happening at the time, or I had a sense it was. There was nothing you could do about it. Here you're sitting watching a nation be had, essentially, by a couple of people and a set of circumstances. And it was a fascinating business.

JY: You think that's as far as you want to go on the people? Or even the circumstances. Was it political, economic?

AS: No. Having said what I said, I should explain it. I think there was an error in judgment on the part of Dave Sensor, who was running CDC at the time. Whether Dave truly believed in his heart-of-hearts what he was saying, or intellectually believed it, or thought it was good or just what, I don't know, and Dave may not know either. Dave pushed hard the idea that there was the possibility of a pandemic of this flu in the United States, and knowing that, the president or the nation could not *not* do something.

Well, FDA obviously got involved very, very quickly, because we controlled the vaccine. And the question was, do you vaccinate everybody in the country, or do you immunize everybody in the country? You know, where does the vaccine come from? Who makes it? It's a rush job, and all that. So FDA--bang!--was right in the middle of this.

Jack Walden sensed that it was going to be a big story and could have the agency look good. I was just very concerned. I asked to see the data. You know, we had the three soldiers in Fort Dix, or whatever it was. I was a little familiar with the whole thing, because I was in the army and C.O. of this little hospital I mentioned in Darmstadt, Germany when the Asian flu came across the United States. This is the truth: the Asian flu arrived in Europe via Darmstadt, Germany and my base hospital, because they gyroed a unit in . . . They used to do what they call gyroscope units. They'd pick an entire unit up and move it and bring in another entire unit in its place instead of transferring individuals.

We had a unit brought in that was incubating the Asian flu from this country, and that's how the Asian flu arrived in Europe. We had a mess on our hands for a number of weeks. So, I was a little familiar with flu epidemics and what the flu could do.

But I looked at the data. And going from a couple of guys at Fort Dix to a national pandemic seemed to me possible, but remotely possible. And not likely.

Exactly how it happened, I don't know, but we had a meeting in the White House in the Roosevelt Room, which is my favorite room. The president, Gerry Ford, and Dave Sensor and I and Ted Cooper, and then all of the great gods of virology were in the room and the president was seeking their advice. Albert Sabin was there and Jonas Salk was there. I kept my mouth shut at that meeting on purpose. Dave Sensor carried the ball and laid this out and spelled out the horrors.

President Ford went around the room and asked everybody around the room to speak up and give their advice. To a man, everyone in the room, including Albert Sabin, said, "Yes, Mr. President, there's a possibility, and you should have a massive immunization." Everybody said it; it was unanimous.

Now, the fact of the matter was that when we walked out of the room, he walked into a press conference and read a press release that had been written before the meeting. So, in a way, it was a set-up.

But, it was the wrong decision.

JY: He could've jerked the press release if the words around the room had not been that way.

AS: Well, if you wanted to do the research and study in particular what Albert Sabin said afterwards . . . He sort of weaseled on his position.

The thing was less than honest. As I sat there in the room, I thought, here's the president of the United States, and here is this thing and it isn't real. It isn't the way to come to grips with this issue. It's not the soundest way possible to make a decision. I think, basically, the error was that the president was misled by his government advisors--that is by CDC.

Now, obviously, if there had been a pandemic, I wouldn't be sitting here saying this. The other thing is that I don't think it was . . . I mean, it's been called the swine flu disaster. I don't think it was a disaster. I think it was one of the most highly successful immunization programs in the history of the country in many respects.

Further, all of the things that happened to people were to be expected. When you immunize a lot of people, you're going to have some deaths and some Guillain Barré. It may sound hard-nosed, but that's what you get.

So I'm not bothered by that; I think it was a great immunization program, and the vaccine was safe. In many respects, it was a marvelous . . . It was like one of these disaster rehearsals we have here, when we pretend the elevated train crashed, and we make up everybody and rush around and rehearse disasters.

JY: It has had an impact upon the making of vaccines, hasn't it?

AS: It's had an impact on the people's trust of the whole system.

JY: Yes.

AS: And you see it reflected today in the DPT thing: you know, the problem with the pertussis vaccine. It's had an impact on lawsuits, product liability suits. It was a bad scene, regardless of what I've said, because of the way it turned out.

But one of the pictures on the stairs going up to my studio at home, which is on the third floor--I have my gallery of plaques and things--one of the pictures is of me standing and talking to a press conference we had at NIH on swine flu. Ted Cooper is sitting beside me and I'm standing talking, and it's a picture taken over my shoulder. It's the best picture I have, in a way, of a press conference. The picture amuses me because there's a forest of microphones in front of me: there must be thirty or forty microphones. It's just a solid electronic mass in front. The back of the room is a solid bank of national media and television. The front row, kneeling down, all of the familiar and famous faces of the Washington press corps, looking up, pencils poised, and so on. Every time I walk upstairs, I get a chuckle out of that picture, because that was another event that was time consuming in the life of the commissioner.

No, I think the FDA is a great agency. Poll after poll and study after study has showed that it's well run, that the people of this country understand it, trust it. The people of the world follow its lead.

I haven't mentioned some of the international activities. Again, Charlie set up something we called the Tripartite Group. What's funny is that Charlie, I think, set it up, but only attended one meeting or so. So, here I was again, another good idea that I got to implement.

The Tripartite Group was, essentially, about four people from FDA--myself, John Jennings, Peter Hutt or Dick Merrill, and then depending, sometimes Dick Crout or Virgil Wodicka, just those top people--who would meet with our counterparts of Canada and England every three to four months, rotating it between Ottawa, London, and Washington. That was highly useful, because if we got together and compared notes and knew what each other was going to do we could get out of the mode of our approving saccharin and removing cyclamate, and Canada approving cyclamate and removing saccharin--which is exactly what happened, as you know. There was some really silly stuff going on. So we met and, again, became friends, and that led to some fun stuff--again, part of the fun of being at FDA.

One thing I got asked to do was to referee a dispute in the Common Market over chocolate and the standard of identity for chocolate. I thought that would be kind of fun and easy to do, so I went to Brussels or wherever it was--and barely escaped with my life. It was straight out of vaudeville, you know, with me, essentially, running down the street, being pursued by people who were trying to kill me, because I hadn't recognized the distinctions between Swiss chocolate and German chocolate and Belgian chocolate and English chocolate. And secondly, the passion with which they viewed chocolate. That's sort of an amusing little story. Of course, they're still fighting about chocolate and they always will. But the idea was that the FDA was good at standards of identity, and so why didn't they get a common standard of identity for chocolate in the EEC.

JY: Is the tripartite arrangement continuing?

AS: I haven't the foggiest idea. I would sort of doubt it, because again, it was one of those things that was internal to the agency. See, if I had done the courting of Congress and the courting of the press that we talked about earlier, I wouldn't have had time to do some of these other things that I did inside the agency.

JY: Now, you went to a proprietary association meeting in Japan. Wasn't that it, an international . . .

AS: You mean just recently?

JY: Yes. Which is another kind of international forum to talk about common problems, I take it.

AS: Yes. Well, there's a group called the World Federation of Proprietary Medicine Manufacturers, the WFPMM, or something like that. I've been to two of their meetings, just talking about broad issues.

JY: Well, there are international dimensions to all of these that your chocolate episode and your trip to Japan and . . .

AS: Well, I traveled to Japan when I was commissioner, and visited there and dealt with the government of Japan and had a marvelous party I was able to host in the embassy in

Tokyo, because we were between ambassadors: Mike Mansfield hadn't come, and the embassy was empty. So, I got to use the embassy and throw a party for the Japanese government officials and pharmaceutical officials in the embassy, which was great fun.

I did a couple of other things. Of course, FDA has always been involved in the FAAO. I first got involved with WHO there. Now at the University of Illinois and WHO, we're doing some things that have the potential for being very exciting. Just next week or so the deputy director of WHO, Tom Lambo, is visiting here, and this will be his second or third trip to the University of Illinois. So, these things kind of feed.

JY: Right. It was very useful, all these contacts, when you came back . . .

AS: Sure.

JY: To advance medical education and the whole realm of attendant activities here.

AS: Right. Well, then, as I mentioned, I'm on the board of directors of American Cyanamid, which is worldwide, and that board also makes trips. So again, a year ago, I was in Japan (this time with Cyanamid) and Taiwan. We met with the premier and the minister of health. I walk in and I had been there a year before, so you can keep the contact going. They sort of say, "What hat have you got on this time?" because it could be quasi-FDA or University of Illinois or Cyanamid or whatever. Each activity helps the other one.

Well, the other thing that's pleasing is that I've been invited to speak to AFDO in June. When is the annual meeting of AFDO?

Paul Hile called me and said, "They have a named lecture." I forget the name of the lecture, but it's a named lecture. He said, "We were just sitting around thinking of who we'd like to hear from. You were unanimously . . . We thought, well, maybe you could do this." So, I was flattered, and said, "Sure." You know that's fun.

JY: Letting you have your own topic.

AS: Yes.

JY: Right. Yes, it is.

AS: Well, I don't think I was the best commissioner, and I know I wasn't the worst commissioner.

Like a lot of people say, "Boy, I wish I knew then what I know now." I suppose, if I had a wish, I would wish that I could start over again, but with the wisdom that I've accumulated by having done it: that would be my fondest wish.

I wish the agency well. I wish, somehow or other, that all of the good stuff of the past could come back to the agency and all the bad stuff would go away. That's what I would wish.

JY: That's a noble hope that we might close on, perhaps, Dr. Schmidt, with our gratitude and with the hope, too, that history, made up of research in archives and reflective comments like your own, may itself turn out to be a help to FDA's future.

AS: Thank you.

BP: Thank you.