History

of the

U. S. Food and Drug Administration

Interviewee:	Gerald F. Meyer
Interviewer:	Robert A. Tucker Ronald T. Ottes
Date:	May 24, 1995
Place:	Rockville, MD

DEED OF GIFT

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Gerald F. Meyer

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INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

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 are a part of the collection of the National Library of Medicine.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 1,2,3

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Adm.

DATE: May 24, 1995 PLACE: Rockville, MD LENGTH: 125 min.

INTERVIEWEE	INTERVIEWER
NAME: Gerald F. Meyer	NAME: Robert A. Tucker Ronald T. Ottes
ADDRESS: [redacted]	ADDRESS: U.S. Food & Drug Adm.
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FDA SERVICE DATES: FROM: 1972 TO: 1994

TITLE: Deputy Director, Center for Drug Evaluation & Research
(Last FDA position)

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RO: This is another in a series of oral interviews on the history of the Food and Drug Administration. Today, May 24, 1995, we're interviewing Gerald Meyer, who held a number of responsible positions in FDA. The most recent and one he retired from was the deputy director of the Center for Drug Evaluation and Research. Interviewing Mr. Meyer in the Parklawn Building, Rockville, Maryland, are Robert Tucker and Ronald Ottes. This interview will be placed in the National Library of Medicine and become a part of the Food and Drug Administration's oral history program.

Gerry, to start this interview, would you briefly sketch where you were born, educated, and any relevant work experience you had prior to coming to FDA, and then we'll cover the highlights of your FDA career.

GM: OK. My name is Gerald Meyer, M-E-Y-E-R, and I was born on September 14, 1936, in Maquoketa, Iowa, spelled M-A-Q-U-O-K-E-T-A. I . . . My father was at that time in the Civilian Conservation Corps, and moved six weeks after I was born. My family then began a series of moves to different small towns with the so-called "Three Cs" until after World War II.

During World War II, because my father had a child and was married, was exempted from the draft and was detailed to the U.S. Coast and Geodetic Survey. He became a surveyor, and surveyed all of Virginia, West Virginia, Maryland, and parts of Pennsylvania, and drew topography on aerial photographs, because at that time the Department of Defense was concerned that if a war was fought in the United States, we had no photography and topography at all for the military to use. As a consequence of these moves, I went to fourteen grade schools. After returning to the Midwest for three years, my dad transferred to the U.S. Department of Agriculture in 1948 in Washington and entered the budget office for the soil conservation service of the USDA. As a result of that, my family has lived in this area ever since then.

I graduated from St. Agnes Elementary School in Arlington, Virginia, and from St. John's College High School in Washington, D.C. I went to the University of Notre Dame and received a B.S. degree in commerce. I actually started as a chemist, but I was receiving my best grades in everything but chemistry and math, and I felt there was a message there.

I left . . . When I graduated in 1958 from Notre Dame, there was a mini recession in the country, and it was difficult to get a job unless you had completed your military obligation. So after some effort, I finally secured a position as a salesman with Proctor & Gamble and worked for them for about three months. I didn't like doing that, and resigned and entered the National Institutes of Health Management Training Program in the fall of 1958. I was also married in August of '58. The . . . I'd been at NIH two months when I received a draft notice, and I served two months basic training at Fort Knox, Kentucky. Then I was attached to the first Guided Missile Brigade, in Fort Bliss, Texas, for Nike missile training.

When I concluded my training, the Washington Defense System did away with the Nike AJAX system and went to a Nike Hercules defense system for the Washington area. This was transferred from the D.C. National Guard where I was assigned, and I was assigned in succession to serve as an MP, and then in the motor pool and I finished my five and one-half years of my reserve obligation as a cook.

I then returned to NIH, completed the twelve months of rotating assignments, and went to work in the budget office for the National Cancer Institute. I spent some years there, then went to Accra, Ghana in West Africa on an NIH assignment to help the government of Ghana build its first medical school. While there, I learned to do a number of things in support of the medical and scientific staff including the installation and calibration of a certain number of instruments to doing histopathology, cutting and staining slides, doing critical chemistries, white cell counts, differentials, stool specimens, urinalysis, and I helped the staff with liver biopsies, and delivered two of the staff's babies while I was there. I also fixed the

brakes on the automobiles, repaired the air conditioning systems in the buildings, and some of the plumbing.

I returned after two years and became an administrative officer for that part of the National Cancer Institute that deals with the cause of cancer. It was then called Etiology. They had a large contract program, about $30 million spread over some three hundred contracts, in addition to a fairly substantial intramural research program.

In 1969, I became the 17th clerk to the minority (and minority staff director) for the U.S. House Appropriations Committee under an appointment that was made by Congressman Frank T. Boll of Ohio. He is now deceased. He was looking for a career employee rather than a partisan political appointee, and my CV shook out better than some of the other people that were applying for the job. I served there for two years and was recruited by Charlie Miller and Bill Forbush to work as the chief of the Health Branch in the Office of the Secretary for the assistant secretary controller, who was then Bruce Cardwell. Elliott Richardson was secretary at that time. This was an interesting job because one worked both for the assistant secretary for the controller in the Office of the Secretary, and also served as budget officer for the assistant secretary for health. The assistant secretary for health had a personal staff of about twenty-five people at that time.

RO: Who was the assistant secretary then?

GM: Dr. Monte Duvall was the assistant secretary for health at that time. He had been the dean of the medical school at the University of Arizona.

While in that capacity, I came in contact with Mickey Moure, Dr. Charles Edwards, who was then FDA commissioner, and Jim Grant, his deputy, because I was responsible for their budget. I also met Ed Steffe and the budget staff in FDA. They recruited me because they were looking at that time for a new director of the Office of Legislative Affairs. They had previously filled the position with an

inspector by the name of Pat Ryan from Baltimore, who was not particularly comfortable in that position. I declined the offer the first time, because they should have an attorney, and I felt I wasn't qualified. Later they came to me again, and I agreed to come. I served in that capacity for about two years.

RO: What year was that?

GM: That was 1972. I actually joined the FDA staff in February of 1972. I served about two years in that position. When Dr. Edwards went to become assistant secretary for health, they asked me to act in Mickey Moure's position as associate commissioner for administration.

RO: Gerry, do you remember anything significant as far as the hearings during your time in legislative affairs?

GM: Well, I remember several things. One is that we had an extraordinary number of hearings. Congressman Fountain was holding oversight hearings in the House during that period, and I thought they were unfortunate in the way they were conducted. Senator Nelson and Senator Kennedy would periodically hold oversight hearings in the Senate.

RO: They were pretty much on what? Health issues?

GM: The issues seemed to be mostly topical and attention-getting. I didn't see any of those hearings ever result in meaningful legislation or resources for the agency.

RT: Was that during a period, Gerry, when the White House was a different political party than the Congress?

GM: Yes. Mr. Nixon was in the White House and the Congress was controlled by the Democratic party at that time.

RT: So these were probably politically motivated?

GM: Well, people could argue that politics influenced the decisions to hold hearings, but I don't think it motivated Congressman Fountain. Congressman Fountain, as most everyone at FDA who was here at that time, had some staff people, one of whom had worked for FDA--Gilbert Goldhamer--who seemed to have some kind of special interest in wanting to embarrass FDA.

RT: He also had a staff person, Don Gray, who apparently was fairly efficient at, you know, digging into our records and so forth.

GM: He did. Mr. Gray had left that staff at the time I came to FDA, so I never met him. I only know of him by reputation. He was considered by Bob Wetherell, who was then my deputy, to be a very thorough investigator. I don't know whether he was good, but very thorough.

In terms of completing my work history, I then went from legislative services to acting associate commissioner for administration. Dr. Schmidt asked me to stay in the job when he was appointed as commissioner, and I stayed in that position until September of 1978. I then resigned to become president of Microbiological Associates, a research and development firm that I had been associated with, had been a contractor when I was at NCI, and had offered me a position on two previous occasions. I finally concluded I should take either the job or I would spend the rest of my life wondering.

So I went there, and it turned out not to be a commercially successful business. The organization had grown and changed into three separate companies, and after a few months, I sat down with the company, and I said, "We can either

spend two years deciding to change this, or do it now." What they had was a large infrastructure that didn't relate to the three businesses they had, and I suggested they break the three businesses up into three separate operating units, which could each be managed by a scientist and an accountant. They could then do away with the entire infrastructure and get rid of buildings that weren't marketable anymore for research.

This company was owned by the Whittaker Corporation, which was a small conglomerate on the West Coast. They agreed with me, offered me a different position, but one that would have involved even more travel, and so I inquired about coming back to FDA. It turned out that the person who then-commissioner Kennedy had recruited to replace me (and which took almost a year) had suddenly turned the job down and took a position with the Park Service. So the position I left as associate commissioner for administration was still open, and they invited me to return to it.

RO: That person never reported.

GM: No, he never reported. No. They went through an elaborate selection process. He was a very able person. Who I believe is retired now. At the last moment, the Park Service offered him an equivalent job, which may have been more fun. I mean, it's tough to compete with Smokey the Bear. And so my old job was open, and they welcomed me back, and I had what amounted to a brief sabbatical in the industry.

I continued to work in that position until the summer of '86, when Frank Young detailed me to the Center for Drug Evaluation and Research in Dr. Temple's office. He then reassigned me to Paul Parkman in '87, who was the acting director at that time. When Dr. Peck was appointed, he asked me to remain as his deputy. I stayed with Dr. Peck in that center until I retired in April of '94.

RO: When you were initially detailed to Dr. Temple's office, what was your responsibility?

GM: Well, it was to learn about the drug evaluation process and see if I could contribute to it, by making recommendations that would shorten the drug review and approval process. I would be less than honest if I didn't say that notwithstanding being involuntarily reassigned there and essentially forced on Dr. Temple and the center's staff, they were all very, very gracious to me. They accepted me and treated me very well.

RO: There was some corridor talk at that time, Gerry, that maybe you and John Norris, the deputy commissioner, didn't get along very well, and that might have been one of the reasons that you were reassigned.

GM: Well, I think that's probably true. I did not seek that assignment, and when it was made formally, it was an involuntary reassignment. I accepted it, because I had to respect the fact that I believe it is the right of the commissioner, and I tried very hard to make a contribution. It was especially awkward because it happened at the time Dr. Parkman was acting director, and Dr. Parkman wanted Dr. Gerald Quinnan as his deputy. So I was leaving a job that I liked and going to work for someone who preferred someone else. Nonetheless, Paul Parkman was very gracious about it, and I told Paul personally that I would do my best to find another job so that he could recruit a deputy of his choice. I was actually looking for such a position at the time Dr. Peck was recruited.

RO: With Paul Parkman as the acting director, that was at the time then when the old Bureau of Drugs and Bureau of Biologics had merged?

GM: That's right. They had merged some four years before that, largely because Art Hayes tried to recruit a replacement for Dick Crout without success. The man he chose to recruit and recommend approval was a clinical pharmacologist, who along with his wife, was indicted for dealing drugs while Dr. Hayes was considering him.

DEA (Drug Enforcement Agency) agents who were undercover posing as home renovation laborers contracted with this physician and his wife who paid them with prescriptions for drugs that were scheduled. So there wasn't much question. (Laughter) Now it is arguable as to how much of this was him versus his wife, and I'm not sure anyone will ever know, because their first names were similar, and it may be that one couldn't tell from the prescriptions who had actually written them.

In any event, Secretary Schweiker's staff person, whose name I don't remember, finally told Dr. Hayes that they couldn't appoint him. (Laughter) Dr. Hayes did not want to leave the position vacant anymore, weighed the option of combining the centers, and asked Dr. Harry Meyer to become director of the combined centers. Then Dr. Meyer retired and went to Lederle Laboratories, and Dr. Parkman became the acting director while Dr. Young began to recruit someone who was knowledgeable about both drugs and biologics. I think Dr. Young felt he didn't find someone with that kind of background, and ultimately decided to split the centers again, and selected Peck. Dr. Peck, in addition to being a very knowledgeable clinical pharmacologist also had experience in blood and blood products and was interested in the combined job. But I think Young wanted someone with experience with vaccines and also respected Dr. Parkman. Consequently, he split the centers between drugs and biologics.

RO: When they merged those two bureaus and Dr. Meyer was appointed there as the director, was the thinking that that's the only way that Harry Meyer would take that job was if they merged the two? Did you know anything about that, Gerry?

GM: Well, I don't know that that's the only way he would take the job. He didn't want to leave biologics. And the merger itself is an interesting thing to talk about. At the time the staffs didn't want to merge. They didn't like each other very much. The drugs staff felt the biologics staff were always lecturing them about being better scientists. Biologics staff felt the drugs staff were non-scientific and were paper pushers. So there was a certain amount of push-pull between staffs. In fact, for whatever reasons, they never truly merged the review staffs. The only components that were merged was the administrative and compliance staffs and maybe some support things like FOI (Freedom of Information) or regulation writing. But the biologics review and biologics research staffs remained separate, and the drugs review and drug research staffs remained separate.

RT: Was there a difference in enforcement philosophy between those two groups as far as taking regulatory actions?

GM: Well, that was certainly the common perception. I don't know how much substantiation there really was for that. They talk different languages and different tones. The drugs review staff was sort of uninvolved with drugs compliance staff. I can't say that they were strong enforcers. The biologics staff, on the other hand, were almost openly resistent to enforcement and insisted on retaining their own inspectional capability, which some of the internal biologics staff felt was pretty inadequate. Dr. Burlington, for example, had a much higher opinion of the value of FDA's field staff than I think was evident among some of the other biologics staff.

Dr. Parkman was always more quiet about that kind of thing. I never heard him be openly critical. Harry Meyer's views were formed, I think, by a couple of incidents that were probably unfortunate, one of which was in Florida involving a snake venom person. I don't know the details. But I know that Dr. Meyer felt the inspector was unnecessarily severe. I don't know how all that sorted out or where "right" existed.

RO: I always felt that when the Bureau of Biologics was transferred to FDA that the staff really didn't want to come into FDA.

GM: Oh, they didn't. No question about that. They viewed themselves as a part of NIH, rather than a part of FDA. But times change and people change, and I don't think that's quite the case anymore. What's interesting, and someone else--I forget who--characterized it as a situation where the drugs and biologics staff didn't want to be joined, and the biologics staff were especially upset. Then when they separated them four or five years later, the biologics staff were upset again, because they felt that this was somehow a tarnish on them that they were then separated. I think that's probably true.

But before I left, there was clearly a beginning growing interest between the rank and file review staffs in some areas, notably cancer, to work together. They were co-located at the request of the review staffs, because they thought they would value a more collegial relationship and not duplicate each other's work. So it's one of those situations where--if you subscribe to the philosophy that I do--an organization will form and move in a direction that makes sense, in spite of people who may want to always reorganize and move boxes around. That's what's happening now. Some of those components are actually merging, and I think you see a certain amount of interest in that on the part of some in devices.

(Interruption)

GM: This is one of those activities that can probably be done in multiple different organizational forms, and the right people can make any one of them work. Clearly there is some common ground between the drug, and device, and biologic review activities, and a case can be made for having those activities together. And there are also some products coming available now that use a monoclonal antibody to deliver a drug to a specific site, and the mechanism for providing the availability of that drug

to the patient is a device. Now, this is really a hybrid product, and fortunately there aren't a whole lot of these at this point in time--but the science separating those areas is not nearly as black and white in every case as some would like to think so.

RO: Do you see the possibility of them combining drugs and biologics into one?

GM: Very much so. I actually think some of the draft reform legislation that you will see advocated by Bio, and the AIDS activists, and perhaps the pharmaceutical manufacturing associations will support that. Some will even support merging biologics, drugs, and devices together. And, as I said, you can argue that pro and con. I don't really believe it will ever generate a big dollar savings. Not having them together certainly causes some craziness when you have a product that crosses lines or falls in between; and having them together creates a big organization that will not move as efficiently, develop the same kind of tight teamwork and do things as well as a smaller organization will do. I mean, I can argue either side of those things, and, as I say, the right attitude and the right effort on the part of the right people can make any one of them work or it can make any one of them fail.

But there are manufacturers who have been caught between them that think a merger is the solution to all their problems. I don't really think that's necessarily true. I think you can merge them, and there are some common interests, but there will be some unique problems that you will also expose by it. It's just a different organization. I'm not very big on organizational solutions anyhow or reorganizing. I always think that the disruption is seldom worth the gain. If you remember, in the fourteen years I was associate commissioner for management and operations (or administration, because it was called two different things) I don't think I ever reorganized the entire time.

RO: Your office?

GM: Yes, my office. I don't believe in it. Every organization I was ever a part of was more disruptive than anything else. The field has never really reorganized either in many ways. I mean, minor stuff, but . . . I believe the basic vehicle in the field is still the district office.

RO: Should we back up, Gerry. First, the two years that you spent as head of the Office of Legislative Affairs, do you think that the department at that time was a little unhappy with the agency as far as that office was concerned?

GM: Well, I made some notes about your first two points, and let me just talk about the first point, and then the second, and come back to your questions.

On congressional influences on FDA, I divide congressional activity into three different kinds: appropriations, legislative, and oversight. I thought the appropriations activities were almost always supportive, professional, and quite useful, and for the most part provided better oversight than any other hearings. They asked good questions, current questions; and were professional in the way in which they conducted the hearing.

The legislative hearings were relatively few, and in the House with Paul Rogers were, I thought, constructive. In the Senate, I tended to think Senator Kennedy would seize on some sensational event and bring in some injured person, and make them more of a media event than a vehicle to try to enact responsible legislation. And I thought the oversight hearings were mostly unfortunate. They took up large amounts of the time of staff. They generated a lot of negative publicity about an agency that I thought deserved and still believe deserves better. And I never saw them really accomplish anything that could only be accomplished that way. And I'll talk about the generic hearings separately.

But I really thought many of the oversight hearings were unnecessarily ugly, and unnecessarily adversarial--and at times almost to the point of being unprofessional. One of the exceptions was the Rogers hearing on the GAO report on food

inspection that was held in the early seventies. And the reason . . . He had learned of a problem, held a hearing, and then talked to the appropriations committee and the Secretary. FDA received additional resources to address the problem. I think that was the system working correctly. Even if it had not identified a problem that needed resources, it was all done very professionally. So that's my views about congressional influence.

In terms of department influence, as I said before the Edwards Commission, with the exception of Elliott Richardson, I could not think of a single thing that any single secretary of health, education and welfare ever did, or anyone else in the office of the secretary, to help us, to help the FDA. I advocated removal of the FDA from the HHS. We could be a . . . For all the good that we got out of being in HHS, we could have been in the Department of Defense. All I ever saw was a giant group of people playing office and contributing absolutely nothing to this agency.

RO: Well, theoretically, the agency reported to the assistant secretary for health. Isn't that right?

GM: Yes.

RO: Often . . . Does that really work that way? Or did you usually go directly up to the secretary?

GM: I also can't think of many of the assistant secretaries of health and their staffs who did anything to help us either. Although I knew some of them and certainly liked them personally, I just don't think that organizational structure was particularly helpful.

If nothing else, it meant we were one further layer down and took one more grade off of everyone that had responsibilities. In fact, if FDA's problems and the issues FDA dealt with were going to be addressed by anyone, they also involved the

office of the secretary. So I think the Edwards commission recommendation that we report directly to the secretary or come out of HHS altogether made a lot of sense. I just didn't see any contribution.

RO: I think there's talk now of abolishing the assistant secretary for health.

GM: Yes, but that has been a cyclical thing, since I've been in the department. They have had . . . When I came to the government in 1958, the Office of the Surgeon General was essentially the assistant secretary for health, and it went from having a very large staff to having no staff, then to have a very large staff to having no staff, to having a very large staff, and now we're going back to no staff again. I just see that as another chapter in a continuing saga.

The fact is that the agencies that are in HHS are important enough to see something of the secretary themselves.

RO: Do you think there was any one secretary that probably dabbled more in the agency's affairs than another one?

GM: No. I think Califano tried a little bit, but I really don't think much of any of that succeeded. This is a pretty strong organization. Certainly at different times we had a commissioner who was busy trying to curry favor from the secretaries. But did they ever actually influence what a regulatory decision--I don't think so.

RO: I was thinking maybe Heckler with her staff there. Especially Haddow.

GM: Oh, he tried. But I don't think he accomplished anything except to aggravate people.

There are strange side stories about that. Haddow . . . I've been told by many people that Haddow does not like me, and he feels this way because I attended

a meeting and told him that I wouldn't do what he asked and didn't pay sufficient attention to him. The funny thing was that I wasn't at the meeting in question. We think he has me confused with Bob Temple or Harry Meyer. (Laughter) I was never in a meeting with him to discuss a product that I can recall. Someone encouraged me to write him a letter and explain that to him, and so I did, but I never received a response. So supposedly he harbors a lot of ill will towards me which is misplaced.

Our staff insisted he did try--although I am told he claims he didn't--to get FDA to accelerate the review of a Mylan product. I want to say it was a nonsteroidal, but I don't remember that for sure anymore. I wasn't in the meeting, so I obviously don't know what was said and by whom. I know it was resented very, very much by our staff. I never believed our staff was available for any price for public pressure, political pressure, or anything else. Like all of us, they may have their own personality quirks, but they don't sell out to anyone. They report, like all the rest of us do, to their own set of values, and the four people in generic drugs are the only exception I know to that in FDA.

I really think there have only been three secretaries of HHS in my lifetime that impressed me, one was John Gardner, another Wilber Cohen, and Elliott Richardson. Some people liked Casper Weinberger and Frank Carlucci, but I was reserved about them.

So my view of congressional and departmental influences on FDA, with the exception of appropriations, they have been mostly unfortunate and haven't added much. I thought the Proxmire and Orrin Hatch legislation to weaken our authorities over food supplements and vitamins were especially unfortunate.

RO: Gerry, before we leave Haddow, it was during that period of time that Bob Wetherell left the Office of Legislative Affairs or whatever you call it, and there was some thought that Haddow had some influence in getting Bob Wetherell out of that office. Do you care to comment?

GM: Well, I was told that too, but I don't know it. I was told that Haddow--or someone up there--felt that Bob was too willing to be accommodating to the Democrats as well as the Republicans, and they wanted somebody who would only be accommodating to the Republicans. If that was their objective, then Bob certainly would not have met that objective, because Bob treated everyone the same way. He did not attempt to respond to inquiries in a partisan way. That was just not Bob's style or belief. And I don't think Bob would have ever wanted to function that way.

I was not privy to Frank Young or John Norris' inner counsel, and I came to believe--especially after I saw Frank Young on television where he undercut Tom Scarlett--that Dr. Frank Young would sell anyone down the river. I thought that was one of the most reprehensible acts I ever saw anyone do in my life, and it wasn't because I thought Tom Scarlett could do no wrong, or he was the greatest general counsel, or anything like that. But he was a good and decent person and I am told correct in that instance, and I just thought that behavior was unworthy of a commissioner.

RO: And then, of course, that colored Tom's departure.

GM: Well, of course it did. I mean, he was very much a party to Tom's departure. Young called me into his office one time and said, "Do you think I'm in trouble over the grape thing?" And I said, "I think you're in trouble over the Tom Scarlett thing." I said, "I thought the grape thing will blow over, in my judgment." But I said, you know, "I think you lost the whole agency, because we're not with you anymore." We never were. I strongly believe that a leader has a first obligation to his staff. His superiors are somewhere down the line. So I would disagree fundamentally with that.

You asked me about my personal relationship with different commissioners, and I thought about that. With Dr. Edwards, I thought was truly excellent, and I consider him the best leader that I ever worked for. He wasn't a homework guy. He

used to make us all nervous as hell. I mean, we'd think he wasn't prepared, you know. But he had the capacity to make people feel intensely loyal to him. He would call my house on a Sunday morning and say, "Gerry, I've got this piece of testimony here for Monday's hearing. Do I need to read it? You know." And I'd say, "Dr. Edwards, you're going to give it. I think you ought to read it first."

And if I wasn't home, my wife would say, "He's out mowing the yard or whatever." And he'd say, "Well, Brenda, don't bother him. When he gets in . . ." He would be so thoughtful toward your family, and my wife would say, "Be sure you work hard for Dr. Edwards today." He made everyone feel important that was around him. I think he was actually kind of a shy person. But my experience with him was that he was a super leader.

Probably Mickey Moure had more to do with my employment than Dr. Edwards did. But when I called Mickey and said one evening, "You know," I said, "I'd like to reconsider that job in legislative affairs." Mickey said, "Well, just wait ten minutes." I thought that was a strange answer. In ten minutes, I received a phone call from Dr. Edwards, and he said, "Mickey called me," and he says, "I have only one answer. The only condition that I would let you come to FDA is if you can start Monday morning." I mean, he really did make one feel pretty darn good.

Schmidt actually hired me for the associate commissioner for management job, and my relationship with Schmidt was really very good. He kicked me one time at a hearing, because Schmidt didn't understand the question and thought the congressman was giving him a bad time. The congressman was trying to help him. So I answered the question, and Schmidt kicked me under the table. It's the only time I've ever been kicked by a boss in my whole career. But I did like him, and I felt very bad for him over the Kennedy hearings, which he took very personally.

My relationship with Don Kennedy was also excellent.

RO: Back up on that Schmidt hearing. He spent an inordinate amount of time personally on that, and there was some in the agency and outside the agency that

really thought the agency suffered because Dr. Schmidt spent so much personal time on it.

GM: It probably did. Mac Schmidt was a person with deeply ingrained values, and he could not believe that a U.S. senator would behave like that. He was so convinced that if he could show the senator that he was wrong, and that the senator would sort of apologize to everyone.

RO: For the record, Gerry, those particular hearings, what were they about?

GM: They were about drug review activities. Senator Kennedy had assembled a collection of malcontents, by my definition, and self-styled activists, and they made all kinds of charges. Some of them reckless and some of them not unreasonable. But the way the hearing was handled as if the whole system was broken, and unsafe drugs were being approved, and there were cozy relationships with the industry, and a whole bunch of junk like that was wholly unjustified in my view.

My relationship with Don Kennedy was very good. He was a different kind of person. He was one of the brightest men that I've ever known. My relationship with Gere Goyan was very good. Gere Goyan also was very much a people's person. He would drop in and sit down and chat with a relatively modestly positioned employee and visit with them and liked everyone.

I still work with Gere Goyan every once in a while in a variety of different ways. I think he is a good person.

RO: Isn't Gere Goyan on the East Coast now?

GM: Oh, he's on the East Coast now, and this venture capital firm, he used to be an adviser to them, and they placed him as the president of one of their biotech

firms in New Jersey. Actually, I haven't seen him for a while. But we talk to each other on the phone every once in a while.

RO: He was kind of an interim caretaker at FDA for that period of time.

GM: My relationship with Dr. Hayes was OK. He had a good relationship with Schweiker, and I believe a more difficult relationship with Margaret Heckler. Probably because he wasn't her appointee. My relationship with him was reasonably good and positive, and remains so. I see him every once in a while in some capacity. The down side of it is that when he was criticized for accepting some honoraria he told the inspector general's office that he hadn't been warned. I felt badly about that, and they came after me with both barrels. My affidavit, I'm sure, and God knows what else, is on file in the IG's office. I have never looked.

I thought I had provided Dr. Hayes with the same information that I had to other commissioners about that kind of problem, but I realized Dr. Hayes felt differently, and I feel badly that I somehow apparently didn't communicate that effectively in Dr. Hayes' case. I didn't know what else to say under those circumstances, and I did feel badly. I don't think Dr. Hayes was a bad person.

I believe that if you scratched the veneer in most of our lives, there would be something we might hopefully do a little better or differently if we had it to do over again. It hurt Art Hayes to have that experience, and I felt badly for him.

RO: Excuse me. That did cause him to leave the agency, didn't it?

GM: I think so. It certainly caused him to look for another job, and he went to a medical school in New Rochelle, New York.

RO: Before we leave Art Hayes, it was under his commissionership that the old EDRO organization was abolished and merged with the associate commissioner for

regulatory affairs. Do you have any insight into what caused the commissioner to suggest that there be that change?

GM: I don't have any insight. I have an impression. My impression was that it was Paul Hile's recommendation, and the commissioner accepted it. I am not certain how much of the previous organization was an acknowledgement of Sam Fine himself and his strengths. Sam was a remarkable human being in a lot of ways. And, I think, he and Paul, worked well together. I believe they respected each other and had no trouble drawing lines between each other's role. I may be wrong, but that's the impression I have. I think Paul probably correctly assumed that with someone else in that role it might be a difficult relationship.

RO: There was some talk that Dr. Hayes was unhappy with the EDRO organization as it existed at that time. I was the deputy director of EDRO then and Don Healton was the director. I was just wondering if you had any comments.

GM: I'd never heard that. Don Healton had a personality that didn't relate well to some people, and perhaps Dr. Hayes may have been one of those. I don't know. But I guess I don't think it had anything to do with the EDRO organization at all personally, and I certainly don't think it had anything to do with you, Ron. I think you have always been regarded as one of the most easy-to-work-with, supportive, and effective people around. I'll probably always feel that way. I don't think there's anything you can say that would ever dissuade me of any of that.

My relationship with Frank Young was certainly mixed. I had trouble admiring Dr. Young, because I thought he was too eager to please the politician levels, and I don't believe that ever gets anyone anything. So . . . And I'm sure I didn't conceal that very well.

RO: We have one more.

I believe organizations are made up of many different kinds of people. In the last fourteen months, I have probably spent time with a lot of companies in one capacity or another, and I've had people say to me that they had an inspection, and it was awful painful. I would say, "Well, how was the inspector?" The response would be, "Fair, but we did awful."

Well, you know, that's pretty darn good. When a firm can say that, it doesn't get much better. I mean, we were treated fairly as hell, but really did a lousy job. If you ever hear Charles Edwards speak, he has a marvelous talk. He gives the firm the results of his previous day's inspection every day before he goes. "Here's what I found." There are no surprises when he walks out the door. He, for example, and

David Durham are considered tough, scrupulously fair, and contribute significantly to improved performance. That's what I'd like all our inspectors to be.

And they're not the only ones I've ever met that way. But they are both so extraordinary that the industry talks about how fair they are. They also consider them tough as hell. They bitch about how tough they are, but they talk about how fair they are and how professional they are. That's the kind of staff we should all be.

In drugs, I now probably see the worst side of the staff, because companies only call me when they have some awful situation. They've sent a reviewer a package, and he refused to talk to them. He told them he didn't bother talking to firms. Cut them off with that means. They are attempting to work with a chemist who spends eighteen months arguing about the environmental impact assessment on the chemistry portion of an application in ways that suggest he doesn't even understand what he has in front of him. I know that because I've seen the correspondence.

Recently I spent time with a firm that spent six months trying to put together a package to accommodate a multiple site change. They're closing a plant and moving, you know, multiple applications. They put together a package that says, "We'd like to suggest that perhaps these could be done as a group rather than individually," and send it in. The person who gets it doesn't have time to look at it. He tosses it to somebody else. The next person doesn't have time to look at it. He tosses it to somebody else. That person, three months later, doesn't read it, but calls the firm and says, "Why did you send me this?" I mean, I really often do not see a not good side of the drugs situation.

Yet, you've got other people down there like Bob Wolters in cardiovascular and renal, who is a wonderful person, is helpful and runs a zero backlog. He just does a fabulous job.

RO: So you think some of the criticism of the agency on drug approval lag is valid.

GM: Oh, no question about that. I'm sure some of the criticism about unfair inspectors is probably valid, too. In my experience, those things are usually personality associated rather than an organizational system. Doug Sporn uncovered an interesting observation along with Bob Jerussi. Anyhow, they ran an IBM listing and found half a dozen or so reviewers who had never recommended approval for a product as long as they had been working there.

Now that makes you think. Every time something that went to them got approved, someone had to overrule them. That tells me the person is not calibrated right. All the products submitted are not unsafe or we'd have everyone dying in the streets.

RT: Well, one of the things I think we were interested in was your view on user fees and any impact on the agency.

GM: Actually I've gotten ahead of myself. Let me go back to . . .

My views on different bureau, center, associate commissioners. I thought about that a lot, and I listed the people that I thought were exceptional in my time. I thought Dr. Crout was really exceptional in drugs. I thought Villforth was exceptional. I thought Virgil Wodika was exceptional, and surrounding himself with Ogden Johnson and Allan Forbes represented a constellation of very good people who continued to make their mark after they left. We never recovered in the nutritional area from the loss of Ogden Johnson and Allan Forbes. I never though Gerry Guest was terrific. Sam Fine was, I thought, great. I thought Paul (Hile) was very good. I thought Jack Walden was exceptional. I thought Alex Grant was very good. His activities were not popular in some circles, but I thought he did a good job. And I thought John Jennings was very good. John made a very interesting transition. He didn't want to leave drugs; Charlie Edwards dragged him over to the office of the commissioner, and he became a much better staff person and a much

better counsel to Charlie and even to Mac Schmidt. But the fact is if you used John wisely, John had wisdom to impart. He is a wonderful person.

So they were sort of my mentors, and my kind of hero list among the center and associate commissioners.

RO: We had one person that we didn't cover with the commissioners, but was a deputy commissioner and acting commissioner for a long time, and that was Sherwin Gardner.

GM: Well, I'm a fan of Sherwin. I thought Sherwin was an excellent performer in many great things for this agency. No question about that.

RT: Well, there was another commissioner that was kind of a bridesmaid acting. That was Mark Novitch.

GM: Yes. Mark is a good person. Mark was more gentle when at FDA, and I think a much better staff person. He's articulate and intelligent, but it is difficult for him to say no and deal with confrontation.

That's one of Bob Temple's big strengths. I mean, Bob is, in so many ways, a highly controversial person. But the fact is Bob can disagree with you and be very charming about it. (Laughter) I'd love to be as articulate as he is in that way.

In terms of FDA reorganizations. We only really had one in my judgment. That was the change that Charlie Edwards put into place, which I thought was a great tribute to him, and the fact that it has continued to endure makes a lot of sense. I consider all the other tinkering in the office of the commissioner in that regard is silliness. As I said, the merger of the compliance and EDRO function was sort of a logical thing. It may have been separate in another day to address particular strengths of particular people, but I didn't see that as a major change. I basically saw it as a merger. That's just my perspective.

Merging, as I said, in grouping drugs and biologics together, and taking them apart (and they may still be grouped back together) was worth a try, and there are arguments both ways. Merging devices with rad health was a very good decision in my view, because clearly the Rad Health people had a reservoir of talent that was not being adequately used, and devices desperately needed that talent. Probably the only mistake in that situation, which has now been corrected, was that there was a lot of hostility and resistance to adequate medical input there, and I was told that was more John's personal views toward M.D.s. I've been working with them all my life, and I wish I was one, so I don't take offense at them. There are some M.D.s that I wish would behave differently, but there are some administrative types that I wish would behave differently, too. So I don't think much about that.

I don't know what more I could say about my reassignment than I did, except that, you know, as painful as it was, it was the best thing that ever happened to me, I managed to go back and be identified with a program again which is always more fun.

The job that I most wanted after the associate commissioner for management job was the Jerry Henderson job in EDRO. It was never the right time. I thought about leaving the associate commissioner job a couple of times when it did become available. Paul knew I felt that way, and I really did.

RO: Well, you were always a good supporter of the field. We knew that, and we liked to have you up in management and operations for that reason.

GM: FDA is a great place in that vein. I certainly never thought about it when I came here, but I have learned enough about the review processes, and not enough people in the industry to now have a little thing, something to do on the side, which I would have never had otherwise. I'm not driven by a desire to be wealthy. I don't charge much for consulting, and I don't live like a high roller. Most of what I make

I give to Uncle Sam or my wife. I drive a pickup truck, and if I won the lottery, I'd still drive a pickup truck.

One of the most difficult situations I found in that regard was that when my dad died, my mother wanted me to take his car, which I felt obligated to pay her for. And I would have never bought that car, but finally did and gave it to my wife. It's a Lincoln Continental. I tried to tell my mother, "That's really not my kind of car, Ma." Anyhow, my wife too a major step up in the car she drives.

Generic drugs problems. There are so many things I could say about that. I hardly know where to start. I think it's very unfortunate for us the way the generic thing unfolded on one hand, because we received a lot of bad publicity about it, and so did an industry that I think at least two-thirds of didn't deserve. One-third did. There were about forty-five heavy hitters in the generic industry, and one-third of them were involved in some way.

In one sense, I'm certainly glad as a person that it was uncovered, but did it have to be uncovered with so much ugliness, and pain, and personal allegations, and accusations, and all that? I don't know.

RO: How much of that, Gerry, did the agency know was happening before it really broke out publicly?

GM: Well, I don't know that. Dick Davis seemed to feel, and I think Hank Avalon also did, that we knew more of that than we actually were given credit for. I just don't know that.

Also I couldn't believe that any of our staff would do what they did--accept money. As you may know, I argued vigorously with Dingell's staff and got creamed for it. And I was wrong. But I would still point out that there were four people that did that out of, whatever, fifteen hundred or a thousand. I mean, I wish there were none, but I don't think that was an indictment of the whole FDA by any stretch of the imagination.

None of them really put an unsafe product on the market. They took products out of turn, and they prereviewed a product on the side for money before it was submitted. They could have helped them as a part of their job, I mean, if they had had time and were willing to do it for everyone, and didn't accept anything. I can still remember Charlie Kumkumian telling me, "Walter Klech. I've known him for twenty years. He'd never do that." And for two five hundred dollar gift certificates to Lord & Taylor, he threw away his whole career. The guy was heavier than I am. You can't get fitted with Lord & Taylor if you're my size. You've got to go over to Steven Windsor's to buy a suit. So I don't know what ever possessed him to do that. That whole thing was pretty bizarre for a lousy five hundred dollar gift certificate.

Mylan did and is also hard for me to understand. They came to us and told us that Charlie Chang was involved in all kinds of things. We asked, "What evidence do you have?" Well, they acknowledged they had none. And they said, "You ought to go out and hire an investigator." I said, "I'm not authorized to do that." At that time, I said, "I would be delighted to act if you have some evidence. But just an assertion that somebody was doing something is not a basis for us to investigate their private lives." I said, "We don't follow people around at night to see what they do." So they went out and hired an investigator and obtained some information. But they didn't bring it back to us. So we never had a chance to act on any of that. They took it instead to Dingell, where they got a receptive hearing. I can assure you that if they would have brought that back to us, we would have had a basis to act and would have done so. I don't have any quarrel with that.

The hearings did a lot of other things. They undermined public confidence in generic drugs. I don't think that was necessary. We made a lot of people frightened about whether they could take a drug safely. In hindsight, from the surveys and analyses and everything else, we showed that was not necessary.

We did put thirteen people out of business that shouldn't have been in business. That was important. We certainly served a warning on the rest of the

industry about what you cannot do, and I think in some ways that was important. I think in some ways we may have overreacted. And I got in a discussion with Mr. Dingell in a hearing about it.

I tried to explain that with respect to the "action integrity policy," if a firm came and said to us, "Look. We have found someone in our company who has altered batch lots, and we want to record that we fired him, withdrew the product et cetera," we should treat them differently than if we uncovered it. We made no distinction. That's all right in terms of getting the products off the market and everything. But I didn't think it was fair in terms of helping that firm get back on the market. I thought that it served then as a disincentive. If you treated the firm where the manager of the firm reported it, found it and reported it to us, the same as the firm where we caught the corporate officers of the firm in a conspiracy, then you provided a disincentive to report it when you found it. Because you were going to get the firm out of business the same as the Bolars.

I couldn't make anybody appreciate that. I certainly failed dismally. I tried in the commissioner's office when ever possible. I said, you know, "You've got to work to get the responsible firm who uncovers dishonesty and acts responsibly back on the market just as you work to keep the one who doesn't off." I believe that. I received a begrudging acknowledgement in between salvos from Mr. Dingell that that was true and that wasn't his objective. But he and his staff were so focused on going after the bad firms I couldn't get much of anyone to listen.

So there were some firms that felt unfairly treated. And I think they were. They got clobbered when they had actually reported the thing. Some inspectors that said, "Oh, well. We would have caught that anyhow." Well, maybe they would have. Maybe they wouldn't. I don't know. But the point is that the firm came forward, and to me deserved something. That to me was a mistake and to me deserved something different for that--or as I tried to point out, it was a disincentive to report a problem.

Another thing that happened is that in our zest for preapproval inspections, which I happen to agree with, we didn't clarify the roles, and still haven't, between what the investigator in the field does and what the review chemist does. We now have a "not good" situation where I think there's a lot of overlap, and there is a certain amount of understandable turf crunching. The industry is pretty upset about it, and it's being reflected in their drafts of legislation.

Now, my position on that, after struggling to try to make sense out of some of the NDE chemists, is that I would take most of it and give it to the field investigators.

(Interruption)

GM: Obviously the review chemists don't care much for that idea. I tried very hard to sort that out before I left, and I was unsuccessful. I consider that partly a personal failure. It actually was even perceived as a personal issue between Dick Davis and I, which I would like to think was unfortunate and not true. I didn't fully understand where Dick was coming from. I'd have to be honest about that. My long-term goal was to shift all the chemistry review to the field, and I was up-front about that. But I said that I think the way to do that, without having everyone screwed into the ceiling over turf, and jobs, and everything else, was to pick some things that are easily done and have those be big successes. Then one could, over time, transfer some more, and some more, and some more.

Dick's approach, at least in my perception was to try to get the commissioner to declare that it would all be done immediately. While that may be understandable, things don't work well that way. So, anyhow, we were kind of pitted against each other, and nothing happened, except that nothing changed, and it's unfortunate.

I wanted to transfer to the field all equipment and facility changes, which I thought the field was better qualified to handle anyhow. Today I would add to that all process changes and analytical procedure changes that do not change release

specifications. But I wanted to do that by step, and I still think it should be done. These changes can be made, validated, and checked on by an investigator after the fact without risk to the patent. But I didn't pull that off.

Now what we have is major legislation that could do away with preapproval inspection totally, and in addition to that, does away with the review chemist function totally. It all seems unnecessary.

RO: Since Dick Davis has left the agency, is there anyone in the field pushing that?

GM: I don't know. I finally concluded that for Dick and I both to leave was the best possible step that could happen. But I don't think anyone else has the same conviction I do about shifting the review chemist activities to the field.

RO: As far as the field is concerned with your retirement then that emphasis was lost.

GM: I suppose so, but I'm not sure how many of them ever knew that I felt that way. I think I was characterized by Dick as being opposed to it, which was kind of a bum rap. But I feel very strongly about it. I mean, anyone who ever asked me that got the same answer. Inside CDER (Center for Drug Evaluation and Research) or in the field. I've always felt that way.

Incidentally, there are a lot of people out there in the field that I learned from and think are great people. Burton Love is among them.

Back to generic drugs. I just wish we could have handled that with less ugliness. We now have a better situation. We have a better generic drug industry, and there's no question that those problems needed to be uncovered, the people needed to be dealt with; but every time we have a problem does it have to mean that we have to rip apart some institution of government. I don't think FDA deserves that. I don't think that those four people in drugs were representative of FDA, and

I don't think the half dozen firms involved were representative of the drug industry. I really don't.

We need to remember that when the drug industry has a screw up, they're the ones who pay (after the patient who is involved). They're the ones who lose the most. They go out of business or they have class litigation that is beyond belief. I don't think our reviewers understand that. Some would say to me, "You can't trust these bastards! We're the guardians." I would say, "Who do you think loses the most? FDA or the firm? If there's an error in a product, or a problem product out there, who loses the most? FDA or the firm?" You get a dumb answer. The fact is FDA may get embarrassed, and they might have a hearing. They may even get an unpleasant newspaper column. But the firm may go out of business, and hundreds of people may lose their jobs--people who had nothing to do with the problem.

With respect to drug-approval time lags. Yes, I think there are some, and I think we're seeing more of them. The fact that CDER's chemists and pharmacologists, toxicologists have basically forced most Phase I drug studies outside of the country is now acknowledged by both the center and the industry. This is a tragedy. I think the proposed change in the Puerto Rican tax law is really dumb. I mean, the industry isn't going to move back to the United States. They're going to move to Ireland or China or wherever.

They don't care where they synthesize their bulk ingredients or even where they do their finished dosage formulation. If it's not financially advantageous to do it in Puerto Rico--and that's why they went there--they'll go somewhere else. They're not going to say, "Oh! OK, U.S. Senate. We'll pay more taxes or we'll move back to the United States to help create jobs." Forget it. They aren't going to do either one of them.

RO: I thought there was a . . .

GM: They have a fiduciary obligation to stockholders, and that is to maximize profits within the law.

RO: I thought there was some emphasis in the center to have paperless NDA, IND submissions by computer.

GM: There is.

RO: Is that going to expedite the process?

GM: About a fourth of those applications are now submitted--28 percent last year--in computer-formatted application form, and that does help a lot. The difference is six months or more in the '94 data when you look at it. But the 72 percent that do not submit it that way are thinking about it, and trying to figure out how to do it. Mary Jo Ververka has embraced this in her initiative, in twenty years will have this thing developed. I mean, you know. For Christ's sake. However, the industry is increasingly reserved about it, because FDA reviewers are now using this data to personally reevaluate every patient which was not what was envisioned in the development of the tool.

We also need to bring some control over the pharmacology tox review. The clinical review is getting better and better. There are still some isolated problems, but they tend to be associated with a particular reviewers personality rather than the system.

One of the things that Charles Edwards does, and I think he is an excellent ambassador for us, is to deal with people in a way that leaves them feeling fairly treated. We need to figure out how to replicate that on the part of our other employees, whether they're review staff or field staff or whatever, and we haven't done that. I mean, I can tell you about firms that have tried to call Dr. Lumpkin for weeks and never receive a call back. They don't receive a call back from the CSO

or the reviewer. So the vice president of Regulatory Affairs has a tough situation. Their CEO says, "So what's the matter with you? Why am I paying you $150,000 a year. You can't even get the FDA to return your phone calls." That's a tough situation to be in. "Or if you do, you can't even get him to give you an answer as to what the status of the application is." Unfortunately, that's too often true.

We have never figured out a good way to communicate the status of an application in a timely and reasonable way. I mean, obviously one cannot communicate the status every ten minutes in a phone call. But once every couple of weeks a firm that has a product worth $100 million in annual sales deserves a little information. It's not unreasonable. Even if the call said, "Look, you know, we had a hearing on whatever, and didn't get to work on your application at all this two-week period." That's a straight answer. Boy, you can't get that kind of answer out of a number of people in the Center for Drugs. Others are very accessible and very forthright.

RO: I guess that's the reason that consultants like Tony Celeste and Paul Hile are hired by these pharmaceutical firms to track the status of their application.

GM: No question about it. They go to any length to track an application because it's such a problem, and it is time lost in sales. It could be thousands of dollars a day. If you go into the old USP building, half of the offices belong to firms and provide space for Washington liaison regulatory people. Much of their time is spent attempting to learn the status of the application?

RO: Then the user fees, which are supposed to give us more staff to do this, isn't going to correct that problem.

GM: I don't think so, and I was opposed to user fees. What I've seen of them so far confirms that. Do we need additional resources? Yes. But what is happening

now is some in drugs are the system. They ask, "Would you withdraw your application? Then we don't have to count it." Or send it back with a deficiency letter the day before it's due, so the clock strikes over. I mean, they're doing all the things that I used to like to think we had tried to get rid of so that we'd just have an honest system. There's a lot of games being played now, so we'll have a big press release once a year about how good we are doing. We have a job to do, and if we can't do it, we can't do it. But I realize other people can hold a different view.

Actually Bob Temple predicted some of this.

RO: Do you think user fees will affect the appropriation? If the Congress sees we're going to get in so many dollars on user fees, is that going to subtract then from the appropriation that the agency gets?

GM: That's hard to predict. That's a great fear, but I don't know that. Let me go back to finish drug approval type things for there's one other example I can provide. There are other things that happen now. A firm was promised an application by a senior official and given a lot of encouragements. He was personally going to continue to review it. Then it was approved for such a narrow indication that it was no longer commercially useful. So the firm abandons the product in this country. Consequently this product will be marketed in every other country except the United States. I now know of three products involving firms like this.

So the drug lag is taking a little different turn at the moment than I think it used to. The firms are going to say, "As much as we'd like to have that market, it's got to pay off." And the firm is caught. I dealt with another firm that made $125 million investment in the development of a product that is approved and used in many other countries. They were then presented with an approval for an indication that was too narrow to use. FDA said, "Well, if you do some more studies, you know, it might get approved." And the president said, "Look. I only have three years

left before the patent expires and there's no more commercial sales. If I do the studies you want, it will take much of that three years."

FDA needs to realize that generic products are sold for a penny or two above cost. The first approval gets a large chunk. When there's one generic, the price drops about a third. With the second, it drops about half or more, and the third generic is a "me too, and a penny more." It would not have been worth Syntex's time to market Naprosyn for what the sales were if it hadn't been approved for OTC use.

FDA needs to at least understand that there are business decisions here that can mean the very existence of a firm. If you only have three years left to market for a commercially useful life, there's no way you can afford to spend another $20 million on three more years of studies so that you can get approval to market a product for which you'll have immediate generic competition and no market. You might as well abandon the $125 million investment as to throw away another $25 to $40 million.

RT: So the time begins when . . . Time starts counting when the application is first submitted to the agency rather than when it's approved?

GM: Well, the useful life of an application is between the time it is approved and the time that the patent expires and generic competition begins. That's the only time you can make a profit. If that gets bumped up right next to each other, there's no return on investment.

Now Carl Peck's solution to some of this is to go back to the front end and design the development plan so that it requires less studies and fewer patients but is very good science. Then a product can be approved earlier. That's what he does. He does it very well. That's how he goes about it.

But from the standpoint of user fee counting, the user fee counts the day the application is filed. The only place they focus on is Dr. Kessler's annual report on how good he did. It doesn't mean much to the industry. The industry could care

less. Make your counts, have your press releases, wonderful, who cares! What industry needs is an approval, and they need it earlier.

If you take the example involving the $125 million development plan that was abandoned, one can concede--in hindsight--that it was not a good development plan. But in addition to that, FDA changed the guidelines on approval during the course after they had started. So there was plenty of blame to go around for that event.

I actually view user fees as generating unfortunate kinds of pressure and expectations and generating game playing as a way of getting around the problems not solving them.

Expedited drug approval for AIDS drugs . . . I don't think you needed all these titles of different political initiatives and grand announcements for the same thing that you could do twenty years ago without any changes. We needed to say that if one had a condition for which there is no alternative course of therapy, and it's a serious condition, the product ought to be pushed ahead. That's all. It's that simple. Do I think AIDS is more important than multiple sclerosis or cancer or ALS--I don't. I guess the epidemiologists do, because they say it's infecting more people. That may mean I'm old fashioned, but I'm not enthusiastic about singling AIDS out as different.

It's very interesting. You don't see the same kind of AIDS problem in other places in the world, except maybe Thailand. I've talked to people and asked "Do you have homosexuality in your country?" Most of them say, "Not much." I don't know why we have so much more homosexuality in this country than the rest of the world. And I recognize it is more than a homosexual disease. But the point is I still think any product that offers relief in that kind of situation--not just AIDS--should be given a priority.

Some of our accomplishments are also not necessarily big sellers. They say, "Oh, we approved twenty-five drugs last year--twenty-five drugs." Unfortunately, many of them are orphan drugs. There haven't been many big blockbusters or major

cures approved the last few years, and we aren't as sensitive about that as we might be.

RO: PPIs (Patient Package Inserts). Would you care to comment?

GM: I think patient package inserts make a lot of sense. But I think we already have them. They're just not ours. If one deals with any major pharmaceutical organization now, such as the mail order pharmacy for Blue Cross (National Rx), they will send you the best little one-page patient package insert you ever saw in your life. It says, "We just wanted you to know you're now taking a new category of antihypertensive. It's called beta blockers. Here are the conditions that you could experience which are not serious; and here are some conditions that you could experience which are, and if you do these you should go see your doctor. Pay particular attention to using this product with (or without) food. Avoid alcohol and/or don't take this product if you are using . . ." That's perfectly fine! You know where they got them? They got them from USP, and they're in simple English.

We've been arguing about patient package inserts ever since Dr. Goyan was commissioner. In the meantime, the rest of the world went and developed them, and we're still arguing about it. We are now saying, "We'll have them in a portion of the labeling, and all the review staff will have to worry about looking at them." Now maybe they'd be a little more precise or not. I don't know. But what consumer is going to pick up that level of precision? The average guy on the street wants to know, "Hey, can I take this thing safely? How do I take it safely? What should I be on the lookout?" That's all you need to know.

I brought those samples of PPIs in one day, and put them on Kessler's desk, and I said, "Why aren't these acceptable?" I never did get an answer.

RO: Do you think that the agency should do more on drug advertising?

GM: Actually, I'm not enthusiastic about that, and the reason is because I don't think we know how to do this. We are out with machine guns in a "ready, aim, shoot" mode. I could care less about drug advertising agencies. I don't like most advertising, and I turn the TV off, or switch channels, or mute it at home. But I don't think FDA should chase advertisers unless they know what they are doing. Our efforts here are worse than going after orange juice. Minor changes in the labeling of fourteen million gallons of orange juice is not my favorite compliance action either.

I think Dr. Kessler's adventures in drug advertising generated a lot more harm for the agency than they have done good. It's interesting, because I think it's been so badly handled that final legislative reform may exclude FDA from this entirely.

I serve as a foil for the PhRMA legislation effort. They ask me, "What do I think FDA will do now? What do I personally think about this proposal?" I'm not a decision maker. I'm not certain why they asked me. Those involved are a number of different pharmaceutical CEOs. I think they asked me because they thought I was honest and fair. I said to my wife, "You know, I could have to resign from this." Because I felt if they had come up with some suggestion that I thought is absolutely outrageous, I wouldn't want to be associated with them.

As it turns out, one, they haven't. There's nothing that they have proposed that is so extreme it doesn't merit consideration. The effort is divided into two groups. There's one group of people who are very angry at FDA and are frustrated. They make some initial proposals that I don't think would ever be passed.

But there is a large number of people. Doug Watson from Ciba Geigy, and Fred Lyons from Marion Merrell Dow, Bob Black from Zeneca, Bill Star from Pfizer, Pat Zenner from Roche, and on, who would say, "Wait a minute now. We need FDA. It is important for us that the hurdle you have to pass through to get your new drug approved is a high hurdle, or we'll have a bunch of schlock competitors out here killing people, and that isn't going to help our business a bit. Why

don't we sit down with FDA and say, 'Here's our frustrations and our objections. Let's see if we can reengineer the process and achieve change.'"

So you can read the bill, and there are some things that are perfectly reasonable.

RO: Is this a trade association, Gerry?

GM: Yes. It is the old PMA. It's been renamed PhRMA, for Pharmaceutical Research and Manufacturers Association. They have a major legislative drafting effort, along with the biotech industry, the biologics industry, the device industry, AIDS activists, some of the far right think tank types. Some of this is pretty far reaching, and some is perfectly reasonable.

For example, one of the items I thought was actually good, was to eliminate the environmental impact assessment for most pharmaceuticals. That would have been FDA's position when the law was passed. But you know what? We didn't bother to do it. We (FDA) never responded to the general counsel when they asked us for comments, and for years we just ignored it. Then suddenly we got caught up. And now we're struggling and struggling and struggling with stuff that makes no sense. The next time you take an antihypertensive or an antibiotic, the amount of that you excrete in your urine and feces is not an environmental threat to this nation or anybody else. For veterinary drugs, we have large amounts of feces in the field and the air supply. Maybe. OK? For radiopharmaceuticals, probably. But the rest of this stuff is just silly to say there is a possible environmental impact. It was an oversight administratively in the formulation of the CEQ regulation, and we ought to correct that.

So some of those kinds of things are perfectly sensible. Making the biologics and drugs regulations one rather than two different sets. That's perfectly good sense. There's a whole bunch of simple stuff like that that's all perfectly fundamental, and then at the other extreme there's some crazy stuff, and you know . . .

A former drugs center director has rewritten the definition for substantial evidence of effectiveness for them in a way that is a distinct improvement. As he pointed out, CDER has gotten itself so convinced that FDA needs two well-controlled clinical trials that these two little well-controlled clinical trials became an end in themselves." And they ignore all other clinical evidence. He says, "What you need," he says, "is you need to take the other evidence into account that you have, and that may very well be better than simply repeating a second well-controlled clinical trial." And he can provide good examples of perfectly good substitutes that are better than simply repeating a second well-controlled clinical study.

It will be interesting to see how that plays out. I suspect it will be, "Oh, my God! He's proposing to do away with two well-controlled trials and the reproducibility of science." No, he's not, but he is saying one ought to use good scientific judgment about all the data, not just et locked into "two clinical trials"--nothing else matters.

(Interruption)

GM: It's about like the Delaney clause. I mean, it may have made sense in its day, but it doesn't make sense any longer. And it should never be an excuse to ignore the other clinical data that you have.

I do think FDA will always have a great future, because it's a great place, it's an important place. What FDA does makes a difference every day, and we have generations of people who are depending on FDA for their safety and welfare. I think we will have good times, and bad times, and grief, and more grief, but I don't think it will ever be easy, but FDA will never disappear.

RT: Do you think that we may see a separation of the drug and device, biologics programs from the food program?

GM: There are people who advocate that out there, and I don't know whether that will happen. From an emotional and historical standpoint, I wish that wouldn't happen; but I can't say that would be necessarily the end of the world if it did. I mean, the arguments for that is that there is a commonality between some of the products. It is a part of the problem of having a very controversial commissioner like Kessler. People begin to say, "Well, how can we limit this guy's authority?" What they ought to do is say, "How can we just replace him?"

But, yes, there are advocates for that. I personally don't support it, but there are advocates for it. They believe it's a solution. To me, it's one of those organizational issues. Yes, that could work; it doesn't have to. It could fail; it doesn't have to. It would depend upon whether the people involved want to make it work. It doesn't have a damn thing to do with absolute truth or science.

It would be unfortunate for the field, because I think our field investigators would lose something. You know, all the reasons we've always argued about being able to mobilize them for a crisis in a particular area still makes sense. Although I think there really was something when an investigator started in food sanitation and worked his or her way up. Because what they did was to learn a whole set of things about how to handle people before they got to a fairly sophisticated industry filled with egos. The foods and vets and feedlot types are all more easy to work with. Then you get into M.D.s and scientists, and they require a little more thoughtful treatment if we want to be successful in accomplishing constructive change.

RO: Well, if there isn't anything else, Gerry, we really appreciate you devoting your time. As we review this, if we think there are some other things that should have been covered perhaps we could arrange another session.

GM: Sure. I live 4.2 miles away. (Laughter) And this is the most important group of people in the world.