

# History

of the

## U. S. Food and Drug Administration

Interviewee: Daniel L. Michels

Interviewer: Ronald T. Ottes  
Robert A. Tucker

Date: June 6, 2000

Place: Rockville, MD

## 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.

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## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857CASSETTE NUMBERS: 1 & 2GENERAL TOPIC OF INTERVIEW: History of the Food & Drug AdministrationDATE: June 6, 2000 PLACE: Rockville, MD LENGTH: 115 minutesINTERVIEWEE:INTERVIEWER(S):NAME: Daniel L. MichelsNAME: Ronald T. Ottens + Robert A. TuckerADDRESS: [REDACTED]ADDRESS: Parklawn Building[REDACTED]  
Rockville, MD 20857FDA SERVICE DATES: FROM: July 14, 1963 TO: June 2, 2000TITLE: Director, Office of Enforcement in the Office of Regulatory Affairs

(Last FDA Position)

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RO: This is another in a series of oral history recordings. Today, June 6, 2000, Daniel Michels, retired director of the Office of Enforcement, ORA, is being interviewed in the Parklawn Building, Rockville, Maryland. Interviewing Mr. Michels are Robert A. Tucker and Ronald Ottes. The transcription of this interview, together with the tapes, will be placed in the National Library of Medicine and become a part of FDA's Oral History Program.

Dan, to start this interview, will you give a brief biographical sketch of where you were born, raised, educated, and any relevant work experience prior to FDA?

DM: Sure. I was born in Lodi, California, October 29, 1941, just before World War II broke out, at least for us. My father, for most of my life, was a winemaker in central California. So my memory with dad is somebody who comes home smelling like a winery. But that was the industry that I grew up with. Lodi was primarily grape growing, but also fruits and row crops. So we were an agricultural community.

I went to the local parochial school. I graduated from the eighth grade and went on then to Lodi Union High School, the usual kind of thing for a relatively small community. Then I went on to the University of California at Berkeley in 1959 to study chemistry.

During those college years, I worked in a cannery, which ultimately became part of a Del Monte chain, but then it was an independent. So I have plenty of experience of shoveling things up off the floor and scrubbing belts with steel wool and that sort of thing. So it was interesting later on to see things from a different perspective.

I graduated barely in 1963. I had . . . I can remember vividly playing back the movies in my head of those days.

I had taken the FSEE (Federal Service Entrance Examination) that was required for most civil service positions in those days, simply as insurance. Now I can tell the tale that I had been brought out here to Washington. I was interviewed by the Central

Intelligence Agency (CIA) for a potential job with them, but it was going to be months before my security clearance was finished.

So I was sitting at home, and this fellow named Victor Rohrbach, who was then a senior inspector with the San Francisco District, drove up and said my name had appeared on two registers, one for inspector and the other one for chemist. He suggested to me that it would be terribly boring to sit in the laboratory, that it would be much more interesting if I should accept the job as inspector.

Well, having no particular reason one way or the other, because I thought this was going to be an interim job, I accepted the job as inspector and joined the San Francisco District on July 14, 1963. So it was strictly by happenstance that I got into the Food and Drug Administration.

As a footnote, I recall Vic going on several years later to work for Lipton Tea. So even then we were attractive to other folks.

McKay McKinnon was the director of the district. Even then he was, I think, referred to as the Dean of District Directors, whether that was a deserved title or not. Monte Rentz was the chief inspector. My first supervisor was Curt Noah, who left the Office of Enforcement shortly before I arrived. He had been through a number of positions in, I think, drugs, but mostly in the executive secretariat with the agency.

So that's really how I fell in. As it turns out, the CIA and I never quite matched up, and here I am thirty-seven years later.

RO: Then how long were you in San Francisco?

DM: Sixty-three to early '67. I had six months out when I went into the Army National Guard for active duty and then spent my five and a half years doing weekends and summer camps. But that was in 1964 when I did that.

There's another footnote, that even in the old days people could think outside the nine dots.

One of my favorite stories is I came back after active duty, but somebody had forgotten to notify Washington that I was back on the payroll. So payday came; I had no check. Being a, well, I should have still been a, must have been a GS-5, possibly a seven—I don't recall—living in San Francisco, that was almost heart attack time.

Well, not to worry. The admin folks issued me yet another travel advance, and they kept issuing me more travel advances until my checks came through, and then I paid them back and went back to baseline. But I thought that was rather thoughtful of them and creative, although I'm sure it wasn't by the book.

RO: What kind of formal training did you have, if any?

DM: Strictly a bachelor's in chemistry.

RO: No, I mean in the district.

DM: In the district? Strictly OJT in those days. I don't think . . . I can't recall when they happened, but there were several "formal courses." One was when the GMPs (Good Manufacturing Practices) became effective. In '63, we didn't have them. I believe it was around '66 that I think it became effective, and so we were . . . One or two of the senior folks put us through that training.

Another one was the application of statistical principles to pharmaceutical manufacturing. For that one some of us were sent down to the Los Angeles District. That was a big adventure then to go that far.

I went to drug school at Rhode Island Basic, and had organoleptic frozen egg examination. Then I was an egg sniffer; did that in Kansas City.



RO: Who ran that course?

DM: I'm blanking on the name, but there was a big guy who had a Ph.D. in education, as I recall, who ran the overall training programs. I'm blanking on his name now. But I don't remember specifically who ran . . .

RO: I guess that was probably after Larry Warden ran the egg schools.

DM: Yes, the name was familiar, but Warden I can't recall having met.

So those were my . . . That was what I recall in terms of formal training. Really a heavy concentration on going out with senior investigators; this is how the work was done. I can remember vividly having to spend probably what felt like half an evening typing up my first collection report, looking up commodity codes, and figuring out, with a guy looking over my shoulder. But that obviously, I think, from my point of view, was largely the best way to do it in terms of the mainstream business that we do. It's so arcane that you've got to get your hands in and get dirty. Clearly, I think that the technical stuff--drug schools and mammography training and all that sort of thing--is necessary, but I think I could make the point about how I think we've fallen short in terms of continuing to keep our people up to speed.

RT: Did you ever get back in that cannery that you worked in, to inspect?

DM: No. I did go on however to spend . . . Married in '66, then they were expanding resident posts to cut down on travel costs. So I volunteered for anywhere they wanted. So they sent me to Stockton which was twelve miles from where I grew up, you know, but I didn't complain about that. I worked with Hank Maher, who was the senior guy there. I became the number two man.

I don't know if you guys remember Henry Packscher? He opened the resident post and had left long before I joined the agency, but we crossed paths later in the Bureau of Medicine, which we'll get to.

RT: Did you, because of your familiarity with the winery industry, get into that field as a specialist at all?

DM: I wouldn't consider myself a specialist, although having literally grown up and walked to . . . We lived within walking distance of the winery where my father worked. So I was intimately familiar from the, you know, it rolling in on trucks to when it rolled out in barrels and bottles and everything in between.

I did take on a personal task of inspecting every other winery in our territory, which wound up to be thirty-some, primarily in two counties, besides my father's, which, I think obviously would have been a bit of a conflict.

But I discovered to my dismay that about every other winery I went into I had a relative or else somebody who had known me since I was in diapers, and it's hard to maintain your dignity when somebody is referring to you when you were four years old or whatever.

In those days, I think there was a de-emphasis on that. There was more of a problem in terms of filth in finished products in canneries and freezers, and then, of course, we had an awful lot of pesticide work. I think I've got more CRs (Collection Reports) on pesticides than anything else. But just huge amounts of that. That was mostly what our laboratory did in San Francisco. We had a couple of mobile labs as well.

RT: Did you get into illicit drug market, OTC buys or any of that sort of thing?

DM: I did a couple of undercover things, and quickly learned that that was not for me. I don't have the psychological makeup for pretending to be somebody I'm not. Thankfully, I was very pleased that other folks did that, yet we still had at that time--it was shortly before the BDAC (Bureau of Drug Abuse Control) got created--some good guys went to work for them and split off, and obviously then further split off from us. Frankly, I lost track of those guys that I knew during that period of time.

Did not do truck stop work. Just basically covered for a couple of guys when they were trying to make some buys, but that was it.

RO: Most of your work out there was probably food, wasn't it?

DM: Oh, yes, by far. Frankly, the pharmaceutical industry was not much to speak of anyway. I think I wound up doing . . . My primary investment was during the IDIP days, the Intensified Drug Inspection Program, where there was a small manufacturer down in Fresno, California, which was actually outside of our resident territory, but none of the investigators down there had the training. So I would drive down there, inspect two or three days, and stay with that one week after week. It went on for obviously a very long time, and it has its own history.

RT: California was one of the early states to get into device regulation. Did you ever get involved in any of that?

DM: No, no. I can remember one or two investigations involving devices, but I don't recall ever doing any inspections of the . . . We would do a lot of hazardous substance stuff back in those days before CPSC (Consumer Product Safety Commission), glue manufacturers, things like that, which was always hard to explain, "Why does the Food and Drug want to come into my place?"

RT: That's correct.

RO: What about import work?

DM: Interestingly enough, Reggie Jang taught me the business. Reggie was one of the individuals who ultimately went on to do the wrong thing and was prosecuted for it, sentenced I guess a couple of years ago. I've lost track a little bit on the time line on that.

Yes, there were two individuals. I'm blanking on the name of the senior one. Reggie was number two. We only had two people on import duty in San Francisco, and then everybody else would pull a one-week or two-week tour a year helping out. Frankly, I think most of us found that an enjoyable break. You saw different things. You got to different things than what you would normally see at the Port of San Francisco and, to some degree, the Port of Oakland, and even the Port of Stockton inland. I would do import work ninety miles inland, because they'd bring the freighters up the rivers. Most of that turned out to be again filth work. We got into salmonella--a big push on that in the late sixties--and I spent lots of time on the docks sampling dried fish meal from Chile which was coming up to go into chicken and turkey feed. Of course, the problem there was economic: if the birds got infected the whole flocks would die. But my wife would gently require me to strip to the skin on the patio after a day on the docks. I was handling that stuff and the wind coming off the river, and then I'd have to take a shower, then I could say hello to her. So sampling fish meal was not one of my more pleasant activities.

RT: These imports that came up, did you say to Stockton? Was that primarily barges or was it larger vessels?

DM: No, it was the ocean-going vessels. They also came up to Sacramento, but there was another resident post up there that dealt with that. We also did a lot of cocoa beans, but people think of Hershey as being the Hershey, Pennsylvania. They had a big plant in Oakdale, California, and I had the pleasure of both aesthetically as well as from a public health standpoint, inspecting Oakdale a couple of times.

RO: San Francisco also had a lot of Asian herbs and things that were being brought into the country for medicinal purposes.

DM: Basically, Reggie was the only one who could, from time to time, determine what the stuff was going for. A lot of small packages going to Chinatown, and unless it was obvious, they would mostly let it go. From time to time we'd find commercial-sized lots that got stopped and questioned. But its, frankly, I don't think too much different today.

I spent some of my time when I was on detail my last month as Regional Director in the Pacific dealing with the Congress on exactly that issue, and an awful lot of stuff is still coming in in small packages. Most of what Customs catches turns out to be commercial-sized or else falls within our jurisdiction and is stopped. But, nevertheless, what you find if you were looking at every package, would be mostly relatively small things.

Speaking of that, I was impressed by an application, I guess if you were to call it that, of enforcement discretion, because when we'd go down to the main post office once a week to go through all of the packages and take the stuff out of the shoes and find the salamis and all that kind of stuff, Reggie pointed out that about once every three months a large box of betel nuts would come in, the kind that the South Sea Islanders chew for the narcotic effect and stained your teeth red. He says, if it goes to this address, let it go.

Well, it turns out that a sailor had married some girl from the South Pacific, and she brought back her mother. So it's this guy's mother-in-law. She's been chewing Betel Nuts all her life; it only goes to her; it's her supply; and FDA said, "Fine. You can have it." All of this was, I thought, just from the heart rather than getting huffy about it and saying you're getting this terrible narcotic substance.

RT: Now from the West Coast, some of the imports that were turned back, did some of those end up at land ports which would still be San Francisco jurisdiction?

DM: I don't think so. Relative to the mainland--at least I never heard of it--relative to the mainland, Hawaii is a much smaller population in terms of demand. A lot of the stuff that came in basically got reconditioned. It was either relabeled, or in the case of spices and nuts, there were whole industries built up around the Bay to recondition, pepper, cassia, cashew nuts, you name it, that they would separate the good stuff from the filthy stuff, et cetera. Cocoa beans again. Cocoa and coffee, we'd get that stuff by the freighter load.

The biggest seizure I had was literally a whole ship load of cocoa beans that had gotten infested after import or after coming into the United States because they had a crappy warehouse in Stockton. I suspect that Honolulu had its own set of problems, probably even more so because of the Asian populations, if you will, but that's an interesting question.

I had dinner with Bob Howell, who was the resident over at Honolulu. He's retired to Stockton now. I was just visiting my mother last month, and so it was a great opportunity to swap stories.

RO: When did you leave San Francisco? When did you come into headquarters?

DM: In 1969. That was a unique, terrifying experience. As you well know, when you signed on with FDA in the early sixties, as late as the early sixties, the system took care of you; that is, that you were dictated where your next experience would be. I can remember very vividly Monte Rentz in those days telling me there was nothing between me and the commissioner's chair but me, myself. In those days, it was true, because George Larrick was the commissioner at the time.

Well, here I am sitting out as number two guy in the resident post of Stockton, I've got no connections, I've never worked anyplace else, and all of a sudden this thing called merit promotion comes along, and you've got to fill out these forms and apply for advertisements. After a couple of years, I had done everything there was that needed to be done or should be done in the Stockton resident post, and I was getting bored frankly, and I wasn't feeling that I was contributing. So it was time to move on. It took me sixteen miserable applications to get out of there, and at this point I'm desperate for anything.

I took a job as a program analyst with the Bureau of Medicine. I hadn't the foggiest notion what a program analyst did; I barely knew what the Bureau of Medicine did. I knew that I shipped EIRs (Establishment Inspection Reports) in there only to have them disappear and never have them come back. But I figured if it went bad I could always retreat back out to the field. Frankly, my wife and I thought we would spend about five years here, get a headquarter's ticket punched, and go back out to the field. There was this vague aspiration maybe someday to be a chief inspector. That would be the highlight of the career is to achieve that.

So I came in in May of 1969. Herb Ley was the acting commissioner. Late in the calendar year, the whole world blew up. Ley was fired, the deputy commissioner was kicked upstairs to the department, and Charlie Edwards showed up. I was doing basically planning--the accounting kinds of things that program analysts do. John

Jennings was the acting director of the Bureau of Medicine. His full-time job, I guess, was director of New Drugs.

Somewhere along the line he had asked me what the Bureau of Drugs might look like. Since program analysts do a lot of "what if" exercises that never come to anything, I said, "Well, what do you want?" So he told me, and I went away and drew some diagrams and boxes, and the objective was to have under one organization, one umbrella in headquarters, everything that had to do with drugs.

So a week or so later I took this thing up to him, we chatted about it, he said, "OK, that's fine. Put it in the drawer." That was the extent of it all. I put it in the drawer.

Six months or some several months later that became the starting point for the Bureau of Drugs in terms of how we began the exercise. So as a GS-12, here I was in the center of this hurricane that was going on, involved with all of the new leadership in the Center for Drugs. I would sit with them and would go through organizational iterations. Ultimately, about a year later, I think I had probably six major packages, five of which didn't make it and the sixth one did, all of them about fourteen inches high. In those days, they didn't have computers. I was drawing all those boxes by hand.

On top of that, this was the great adventure. Knowing that we were going to be moving here to Parklawn, Karen and I bought in Montgomery County rather than over in Virginia at Crystal City where we were. So I commuted down to Crystal City every day which was not a great deal of fun. But consider this: Charlie Edwards came in about the end of a year—I've forgotten exactly where. We were scheduled to move into this building where we're speaking now in February of 1970. He decided to reorganize and move at the same time.

Well, the building had been constructed on the basis of the old organization. So with two days to go, that message came down. So I sat down with our new organiza-



tion, our sort of interim thing, with the space manager, and we respotted all the people. You know, it as one of these squint your eyes, and "Well, we think we can fit a division in here." Well, we had some administrative officers that nearly had nervous breakdowns because of all of their telephones and electrical outlets and layouts were designed for the previous place.

We started on a Saturday morning in a blizzard. It was in February. Tuesday evening, my boss, Frank Desmond, who was the acting executive officer for Medicine, and I had spent all day here. We had dinner at McDonald's on the Pike, and then decided to drive down to Virginia to see how the move was going down there.

On the radio on the way down, we heard a report that the Parklawn Building was on fire. Well, we laughed because there had been a couple of construction fires during its construction, and by the time we got down there we found it was true. Frank had to make a decision on the spot, and he called the move off. We had one truck on the way we couldn't do anything about; another truck half loaded that had to be unloaded. We arrived back, rode up on the B Wing elevator. I believe it was twelfth floor, B Wing. The doors open, and we thought we had lost everything. Smoke throughout, an inch of water on the floor, emergency lights strung down the hallway.

As it turns out, in those days you could smoke in the building, obviously, and somebody had tossed a lit cigarette butt in some trash, and that had made a large mess. Nevertheless, we had to clean and move every piece of furniture and every file on that floor into swing space and have it reconstructed because of all the damage. The heat literally was so intense it melted the plastic under the light fixtures, and so it drooped down on typewriters and that kind of stuff.

The other part of it . . . A terrific part of my career, worked a lot, was Frank had told me, "It's your responsibility, Dan, to make sure we lose no applications, no jackets." The reason he said this was when they had moved from downtown out to Crystal City several years before, he had driven across the Fourteenth Street Bridge at

11:00 at night picking up NDA jackets that had fallen off moving trucks. I know that's hard to imagine.

Well, I designed a triple inventory system so we knew where every jacket was, at least box by box. Then I considered, being a good investigator, how could I attest to the authenticity of this sample, *i.e.*, this truck, should anything arise.

Well, if the truck broke down, I couldn't guarantee that somebody hadn't taken something out of it. So Michels' overkill system said there will be a car following every truck with two people in it; one that will stay with the truck and the other one to go get help if it's necessary.

Well, I was hurrahed like crazy until the second truck broke down and I was vindicated, because then we could truly attest that we didn't lose any records, and we didn't.

So that was the adventure of coming to headquarters. I spent . . . Let me see. That was '70 through '76 doing program analysis; I advanced to become supervisor branch chief and then division director of the Division of Planning and Evaluation in the Bureau of Drugs.

RO: Now back up a bit, because remember while Dr. Edwards was commissioner, he had staff meetings, not only the general staff, but also the bureau staff, etc. If my memory serves me right, you were the program manager for one of the programs that was being monitored.

DM: That's right.

RO: What was that?

DM: Drug Quality Assurance. There was . . . Well, I guess I'll take some credit and some blame on the thing yet.

We had a thing called PMS, the Program Management System, which we fundamentally redesigned how we did business. I'm glad you raised that, because Charlie had, come with the principle that there ought to be bureaus in charge of program entities, he recognized that that was not always possible, and we had a thing called project management to crosswalk or matrix to the location of the resources wherever they were that went to cosmetics or foods or whatever. I helped design or designed the basics of that within the drugs program. We had, I think, thirteen PMS projects, one of which ultimately was Drug Quality Assurance. But to be accurate, Ron, I did not technically become manager of that until I went to the Office of Compliance in Drugs which was '78. So it was a little bit later after Charlie. But I was fully engaged in restructuring how we accounted for resources, both people and dollars.

I remember taking a wall that was about eight feet by probably at least twelve or fourteen, and wallpapering it with all of the ledger pages that were necessary to account for everything under that system. But it was truly revolutionary and forced people to think outside their little box that, for example, a director of Office of New Drug Evaluation owed the director, the project manager for Drug Quality Assurance some time for case work or whatever there may be. So that was fun as well and provided me an opportunity to engage with the then bureau top management as a relatively junior person.

RT: Well, the whole matter of security for drug records is much more secure now.

(Interruption)

RT: In certain times, drug records storage was on the third floor of HEW North. The drug records were right off the elevator, and there was no enclosure for them at all. So the agency has become more cautious.

DM: I remember when we moved into the Parklawn Building recognizing that we were in more modern and then, by definition, more flimsy internal structuring. Actually they defeated the system by simply boosting somebody over the wall by pushing up the ceiling tiles, and that then forced us to put in a motion sensor detection system, at least for the time being. But yes, you're absolutely right.

Well, that's one of the sad parts about our society today. We can remember, aside from the White House, we could walk into any public building in the United States unchallenged, and now you can't even get into this place without a building pass.

RO: Who was the first bureau director, because I think John Jennings was acting then?

DM: That's correct.

RO: Was it Dr. Simmons?

DM: That's right. Simmons came in with Edwards. He was actually an SGE, Special Government Employee, for the interim, and then he groomed or, as it turns out, I guess, Dick Crout was groomed then and frankly spent more time as director of the bureau compared to Simmons. Simmons was more of a change manager than a program manager, so that he worked us through, along with George Leong, who was a Ph.D. pharmacologist. They literally interviewed every professional in the entire conglomeration of the new Bureau of Drugs before they settled on what the structure

ultimately would be and where everybody would be assigned. It took a long time, but I think paid off because they had some sense of who people were, what they wanted, and what they were capable of, rather than just trying to do it very rapidly.

RT: About how many personnel were in that operation at the time? Do you recall?

DM: Well, I would guess about 850, because if you take the Bureau of Medicine and then add the compliance and the lab functions which had previously been part of the old Bureau of Pharmacology, Bureau of Chemistry, and Bureau of whatever it was called, of Regulatory Compliance in those days, and moving them together, it was a substantially augmented facility.

One other footnote, before I forget, because it's just a charming story, I think. Probably many of us in headquarters remembered Elizabeth Kelley. She was a retiring, bookish, librarian-type lady, who was in charge of the medical library, and, of course, I knew her virtually instantaneously when I came to headquarters.

Well, as is usually the case, one doesn't always get what one wants, and here at Parklawn she was being given less space than she had at Crystal City, and that was sort of an incentive for her to get rid of some old journals and texts that management felt she ought not to worry about retaining.

Being a good librarian, nobody was going to tell her what her retirement schedule should be. So notwithstanding the fact that she had less space and had been issued fewer boxes than was appropriate, the night before the move started, she went downstairs, along with some of her staff, and stole a whole bunch of boxes off the Bureau of Vet Medicine in order to pack up everything she had, and it came out here. So, again, where there's a will, there's a way in institutional . . .

RT: Well, that's kind of common with historical records. There are those that don't recognize their value.

DM: That's right. That's right.

Where are we? We're . . . I'm now a GS-15 division director, program analyst, and bored out of my mind. I have a terrific staff. I come in at eight, and by 8:30, I'm finished, because if I start getting out and wandering the shop, I'm just going to get in people's way, and it was time to find a new challenge.

RO: This was the Division of Planning and Evaluation.

DM: Planning and Evaluation. We had just gone through the Industrial Biotest Lab case, which beefed up or actually created for the first time an incredible bioresearch monitoring program. The famous number was 606 new positions got thrown at the agency at one time for BIMO (Bio Research Monitoring). I'll give Dick Crout the credit for that.

Well, that was an animal tox lab problem. He made it generalized in the politicians' minds to deal with clinical investigators, institutional review boards, the whole spectrum of research. Otherwise, we wouldn't, by far, have gotten those numbers of positions.

I had had the opportunity to do the planning and the budget work for BIMO, if you will, creating it out of whole cloth. Certainly I don't take the credit for the ideas, but I'll take the credit for packaging it. I think that it worked with Dr. Frances Kelsey, who was head of then the Scientific Investigation staff. She had herself, Al Lisook as another M.D., a couple of CSOs, and a couple of clerks. I think it was a total of six.

Al went out and did the inspections of the clinical investigators, because he was the doc. I guess maybe Frances used to from time to time, but I don't recall in my time

that she did it. But in any case, of course, she was St. Frances of Kelsey to many of us. Those of us who had come in post '62 amendments, at least for the first couple of years, believed we owed our jobs to her.

So I went to then Carl Leventhal, who was--this was 1976--who was the deputy director to Dick Crout, and said Dr. Kelsey couldn't manage her way out of a paper bag. She's a great scientist, but you need somebody to ramrod and make something out of this thing. You're not hiring people; you're not doing anything. So he talked to the boss, and they said, "OK. We'll give you a chance. They sent me over to become Frances' deputy." Now I had a blast. For a couple of years, I was doing everything from writing functional statements, position descriptions, and hiring people and ordering furniture and arguing about space and the whole thing. We went from a staff of six to . . . We were . . . Our objective was a division of fifty-four, but, as is usually the case, the powers caught up with us, and we were cut back at about thirty-two or thirty-three when the ceiling cuts came down. But we did make full division status as part of then what was the Office of New Drug Evaluation. So I felt very proud and good about having worked with Dr. Kelsey and having pulled all of that off.

Then sort of in between, Jerry Halperin, who was the deputy director for New Drug Evaluation, working for Marian Finkel, who was the director at the time, was elevated up when Leventhal went back to NIH and became the acting bureau director.

Well, the phone rang one morning and it was Marian Finkel on the line saying, "I'd like you to show up tomorrow morning to be my acting deputy director." That was one of those (deep breath), "OK," not knowing what I was getting into.

The next morning I showed up. Jerry spent forty-five minutes with me showing me where the piles of paper were. The bottom line was much like what I had with Dr. Kelsey. Dr. Finkel takes care of the drugs, you take care of everything else. So I was really a manager manager for a number of months.

It was fascinating to see the world through a direct line headquarters operation.

RO: Now Marian was in charge of what?

DM: New Drug Evaluation. That was . . . We had about six divisions in those days. We were responsible for both monitoring INDs as well as NDA review, supplement review, and then review of annual reports, et cetera. Everything was combined. But both pre- and post-marketing in terms of the applications themselves, but self-contained in one office. Generic Drugs was located elsewhere, to the extent that there was any. Advertising belonged to New Drugs as another division. But Dr. Finkel was basically the final authority on close-call approvals, that kind of thing.

So then as it turns out, it was annoying at the time, but God has blessed me more times than I can count in terms of funny things happening to me. I was told I couldn't compete for the position as deputy director for New Drug Evaluation because I didn't have an advanced degree. So I became irritated and came down a couple of floors and saw a man named Heaton at the time, as I recall, saying, "I'm a little tired of where I am. Donald, do you have . . . ? Keep me in mind if you've got anything happening."

I think Donald was a wise man in many respects, and I suspect that he picked up the phone and called my bosses, because in a matter of weeks I was reassigned as deputy director in the Office of Compliance. So . . .

I'm sorry! In between, Dr. Kelsey was on her way to Dr. Crout's house for the annual Christmas party he had for a number of the staff, and her Cadillac and a telephone pole on Wisconsin Avenue disagreed with one another. I'd forgotten about this. She wound up in the hospital with pins in her legs hanging from hardware. They sent me back to Scientific Investigations to hold that fort there until she could get back.

Well, that was a unique experience with me slipping down to the hospital every day with her in-box and taking her out-box because she didn't miss . . . She missed a step, but only literally. She didn't miss one figuratively. She was a kick to work for. It was a real adventure.



But then I went on to work for Ted Byers, who was then the director of the Office of Compliance in the Bureau of Drugs.

RT: Were you the first deputy director that she had?

DM: As division. She had had . . . I'd characterize it. I'm sorry I'm blanking on their names. John Holten was the senior CSO, when it was still a small staff. But she always had a senior CSO that she would lean on.

To be honest with you, I found that a very common practice in the Bureau of Drugs, at least in those days. There was always a senior CSO that . . . Merv Shumate was one. You know, you can tick off a whole bunch of them at the bureau and the office level who were the trusted individuals to advise and really get critical things done.

RT: But they weren't really position-designated deputies then?

DM: No, no.

RT: Just selected then?

DM: Not when they were as a staff. But, yes, I was division director, followed by Heinz Wilms, followed by Ross Laderman, and when Ross left . . . I'm sorry I've lost track after that.

RT: I just wondered when . . . You were really her first deputy director?

DM: Yes.

RO: When you were Marian Finkel's deputy in New Drug Evaluations, there's always been a lot of emphasis on the agencies' drug lag. Did you, in that position, create any initiatives in order to overcome that?

DM: I will acknowledge that that's a universal theme. It's an interesting point. Whatever it was, we didn't do it fast enough. At the same time, whenever a drug went bad, somehow we had screwed up. You know, we should have known that there was a one in a million chance it was going to destroy your liver or whatever.

No, I don't . . . I was not personally engaged in, if you will, any substantive efficiencies, but I will give Dick Crout huge amounts of credit for having forced the whole operation to recognize it was dying under the amount of paper. This was back early seventies. That's right, because once we got things settled down about 1972 to 1974, he called in some consultants who taught virtually every manager in the place how to map their processes. Basically it was systems management.

We started with every piece of paper that came in, every piece of paper that was created and how many copies, where it went, and we literally could imagine the usual large conference room that we have here in Parklawn. The IND paper flow covered virtually every wall in that room from I'd say about five feet high. So just massive amounts, wrapping around, huge amounts of paper. That was for NDAs and all of the corollary documents as well. This took months of time, and then once it was mapped and everybody agreed that's the way it should be, if it wasn't in fact in some cases, we went through an efficiency exercise. He himself led the group around, "Is this piece of paper necessary? Do we really need to have it? Do we need to create it? Is there a way of making it shorter? Is there a way of doing without copies?" And I suspect we became 30 to 40 percent more efficient just by cleaning up the simple stuff which was outdated.

RO: I think about that time didn't they initiate the fast track?

DM: It was a little bit later than that, I think. The fast track probably began in the late . . . The late seventies is really when Bob Temple and some other folks became engaged in whatever the terms are for treating applications differently than the usual.

RT: Was that primarily prompted by initial oversight hearings? Or was that an internal initiative of the agency to speed up the process?

DM: Bob, I take it's probably . . . I wasn't close enough, but I'm going to suggest that most of the good new ideas we have ourselves. There are very few good ones that come from the outside. But too often--either because we're lazy or because there's not enough interest--it takes the Congress to kick us in the behind to make them happen. But I think that was really it, that there were a fair number of thoughts floating around, but, gee, we don't have them in regulation. We'll get criticized if we do it, and then Congress comes along and starts pushing us.

Probably I think the greatest example of a collection of largely stuff the agency itself had developed from the application initiatives was to have the good guidance practices. Congress simply takes it and translates it into law. But, no, I've come in my old age to recognize that oversight hearings do have some purpose in terms of, (a) keeping us honest--I'd hate to think how it would be, you know, if we had nobody who we were accountable to--but secondly, (b) for pushing us to do things that we normally would not. Long answer to a short question. But the existence of the drug lag and the pressure to move the freight has always been there, at least as long . . . From the time I walked in the door in May of '69 in medicine, that's been a problem, that's been an issue.

RO: Since you left there, user fees have come into being. Do you see where that would have been a big help?

DM: I'm now a private citizen, am I not? Therefore, I'm going to speak my mind. I think we made that mistake once and didn't learn from it. It's called antibiotic certification. There was a need back certainly, *probably* when antibiotics certification was started, but we didn't know what the heck it was that we were dealing with. By the time I came to know it as a program analyst, it was 234 positions that I had to make come out 234 no matter how many people were there. It was a backhand accounting system that we had to preserve. The Congress said, "You will spend at this level for this particular program. Therefore, it is a protected program." By definition, it has a higher priority; no matter what you think about, it has a higher priority than everything else. That's true of the drug review program.

If we have another kind of problem, it doesn't make any difference. We'll have to deal with the resources for that problem out of the remaining pool. I think it arbitrarily skews the public health issues and prevents us from debating really what the true and proper balance ought to be. That's the primary problem.

The secondary one is inevitably you've . . . The entity that we're to regulate is now a stakeholder in our budget process. How can you possibly not somehow get pinched by issues of conflict there? That bothers me terribly. I don't see how ultimately you can walk away from the ethical problem, but the Congress has decided that we will have a different system. But that's where I'm coming from.

Congress could easily have decided they're going to appropriate the money to make this thing happen in the same way. They did it with BIMO through 606 FTEs (Full-Time Equivalents). But the reality was that BIMO became less of a problem, and we reprogrammed positions out of it. We don't spend 606 on BIMO, not by a long shot. That's probably good, because we decided there were other more important

things to do. Of course, as BIMO program manager I would have argued strongly against that, but that's my job, just as much as it was my job when I was in drugs compliance to be the world's biggest advocate for drug quality assurance, which meant post-market surveillance, laboratory analyses, investigators, all that kind of stuff. Then let the chips fall where they may.

RO: I guess before we interrupted you, you were deputy director to Ted Byers in Compliance.

DM: That was an interesting time.

One of the reasons I was selected was I had a reputation for being a manager rather than a specialist in a particular area. Suffice it to say that it was a manager's dream. Everything was so screwed up in that office that no matter what I looked at was easy. They didn't know where the cases were. They didn't know how long they had had them. They had a policy that once a case didn't look very good, maybe they were going to disapprove it, they set it aside and worked on something that was more likely to be approvable. So the field never heard back, and I literally found cases close to two years old. So the first job was simply to begin inventory.

Number two was the office had a lousy reputation for communication with the field. There had been, if you will, a go-away that Dick Crout had arranged. I guess it was with . . . I can't remember who was in charge on the field side at the time. It must have been . . . I can't recall. It would have been '76 or '77, thereabouts.

Be that as it may, whoever the personality was, they agreed they were going to make life better. So my marching orders were, "Let's get on the same page." One of the things I did was I made a commitment to myself that I was going to get out and visit as many districts as I could as quickly as I could. So if I wasn't invited out or wasn't out making a speech and doubling with a district visit, in any month I invited myself out

arbitrarily, and I would bring home pages of notes. They'd hate to see me coming back. About all this stuff that, you know, policies that we were inconsistent over, things that we had screwed up.

Finally, after about two years of making the rounds, I can't remember which district it was, but I went in and said, "I'm here," you know. And I knew people by this time. "You guys got any problems with drugs?" "No, but let's talk about the performance appraisal system."

When I walked out with no action items, I knew I had turned a corner. You know, you get one or two, that's fine. But their gripes about performance appraisals were the same ones I had, so we had a great time of criticizing it. But that was the primary investment, was reestablishing open, honest relationships with the field, getting some behavior changes in my organization, as number two, and that was not easy, because I had not come from the traditional side of the house. I had come up through a program analysis rather than being grown up as a compliance officer, as most of them had.

Ted was not the most communicative individual in the world. I finally got used to the idea sometimes when I would walk into the office, and I'd ask Diane, "Where's Ted?" "Oh, didn't you know he's up in New Jersey giving a speech." "He never told me that. It's okay."

I learned a lot from him, and I'm grateful for that. He taught me how to be a compliance officer to the extent that I ever was one.

RO: Did the bureau have a go or no go on the field recommendations once they'd come in?

DM: I would say yes.

RO: Of course, there were a lot of appeals though.

DM: There probably were that may have predated me a little, because Shumate was the OE, director of the Office of Enforcement, that I recall primarily dealing with. I don't remember much of a personality earlier than him. He frankly did not have a very good reputation of moving stuff along himself. That's not necessarily fair, but I'm speaking my mind here.

After a while, I don't think the appeals were very attractive, because they didn't really buy anything except maybe the satisfaction of having a hearing, but nothing changed.

Then when Al Hoeting came in, he put out the word that he didn't like appeals. So whether right or wrong, he intended to make it go away. Whether or not there's a final sign-off, and frankly I had signed off either directly for disapprovals or endorsed approvals--every regulatory action I had to sign off on when I was director.

That changed when Kessler came in and we did a lot of decentralizations, and rightfully so, because most of the crap I didn't need to see. The reality is whether or not--at least under the present construct--the centers sign off, you're going to have to go to them, if you're litigated, for some kind of scientific or technical support, either directly or else they're a conduit to the outside. That may have been different in the old days, but I'm speaking of this in my tenure.

So the way I characterized it, when I was the director of the Office of Compliance, I looked to Paul Hile as my primary supervisor 90 percent of the time. The other 10 percent of the time, it was Hank Meyer or Carl Peck or whoever it happened to be at the time, whose interest I ultimately had to respect because if you looked at the TO (Table of Organization), I worked for the director of that organization. Paul might want something else or the field might want something else, but if I viewed that as contrary to what was in the best interest of my center or my bureau, then I had

to do what I thought was right, but also be able to articulate that. That was ultimately the thing that was the most frustrating for the field was to get turn downs, but without reason or with BS reasons or political paper reasons. Just tell them, and they'll be happy.

I don't think that balance of power has changed remarkably if it really comes to significant cases that you have to have the center signed off to one degree or another. But for you guys, I think there's another piece that maybe isn't obvious, particularly in the pharmaceutical industry. Centralization or consolidation of the industry has made it look more like the vaccine industry than ever before. Ultimately, we're having fewer and fewer firms manufacturing individual products, so that if you go in and enjoin firm A, it's not uncommon that you're going to run into a medically necessary drug. That is notwithstanding the GMP problems. You're going to have to let it stay on the market, because people are going to die without it. These are much more difficult decisions, cause a lot more tension between the ORA side versus the headquarters side than has previously existed.

I was pleased that that was one of my legacies that I left when I left Drugs to come to ORA, that we had worked that out, because we were the first to begin dealing with those issues. I suddenly realized that compliance was the wrong place to be dealing with them. It was a scientific medical decision, not a regulatory one, so that what we . . . First of all, we had to make sure that we were recognizing the problem, then get it shifted over to the appropriate review division where the docs could make the decision. We got that regularized, and I think largely have not had problems with it. Biologics is much tougher to deal with, if for no other reason vaccines are a peculiar product line. But more and more it's also happening in blood plasma fractions.

RT: Biologics. Are they, as a group, a little less regulatory oriented?



DM: Depends on your point of view. Let me say this that for . . . It was the great shotgun marriage of Drugs and Biologics, and I'm proud to say that Compliance and Statistics were the only two offices that really integrated the two functions. We did away with any label that said, "Drug or Biologics." So if you were a quality guy, you worked on either one, et cetera. So we were merged for a couple of years.

I had been selected by Dick Crout as director of the Office of Compliance, and the appointment was held up because of the merger. Hank Meyer came on, we had a chat, he checked his connections, and said he'd be happy with me--or at least not unhappy. So it took me a year to the day between when I was selected and when I was officially beknighted, so to speak.

I lived for two years with Drugs and Biologics, and when we split up, I got rid of 9 percent of my resources and 25 percent of my headaches. So that'll give you a sense of the problems.

Blood and blood products, very distinguishable, though they were treated the same way probably in part because they were inspected by the field. Be that as it may, Hank Meyer was very proud of being regulatory minded.

(Interruption)

DM: On the other hand, the vaccine industry and some of the other more exotic products clearly were treated differently. Biologics has a different culture. They started with a different act in a different year--earlier than us, and they're quite proud to point that out--and to this day I can honestly speak my opinion that the mainstream biologic function is not integrated into the FDA.

Cathy (Catherine) Zoon has done a terrific job to try to make things happen as director of that center. I have the greatest admiration for her. But the intransigence of

some of the old-time staff who simply will not recognize that we have moved on to the twenty-first century is very, very difficult, and I have great sympathy for her.

Now, at the same time, I want to tell you frankly that Hank Meyer was my best boss as bureau or center director for all the time I was in drugs. He was there when I needed him.

Do you remember the E-Ferol case? That was when a Vitamin E preparation was marketed. Vitamin E is necessary for metabolism of oxygen in premature infants, to prevent blindness. Their lungs are ill-formed. Consequently they can't get enough O<sub>2</sub>, and they tend to go blind. The problem is Vitamin E is not water soluble. Mostly injectable preparations are oil-based, they're painful, and they don't get into the system very well, et cetera.

Some little outfit out in the Midwest came up with a water soluble formulation. In those days, the policy was that once a general product was approved, you did not have to file an NDA. That was a patent issue. So that this outfit came on; we knew it was there; it had been reported to us; but the consumer safety office in charge of that class of products said, "It fits over here, this category of vitamins. We will get to it eventually in the DESI--the drug efficacy study implementation process." It was a judgment call. It turns out that the formulation was killing infants. It was probably the surfactant that they were using in the formulation to make the product soluble. But the kids were blowing up; they were just retaining water and drowning.

We had a . . . It was my first hearing in front of twenty-three television cameras. Congressman Weiss. They were never comfortable. But Hank . . . First of all Rudy Apodaca, who was in charge of the division, I can remember him coming in to tell me that this problem that we were dealing with Vitamin E, we were into it for about a week when he had discovered that we were aware of the product, and he had to tell me and he told me why, and I had to tell my boss. The minute I told Hank that, he said, "You guys must have to make hundreds of those decisions a month." I said,

"You're absolutely right." And he was a bear. He did everything he could do to lessen the blow to protect us.

So notwithstanding Meyer's reputation as being de-regulatory, he only changed my mind once on some OTC labeling problem that really didn't probably mean that much in the long haul. Frankly, when Tom Scarlett wasn't going to support the matter, Hank Meyer probably wasn't going to support it either, so I lost on one case.

Similarly, Dr. Berzinski in Texas came on our radar screen when Hank Meyer had just become director of the combined bureaus. This was when Berzinski was still using his original formulation of extract from Texas prison system urine, you know, really the worst, inserting subclavical catheters and leaving them there indefinitely. It was really bad.

Knowing that this was involving a physician, knowing that it had political sensitivity, a lot of the parameters, as was normally the case, it was an outlier that I would go brief the boss on. Most of the cases I never bothered with, because the boss, whoever he was, trusted Compliance to do the right thing.

So we went up and presented. In ten minutes, Hank said, "OK. Sounds good to me." We walked out, and we had his complete backing on that case forever afterwards. Now, it took its own twist in the courts. We didn't do as good a job as we might have on it, but, again, I wanted to, for the record, indicate that Hank was one of our strong supporters.

There were times I'd have to go in and tell him stuff he hated to hear, because he was bored silly. But he put up with me, let me say my piece, and then get the heck out.

Paul Parkman was much the same. He was Hank's deputy. He was director for about a year, and then he retired. Followed by Carl Peck.

Carl was a true scientist. He was . . . I could never get him excited unless I had a bioequivalence issue I could tie it to. But like every good manager, one figures out

how to get to the boss. Well, Carl was one of the very first e-mail mavens, and I quickly learned that I had better get myself a computer that's compatible. Well, it turns out that I'd never get through to him on the phone, never get a meeting with him. But if I sent him an e-mail, I knew at 10:00 at night he'd be at his kitchen table at home answering all his e-mail. I'd come in the morning, I'd have an answer to my problem, and I could get on with life. So Carl may not have been a face-to-face guy, but he was a . . . I could get what I needed from him.

We went through some difficulties from the standpoint that Biologics took some good people from us. We had a lot of good people, and we had to do some reconstructing back in the now late eighties. Then comes the next story.

Just about the time that we had recovered, Sammy Young had come from Biologics and stayed on as my deputy director. Sammy was an excellent inside guy. I was the tap-shoe speaker, outside, go-to-meetings guy; he stayed home largely and took care of business.

We rebuilt the place about 1988. We were feeling pretty comfortable, and then generics came along. But I'm overlooking a couple of things, and they were called Tylenol.

The first Tylenol tampering. I'm not sure that if it had gone on much longer my wife would have stayed with me. I was working in . . . This was '82. I was working in Drugs Compliance at the time, and this was largely an ORA field issue. But I felt that I needed to stay engaged with this, and I spent huge amounts of time down in Emergency Operations just being available, just to be there. I spent a lot of time working on the initial draft of the tamper-resistant packaging regulation. That was, as far as I know, is a world record setter. I wish I had the blackboard, because it would be good for the Smithsonian as the first draft principles went on that blackboard. Six weeks later we were in final, publishing. Then I went on the road to preach the gospel with tamper-resistant packaging for a number of months with the industry.

Eighty-six was harder, because the first time there was a panic that: "Should we have OTC products?" and Art Hayes, I think, properly said, "Absolutely no ban. We will not succumb to taking over-the-counter preparations off the market." He said, "What's next? You know, it's the whole supermarket, the whole principle by which we do business, and the United States is going to fall apart." He took huge amounts of heat.

Frank Young had it revisited in spades, because it was the same problem all over again. I can remember very vividly sitting with some folks down in Emergency Operations with Frank about 9:00 one night when we had a breather in '86. He said, "God forbid that we have three options here: that this is an inside job, that it was a targeted murder, or else somebody in fact did defeat the TRP (tamper-resistant packing) features of Tylenol." It was the last one that was true. There were three features, two of which were really good. They got defeated. Frank has to take the heat.

We're also in a Republican administration, not inclined to be very happy about additional regulation for the industry in any way, shape, or form. The Proprietary Association was beating on us hard to get an additional regulation out to put restrictions on unsealed two-piece hard shell gelatin capsules, which were almost always the vehicle for the tamperings.

Joe Levitt and I went down to the Office of Management and Budget. He was the director of executive operations under Frank Young. It was like talking to a brick wall. It was a marginal cost to society and it was regulation, and they didn't care whether the industry wanted it or not, they wouldn't hear about it. Well, ultimately the administration changed. We got a watered-down regulation through in general to deal with that in part, but that was one of the more frustrating experiences.

But also a time when, to be honest with you, when I got my badge last week, it's times like that that made it worth it. We all knew what we were here for, and we all pulled together, and there was just no question. People put in the time, no matter how

much it was necessary to get the job done, and they're still there. They're ready to go; just tell us which way.

RT: One of the things that Dr. Young implemented, as I recall, was his plan, his action plan. What impression do you have of that?

DM: I thought it was terrific, because he quickly got out, again, all our good ideas. He chose among them what he was going to do, and he made them happen. I think it was fine. We went through the skinny rabbit, fat rabbit thing, however you want to characterize that.

The downside of it is . . . And, again, I don't want to blame Dr. Young. I admired him greatly. I saw him at his worst moment during the Tylenol problem. It was about 1:30 in the morning, and he couldn't get his testimony cleared for the next day in the hearing, and he was afraid that he was not going to do the agency well. That's where his heart was. His heart was always with us.

But that was the era that began the demise of the formal planning system that the agency had had as long as I can remember. I came in as a program analyst. I started doing planning work in '69. Jake Barkdoll was the best planning, strategic chief that I've ever known in my life, and it started to fall apart in the Frank Young tenure.

Now maybe it would have fallen apart anyway. The political times had changed; there was no longer "a need" for that kind of thing. I always felt good that every year we went through an exercise, a rationality. We polled our client groups—we didn't call them clients in those days—but we polled the outside world. What's important to you guys? And then we'd match it up with what's important to us and make some decisions. That doesn't happen anymore. We're working at the margins now. . . .

I could go on for quite a while, so that's one of my disappointments about that. I don't know whether that was planned or whether it was just happenstance, but in the

short term, I think it was good; in the long term, I think it was a beginning of a downside—just as much as I'll say that about tobacco, that I think that I admire Dr. Kessler greatly for what he has accomplished in American society, but I don't know that we've been able to count the cost to this agency yet. I think there have been some very bad downsides in terms of our reputation on the Hill, to name a number of issues. I think if it stays where it is it will probably go away, because we're basically out of the business. But God knows what the political side will create or what will be demanded of us and the extent to which we are sucked into this thing, which we're not very good at. It doesn't fit us really well. Sort of like methadone clinics: it never exactly fit well with what it is we do. We're good at products; we're not good at other stuff. Tobacco is an issue which is not a product issue. So that I think it was a continuation on a focus other than a rational FDA-wide what's important to us.

For example, I think it's very important that we ask ourselves every year, "Should we put more resources on cosmetics?" The answer almost always is, "No," but we need to ask the question anyway. But we don't do that in any organized way now.

RT: This former—I guess it was former—management style of the policy board, how did that complement what we're talking about here?

DM: Whatever you call it, the question is, "How much discipline does the commissioner exercise?"

Go back to Charlie Edwards. He was more an Eisenhower, in my view, not fully engaged in all the issues. But he knew where he wanted things to go, and there were expectations about meeting them. Maybe another one is like Old Man Cooke of the Washington Redskins. I'll pay you lots of money, but you'd better perform.

Those loops exist today, but . . . Again, I don't wish to fault Dr. Henney. I think she is the best commissioner we could have for the moment. But the reality is our environment is not conducive to a lot of team play, and frankly, that was one of my frustrations over the last couple of years, was what I characterized as a balkanization of the agency. It started with Kessler, because he divorced himself disciplining his top-management staff.

So what happens in the absence of direction is five centers end up going up five different directions, if not more so if you count Seafoods--tongue in cheek. For the one place, and my people were very proud of this, the Office of Enforcement is the one place where everybody thinks agency, no matter what their portfolio. It's terribly hard for that kind of policy group to get the rest of the agency on the same page when Dr. Feigal is going off in one direction in terms of reinvention, and Dr. Zoon is going off in another direction to protect the blood supply. And you name it; we don't have any common themes and threads in this. It's terribly hard for an ORA staff, in my view, to live in that kind of environment.

I was pretend director of the Office of Regional Operations from July, when Gerry Vince retired, to December a year ago, and all it did was make me crazy, because what I experienced on the policy and case side was true in spades on the operational side. You could never get people to agree on what the strategy was for the moment, let alone how many resources ought to be devoted to it, and then you get them criticizing how you allocate your overhead. Well, that just irritates the snot out of me, because I would never think to question how Joe Levitt allocated his overhead in his center, but that's another story.

RO: Back when you were in the Office of Enforcement in the center, there was a Compliance Policy Council that was the compliance officers of the agency that



supposedly met every week or so to kind of give uniform compliance policy. Was it successful?

DM: It was successful in a different environment. Paul Hile was the number three in the agency or number two, however you wish to characterize that. The power structure was unbalanced when Kessler pushed Chesemore down to being "the same as" the center, as part of the Office of Operations. But once that happened, the Compliance Policy Council lost a will, because it didn't have a strong enough leader.

I'll confess I tried six ways from Sunday. Chesemore gave me that responsibility, and the longer and harder we worked at it, the fewer times we were successful. It largely turned on the view that . . . I'll be up front about it. Stephanie Gray, as my successor as director of the Office of Compliance and Drugs, did not believe there was a need for agency policy except in extremes. Leave the centers alone. They'll do their thing.

I think, unfortunately, not recognizing where she came from, is the more different you are, the harder it is for the executing organization—that is the field—to do it right. You give people fourteen different instructions on how to issue an FD483, I guarantee you that they're going to screw it up more often than not than if we always do it the same way. I'm not saying people are dumb, but the world is complex enough; let's not make it anymore complex. I finally gave up. We probably had three meetings in the last two years.

I want to go back to where the power comes from. Leaders must have the power to exercise it. Another thing is it's not just the chairperson or the conferred power of that chairperson from the ACRA (Associate Commissioner for Regulatory Affairs); it's what the members bring to the table. The directors of all of the Offices of Compliance do not have the power to speak for their groups like they did when I was there. That's

just the simple reality of it. I could come to the table and cut a deal ninety-nine times out of a hundred with my peers. End of discussion.

Hank Meyer, I might report to him, or Carl Peck or whoever, but most of the time we were trusted to do our job and do it well. Consequently, we had the power of the job to make it happen. It doesn't happen now. Have to go back and confer; have to go back and talk to the boss. If it has to do with day-to-day compliance policy, if I were a center director my eyes would glaze over in boredom. I mean, this is not my thing. I'm not defending or attacking. I'm trying to represent what I view as reality. And I think we've lost a great deal of them, if I want to be pejorative about it.

What you see today in the way of enforcement actions is more of a process of accident than plan. I'll admit that probably 40 to 60 percent of the cases the agency ever generated were never planned. They're a function of what you find. But right now there is an insufficient focus on what we really want to get out of using the two-by-four.

Some folks were asking me, when I left the Pacific Region, what I saw for the future, and I said, "A lot of injunctions. A lot of big injunctions, which is not necessarily the best way to do business."

RO: Costly.

DM: You bet you, particularly when you've got a bunch of them like Los Angeles does.

Well, if we're not inspecting at a sufficient frequency, firms are going to drift. We know that. Even the good ones will drift over time. When we find problems then, they will have gotten to such a magnitude that sort of, you know, "Do not pass go. Do not collect two hundred dollars. We've got to go directly to jail." That means that when those problems come up, they'll tend to come up to my attention or my x's

attention, and the enforcement is a warning order from either a district or a center. We've got a multi-district, multi-national firm. We're going to have to go after it. Therefore, it's choreography time. Plan the inspections, make sure that we've got, you know, sufficient numbers to represent that we're going for the injunction for the corporation overall.

So I would say the outcome is largely the same number of prosecutions, mostly out of (Terry) Vermillion's place, which is proper, the way things are structured today. Fewer warning letters. Seizures only when we can't get the recall, to be perfectly honest with you, and I'm going to also claim that probably a third of the seizures in the old days we didn't really need. But we went for the "tickee" mark.

But unfortunately I think we're going to have maybe more injunctions than we can handle, Ron. I think you're right on point. It's unlike a warning letter. Well, you should follow up on a warning letter, reinspect sometime. But unlike a lot of other things, there's an open-ended cost to doing an injunction. If you're going to do it right, you're monitoring that firm forever until they're certified in compliance and you go back to the court and take them off.

RO: Let me ask you, the different kinds of letters that you have today. You mentioned warning letters. Is there a warning letter or regulatory letter or what is it?

DM: There's a one and only one by the book. In reality, a lot of stuff goes out untitled that should have been warning letters, because of absence of discipline.

RO: They go out as an untitled letter?

DM: Yes, with nothing on top. You'll find threats in them. Some centers are notorious for doing that; some centers also have invented lesser . . . It's the advertising

program in Drugs. It's always been marching to its own tune. Totally unsuccessful in terms of bringing them into the compliance fold.

We had a problem when Chesemore was the ACRA . . . I've forgotten the product. One firm got a pass on an advertising issue, and the other firm got a warning letter for exactly, exactly the same violation. The problem was that one was out of one center, and one was out of another center. We got them together, but, again, the cats wouldn't herd. Each unit was doing its own thing, and we did not have sufficient clout to draw them together.

RO: In the Commissioner's Office now, is there a deputy commissioner or associate commissioner or whatever for policy coordination or something like that? What is Bill Hubbard?

DM: I can't speak to what Hubbard's organization does at the moment. I can go back to the predecessor organization which was largely I would characterize it as Dr. Kessler's political arm. When he wanted to float something remarkably new, when he wanted to do something independent of the rest of the organization . . . It's where tobacco was sparked from, but that was quickly isolated and properly so. I think that was a wise decision on his part, is to keep it small, relatively small, and keep it separate from the rest of the place.

I was frankly worried about it originally that it would poach into compliance policy. It turned out it largely did not by virtue of the kinds of interests that it had. It was also the place where the reg writers ultimately--or the commissioner's reg writers--ultimately resided. The folks have the interface with the FR (*Federal Register*) writers now.

So policy is, I guess, in the eye of the beholder. I would have assumed that it would have been engaged in a more functional activity. Largely they did not, with the

exception of dietary supplements and Internet policy. Dietary supplements, I begrudge them nothing. The act has made such a debacle out of public policy.

Joe Levitt has ultimately done, I think, the right thing as director for Center for Foods in laying out all of the things that need to be done and recognizing that current resource levels maybe ten years from now will have some things accomplished. It was terribly complex.

From the standpoint of the Internet, it was a vast disappointment to me. I think the Internet and the compliance issues are totally overblown. My thesis is simply that the Internet is another advertising vehicle, and the issue is more complex only because it's harder to find the source of the product. Aside from that, let's go out and kick some butt. For three years, those folks did nothing with that policy, and now it got so bad that we're spending too much staff time running around working on the problem. Time will tell us whether I'm right or not. But when they . . . They've gotten into direct . . . If you have anything that smells or looks like it's compliance or enforcement, to that extent I don't think they've done very well with it. But I've not felt threatened by them largely.

RO: Is there still kind of a little competition between the centers and the ORA that there used to be? You used to be over in the center, and you know what debates there were about . . .

DM: There will always be tension by definition. When I was in Drugs, I tried to characterize it as healthy tension. The way I put it, Ron, was that while other people might view it differently, I always wanted the investigators in the field to push the compliance officers or the compliance branch in the field, in terms of what the boundaries are. We've never done it before, it's not in the book, that kind of thing.

Similarly, I wanted the compliance officers in the field to be challenging my compliance officers in headquarters, because we're always in a grave if we approve 100 percent of what comes through the system--we ain't doing the right thing. There ought to be some turndown note that we can live with and still be friends. If you . . . You know, it's the old send up a flyer, however you want to characterize the case, that says, "This one doesn't conform to the usual things," but let's talk about it. Usually the best way to do that is in a specific case context.

The problem, in my view, goes back to what we discussed earlier, the Compliance Policy Council.

(Interruption)

DM: Members do not have the same level of authority and accountability that they used to have, so that you can't cut the deal--I'm saying that but not in a pejorative way--get an agreement done with a peer center.

I used to go down, and I'd have a talk with Taylor Quinn or John Taylor or whoever, and we'd come to an agreement and get on with life. That's much, much harder to do these days. That's, frankly, what I'm hopeful that will happen if there's a change in administration, presumably the new commissioner, can bring that sense of agency back to us, and it will be reflected down the line. I think Jane can do it as well, but in the last year, with the lame duck administration, just survival is about the best you can hope for.

RO: Would you care to comment on the change in the structure in the field as far as doing away with a compliance office?

DM: In many ways we did the right thing in some of our reinventions. Device initiatives, for example, prenotification, annotated 483s, et cetera, were exactly the right things, and we've been told from a political side that ORA saved the agency from some very bad damage. And, ultimately again, it was common sense stuff. While it didn't fit the old paradigm, it certainly was consistent with the new one, and I think that's where I have to remember that my roots bear very little relationship to today's reality. Citing for warning, never talking to the industry then, and times have changed. That's just no longer acceptable. Now, how we do this in an honest and open and fair way.

The flip side of that was with a thousand flowers blooming, you're going to get a lot of weeds, and I think that's what ORA did. With all due respect, we started reinventing with no sense of what the standards were by which we judged success stories. In particular, having CSOs write their own warning letters by disestablishing compliance units and trying new ones could have, in some organized way, I think paid off. I'm not sure that that, in fact, is the case.

I'm worried about two things. One is the independence of the compliance officer as a check on the bias that I certainly would bring if I were an investigator. I'm trying to sell the case. I'm the first guy; I collected the evidence. That's like letting the beat cop go into court and prosecute the case. That's not how our system is set up.

The other one is harder to deal with, and that is, whether or not we would have restructured, the reality is we are taking many fewer litigated matters to court than we used to. That's the reality of our environment. The vast majority of our seizures now are uncontested. A lot of our injunctions are settled in advance and just simply filed.

Be that as it may, if you take the same number of compliance officers we used to have, take the numbers of actions we have today, you'd be lucky if you see a seizure every three years, let alone an injunction maybe in your career on average. Oh, we've got some smart folks, though. That started happening immediately.

I remember Gene Leger, who was one of my senior compliance officers in OE, came in and told me he got a call from a district. I won't embarrass them. The compliance officer had been on the job for a couple of years and had to do a seizure. He didn't have the foggiest notion how. He was smart enough to call for some help. Gene talked the person through on how you do the legal side, put him in contact with Foods for the technical side. We got the job done.

It may be that having compliance branches in district offices--particularly district offices--may not be the best use of personnel. The reality is as a resident inspector, I didn't see a compliance officer unless we went in for the annual meeting. So proximity is not the issue.

One of the things I begged the regional offices to consider was centralizing compliance function at the regional level, pulling compliance officers out of the districts, put them in there, because I would argue that because of the unique specialty, they need to be with each other. We discovered that with team Biologics, having one here, one there, one there. Compliance officers needed to be together, not necessarily with the investigators. So you need that kind of synergism to work.

The bottom line is we need to have those people . . . The question is, are we smart enough to put them in the right places and grow them so that they can handle cases, rather than just throwing them into the deep end of the pool every time.

RO: You mentioned seizures and injunctions, but I haven't heard you mention prosecutions. Aren't there any?

DM: Essentially none that my office would have traditionally handled. Vermillion, Office of Criminal Investigations, generates the vast majority of them. I can't think of the last year that one did not, of any that did not process through his office since his



office was created. There may have been two or three that he decided that he did not want to take, and we worked through the "old side."

The real question, Ron, is not the numbers, but are they the right ones? I have no idea. Because of the history--going back to generics--of how the rest of us could not be trusted, Vermillion's organization is an entity unto itself with its own decision processes that do not intersect, except in the extreme, with the rest of the organization. He decides what cases to take, what cases not to take; what cases to take and how to take them. So, for example, if I were sitting in the Center for Drugs, I would want to know that I have some influence over my PDMA cases versus how many counterfeiting cases or whatever that x is, I would want to be part of that. Nobody is engaged. I'm not even sure that if they wanted to be engaged, up until recently, they could have broken into the show.

I'm not blaming Terry. Again, I don't want to personalize any of this, but that's the way it is. He and I have had more barroom conversations by far than we've ever had in terms of on-the-job. He does his thing. I wound up being basically the civil side.

RO: Is that because of intent, proving intent to prosecute or . . . ?

DM: I would say it was certainly intent under Kessler. He had a direct pipeline to the commissioner. The issue was thrown in Chesemore's face more times than I ever would have taken had I been Chesemore. Chesemore endorsed that style of management. End of discussion.

So, you know, I didn't walk in Chesemore's shoes. I'm not about to criticize him either, but also we haven't talked about generics. Knowing the history that came with that, it's not at all surprising that we have this kind of outcome, because the whole institution was under suspicion, every one of us, every Jack man of us. Consequently,

how can you have the Criminal Investigations Unit which comes out of a corrupt organization. You have to start with something entirely different, you know, let alone expertise that . . . And I'll admit that Terry's folks do bring expertise, but they don't have the only expertise.

Do you want to talk about generics?

RO: Sure.

DM: Two of the worst years of my life. We talked about my blackboard for tamper-resistant packaging. They had a couch in my office. We called it the liar's couch. We used to have generic folks in. Whoever wound up sitting on that couch wound up lying through their teeth. It was unbelievable. We used to laugh at it after a while. Who's going to sit in it next time? It should have gotten donated to the Smithsonian.

First of all, for the record, I think that one of the many heroes, but probably the most unrecognized hero, of generics is Tony Lord. Tony worked in the Center for Drugs, Office of Compliance. His wife still works for the agency as an investigator, a compliance officer. She may have returned to Drugs. Be that as it may, Tony went on to do consulting several years ago.

We were into this mess with the belief that some of our people had been on the take, that the system was vulnerable because we only inspected about 5 percent of the NDAs—that was the old days. So we were under the gun to redesign the system on the fly, to do inspections of virtually all applications, and prevent it from ever happening in the future, and investigate all the wrongdoing as well.

So at one point, Ed Fry, who was the director of the Division of Manufacturing and Product Quality, one morning came to me and said, "I can't do it anymore. I can't run the division and deal with this generics thing." I said, "OK." I turned out to have done something that was wise in retrospect. I never thought it was wise, you know, you

just do things. I said, "You've got to head up the generic drugs enforcement staff. I'm going to pull you off, Paul Vogel will be your deputy, you name yourself a senior compliance officer, and I will give you whatever is necessary whenever you need it. Your deputy will take over the division indefinitely for the day-to-day operations."

We had as many as thirty-six people working on that staff at one time, either full time or part time. I just pulled people wherever I needed them. They'd drop off when we were finished. Then did not count anybody from outside the Office of Compliance. It turns out that I made marks by recognizing that we had a problem early on.

We wound up working twelve hours a day, six days a week for months over there working our way through this thing. As it turns out, Bolar's Diazide and Tony Lord were the starting point for shifting the attention away from us and onto the industry. Tony had been looking at some inspection records of Diazide which was a huge money maker for Bolar. Nobody else could seem to duplicate it. Tony couldn't believe that the product had been developed the way it should have been.

One Saturday, mid-morning, a lot of us were in on a beautiful summery day, as I recall. Vogel says, "We've got to brief you. Do you have time?" I said, "Well, where am I going?"

Well, he and Fry and Tony and maybe one other person came in and wallpapered my office with flip chart pages showing how Bolar could not have gotten their approval on the biobatch that they claimed. I said, "Crap. If that's true, they lied to us. If they lied to us, who else is lying to us?" I mean, this was the flagship of the industry.

So I called up Carl Peck and Jim Benson, who was the acting commissioner at the moment because Frank Young was out of town. At 1:00 that afternoon, they're both in my office, on Saturday afternoon. Carl had been mowing the lawn, and he's got shorts on, he's got grass on his legs, he's all hot and sweaty. We do the same dog and pony show for them, and their eyes started to bug out.

So we called the Bolar folks, and Bob Schulman listened to us, "Oh, gee, I didn't know you needed that." The linchpin was a missing encapsulation record. "Well, we'll find it for you." So they went back, and we subsequently discovered they graphited the thing and sent it into us.

Tony was the guy who found the loose thread and started to pull on that one. Ultimately, every one of the hundred and fifty-six ANDAs (Abbreviated New Drug Applications) that Bolar had submitted to us was found to be faulty, either by direct inspection on our part or through criminal investigation through the Grand Jury on the others.

I got beat up by John Dingell more times than I can count. We had biweekly conference calls, if not visits, with the lead investigators for the committee going over every case that we had open. He had on-line real time information through multiple sources, so there was no possible way to sandbag him, had we cared to. It was just terribly irksome to have to deal, to tell this individual every step of the way where we were on particular firms, to be second guessed by somebody who didn't really know the business and to feel as helpless as we were.

Two other stories. One was Bob Eccelsten, who was another hero, who was working as assistant to Jim Benson at the time. One of the finest writers under pressure I have ever seen in my life. He could have six people, including me, yelling in the room about what should go on the piece of paper, and he's calmly sitting there writing it out. By the time he's done, you've got a perfect piece of work. He was a marvelous, marvelous individual.

Where was I?

RT: Eccelsten.

DM: Eccelsten arranged to have a friendly hearing. He said you guys have been beat up enough. It's time you got some credit for what you're doing. I don't want any credit. I don't want to go out anyplace. Well, it turns out that it was in the best interest of everybody, and Dingell wanted to beat up on the industry for a change.

So yours truly and Paul Vogel are the prime and sole witnesses for the agency--no attorneys, no nothing. We're the first panel, and then after that, some industry people will get their turn, and not get the snot beat out of them. Now, we're promised this is going to be a friendly hearing. I can't imagine.

Believe it or not, they sent us the questions in advance. We edited the questions to make them better, sent them back, along with the answers. Everybody had a script. It was like Hollywood.

So we get up there and Dingell extols the virtues of Michels and his great and wonderful staff, what a terrific job FDA is doing. You ought to take a look at the transcript of this thing. Make you a little bilious. Then I come back, thank the good Chairman for all the support that he's given me in the agency, yada-yada-yada. And Vogel is there as the technical expert, and he was truly a champion, another unsung hero. He had a mind for detail that was unbelievable. There were going to be twenty-one firms discussed. He had twenty-one manila folders on a stack at the witness table. He never referred to them. He said, "This firm makes these kinds of products, screwed up in these ways, this is where we are, ta-da-ta-da-ta-da." Just took them . . . He was like a machine. It was unbelievable.

What was funny though is that Dingell was in such a magnanimous mood after the opening statement that he handed the questioning off to one of the minority members right from the beginning. Well, the minority member's question was in the middle of the book. So he asked the question, and I'm going through the book trying to find my answer for it, and I'm fumbling and doing the tap dance trying to give him some answer off the top of my head, and he's getting irritated because I'm not giving him word-for-

word what's in the book. But we finally got on the same page and got it choreographed.

Three months later, Chesemore, (Ray) Mlecko, and I, and a number of other people, are back up in front of Dingell getting beat up for being soft on crime. So, you know . . . It only lasts for a while. That was one of the very low points--speaking of Mlecko--was when they accidentally trashed some of the inspectional records on one of their generic firms. He and a number of his staff had to take lie detector tests to prove to the rest of the world--specifically the Congress--that they were not covering up something. I feel so sorry for those people, so sorry.

Then the last one was Bob Schulman's sentencing. Bob was the co-founder of Bolar: Bob, B-O, and the L-A-R, Larry was the other guy. Larry must have been smart as a whip because he never even got anything pinned on him, but he was money guy rather than having anything to do with business.

First of all, Bob turned state's evidence, once we got our hooks into him, telling how he had influenced other people to lie to us, that his R&D (research and development) chief had lied to us, turned witness against him. Unfortunately, I can't remember which way, the R&D chief's daughter was married to Bob's son or vice versa. You can imagine the God-awful things that were happening in that family. We could spend probably another hour talking about generics, but let me finish this story about Bob.

After he had lied to me this time, I suddenly recognized I'd had him in four years before and he had lied to me on another subject, but he got off the hook because he was a very plausible liar--at least I didn't recognize that I was being lied to that time. The one sentencing, of all of the fifty or so folks in generics that were ultimately prosecuted, that I went to was Bob's up in Baltimore. Of course, a number of us showed up for the event. It was a fairly *pro forma* kind of thing.

One of the interesting points was there was an IRS attorney that was providing testimony about Bob's support to the IRS on some tax evasion stuff, so that should reduce his sentence.

Well, at this point, the judge had been through so much of this that he had already done his formulation about what Bob's sentence was supposed to be. In any case, Bob did his pleading to the court, the judge gives him, as I recall, five and a half years hard time. I don't remember exactly, but he was going to spend some time in the slammer; a million dollar fine, this, that, and the other thing. But he was on his own recognizance until he reported for incarceration in about three weeks. The gavel comes down, and we all stand up, and we're feeling very pleased.

A woman in black stood up from the audience and said, "Judge, can I speak with you?" Since court was no longer in session, the judge says, "Sure, come on up." Tony Lord's wife, Anna Irizarri, was there being a good investigator, and she sort of moves over in the courtroom so she's within earshot. None of the rest of us were really paying that much attention.

Anna came back to report that it was Bob's sister who told the judge, "You better throw him in jail now; he's going to skip. We've been waiting twenty years for him to get his." His own sister was advising the judge that her brother was a rat. He didn't skip, but that sort of gives you a sense of some of the folks that we were dealing with at that time.

Life went on, and generics settled down. We got some new legislation. Then Sammy Young retired. Then I thought, now it's about time that I started making some changes, do some restructuring and that sort of thing, and that was next line after hiring myself a deputy.

Then when Shumate had left, Gary Dykstra had asked me to consider an OE job, and I said, "Do you think I'm crazy? That's nothing but a headache. In fact, I'm happy where I am."

So a few months later they asked me again, and at this point, I said, "Well, maybe it's time to give somebody else a shot in Drugs." I'd been there for ten years in that position. So I came over to OE, and I had a blast.

The way I characterize the difference between the two jobs, when I was in Drugs, when something came through the door, I had to deal with it immediately. In other words, if it's a recall, it's a class what? Do we need to tell the boss? Do we need to tell the press? Do I need another sample? Do we need to check the method? There was something, you know, of great instantaneous whatever. In enforcement, by the time it got to me, it was so screwed up that I didn't have to make any instant decisions. You know, percolate on it for a while, staff it out for a couple days, have a little sort-out of what needs to be done. It still had its own stresses, but I got to worry about a lot of other things besides Drugs.

My first ad hoc meeting was on a device. I didn't know device law from nothing. They had changed the law since I had come in from the field. I'd never had to learn it; I was on the drug side. All I knew was you stuck this thing at people, and when you took it out, it left radioactive parts behind. That was not good. So we worked our way through the meeting, with a lot of help from a lot of other people I learned a few things and made life go on.

But that was ultimately really the fun part of the whole thing, as you guys well know, was just all of a sudden something was going to pop up that you had never experienced before in your life to add some satisfaction and goosing a little and shaping a little bit and having a piece of the action.

RO: Why did you decide to leave that good job?

DM: A friend of mine is probably the world's greatest fan of Moses—a long story. A short question, a long answer.



Moses had three careers, forty years each. The first forty years he was Prince of Egypt; the next forty years he herded sheep; and the last forty years, an eighty-year-old man, he gets this job, and he's got to herd the children of Israel out of Egypt into the Promised Land. Not only that, he never even made it there himself.

So I spent thirty-seven years, add my sick leave on to it or however you want to characterize that. Maybe it's time to start a new career. No one reason. Ultimately, I lost the energy to fight. Like, I've seen the problem before; I lost the last time; I don't have the energy to lose again. Forty-seven different reasons, none of which . . . I'm not mad at anybody. Also from a transitional standpoint, saying maybe now is the right time for somebody else. The standard line is five years and move on. Well, maybe this was the five-year rule as well.

Also an interest in . . . Well, the family environment has changed. The kids get out, you know, and a chance to do something else without the traditional need for security that's driven me a lot in terms of staying is that one of the things I liked was the security. So now I can take some chances.

Also my fantasy is to become a disc jockey, and I can't be on the radio at 3:00 in the morning and come to work at 8:00.

I've taken a course in audio production for radio. The problem is I'm a jazz fan, and that's a very narrow niche population. But I will have time to go down and volunteer in some of the public stations, and we'll see what happens.

RT: Well, we'll know who it is if we hear you.

RO: Well, Dan, we sure thank you for this.

DM: Thank you for caring, because my stories I think are . . . I feel good about them, I think they're important, along with all the other stories. As our pastor characterizes, everybody has a story that needs to be captured.

RT: Now you've shed some light on one or two persons at least for me were different and maybe for the researchers as well.

(Interruption)