

History
of the
U.S. Food and Drug Administration

Interviewee: James C. Morrison

**Interviewer: John Swann, Ph.D.
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TAPE 1, SIDE A

RT: This is another in a series of FDA oral history recordings. Today, September 23, 2003, we're interviewing James Morrison, a retired senior advisor of the Center for Drug Evaluation and Research, FDA. The interview is taking place at the Parklawn Building in Rockville, Maryland, and is being conducted by Dr. John Swann and Robert Tucker of the FDA History Office.

Jim, we like to begin these interviews with a brief overview of your education, where you were born and educated, and any experience you might have had prior to joining the agency which might be relevant to your career, and then proceed into the career itself.

JM: I'm actually unusual in that, outside of a summer job at UCLA, my whole career was with FDA.

I was born in Oakland, California; moved to and grew up in South Pasadena, California, went to UCLA, and got a bachelor's degree in chemistry. Then I went to the FDA office in Los Angeles and spent seven years there, and then got a job in the Office of Compliance in Drugs. I had two different jobs there. The first was a general regulatory officer, and then I went over to what's now drug-labeling compliance and was head of the OTC [over-the-counter] Branch there for a couple of years. Then I was special assistant to the Director of the Bureau of Drugs, Dick Crout, and the Deputy

Director, Jerry Halperin; Carl Leventhal was Deputy before Jerry Halperin. Then I was head of Regulatory Affairs for the Bureau of Drugs, which was responsible for all the regulation writing. I was there for 18 months. They restructured the Bureau into the Center for Drugs and Biologics, and the reg-writing group was moved to the Office of Compliance, but I took a job as deputy director of the Office of Drug Standards under Peter Rheinstein, and I was there for about 11 years, after which time Peter Rheinstein left. There were a couple of reorganizations, and I was the acting director. Finally, that office was abolished, and I was deputy to Bob Temple in the Office of Drug Evaluation I. After that I was CDER [Center for Drug Evaluation and Research] ombudsman for seven years and senior advisor to Janet Woodcock.

JS: Just a couple questions about that background that you just told us about.

I'm just curious what things interested you in, first of all, in chemistry -- you must have had an interest in science, I take it -- and also, what led to your interest in FDA?

JM: Well, I sort of fell into chemistry. In college, I was going to be a physics major, and then I started taking chemistry courses, and I liked them so much better than physics that I switched majors.

At that time, you know, it was fresh after the thalidomide disaster, and the agency really had a lot of good publicity and high visibility, and so it was a place to go if you wanted to help out. And I viewed it at first as, because I wasn't in the draft for Vietnam, as putting in a couple years of public service. Once I got in, it held my interest for 37 years.

RT: Were you approached by an FDA staff person, recruiting staff?

JM: No. I approached the agency. I was working at UCLA but didn't see that as a long-term kind of a job. But no. I had picked FDA, and that was the primary agency I wanted to work for.

JS: Isn't it interesting that what got you interested in the agency -- thalidomide -- was a fiasco here. But it wasn't too long before you actually came to work in the same part of the agency as Dr. Kelsey.

JM: Yes. In the field as a chemist, after the initial training, one specialized, and it was pretty clear that the drug chemistry group was the place to be. That was my interest anyway. I was not interested particularly in food science, although it was interesting, but I was pretty much headed for drugs all the way.

RT: Who was the director of the district when you joined?

JM: Gordon Wood, and he was one of the old-timers. He used to have regular meetings downstairs, and he would tell all the old war stories. And then I guess it was in the late '60s, he retired, and Abe Kleks was the district director.

RT: Who was chief chemist when you came in?

JM: John Weatherwax. He was there the whole time I was there.

JS: What stands out, if anything, from your experience in the Los Angeles District?

JM: Well, I learned a couple of things. One is that my attention span for any one job is probably seven years, and that's been pretty true to form throughout my career.

As you know, the field was always one grade lower than headquarters, and it was very difficult to get from the field to a headquarters job because the GS-11 was sort of the ceiling for a journeyman chemist, and you pretty much had to be a 12 to get a 12 or a 13 at headquarters. So I kept applying and applying.

What I think stood out was that I gave my supervisor a lot of heartburn. When he was gone, I was acting supervisor. But I wasn't afraid of making waves. I remember writing up a memo that was somewhat critical of the inspections, not the inspectors themselves, but particularly surveillance sampling, because we would get samples of three consecutive lots of a drug with 90 percent active ingredient and so forth for surveillance samples. And I said, "You're never going to find a violation in those." So I came up with a proposal for surveillance sampling based on firms, their track record and low-dose drugs and looking for where the problems might be, and I worked out a schedule for the samples. In the district, a chemist poking into the inspection area was not politic.

So to make my suggestions easier to accept by the inspection staff, they had me do an audit of the lab first. I did a three-week audit in the lab. Going in, I figured it

would standard, quick and easy. Everybody did. After three weeks, I spent eight hours debriefing John Weatherwax about all of the things that were not done according to SOPs [standard operating procedures]. So there were a fair number of changes instituted in the lab as a result. Anyway, the sampling thing eventually got adopted.

JS: While you were still there?

JM: It was either while I was still there or shortly after. All this occurred in '70-'71, and I left in '72, so it was around that time that it was adopted.

JS: I'm just curious. Do you know if any of the other districts adopted the same proposal?

JM: No. When I moved, I was mainly doing regulatory casework. I didn't get into that surveillance area to really know whether other districts did that or not. Actually, after a time, they discontinued that whole approach of surveillance sampling by districts, and they went to what was called IDIP [Intensified Drug Inspection Program], which was a similar philosophy from the GMP [good manufacturing procedures] standpoint. IDIP would target firms that had gotten into trouble, and it would go in with intensive inspections and stay there until they cleaned up the plant. And I felt that was a good step.

RT: When you came into headquarters, did you come into the Compliance Branch?

JM: Yes.

RT: Were there any particular issues or problems at that time that you were engaged in there or had an impact on?

JM: About six months after I got there, a big recall of hexachlorophene products occurred, and I coordinated the recall, which was a full-time job for quite a while. It taught me a number of things. It taught me that the agency wasn't as aware of products as it should have been. Product listing requirements had just been instituted that year. So when issues came up with a product, people really just scratched their heads as to how many products there were out there with that ingredient in it. I remember reading a commissioner's meeting minutes where they opined that there were probably something like six to 12 products that had hexachlorophene in them. It turned out that there were something like 1,500 products with hexachlorophene.

JS: Fifteen hundred?

JM: Yes. They were off a little bit. About 600 of those were recalled. It was a complicated recall because some of the products, depending on the percentage of hexachlorophene they contained, could stay on the market. They were mostly products that used hexachlorophene as a preservative; if the percentage was not minimal, up to three-quarters of a percent, they were moved behind the counter as prescription products; and if it was more than three-quarters of a percent, it was recalled. It was a learning

experience, and we talked with the French doctor who first alerted everybody to it, and there were deaths in France.

RT: What was the problem with hexachlorophene?

JM: Well, supposedly -- and to this day, I'm not sure that I actually totally believe it -- there was a baby powder manufacturer in France who mistakenly, instead of making a 3 percent hexachlorophene powder, supposedly made a 6 percent hexachlorophene powder, and it devastated a lot of babies. We looked at the photos, and their behinds were fire-engine red. Six of them died from brain lesions. That was the effect.

JS: It was absorbed systemically?

JM: It was being absorbed systemically.

Now, since 3 percent was the standard potency for hexachlorophene scrubs and lotions, I always questioned whether it was really 6 percent hexachlorophene in France or whether it was maybe improper mixing, where part of the batch was a much higher percentage. But in any event, whatever it was, it was clearly too toxic for the OTC market.

RT: On the hexachlorophene, did I understand you to infer that was a preservative?

What was the function of this compound?

JM: Well, it was antimicrobial, so at low levels it was a preservative, and then higher, it was a surgical scrub and topical antimicrobial. It was used in everything. It was used in deodorant soaps, and that was where the three-quarter percent level came in. Dial and many other soaps had it. It was the next big thing after chlorophyll, you know, where it was in every product.

JS: Did we have an NDA [New Drug Application] for this?

JM: Yes. There was an NDA for it. And I worked pretty closely with the Anti-Infective Review Division, and I learned a lot of things.

JS: Well, we certainly learned that. You said the problem with the drug listing, how many products were out there, and obviously led to an effort to correct that problem.

JM: Congress had corrected it, but it was slow in being implemented. At that time, there was no hope that it would be implemented within a month or two. It was a huge job.

I did some overtime at Drug Listing, which was horrible. They were above a furniture store in downtown Silver Spring, and the roof leaked, and it was horrible place, but that was the only office space they could find on short notice.

RT: You became chief of the OTC Compliance Branch. How long were you in the branch before you assumed the leadership role?

JM: The way that Compliance was organized when I got there was basically a functional orientation. In other words, there was one group, DRO [Division of Regulatory Operations], that handled all the regulatory issues, reviewing the field submissions for regulatory action and that type of thing. Then there was a case-management group that handled cases from there on, worked with the General Counsel's Office and so forth. So DRO did everything. I mean, we did GMP cases, we did labeling, you name it. In 1974, it was reorganized according to subject-matter areas, so there was then a Labeling Division and a Drug Surveillance Division and a GMP Division and so forth. So when that split happened, I became head of the OTC Compliance Branch in Drug Labeling.

It also taught me something about management. We had talked on a daily basis. Everybody had a specialty, and if you got a case on GMPs, you'd go to Dave Fry and talk with him about it and so forth. The day that we were restructured, it was like doors closing. I mean, nobody ever talked to anybody outside of their own little group. So it impressed me that organizational structure has a lot to do with how people communicate, and you can either facilitate or not facilitate communication.

JS: What again was the reason for this particular reorganization?

JM: The reason was basically that three-quarters of Compliance was in DRO, and they needed some way to make it manageable.

JS: I want to go back briefly just to pick up on your experience with hexachlorophene, not on that specifically, but I know when you were special assistant to the Bureau

director and one of the things you were involved in was with the task force on market withdrawal of products. I wonder if you could talk a little bit about why that was formed.

JM: Well, there were ad hoc task forces whenever something came up. NCI [National Cancer Institute] was testing all common chemicals and drugs for carcinogenicity, and chloroform came up as a carcinogen. There were a lot of OTC products with chloroform in them: Benadryl Elixir had chloroform in it. It helped you cough a little bit. So I headed a couple of those ad hoc committees.

I remember another one on methapyrilene that resulted from NCI determinations that it was either a likely or definite carcinogen.

The problem was, we had to work fast, because NCI would give us a couple days heads-up, but not a lot of time before they went public. Once they went public, of course, the news media would immediately ask, what's the agency doing about it? So we had to work pretty fast to make decisions as to what was appropriate to do and so forth.

But it was all ad hoc. It would be very difficult to write specific guidelines about when you take a product off the market, and if you look at it today, you see the same thing in drug safety. Sometimes it's a mystery as to why some products are taken off and others aren't.

You look at Lotronex, which was basically for irritable bowel syndrome, and became a big seller. Then three people died, and it was immediately taken off. Now, this is a prescription drug, and it was taken off the market. And yet NSAIDs [non-steroidal anti-inflammatory drugs], which I've heard estimates of 10,000 people, 16,000 people a year die from basically gastrointestinal problems caused by NSAIDs, and they're still out

there. So it's pure OTC. And quite a number of them are OTC.

You have to ask, what is it that makes people accept risk? I mean, we know some of the factors. They have to do with familiarity, and a new drug is much more likely to be taken off the market than an old one.

JS: Each case has its own circumstances _____.

JM: But each case has its own. I've never seen two cases that were so identical that you could use a cookie-cutter approach to them.

JS: Also, when you were in the same position, one of the other task forces that you were involved in developed a new drug approval process, and this in the period of the late '70s, early '80s. I believe this is also a period when the agency was very deeply involved in trying to basically completely redevelop the new drug process.

JM: In fact, that carried over to when I got into Regulatory Affairs in '81; '82, I guess it was, early '82. The NDA rewrite was one of the regs that we were working on, so I was working on it for quite some time, and it was a challenge. It was extremely difficult to make major changes in the way that new drugs were reviewed, and part of the problem was that the people in the agency had a certain way of looking at New Drug Applications, and they wanted to know all these things, you know. The industry had adjusted to that, and their people were used to producing information to answer those questions. People hadn't really stopped to say, well, why do we need that information, or

do we need some other information more than we need this information, and how can you do it? And the chemists were always a tough group to try to get a handle on what it was that they really needed.

I always use the example of a cap liner. You know, they want all the chemical background on what went into the cap liner on a bottle of tablets, and how many deaths have been caused by the cap liner on a bottle? Given that, most of the stuff that they use, the plastics they use, were food-grade plastics, so they had gone through a lot of testing. But they had to have their information.

And Hank Meyer -- this was later; this was in '85, '86 -- Hank Meyer made a real attempt to try to tease that out, and he had the chemists almost on the ropes, and then he left, and that was it. The regs just stayed sort of the way they were. Nobody really was pushing that hard on trying a zero-based approach to drug regulation, and particularly not for drugs. We're getting closer to it now, but there still has not been a top-to-bottom re-look at it.

JS: Were there criticisms with the process as it existed that there was just too much redundancy in the process, or was it something more, something other than that?

JM: Well, in those days -- this is before PDUFA [Prescription Drug User Fee Act] -- there was a statutory provision which said that the agency will act on a New Drug Application within six months, which was routinely ignored. There was basically no time limit. I mean, there were drugs that took 10, 15 years to get approved. I think fundamentally, the rising chorus against the drug-review process was primarily based on

the time element and on the uncertainties. A company would submit data, the agency would review it, and would come back with some deficiencies. The company would then correct those deficiencies, and FDA would come back with more deficiencies, you know, different ones. The industry was driven crazy because there was no time limit and the agency could keep an application hostage forever just by asking more questions. I think more than anything else, it was the lack of certainty and the lack of a time limit which was responsible for this.

As a consequence of this sort of failure to make quick decisions, there were a lot of studies done which showed that the U.S. was about last in the approval times for new drugs as opposed to Europe and Japan, so there was a lot of pressure to get things out.

JS: So this is, in part, fallout in the whole drug-lag debate?

JM: Yes. The drug lag has been mentioned from, I don't know, I guess the mid- to late '70s.

RT: Medical claims for certain foods occurred about that time, too. Can you address that problem?

TAPE 1, SIDE B

JM: Basically the problem in foods was that health claims were being made, and one of the big points of discussion was, how much evidence was needed in order to justify those

claims? It's always difficult when you're dealing with the dividing line between two regulatory authorities, and you've got drugs, which has like total death-lock control over the products they regulate, and then foods, which has much less control, and you see the same thing between drugs and devices as well. A lot of the discussion centered around what was appropriate, and as I recall, we finally came up with something to the effect that the food industry didn't have to submit the data, but they had to have the data available if we asked for it.

RT: Did you have a task force or a liaison group between drugs and foods in this area?

JM: There has been over the years a continuing liaison between foods and the drugs area, actually, multiple ones. There was a standing one between the compliance offices because part of this need had to do with defining what was a food or when a food or a cosmetic crossed the line into a drug, and so that came up fairly frequently.

Then there have been, from time to time, various committees that are cross-center committees. Most recently, the most prominent one is the Herbal International Products Group that looks at whether something is a food. And, again, it's one of those issues where you have these products, some of which have components that are very similar to prescription drugs as part of them. For example, red rice powder, I believe, which had a statin in it, which was claimed to lower cholesterol, and probably did.

JS: This is not naturally occurring?

JM: Yes, it is naturally occurring. And so you get these things that are sort of neither fish nor fowl, and I think they decided that it had to come off the market because statins do pose some risk, and there's a danger that people will just use it indiscriminately if it's in the stores.

There's issues like that all the time.

RT: I think at one point, there was a situation where the National Cancer Institute was somewhat favorable to, I think it was a cereal product. I don't remember the product name. FDA was a little reluctant, but I think . . .

JM: Yes. I think it was Quaker Oats. Quaker Oats was pushing oat bran both for lowering cholesterol and for preventing colon cancer. From time to time, food companies sort of push the envelope a little, and the agency would push back. You can understand why. If you're looking at it from a clinician's point of view, you want to see cancer cases reduced by whatever means necessary, and the agency has to get some handle on the truthfulness of the claim. It's tough to walk that line.

JS: Times have changed now in the policy of the agency when it comes to claims, medical claims for foods, hasn't it?

JM: Yes. I think part of that is because we know more about foods. I think also, looking over my career, the agency has gotten a little looser, not lax, but more realistic and less bureaucratic in its regulation of products, more viewing the real world as it is as opposed

to the bureaucrat who would like not to let anything out until it's absolutely perfect.

JS: I think you also were quite active in the marketing and drug-pricing arena. Can you speak a little bit about that?

JM: In the mid-1970s, there was an experiment called the Maximum Allowable Cost Program, which was run out of the Health Care Financing Administration [HCFA]. Originally it was a committee of various agencies chaired by Ted Cooper, who was Assistant Secretary for Health. Out of that grew this program where HCFA took prime responsibility. It was transferred from the Assistant Secretary for Health to HCFA, but it was still multi-agency. There was a lot of pressure from the brand-name drug companies, and they put stumbling blocks in its way. Basically, as a prudent buyer, the government - - meaning state Medicaid purchasing agencies primarily -- will not pay more than X amount for a particular drug. And the MAC [Maximum Allowable Cost] program would pick some figures based on the wholesale advertised price of a particular brand or generic and say, "We're not going to pay more." Since the federal government funds 55 percent of the state Medicaid payments, it had a big voice in how the money is spent.

FDA's role in this program was to assure that the drug they picked, or the drugs they picked, were arrayed by price and a line was drawn someplace to assure that the drugs available below the price line were equivalent to the drugs that were above the line. It got into a very, very politicized kind of thing. When I was special assistant to Dr. Crout, I was the FDA representative. The MAC [Maximum Allowable Cost] staff would do drugs in groups. The first group was just one drug, and then they started bunching

them. And for the group, I would go through and poll the different offices in the Bureau about the quality and whether the companies have been inspected, any bioequivalence problems and so forth. I would get documentation from the divisions, and we'd wind up with a 500-page packet which we would then deliver to HCFA.

There was a committee that was formed, the MAC advisory committee, which included drug companies, it included consumer groups, it included everyone. There were economists from the Council of Economic Advisors and so forth. Herb Klein was on it. There were a lot of high-powered people on it. They would endorse or not endorse the prices and drug products that HCFA would present based on its price data and the quality data FDA provided.

I remember in 1981, I think it was just after Reagan got in, there was a meeting scheduled of this advisory committee, and at nine o'clock in the morning, when the meeting was supposed to start, attorneys from the department walked in and said, "This is an illegal committee. You have to disband." They had determined that you couldn't have voting members from all these different interest groups on a committee, under a provision of the Advisory Committee Act. So everybody looked at each other, and went home. That was the end of that, and it was pretty well the end of the Maximum Allowable Cost program as well.

How effective the program was, I don't know. But it got people noticing generics and it helped cut costs a little.

JS: Did you have a problem with generic drugs when that was occurring at the time of this initiative? Perhaps this was later?

JM: Well, the big generic problem or scandal was well after that. There was a minor generic problem around 1980. I remember being in my office when Dick Crout came in and said, "There's an emergency. You're now head of generic drugs." And so I had to meet with the whole division and explain to them, not what had happened, because I wasn't aware of really what had gone on, but that five people, including Dr. Seife, who was the head of the division, were placed elsewhere in the Bureau of Drugs because of allegations of gifts and things like that.

JS: This is in 1980?

JM: Nineteen eighty.

For about six months, I was head of Generic Drugs.

The five people, who included the people making the charges and the people they accused, were working in other areas. At the end of that time, Dick Crout had to decide whether they could come back to their jobs. Even though there were allegations of gifts and fur coats and one thing or another, there was insufficient substantiation of those charges after an investigation. I don't know how good the investigation was. We didn't have the same kind of apparatus as we do now. If it were up to Dick Crout, Marvin Seife would have been out the door.

Now, I read in Dick Crout's oral history, he thought it was the Dingell Committee that had put pressure on the FDA to keep Seife in place. My recollection -- and I don't have any firsthand information, but from just reading newspapers and so forth -- was that

it was a senator from Tennessee named Al Gore, Sr. who put the pressure on. But anyway, there was congressional pressure to keep Seife in his position, and that decision set up the later scandal.

JS: That's interesting. Was it Commissioner Hayes at the time? This was right after Jere Goyan's tenure, right?

JM: I'm trying to think. This was early 1980, and I think Jere Goyan was still there. Remember, he hung on thinking that even with the change in administration, he would still be asked to be commissioner, and that was not a shrewd assumption.

JS: No, it wasn't, especially after how he departed this agency.

JM: Yes.

JS: But what my question is, did the commissioner -- what was the commissioner's involvement in this? I mean, did it basically just fall on the shoulders of Dick Crout?

JM: Obviously Dick conferred with Dr. Goyan, I'm sure, and the Office of Legislative Affairs and all the appropriate people. Jere Goyan's style was very much management by exception. He said it right out when he came on board: "As commissioner, I'm going to let you do your jobs, and I'll let you know if you do something wrong." So he delegated a lot of decisions to the bureaus, as they were called at that time. So, unfortunately, it fell

mainly on Dick Crout to decide about generic drugs.

JS: It's curious. This wasn't interpreted as a warning sign. Or maybe it was a sign that they could get away with it.

JM: Yes, that's why I said it set up the later scandal because it emboldened Seife to be even more like he was, which is not telling his boss what was going on and lunching with industry people. Of course, being his boss later, around the time of the big scandal, was a real problem. He out-and-out lied and he covered up. It is every manager's nightmare to have somebody like that under you. He was the only one, I think, who went to jail out of the scandal in FDA.

That generic drug scandal was doubly bad because it involved not only allegations of bribery, but wrongdoing by the generic industry as well. I think had there been somebody who was more of a regulator in that job, maybe the generic industry wouldn't have felt as free to do some of the things they did.

But that was the low point for me in my career. I mean, it was just a terrible thing.

JS: It was for many people in the agency, I think, who had to suffer from that, and be tainted by that by association with the involved individuals.

JM: Yes.

JS: I want to ask a little bit about Waxman-Hatch, but we're trying to do this somewhat chronologically. While you were director of Regulatory Affairs (it may have been Bureau of Drugs), one experience that you mentioned is the Tylenol tampering case. I wonder if you could tell a little bit more about it from your perspective and how you were involved in it.

JM: Right. Well, as an aside, that that was my shortest job anywhere in my career, and when I was first interviewed by Dick Crout for special assistant, he said, "What job, if you could have any job in the agency, would you like to have?" and I said, "I'd like to have Mary McEnery's job." She was head of Regulatory Affairs. Sometimes the job changes out from under you when you think you've got the ideal job.

Getting back to the Tylenol incident, as you remember, in 1982, there were six or seven deaths in Chicago from tampering with Tylenol, putting cyanide in the capsules. That led to the tamper-evident packaging, and it fell on our group to write the regs. This came at a time when the Reagan administration was clamping down on regulations, so, unlike previously, all regulations had to go through the Department, I don't think they had to go through OMB [Office of Management and Budget] at that point, but they had to go through the Department. In spite of all that, from the time of the last Tylenol death to publishing a final rule was 35 days, which I think is still a record. You don't have to publish a proposal if it's a critical health issue, an emergency. The Department decided that it was an emergency, and so we got a fairly substantial rule published in that short a time. It involved everyone's coordination. We had meetings with the commissioner twice a week, we briefed the secretary, and it was a high-profile endeavor which I was

pretty proud of.

JS: You obviously had, I assume, liaison with the industry.

JM: Yes. We had meetings with the Proprietary Association, as it was called at that time, the OTC [over-the-counter] drug industry association, which had a big stake in packaging. They had already pledged to do a lot of the stuff that was in the reg. But we felt, because of the need for it to be universal, it had to be a regulation. It couldn't be handled by just voluntary efforts.

RT: This may have occurred after the period you're speaking of now, but at least in more recent times, there's been discussion and concern about the, shall we say, exportation of American-made drugs and the re-importation of those drugs, presumably at less consumer cost. Do you have any thoughts about that?

JM: I have mixed feelings about it because, as ombudsman, I had to field a lot of complaints from patients, and some of them quite tragic, about the inability to pay for drugs. The drug companies have programs to give indigent people drugs for little or nothing, but they don't work all that well. There are a lot of elderly people, even more elderly than me, who have to make the choice between whether I eat cereal every day and buy my drugs, or do I eat a balanced diet and not have my drugs? And it's tough. So, philosophically, I'm in favor of less expensive drugs.

I also think, because the U.S. is the only developed country in the world that does

not have price controls on drugs, we wind up making up the difference for a lot of other countries. If you look at Europe in the last few years, prices of prescription drugs in Europe have actually gone down a few percent while it's been rising 15 percent in this country. So I have mixed feelings about it.

Given the situation as it is, I'm not totally comfortable with the policy now. I do recognize that you don't want to open up a door for counterfeits and that type of thing. But the fact is, we've got plenty of counterfeits in this country; forget about importation. And particularly for people who want to get prescription drugs from Canada, on an individual basis. It's pretty hard to argue that this is a health hazard for them, or immoral or anything else. But, on the other hand, I understand the need to regulate and keep control on drugs. So I wind up on the fence on that whole issue.

RT: Now, one of the initiatives, I think, that you implemented in the drug program activities was use of computers. Heretofore, it had been more labor-intensive. Have the computers expedited drug approvals?

JM: Yes. I can't take a lot of credit for it. I know, in the generic drugs area, Marvin Seife was wedded to his card system. He kept a card file on his desk so he knew where everything was. I pushed a lot and got a computerized system for that purpose. For one thing, it was too easy to finagle the cards.

RT: Was that the principal problem:

JM: Yes. One could move things around in the priority line a little too easy with a card system. In terms of the generic drug scandal, I had early warning of it a year ahead of time, and that was a tough year for me. Or perhaps I should say, I had early allegations of it, and I'll come back to that. But at that time, the computer system was up and running in generic drugs, and when we suspected there was a problem, we ran printouts every which way you can imagine to try to see if there was favoritism by drug company, by type of drug, by whether important drugs were being given first to certain companies routinely, We could find no pattern of any favoritism. So after the scandal broke, our conclusion was that gifts may have been taken, but people hadn't actually done anything differently in the review process that could be detected. It would be impossible to detect an application here or an application there, but there was no systematic favoritism towards companies that allegedly gave gifts.

RT: No clear sign of any *quid pro quo* or review decisions and gifts.

JM: Right.

Returning to the early warning, back in, I think it was June of '87, Val Miller, who was an attorney in D.C., called me and wanted a private meeting. And he came in -- actually, he came in representing Mylan Laboratories on an issue. At that time, I was ombudsman for generic drugs as well as deputy office director.

A lot of people don't know this, but the ombudsman function went back to 1985. The new-drug review regs created an ombudsman for generic drugs and one for new drugs, and, unfortunately, they designated deputies in the line of command, which is not

what you do for an ombudsman. So there were relatively few contacts for the ombudsman. But the contact with Val Miller was in my role as ombudsman.

Anyway, he came in. After he had finished with the Mylan issues, he had a face-to-face meeting with me, and he said, "I just want you to know that we've got private investigators following Charlie Chang, and we've gone through his trash. We've tailed him and all this kind of thing, and here are the things that are happening." He said, "But don't tell anybody." And I said, "Right. You've got to be kidding!" And I further said, "No, I can't say that I'm not going to tell anybody. I'm not going to call up *The Washington Post*, but I've got to tell certain people here."

TAPE 2, SIDE 1

JM: Okay. I was talking about Val Miller, a local attorney who had asked for the meeting in June of 1987 and told me that they had a private detective on Charlie Chang, who was a supervisory chemist.

Incidentally, he was also the whistleblower in the 1980s.

JS: Was he an attorney?

JM: No, Charlie Chang was a chemist, and he was the whistleblower who had made allegations against Marvin Seife in 1980. Marvin Seife, by 1986, had promoted him to supervisory chemist. The big problem in 1980 was Seife going out to lunch with drug company people and letting them pick up the tab. That was what Charlie alleged. Then

there were counter-allegations, but none of the counter-allegations were really substantiated. So Peter Rheinstein and I didn't have any reason not to approve Chang's appointment.

Anyway, Val Miller had come and said that they suspected Charlie Chang and that they had private detectives on the case. After I talked with Peter Rheinstein, the Office Director, we went to Gerry Meyer, the Deputy Center Director. After we went to Gerry Meyer, we talked with Tom Scarlett, who was the chief counsel. And Tom Scarlett said, "Well, that's interesting. How much do you believe Val Miller?" And I said, "Well, it's so closely wrapped up with Mylan's interest in several drugs that I'm not sure how big a deal it is, because they may be blowing it up to try to get some advantage in jockeying their drugs." He said, "The reason I ask is that Val Miller worked for the general counsel's office." And he said, "We fired him because he lied on his application, the part that says, 'Have you ever been convicted of a felony?'" And, according to Tom Scarlett, the main reason that he was fired was that he was getting government-paid trips to Utah on the pretext of handling cases so that he could go back there to serve his weekend jail sentences."

JS: Amazing, amazing.

JM: Mylan picked probably the worst person in the world to come and deliver this news.

Well, so I also talked with John -- I forget his last name. He was head of the Ethics and Integrity Office at the time. And he said, "Oh, yeah. We've got three file drawers on Charlie Chang." And he said, "Look, here's what you should do." He said,

“You cannot be involved in an investigation and run an office and be involved in the investigation. I was used to that because of the first generic scandal. I was kept out of the investigation part of it. I just managed the division. So he said, “We will get in contact with Mylan and see what they’ve got, and we’ll work with them,” and so forth, “so you go ahead and do this.”

I spent the next year waiting for the shoe to drop. Val Miller’s behavior after that initial visit strengthened my suspicion about trying to use that as leverage, because he came in on a weekly basis after that, trying to get some of Mylan’s applications through faster. So that whole thing left things up in the air in my view. Had I the opportunity to do it over again, I would have immediately contacted the FBI and told them. As it turns out, Ethics and Integrity dropped the ball. They may have contacted Mylan once, but they never got back in contact. So the next public interaction on this whole thing was July of ’88, when the cops came into the division.

So that was a painful lesson in how much to trust the bureaucracy. I think it’s a lot better now. I mean, currently I would have much more confidence in criminal investigations and internal affairs. They were set up by Dr. Kessler afterwards.

But anyway, it’s tough -- it’s a nightmare for a manager to try to deal in that environment and.

Just to give you an example, we would have regular meetings with all the divisions, and after one of the meetings, Marvin Seife said, “Oh, by the way, I don’t think I told you guys, but one of the chemists came to me six weeks ago and said that he had gotten an envelope from a drug company that he found on his desk. He took it home and he didn’t know whether to open it or not.” It was clearly a package with money in it, or it

appeared like it might be. “And I just forgot to tell you,” you know.

And then we said, “Well, is there anything else that you haven’t told?” “Well, there was this other thing,” you know, and it’s . . . When you have a manager like that, it’s very, very difficult to try to deal with the situation. It’s a nightmare. And, appropriately, he went to jail for perjury. He didn’t go to jail for accepting a bribe or anything. He went because he said he couldn’t recall that he ever went out to lunch with anybody from the industry. The investigators had all the records there, and it was clear that the 1980 business hadn’t slowed him down at all in terms of going out to lunch with industry and letting them pick up the tab.

It’s like the docs with the detail people from the drug companies, and the free golf trips and the cruises and all that. They say, “Oh, yeah, I can. It doesn’t change my mind about how I treat patients at all.” Anybody who says that is lying either to themselves or to everybody else. It does change your outlook. There’s no way that it can’t, in some way, change the way you do business, if nothing else than just getting too cozy.

JS: Well, we changed our business after this happened.

JM: Yes.

JS: In many ways.

JM: Yes. And for the better. I think it’s much less likely that something like that would happen again.

RT: Well, the matter of user fees also came into play. Does that relate at all to what we've been discussing in terms of perhaps averting those kind of complexities?

JM: I don't think so. I don't think that user fees were at all tied to the generic drug scandal.

Actually, when user fees first came in, I had mixed feelings about it because I thought that there was a danger that if you set a rigid goal date and a reviewer maybe hasn't looked carefully enough at an application and in the last week of review finds some issue, then that reviewer has to decide, is this going to be the one application that goes over the goal date? Shall I ask for more information about this? Or do I just let it go through? Reviewers are different in how they withstand pressure, and I was concerned that drugs might get through that shouldn't because things were glossed over in the haste.

I don't think this has occurred. Certainly the statistics don't show it has.

Sometimes, by making a time-limited decision, it actually hones one's analytical ability. If you think you have three years to approve something, you may be a little more lackadaisical about looking at it than if you know that you've got to have it in at a certain time. So it may focus reviewers' concentration a little better. Although at the end of PDUFA 2, it was getting really bad in terms of morale, because review resources were really pushed to the limits. They were taking work home and working long hours, and you can't have that either.

RT: Now, as ombudsman, you probably were involved in dispute resolutions. Are there any that you would care to mention that you've dealt with?

JM: Well, those are all confidential. I think that there were some which stood out as ongoing problems in the agency. For example, many had to do with importation of drugs. There were a number of cases where drugs were detained when clearly they should not have been.

One example that comes to mind was a family from Canada who were vacationing in Miami, and they had a five-year-old girl who got really sick and had to be hospitalized, so they had to stay longer than they thought. They ran out of her medication. They wired the pharmacy in Canada. It came in and hit a Fedex or DLH hub, and the district said, "Nope, can't let this go through." And even after a lot of pressure, it took something like 10 days for that to get cleared. In the meantime, the girl didn't have her medication. As I recall, this was a drug that was approved in Canada but not in the U.S.

One of the things that the ombudsman job did was show you the other side of the coin on a lot of things, and as an ombudsman, basically I would get a complaint, whether it was from a consumer or a drug company. Then I would call the division that they were complaining about and just say, "What's the story on this?" Because even if I got off the phone saying, "How could those idiots do this?" more than half the time, when I heard what the division had to say, it made a whole lot more sense than the way it was first presented. So it did teach me, too. I'd already had law school training, so I was prepared to look at both sides of the issue. But ombudsmen really do have to see both sides of

issues, and it's important when you're regulating products to be able to make those distinctions and not bureaucratically just say the line is drawn here and there is no way can you cross it.

JS: I just want to interrupt for a second to ask about the position itself. Were you the first ombudsman in this sort of general position for the center? You mentioned you were in a position at an office or division level.

JM: The deputy office director level.

JS: Right. But had there been a center-wide ombudsman before you?

JM: No. One of the things Dr. Kessler did was to create an ombudsman office in the agency, and he had brought Amanda Peterson from FTC over to head that. That was around 1991. When I was still deputy to Bob Temple, I had proposed that the Center should have an ombudsman. And then when Janet Woodcock came in, she liked that idea and asked me to be that. Then I became a direct report to her, because the ombudsman has to make a direct report to the highest level in the whatever group it is that they're ombudsman for. When you're an ombudsman, you cannot get involved in any dispute involving your boss. It's that simple. I mean, the conflict is too great there. So if any dispute centered on the Center director, that would go to the agency ombudsman.

JS: To Amanda Peterson. If I can interrupt, did anything specific lead to the creation of an ombudsman office for the agency?

JM: For the agency? Oh, it was in the wake of the generic drug scandal. It was part of that whole business of creating a criminal investigations unit, internal affairs, and it was created with the idea that if people felt something was amiss, this would be another place where they could come to complain confidentially, and then that information could be used to try to solve whatever problem it was.

The ombudsman concept is an old one, but in this country, it hadn't really caught on much. But the universities were among the first adopters of ombudsmen. I think that perhaps, coming from an academic environment, maybe Kessler had seen how it had functioned there and thought it was a good idea.

Anyway, Janet Woodcock thought that it was good. It was about time for the Center to have an ombudsman, and the agency ombudsman's office was supportive of that, because they got a lot of complaints which involved technical issues that the lawyers didn't really feel competent to sort through. So they were glad to have somebody who knew the turf better that they could delegate to.

JS: I'm guessing that a majority of the tasks that you had as ombudsman were dispute resolutions between industry and the agency? Is that fair to say?

JM: Yes.

JS: You know, without obviously betraying any confidences here, I wonder if you could characterize how the dispute resolution process is played out, if there is a complaint by a firm. It might involve speed of a review or something like this. But how, if there is such a thing as a typical resolution process?

JM: Well, when I first got the job, I thought, well, I'm going to be doing a lot of mediating. I've had plenty of negotiation courses, but I haven't had any training as a mediator. So I immediately took a one-week course in mediation. I almost never used it in the seven years that I was ombudsman because formal mediation only works when you've got two people of equal power who want to get something settled.

By definition, when you're talking about a regulated industry and a regulatory agency, they're not of equal power, and the industry recognizes that. And so they didn't really want mediation. They wanted what I call shuttle diplomacy. They wanted someone who they could complain to who would then go to the complainees and figure out what was happening and then seeing what would work, going back to them and going back and forth until things were settled. And it was pretty successful.

I would say that in the early going, there were a lot of things slowing reviews, because there was still some leftover applications from pre-PDUFA that were hanging around. So there were a fair number of timeliness issues. That dwindled to almost none by the time I left as far as timeliness of new drug applications is concerned.

Now, generic drugs was another matter. ANDAs [Abbreviated New Drug Applications] and timeliness of other decisions that were not related to PDUFA [Prescription Drug User Fee Act] remained problems. But mostly problems had to do

with just communication. I spent most of my time trying to straighten out misunderstandings of what each side wanted. You know, the company would think the agency was asking for a, b, and c, which they thought was ridiculous, and the division would say, "Of course that's ridiculous. We didn't ask for a, b, and c. We asked for d, e, and f." And then you go back to the industry and, "Oh, okay, we can do that." That was one common type of complaint.

Another is simply a disagreement about policy or the science or the law and regs. And basically what I would do in that instance is simply guide complainants through the appeal process, because the ombudsman can't make any decisions, only be a facilitator. So I would guide them through the appeal process. There was a lot of cynicism on the outside about the appeals process even working. All the Centers adopted in one form or another a formal appeal mechanism. The process for Devices is very elaborate. Drugs and Biologics was up the chain, ending with the Center director.

JS: But the appeals process is done within the institution itself?

JM: Within the Center. And done by basically line managers. And in actuality, it was one of the requirements of PDUFA, so it was established, and I guess it was in the early '90s -- '93, '94 -- that it was created, but it was formally written in the late '90s.

And one of the things that companies didn't get the message about was that, at least in the early going, half of the appeals were successful. So a lot of times companies would say, "Oh, I'm not going to appeal because all it'll do is tick off the division, and I'm not going to get the answer I want anyway." So part of my job it was convincing the

industry that this is a viable appeals mechanism, and sometimes you win. I also gave guidance to them on how good I thought their chances were of prevailing. So that was part of the function.

RT: During the course of your work, the Congress had quite an interest in drug approvals, and I assume you were involved with assisting in the preparation for some of those hearings. How were you involved?

JM: I did a lot more preparation for hearings when I was special assistant to Dr. Crout, not unexpectedly. A lot of people don't remember that period back around 1976-77, with an extremely hostile Senate particularly. I think the agency averaged three hearings a week, and at least one or two of those would be drug hearings. They were not particularly gentle. Those were the times of the 10 or 12 conscientious objectors in the Bureau of Drugs, who would be feeding all sorts of information to the Hill. And there were some pretty brutal hearings. Commissioner Mac Schmidt used to say, "We were beaten about the head and neck." That was always his line.

JS: Dick Crout talked a little bit about that in his oral history and how I guess Mac Schmidt must have taken it upon himself to bear a lot of that brunt indirectly.

JM: And Dick Crout got his share. And it was just a brutal time. After that session of Congress, things changed somewhat in the makeup, and it became much less adversarial. I remember, after that siege, Dick Crout just sort of closeted himself. He handed the

reins over to Jerry Halperin. It was either Halperin or Dr. Leventhal. I can't remember who was deputy director at the time. I guess it was Halperin.

JS: Yes, Halperin.

JM: He just closeted himself for something like five or six weeks, and the rumors were flying that he was going to be leaving, that he had had enough of the battering. After that six weeks, I remember that it was around Christmastime because he had a Christmas party at his house, and everybody was expecting that he was going to announce at the Christmas party that he was leaving, but he didn't announce he was leaving. Come January, he was in fighting shape and came right back and went on for another six years or so. That impressed me.

JS: What were the issues? At that time, what was Congress's problem with the agency?

JM: Well, they were being fed all this stuff, I mean, some of it true, some of it exaggerated. Some of the conscientious objectors were pretty far off the wall. There was a lot of stuff that related to the day-to-day management of the Bureau and how things were done and so forth. And the Congress would take everything that the whistleblowers said as gospel, start from that premise, which is a bad position to be in.

JS: Do you recall who some of the objectors were?

JM: Oh, there was Burt Appleton, John Nestor; these two come to mind. I remember Burt Appleton, after he left the agency, used to write these long letters, 10-page, single-spaced letters, just rambling on and on and on.

JS: He calls the History Office from time to time.

RT: Well, Dr. Nestor was kind of an enigma of his own, wasn't he?

JM: Well, he was. You know, the thalidomide thing had really polarized the agency, and the way to be the hero in the agency was to stop the approval of some harmful products, so everybody was looking for the worst in whatever product was coming through the door. John Nestor used to brag that he had never approved a product.

JS: This came on a little later, but there was quite an uproar about . . .

TAPE 2, SIDE B

. . . AIDS treatment drugs. Did that create problems within the Center? It certainly did for the commissioner at the time.

JM: Well, you probably remember, in '88 or '89, there was that big demonstration where they had to lock the doors, and they barricaded the streets and all that kind of thing. It was rather poor handling by the police. And after that, I think things changed. I mean, in

spite of the ill will that the demonstrators might have personally created in people in the building, I think that crystallized the commissioner's thinking that something had to be done. And after that, the Center for Drugs created a division for antiviral drugs, and they kept pumping it up. I think at its peak it had 70-some or 90-some people in the division, which is a huge number for reviewers. It burned out some division directors. That was a hot-seat job because it was a no-win kind of a deal. I mean, if a drug didn't come out, it was our fault; if a drug came out and it didn't work, if it wasn't a wonder drug, it was our fault, so it was bad. Understandably, it was awfully hard to convince people, particularly AIDS patients, that drugs take a while to develop. When you don't have any time, saying that in three years we'll have something, when you've got six months to live, it really focused a lot of people's attention inside and outside FDA. It spilled over into diseases other than AIDS, cancer, and other fatal diseases, with regard to the agency trying to develop a more humane way of making drugs available to people who really didn't have any other options.

JS: We did develop ways to accelerate access at the IND stage.

JM: Well, that, and by creating the Special Health Initiatives Office in the commissioner's office. It gave people a place to go, so it was almost like an ombudsman function. In fact, I referred quite a few people to that office, because they are very good at not only seeing what they could do to get access to the drugs, but also in providing other sources of assistance to patients.

JS: Is this the office headed by Randy Wykoff, or was this before that?

JM: Well, Terry Toigo was, I think, the last one that I recall. I don't know. Randy may have been there. I kind of remember Randy as sort of a jack of all trades in the commissioner's office, and he may have had that responsibility at some point.

JS: With regard to orphan drugs, drugs for which there is a limited consumer clientele, were you involved in negotiating industry interest in some of those preparations?

JM: Not really. The orphan drug group was kept separate from the Center for Drugs, and they had more of an encouraging, promoting role, and it would have been inappropriate to merge that with the regulatory review. I didn't have much input into that. I interacted with them periodically but didn't have a whole lot to do with that program.

JS: One other thing, and this is really about the last thing I wanted to ask about the ombudsman position.

Among these responsibilities, I gathered you also deal with employees, with CDER employees who have problems with their positions. Is that right?

JM: I started out doing that. On paper, I did the whole time. When I first started out, probably a third of my work was internal. And I'll tell you, I would trade one of those for 10 industry complaints. Those were always the toughest to deal with, and there was a

pretty sharp demarcation. When the union came in, the complaints to me dropped to almost zero. In fact, I generally would steer people to the union, figuring that the union could do more than I could. I would still talk with people, listen to them and tell them that there was a limited amount that I could do, because I found from experience that there wasn't much I could do. Getting in the middle of those personnel things was really, really difficult.

So anyway, after the union came in, which was . . .

JS: A few years ago.

JM: Ninety-six, '97, something like that, it dropped remarkably.

JS: Was there a very large number of employees that joined the union? I assume not a large number as professionals.

JM: Oh, you'd be surprised. I was surprised at the number of clinical and other reviewers who joined. I never had a list of those who joined or anything, but just total numbers. The union came out with figures. I was surprised at the number of medical officers and other professionals who joined.

I think, frankly, there's been a history of some bad management practices. I was on the committee for leadership development for the agency. One of the really big problems was that it was assumed that anybody with an advanced degree automatically knew how to manage people, and it isn't true. People were promoted for their technical

skills, not their management skills. Consequently, people just fell into all the traps that were there for managers to fall into. That created a climate for unionization.

I think also what helped create the climate was that in the beefing up for the PDUFA hires -- you know, the size of the Center for Drugs is now close to double what it was before PDUFA -- that a lot of the hires were staff fellows. Staff fellows don't have any of the civil service protections. They're one step above indentured servants. I think that when civil service medical reviewers saw how some of these staff fellows were treated, it convinced them that the union was needed.

JS: Medical officers had tried to unionize many years ago, prior to NTEU's [National Treasury Employees Union] successful effort here in the '90s, but I guess they had not convinced the Labor Relations Board or whomever would make that decision.

But before the union, before the Center had an ombudsman, if employees had a problem like this in the Center, of course, you were an ombudsman at the division level.

JM: Well, not really. See, the ombudsman function in generic drugs and new drugs were not geared to internal ombudsing. I was the only one of the ombudsmen in the agency to do internal as well as external. And so that function was not conceived as being for internal issues.

JS: Do you know how the agency was able to resolve the sorts of differences that they would eventually bring to an ombudsman?

JM: Well, there was merit promotion.

JS: Through the civil service process, I gather.

JM: Yes. And a lot of EEO complaints and grievances and all that kind of thing were dealt with in not terribly productive ways. Now they're getting smarter. They're getting into more mediation sooner into the process. In fact, the only mediation that I did in my stint as ombudsman was when EEO asked me to do some mediation.

RT: Did the implementation of the performance plan system either advantage or complicate administrative matters?

JM: I had seen in my career at least a dozen performance schemes, performance evaluation schemes, and I haven't seen one that did anything.

I have to step back a little bit. The one that was in place in the mid- to late '80s, which allowed a certain flexibility if managers were willing to use it, was pretty good. I actually used it to some advantage, by creating common goals for everybody in a division to, for example, reduce backlogs so that everybody either sank or swam by how much the backlogs were reduced. I was able to get reductions of 25-30 percent in backlogs each year by that because even though the bonus money was really kind of skimpy, it became a pride thing and people would do it. But I don't think very many managers really used the performance system the way that it can be used.

RT: You've served under several commissioners and political administrations. Do you have any observations about good times and bad times under those various tenures?

JM: Well, the commissioner that stands out in my mind is Don Kennedy. He was able to generate morale and an esprit that not many leaders that I've witnessed have been able to do.

He used to drive the bureau directors crazy because he would pretty soon find out who was the expert on any given subject, and he'd call them directly and say, "Now, on this issue here, what do you think about this? What do you think about that?" Well, first of all, that really raises people's morale when the commissioner asks them for advice, number one. But he had an ability with people that was absolutely remarkable.

When he came in, he said that he wanted to meet everybody in the agency on some kind of personal level, and so he set aside a morning that he was going to go through the Bureau of Drugs and he was going to start on the 18th floor of the B wing and work his way down. I was appointed to honcho him around. I was a special assistant to Dr. Crout then. Dr. Kennedy would go into an office, and within five seconds he would pick out something in that office that was unique to that individual, whether it was a picture or whatever, that he glommed right onto that indicated their interests, and he'd start talking about it. He never forgot a name or a face. There would be people who said, "You don't remember me, but I took your freshman course at Syracuse 15 years ago," and he'd say, "Oh, yeah. I remember. You were the one who used to . . ." you know, whatever. And they would just be floored. Consequently, he had everybody eating out of his hand. He had this charm and this ability and ease with people that I have not seen

before or since. He would have made a great politician. He was just phenomenal.

Unfortunately, his tenure was just too short.

I enjoyed working with Art Hayes. I thought he was very level-headed. I saw him last week, 70 years old and he doesn't look much different than he did when he was with the agency.

I have seen most of the commissioners. The first commissioner I saw was George Larrick. He made kind of a farewell tour of the districts and visited L.A. District, smoked the whole time, never a cigarette out of his mouth. But I didn't really know Goddard and Edwards and Ley and so forth. Mac Schmidt was the first one with whom I really had much interaction. But Don Kennedy stands out head and shoulders.

RT: Well, is there anything else that we should add?

JS: No. I think you've covered so much, and you obviously have had, as I said, a wide range of experiences here in the agency. I want to thank you for taking so much time to spend with us. It really does fill in a substantial gap in our oral history collection, and we appreciate it.

RT: Yes, we appreciate it very much, Mr. Morrison.

JM: Okay. Glad to do it.

END OF INTERVIEW