History

of the

U. S. Food and Drug Administration

Interviewee: Gerald L. Barkdoll, Ph.D.

Interviewer: Robert A. Tucker

Date: September 30, 1998

Place: Rockville, MD

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Gerald (Jake) Barkdoll

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INTRODUCTION

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

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Adm.

Date: September 30, 1998 Place: The Parklawn Bldg., Rockville, MD 20857

Interviewee(s): Gerald Barkdoll

Address: [redacted]

Last FDA Position: Associate Commissioner for Planning and Evaluation

FDA Service Dates: March 1971 - April 1994

Interviewer(s): Robert A. Tucker
FDA

Number of Tapes: Two Length: 80 Minutes

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Attachment: Gerald Barkdoll's Curriculum Vitae

RT: This is another in the series of interviews in the FDA Oral History Program. Today the interview is with Dr. Gerald "Jake" Barkdoll, former associate commissioner for Planning and Evaluation of the Food and Drug Administration. The date is September 30, 1998, and the interview is taking place in the Parklawn Building in Rockville, Maryland. Present with Mr. Barkdoll is Robert A. Tucker. The transcript of this interview will be placed in the National Library of Medicine and will become a part of FDA's Oral History Program.

Jake--the name we'll use in the interview--we like to start the interviews with a brief autobiography. So if you could begin with a brief resume of your early years, where you were born, raised, educated, and relate the work experiences you had prior to coming to FDA.

GB: I was born on a farm in Pennsylvania, between Quincy and Mont Alto, which is about seventy miles north of Washington. I was born in 1934. The farm was my grandfather's until my father took it over. My father had three sons. Much to his chagrin, none of us chose to stay on the farm. I went to a one-room schoolhouse, and then a two-room schoolhouse, and then finally to a small rural high school that doesn't exist anymore. We had thirty-six students in the graduating class. By dumb luck, I learned about a college in Philadelphia that would allow you to work your way through--it was Drexel Institute at that time, the name was later changed to Drexel University--and I decided to get an engineering degree there. I was supposed to become a mechanical engineer so I could design better farm equipment, because ours was always breaking down. My father was always irritated at the breakdowns, so he thought he ought to get an engineer in the family to solve that problem.

During the course of my study at Drexel I switched to civil engineering, because I decided I wanted to be outdoors. It was the usual case of an eighteen year old making career decisions with little or no real knowledge.

RT: Sure.

GB: I finished my civil engineering degree and since I was in ROTC and had two years to serve in the Army I chose a tour of duty in Germany versus. Korea. I got free transportation

to Germany and lived there for two years. It was my first experience traveling out of the United States and I enjoyed it. In fact I seriously considered working overseas later in my career. Drexel was a cooperative school which meant that I had worked two years in co-op assignments by the time I graduated. When I returned from Germany I went to work for Mobil Oil one of the companies I had worked for during college. While working for Mobil I went to graduate school four nights a week and earned an MBA from Drexel.

By then I was a twenty-nine year old and had a burning desire to have my own business and be my own boss. I bought a franchise from Snelling & Snelling to open an employment agency in Warren, Ohio. Setting up the office and getting it started was great fun, but I discovered I was very bored running it on a day to day basis. It was a great learning experience but after a few months I sold it and moved on.

RT: Jake, as we cover your background, what were the years of your graduation from Drexel and from the . . .

GB: I started Drexel in '52 and graduated in '57. It was a five-year program because of the co-op requirement to work half time. By the time I returned to Mobil Oil Company and earned my MBA it was 1963. That was also the year I set out to try my hand at running my own business.

Although I didn't run the employment agency in Warren, Ohio very long I've used some of the skill I learned there throughout my career at FDA. To successfully run an employment agency you have to learn to match people to the jobs that are right for them, you learn how to interview people, and you learn how to sell your services. I'm a fairly strong introvert, so some of those things were hard work for me, but the skills I learned setting up and running a business were invaluable later on in FDA.

RT: We had an interruption a moment ago, and perhaps you mentioned Snelling & Snelling. What kind of an enterprise was that?

GB: It's an employment agency. They franchised offices in cities all across the country.

When I worked at Mobil Oil Company I had done industrial engineering types of projects, warehouse consolidation, distribution systems, and that sort of thing. When I left my business in Warren, Ohio, I went to work for Firestone Tire and Rubber Company in Akron, Ohio. At that time, Akron was said to be the only city in the country that would be happy for New York air. That was because the tire plants in Akron produce so much bad smelling pollution.

I decided I wanted to continue my education and get a doctorate degree. I believe I had become addicted to education. I enjoyed it. There were no opportunities to get a doctorate in Akron so I went to work for Union Carbide in New York started a doctoral program in Business Administration at New York University. I remember discovering there were some very, very smart people in the doctoral program at NYU. It was a good experience. Union Carbide asked me to move to New Jersey and to help turn around an unprofitable part of the business. By developing relevant new data then getting the right people in the room once a month to discuss it, we were actually able to turn around Union Carbide's vinyl business from an unprofitable to a profitable business. I didn't realize it at the time, but I was learning to be a management consultant. I was never called that, but I was asked to go to a variety of places and do a variety of things to help improve management processes and decision making,

I was then asked to go to Chicago to solve another problem. Union Carbide had unfortunately bought the Englander Company, a furniture and mattress manufacturing company. It was not a wise decision and they were having great troubles with it. I was asked to the company first in a planning role, and then later I became the controller and chief financial officer. That was a terrific learning experience, too.

At some point, I decided I really did want to try my hand at consulting, and I joined an organization named On-line Decisions. It was a brand new start-up, high-tech kind of consulting firm that built mathematical models of corporate finances. The dates of my time at On-Line are in my resume so you can add them later if you like.

RT: OK.

GB: What's interesting about On-line Decisions from the perspective of current technology is how far their idea has spread. Everyone who has a computer sitting on their desk and has Excel, Lotus or one of the others with the ability to do spreadsheets and build models. In 1970-71, we were the only people in the country who had that capability although the calcualtions were all done on a big computer out on the West Coast that you contacted with a terminal on your desk. As far as I know, that was the first. I'm not a computer, but by then I had been a corporate controller and knew the financial aspects of what we were doing. We were the only ones around who had the capability. It was just amazing. We could go into almost any company and say, "Look here. You can run 'what if' questions (What if we change our price? What if we decrease costs? What if we change something else?)" and see the financial implications of it. I remember demonstrating that capability to corporate executives and them being amazed at it. The system On-Line had was a precursor to what is now available on millions of desks. It wasn't called a spreadsheet at that point, but that is what it was.

I was very upward oriented, and pushing hard, and making good money for my age, and probably could have continued on up the corporate ladder. One of my bosses told me, "Hey, I could get you to go anywhere and do anything if I just told you it was a promotion." Fortunately I developed a nagging social conscience. I said, "There's something missing here." Although I didn't know much about it, I thought maybe that if I worked in the public sector for a government agency that might satisfy this unmet need. I could have possibly satisfied my social conscious by teaching but fate intervened.

I saw an opening for a budgeting job in HHS (Health & Human Services), and I applied for it. I received a very nice letter back from the HHS head-hunters. In a very nice way it said "thank you very much for your resume....it doesn't quite fit what we want, but we'll keep it on file." I had written a lot of those kind of letters myself, so I wasn't quite sure if I could take it literally. I called the HHS head-hunter and said, "Look, I'm serious about

working for the government. I think I can make a contribution." He said, "Hey, I wasn't kidding. You really do have good credentials. You've got a good history. You've got a good education. We will be looking."

I had described what we were doing with corporations as building computer-based planning systems that they could use to plan their finances. They could explore what if questions: What if interest rates change? What if sales increase? What if . . . ? It was less than two weeks later that Sherwin Gardner called me. He said "I have your resume and I see you have some planning experience. We need to rebuild, redesign, basically replace the current planning process in FDA. Would you have any interest?" And I said, "Sure."

So I payed my own airfare in from Chicago for the interview, and later, after Sherwin hired me I payed my own moving expenses. You know, I had to pay to get the job but it turned out to be a great investment.

RT: That's right. You do have to pay your moving costs when you first come in.

GB: And I took a pay cut, but it was the best decision I ever made, personally and careerwise. So I was brought into the agency to replace the planning process. This was the beginning of the end or perhaps midway through the end of the old PPBS System (Program Planning and Budgeting System). When I got to FDA I had piles and piles of computer printout. The level of detail was just staggering. We used to joke that the only thing we could use the printout for was to prop doors open, because no one ever read it.

So I came in as Sherwin's deputy, and I also ran the planning staff....double duty. The idea was to redesign the FDA planning process. Basically start from scratch. One thing that became very clear to me early on was that I actually had a lot more freedom to try things, to do different things, to invent new things here in FDA than I ever had in industry. People think of the government as being bureaucratic and tied up in red tape, but I really never experienced that in designing new management processes. That doesn't mean that I could do anything I wanted to, but it meant that I could be very creative. I had more degrees of freedom.

RT: Now, at that juncture you were a deputy to Sherwin. What was your title then? Were you an associate commissioner at that time?

GB: I think Sherwin was called an assistant commissioner. That was back when the agency had assistant and associate commissioners. Sherwin was the assistant commissioner for Planning and Evaluation. Charlie Edwards had brought Sherwin in from Booze Allen. As a matter of fact, most people thought that I came from Booz Allen, too, because I had come from a consulting firm, and apparently that was the only one they knew. They figured everybody who had been a consultant came from Booz Allen. I was called deputy assistant commissioner for Planning and Evaluation. I never had a title that long in industry. In industry you were a vice president, or you were a controller, or you were something. I remember being amused by the long title, but I quickly got accustomed to long titles.

When we started to think about designing a new planning process, we knew from the very beginning that it had to connect to the budgeting process or it wasn't going to be viable. Fortunately, Mickey Moure was here. Mickey could have stonewalled the process and not let planning and budgeting work together. I think some of the things I had learned in industry, some of the things I had learned in the employment agency, and some of the things I had learned in consulting helped me work out a good relationship with Mickey. Sherwin had a good relationship with Mickey too so we were able to get the job done.

Over the next fifteen, or twenty years the planning process and the budgeting process were always connected. We described it as handing off a baton mid-way through the planning-budgeting process. The planning and budgeting staffs published joint schedules, and we involved each other all the way through. I now know from talking to lots of people in the classes I taught at USC (University of Southern California) and in the consulting I've done, that planning and budgeting staffs working together is a pretty rare event--a rare partnership. It was special in that way.

RT: Now at that time Mickey Moure apparently had quite a bit to do about the organization. What title did he carry at that time? Do you recall?

GB: I believe his title was associate commissioner for Management and Operations. He might have been an assistant commissioner, I'm not sure. At some point, it was probably five years after I came to FDA, all the "assistant commissioners" were retitled as "associate commissioners."

It took me a little time to get comfortable in FDA but I figured out I could make a contribution. We had a real opportunity to improve the planning process, and in the beginning planning was the only thing I was basically focusing on.

One of the things I recognized quickly was that there were some very talented employees in the Planning and Evaluation shop. We had some good operations research analysts; some good mathematicians; and some other analytical types, many of whom had been previously out in the consulting world. The organization had attracted some of the analysts who were moving out of the Department of Defense because it was downsizing. These folks had analytical skills that we could put to work. So I was impressed by the folks here. I was just like many new managers when they come to work for the government...I wondered what are the people going to be like? It didn't take me very long to figure out that at least in FDA, these are good folks--they're smart, they're dedicated, they work hard, and they know a lot. It was a good feeling when I recognized that.

Then it happened. I can remember it as clear as if it happened yesterday. I got a phone call at home one night from Sherwin Gardner. He said . . . I'm blocking on the deputy's name. It was Charlie Edwards' deputy.

RT: Was that Jim Grant?

GB: Yes. Thank you. He said, "Jim Grant is leaving." And I said, "Oh, shit. That's bad news," because Jim was a terrific manager. He was information oriented, he had a good

touch, and he was smart. I can remember going in front of him with studies we had done. You had to know what you were talking about. He was quick. So from my perspective he was a terrific deputy, and I didn't want him to leave FDA. Then I asked, "Oh, who's taking *his* job?" And Sherwin said, "I am." And I said, "That's terrific, because I had a very high regard for Sherwin." So in that instance I went from feeling very badly to feeling very good. Then I said, "Wait a minute. Who's taking your job?" He said, "You are." I said, "Oh, shit," because I hadn't been in FDA very long, and I really didn't know if I was up to that job. Sherwin had done it very well and had set a very high standard. That part of the phone call was very frightening. But I took the job.

Prior to being asked to take the Planning and Evaluation job, Charlie Edwards and Sherwin had asked me if I wanted to be, and I don't remember the exact title, but it was the equivalent of the assistant commissioner for Legislative Affairs. I said, "Look, I like the FDA. I'll do whatever you need me to do, but I don't think legislative affairs is my strength." I hadn't run into a thing called Meyer Briggs type indicator by then, so I couldn't say to them, "Look, I'm an INTJ. Legislative affairs probably takes an extrovert, and it probably takes someone who's good at lots of details, and lots of names." But intuitively, I knew that would not have been a good job for me. So they were smart enough to figure out that wasn't my job, and so they kept me as Sherwin's deputy until the phone call when Jim Grant left and I got that Planning and Evaluation job.

RT: Do you recall who was in legislation, or who came into that position eventually?

GB: It may have been Gerry Meyer.

RT: It probably was.

GB: Yes. The cast of characters has changed so much. I have a collectible at home I should bring to you, because it is a picture of the first Policy Board and . . .

RT: That would be good. The History Office would like that.

GB: Well; there are two versions of the policy board picture. One is a funny version where everybody is saying something. There are balloons over every head just like the comics. The other version of the policy board picture has stickers over the faces of the people who left. I think I've been carrying that around from Maryland to New Mexico and back. If I can find it I'll get that into you.

RT: Now the Policy Board was actually initiated . . .

GB: . . . much later, by Mac Schmidt. Yes, that's another part of this story. I remember my very first--it wasn't a "go-away," but it was a policy board session where we were going to identify and resolve important issues. It was the key people in the agency. They weren't yet called the Policy Board. We were going to spend a number of hours in a room trying to sort out the key agency issues. It was the beginning of a process. The planning process almost always started with a meeting like that. This was the first attempt, and it failed. I figured out in a hurry why it failed.

We made a matrix. Across one side was Drugs, Foods, all of the program areas, and across the other would be Legislation, Regulation, Administration, Science, and other functions. That created a lot of boxes in the matrix. We looked for issues in the matrix. I don't remember how many issues we had. It might have been twenty or thirty issues. So we assembled this group in a room to address twenty or thirty issues. And without much preparation. These top management of the agency started to work on these issues. Well, I think by noon we had gotten halfway through the first issue, because everybody had a speech to make, and everybody had a strong opinion and some of the participants were verbose and aggressive.

That was a wonderful learning experience. After that we always did a lot of preparation and boiled down the issues to two or three that everybody was dedicated to.

Before the go-away we gave them opportunities to express their opinions. We tried to make progress on issues before we got in a room together. That meant when you went to a go-away you could focus on the important topics. It sometimes surprised me that we could make a mistake in the design of a planning process one year but everyone was willing to participate the next year.

RT: Let's see, the first go-away, what was the year of that? Do you recall?

GB: No. I would guess it was somewhere around 1974-75.

For some reason we coined the word *go-away*, and it always . . . It got so established that when we stayed here we called it a "stay-at-home go-away."

About that same time I had started into a doctoral program at the University of Southern California (USC). The whole program was taught in Washington at the USC Washington Public Affairs Center. The center is still there. The doctoral program was very adult-oriented. The faculty have a very high respect for the knowledge and experience students bring to the class. For that reason, they would attract some SESers, GS fifteens, and GS fourteens--folks in very responsible positions. Many of the things I learned at USC, either learned from other students or learned from the readings and the faculty, were brought right back to the FDA and put to work. A lot of the things I learned had to do with integrating organizational development, behavioral sort of stuff, into the analytical stuff. These two approaches were combined in the planning process. So many of the go-aways focused on team building, communications, and other topics I had just picked up at school. FDA helped pay for my education, but they got an immediate return on their investment.

The classes at USC are conducted as intensive learning experiences. For each class you do four or five weeks of preparation, and then you attend class for four solid days--Thursday, Friday, Saturday and Sunday. Then you do some additional work back home and then come back to school for another Thursday, Friday, Saturday and Sunday session. For each class you have eight solid days together. It allows you to really get your head into the

topic and keep it there. It isn't like evening classes because you aren't tired after a day of work. I had been in a doctoral program at GW a few years earlier and concluded that I didn't like the way they taught. I thought they were teaching me to do the job I was already in, and I thought they were teaching me to do it wrong. I dropped that doctoral program, but the USC experience was terrific.

By the time I started the doctoral program at USC we had established a planning process in FDA that was very participatory. One of the things we found out was that there was a normal conflict between the line and staff managers. When the line organizations would come to make presentations to the commissioner about their priorities and their need for more resources, the staff people, the associate commissioners, would ambush them.

RT: Now was this still during the tenure of Dr. Edwards?

GB: No. This was I would say at the end of that or . . . Who came next? Schmidt?

RT: I think so, as I recall.

GB: Yes, I won't necessarily get my commissioner's in the correct order. . . I went through seven of them, so I won't necessarily get them in the right order.

RT: Sure.

GB: To be honest, I don't remember when we came up with this process. When we discovered that the associate commissioners were ambushing the line managers during the planning process we said, "Look, we have to do some preparation for these meetings...we have to exchange some information" So we sent out an internal questionnaire that asked the associate commissioner "What do you think the agency's priorities ought to be?" And we asked them to identify themselves. We didn't always ask them to identify priorities by

program. Sometimes we would ask them to give their view of priorities by regulatory vs. scientific vs. consumer education vs. other functions. We could use the process to cut it different ways. Or we could list all the programs in the agency and ask for their priorities.

One of the management initiatives that came along at that time was the PMS system (Program Management System). Sherwin said, "We need to build a taxonomy of all the things the agency does." I thought it was a dumb idea, and I was absolutely wrong, because it was a terrific idea. Developing PMS took a while. There were big fights to decide what's a program and what's a project and how to group activities. But we said from the very beginning, "This isn't cast in stone. Every year we will challenge the list of projects and programs. Every year we'll look at it. The agency changes. Maybe we got it wrong the first time. The idea is to have a structure that best describes what the agency is doing right now."

In the beginning PMS was used just for planning processes and activities, but later it became the basis for evaluation, it became the basis for budgeting, it became the basis for communication. So it went on for a long time as the fundamental way we talked about the agency. . . Other agencies and organizations wanted to hear about this structure. I remember going around to agencies and conferences making presentations about PMS. One of the articles listed in my resume is the description of that PMS system and the planning process that it supported.

Once we had the PMS structure and we had the associate commissioners publicly staking out their priorities and committing themselves before the line folks had to stand up and describe or defend their priorities, the system worked well. Then fairly early in the seventies the consumer groups became very active and basically said, "Look, you guys at the FDA make up your mind about what you want to do, and then you put it in the *Federal Register* looking for comments. The fact is it doesn't do any good because you've already made up your mind. We want to be involved early on. We want to be involved before you make up your mind."

RT: Now, I might ask you at this juncture . . .

(Interruption)

RT: Just before the side of the tape ended I was asking, Jake, how your planning operations related, if they did, with those of Alexander Grant.

GB: Right. Well, what happened when the consumer groups came in and insisted on being involved early on, we asked ourselves, "How are we going to do this?" But we looked around and said, "Look, we have this voting process in place that gets early input from the associate commissioners. Why don't we just expand that process to include consumer groups? Why don't we ask them for their priorities?" We had this type of questionnaire; it was a way to vote, like a ballot, and why don't we ask consumers to vote. I can remember there was a lot of nervousness in the agency about asking the consumers to give us input. Agency managers said, "Well, what if they tell us lots of stuff we don't want to hear, or what if their opinions are different than ours? We're going to be stuck with information we wish we didn't have." But we did it.

That made us think very hard about how we make decisions here in the agency in terms of our priorities. We developed a scheme that we used to elicit input from consumers. We asked them to rank all of the agency's programs on the basis of three criteria. The first one was, Where is the real risk? Some things have high risk; some have low risk.

RT: Now Jake, just for the record here, this new initiative began about when?

GB: In the Mid-seventies.

So the first criterion was risk--what's the real risk associated with this program?

The second criterion was, will additional resources do any good? There were some problems that the agency has been given responsibility for, that could not be solved by additional resources; either the technology wasn't available or it was too big an issue. We could throw all the resources of the agency at some problems and not solve them.

And the third one was sensitivity. We didn't know how to say that at first, but it was the sensitivity of the program: If children are involved, if handicapped people are involved, if folks who can't look out for themselves are involved, never mind what the real risk is, you have to multiply it by some factor because it's a sensitive issue.

So those were the three criteria. We had previously asked the associate commissioners to rank each of the agency's program on those criteria. Now we asked the consumer groups to do the same thing. And it worked out . . . That's where Alex got involved, because he was the contact with the consumer groups. His shop did a lot of work, and our shop did a lot of work. Alex would sign the sign the letters that went out to all the consumer groups, because they knew him, and it would have our questionnaire attached to it. When the questionnaires were returned we put the data in the computer and analyzed it.

Either through dumb luck or good planning--I can't say good planning, because we didn't figure this out in advance—we discovered this process was a great educational tool for consumers. Most of the consumer groups had a particular interest, they had one program or project or issue or problem that they were oriented on, and they just didn't realize all the other things that the agency had to do. When they saw the total list of our responsibilities... I can remember them saying, "You have to do all these things?". It was very educational. They found out that setting priorities wasn't such an easy thing. They also found out that they didn't agree among themselves as to which program was the most important. So it wasn't any longer the consumers against the agency, it was, "Gee, we're all in this together and it's a complicated kind of thing."

RT: In an interview with Alex Grant earlier, it was my understanding that he really was brought on board to cope with this consumer . . .

GB: Uprising.

RT: Uprising is a better way to put it.

GB: Well, in a way it was. The consumers became very strong and very vocal. They are voters, so you know, there is a lot of clout there. The priority setting process was one of the mechanisms we used to involve them . . . Alex did a lot of things, but this was one mechanism that gave us a chance to really reach out in a very legitimate way to all consumer groups. They realized they were doing something tangible.

RT: Now I guess that outreach initiative also included the cooperative officials at the state and local levels of government.

GB: Yes, that's what came along later, because the state folks said, "Hey, why are you only listening to consumers?" I don't know how they learned about the consumer involvement...we may have asked them, "Do you want to get involved?" or they may have heard about it and wanted to be part of the process. I don't know. I do know we ended up with state officials; trade associations; professional health care organizations, and others. We had four or five fairly large groups, and we were getting literally thousands of ballots back.

RT: Did this input help, in your view, with congressional oversight hearings that probed what the agency was doing?

GB: I don't know if it helped with congress, but we certainly had a lot more confidence. We knew that we were not going to get blind-sided by any of the groups, because we knew where people were coming from and they had had a chance to vent to us or to express their opinions to us. So to the extent it helped in legislative hearings I would say it helped that way. One of our dilemmas was that here we were sending out something that looked like a questionnaire or a ballot; we were collecting literally thousands of votes; but we had never gone through the OMB approval process for a survey. OMB may not have approved it had we asked.

RT: Probably not.

GB: And yet, these people–consumers, trade associations, professional organizations and state officials–were happy to do it. They wanted to do it. Even when we reached the point where we could accurately predict what they were going to say, we continued to do it because of the involvement. They didn't want to be cut out and they told us that. The nature of the process changed.

RT: It's a good public relations thing.

GB: It was good PR, yes. And it was a good opening up of the agency–it really was–and it took off some of the fear of hearing from our stakeholders. I mean, the agency was a lot more closed to input early in the seventies than it was by the time we got through. The article I wrote, because other agencies were getting interested in this, was called, "Involving Constituents in Agency Priority Setting: A Case Study." And it was published in *Evaluation and Program Planning*, and that wasn't written, actually, until 1983. That was after we had had probably four or five years of lots of participation. If you're interested, that article includes details like the date the process started. It shows the increasing number of participants as we went along. The article is included in the list of publications in the resume I gave you.

RT: OK, in the attachment. That's fine.

GB: Yes, it's on page 4; it's the second one down.

RT: OK.

GB: So that was creative, state-of-the-art stuff. What's interesting now is that Congress has just passed a law that requires the agency to get input from outside individuals and organizations. We were doing that a long time ago and doing it very well. The agency is doing it differently now because we're having hearings all around the country, but it's interesting to see this idea come around again.

RT: Well, in government, over passage of time, it seems many concepts or ideas recycle, don't they? With some modification usually, I guess.

GB: Right. Let me mention one more thing about planning, and then I want to talk about evaluation a little bit, because it was a real challenge. It took us a while to figure this out, but we finally decided that the way planning can make the best contribution to the agency is to think of it like a funnel. You start at the big end and say, "As we start into each planning cycle, let's step back and get the broadest view we can. Let's find out what's on people's minds... what are the issues?" Some of the most thoughtful work we had to do was clearly articulating the issues. After we identified the issues we sent them to policy board members in a secret, very secret, closely held, hand-carried set of questions. We asked them two questions "Where are you on this issue? Is it an important issue–should we discuss it?"

I remember one of the issues. It was "what kind of agency is this? Is this a public health agency, is this a consumer protection agency, or is this a regulatory agency? We were having big debates about specific issues that were caused by the fact that different people saw the role of the agency differently. We were being pushed and pulled by different people. As Alex Grant or other associate commissioners would come on board, or as we would take over Biologics or Rad Health from other departments with really other cultures, the balance of opinion would change. So John Villforth would argue one way, and the Biologics folks would argue another way. Biologics came from NIH so they had a different mind set. So those kind of basic issues we addressed at the beginning of the planning process. I remember that was one topic that surfaced, and we had a whole go-away on it.

I remember saying to the policy board members, "Look, we all know we are some of each of those three things, but it's the balance that counts and which of the three you believe is most important." So I asked each person to indicate their first, second and third preferences. Of course, Paul Hile would say FDA is primarily a regulatory agency. John Villforth would say, "We're a public health agency." So I had all of them pick their first choice; then I got them to pick their second choice, and finally I asked them to pick the one they thought was the least important role of the agency.

Then I said, "OK, this is a test. We're going to see if we've been listening to each other or whether we're just closed-minded." We took all those folks whose third choice was regulatory agency and we put them in a group. That's their third choice, their least preferred. Then we said, "If we really were a regulatory agency, how would we behave; what would it be like; why would we want to be that way?" This was a small group exercise, and each group knew they were going to have to face the true believers. They went off in a small group and thought about that and tried to figured out how they were going to explain to people who really believed that was our primary role. It turned out that people had been listening to each other. They could explain the other person's perspective quite well.

That was a good experience. It was kind of a team-building experience for the whole group, because then people weren't saying, "Well, they can't hear me, or they won't hear me, or they don't understand." They said, "They have been listening. It's just an honest difference of opinion, and that's different than ignoring me or saying I'm wrong." I remember that as one of the go-aways that was particularly productive and exciting.

The go-aways over the years changed a lot. We tried all different kind of forms. A lot of them were overnight, because the social aspect was as important as the business aspect of it. We sometimes would include deputies and sometimes not, depending on where we were and what was happening.

Sometimes it was just a catharsis. When Reagan was elected and there was all the rhetoric about doing away with regulatory agencies, we had a go-away--it was down at NIH. There were people in that room who weren't going to be around in two months or three

months, because they were political appointees and the world was changing. We discovered that almost everybody in that room was worried about the agency's future: Was it going to survive? Was it going to get cut in half? What was going to happen? So that go-away turned out to be a catharsis in that people went back to the roots and the foundations of why FDA existed, and what we were doing, and where our support was. We came out saying, "Sure, it's going to be hard times, but we'll survive. We perform an important role, and we'll be here . . ." They didn't say . . .

RT: After Reagan.

GB: They didn't say, "We'll be here after Reagan," but "We'll be here in the future. There will be an agency." So the focus of the go-aways went to whatever was needed, and sometimes it was dealing with loss like that, and sometimes it was making great progress.

I remember one go-away when we addressed individual roles. This was while Sherwin Gardner was still here as deputy commissioner. We broke people up into teams, and each team was supposed to describe an individual's role or job. One of the small groups of three or four people was responsible for describing Sherwin's job–he was the deputy at that time. They went through this long discussion. I think they probably had forty-five minutes to make flip charts and all that. When they came back, of course, we brought Sherwin right up front and he listened to this presentation. They told him what his job was. Sherwin listened to the whole thing, was quiet for a few moments as usual, and then said, "Well, that's one way to describe it." At that point we knew we hadn't quite got it right, at least not from his perspective.

RT: Not in his mind.

GB: Yes, not in his mind. But, you know, we all had a chance to tell each other how we saw their jobs. The field told the centers, and vice versa.

RT: It was probably good for him, and for others, to get a perception of how other people viewed their activities.

GB: Oh, yes, and what they thought they ought to be. We did other things at the go-aways too, for example we had field representatives talking about one of the bureaus. The field's assignment was to describe what they thought the bureau did–well, what they should be proud of. The field told the bureau what they did well. It was sort of a mutual admiration thing. That was the first round, and you could just see the policy board members smiling and saying . . . "I didn't know you thought I did that well. I didn't know you were proud of me for doing that. I didn't know you saw that as a very positive thing." So you could just see them puffing up and feeling good.

Then in the second round we asked people to talk about the future. They were to say "if we have a meeting like this again next year, here's something I'd like to be able to compliment you on" which is a nice, gentle way of saying, "You know, here's something you ought to work a little bit on." So people could hear the suggestions for improvement because they had first been told that these other people have a very positive regard for them, and they were told they were doing a good job.

Those were the kinds of things at the retreats. You know, those are pretty touchy-feely. I mean, that's getting pretty close to feelings . . . And so some people were uncomfortable with that. Paul Hile always publicly complained about go-aways but privately he told me they were some of the best things that happened here. Once he got locked into having to complain about them publicly, he had to continue to complain about them. (Laughter) It was sort of his role. You know, "Aw, not another go-away! . . . But if you have one, I know something we ought to do".

RT: Now, you've talked quite a bit about planning. The evaluation phase or side of your operation also was challenging, I'm sure.

GB: Right. Yes, let me get to that, because I was brought into the agency to rebuild the planning process. It was something that was fairly easy for me to figure out since I had known about it before. I brought a lot of planning experience to the agency, but this thing called evaluation was brand new. At that time there basically were no evaluation staffs or people called evaluators in industry. The only evaluators you needed in industry were the accountants and financial analysts, because they evaluate whether you're making money or you're not making money. So life was a lot simpler. It's gotten more complicated now, and there's actually a thing called balanced scorecards in industry where you're measuring more than just the bottom line. You're measuring three or four other dimensions. I recently had some experience helping install a Balanced Scorecard in a company out in New Mexico.

Anyhow, here was this thing called evaluation, and I couldn't figure out what it was. I could read some books and that sort of thing, but to me it was initially very worrisome because it sounded like auditing. It sounded like things the GAO did that irritated people and made them mad. As far as I had seen most program managers would put all their energy into fighting as opposed to making changes. So I was trying to figure out how to do this thing called evaluation in a way that was positive and could make a contribution.

I brought Billy Don Weaver in; he came from a consulting firm. Billy Don had a wonderful touch. He was smart. He was actually quite analytical, but he was a southern gentleman and had a nice gentle touch and manner about him, but he wasn't a cream puff either. He wouldn't give on things that he didn't need to give on.

I almost lost Billy Don early on in his employment here because I said, "I don't know what evaluation is. Come up with a theory that we can use around here." Well, developing a new theory wasn't Billy Don's strong point. I mean, he's a great practitioner, but there he was . . . And besides, nobody else had figured this out before. So I was asking him to do something no one had ever done and maybe wasn't doable at that point, so he was very discouraged. So we said, "Look, forget the theory. Let's just do things. We'll just do studies, and we'll do analysis, and we'll do anything that looks useful, and we'll do the best we can, and then we'll call it evaluation for lack of something better."

When I first got here, the evaluation staff was full of auditor types and there were a fair number of former field investigators in there. So you can guess how they went about doing evaluations. They were looking for what was wrong, (and this is overstating it a little bit) but then they publicly punished or embarrassed people into behaving correctly. I knew that approach wasn't going to work. If we were going to maintain the good working relationships we needed to make the planning process work and support and trust, I knew that wasn't going to work. So our first approach made the pendulum swing the other way, and we went to very analytical kind of work--model building, simulation. We had some really smart folks. Carl Blozan was brought in about that time. The good part about the analytical approach was that it wasn't threatening to anybody, because we were just trying to understand the world, and explain it, and help program managers. On the other hand, it wasn't always useful because program managers couldn't understand what we were doing or saying. We got publications out of it and all of that, but it didn't always help the agency.

And then Don Kennedy came along. Don Kennedy said--I still remember this discussion, too--"I want you to do evaluations on our major programs, and I want you to do them in three months." And I said, "I'm in big trouble here! First of all, I don't know what evaluation is, and second, I can't do it in three months." But the fact was, we did it. We figured out a way to do it. We invented a new approach to evaluation. It involved a team approach. The team included a lead analyst, one of our good analytical folks from Evaluation. The team included program people, and participants from the field, and it often involved representatives of associate commissioners if they were interested in this particular program.

We figured out right away that Don Kennedy had some programs he was worried about. That's why he wanted to get this started. But I said to him, "Look, if we just do programs that are in trouble, you know then that anytime an analyst comes to a program manager and says, 'We're going to do one of our famous evaluations,' they know they're in trouble." I said, "What we have to do is to say, 'Look, we work for the federal government. These are taxpayer dollars. We're going to evaluate all programs. It's not a matter of if; it's

just a matter of when. We're going to work through the whole list of programs.'" He was OK with that, so from the very beginning we picked programs that maybe somebody had a concern about and programs that no one was concerned about to do our evaluation.

RT: When Don Kennedy came in as commissioner, did he already have some guidance on changing the agency with those programs or were these programs that he identified himself, do you think, as . . .

GB: As far as I could tell these were his choices . . . Now, he may have been getting some pressure from outside, or some criticism from outside, or whatever, but it was primarily him looking at the agency--I think--and saying here's a program that we could probably do better.

RT: What would be some examples of the kinds of programs?

GB: Well, by then we had Sherwin Gardner's famous Program Management System, and so we had taken the agency and broken it up into--oh, I'm guessing at a number--forty to fifty individual projects. Food Safety would be one project; New Drug Approval would be another project. Those would be two of the bigger ones. But then there would smaller ones, the advertising program over in Drugs for example.

RT: Both Foods and Drugs were the subject of some GAO or congressional interest.

GB: Yes, outside evaluations and audits had been going on for quite some time. In fact when I did my doctoral dissertation in 1983, I was able to find thirteen programs that both GAO and the FDA evaluation staff had studied. That's what my dissertation was all about: did those two groups approach evaluations differently. We said from the very beginning of the evaluations we did that we were going to act like supportive consultants. We're going to help the program . . . We assume that the program managers want to do the very best job

they can, so our job is to give them the insights they don't have, maybe do some analysis that they don't have time or the skill to do, but our job is to help them run their programs better. And at the end of these three-month evaluations, it was the program manager and the evaluator who made the presentation to the commissioner.

RT: Part of the evaluation process, I guess, really was a, well, you've touched on it already, an analysis or an assessment of the consumer goal achievement or purpose achievement of programs. In some areas that was rather difficult, wasn't it?

GB: Oh, yes. Evaluation is very challenging--even conceptually, it's very challenging. As I said earlier, in industry you have a bottom line. Here, in the federal government, in FDA, you either have no specific bottom lines or a lot of confusing bottom lines, because Congress may have told you to do competing things. We spent a lot of time trying to figure out and help program managers figure out, what their program was all about. Some of what we did was more like research. We did a study working with the field to try to decide how to measure their success. What's the measure? We finally decided the measure was going to be the percentage of the firms in compliance. And then we asked what is it that brings firms into compliance?

At one point we actually built a mathematical model that demonstrated that if you don't go back to inspect firms, they tend to drift out of compliance. We actually were able to demonstrate that mathematically. Understanding that relationship helped us come up with a strategy. I can remember that also helped us support budget requests. We showed that mathematical relations to Vic Zaffre at OMB. We showed him the curves that we had plotted, and we had actually developed curves for different industries. The message or theme to him was like a bumper sticker: "Don't let us slide down the compliance curve." All of the compliance curves were very steep in the beginning, but once you get up to some number, 80, 90, 95 percent in compliance, it was very, very expensive to achieve the last 5 percent. There are always the ne'er-do-wells and the folks who would rather fight than switch. We said,

"Look, we're still on the steep part of this curve, so we can get a lot of increased compliance from additional resources, and if resources are cut we're going to lose a lot."

Now, to be honest, we had never demonstrated that cutting resources you'd slide down. I mean, there was a leap of faith here. But we had it demonstrated analytically, and it was a pretty rigorous analysis. I have to tell you, we were looking at that all the time. Five years later we looked at it, and the relationship had disappeared. The world had changed somehow. What we found were basically some firms who were always in compliance and some firms, some small percentage who for whatever reason, were always out of compliance. We used what we found to develop a new model that included the good guys and red band, the folks always out of compliance. That was the kind of work the evaluators did for program managers when they weren't doing the evaluations Don Kennedy had mandated.

In the beginning, everybody was concerned and anxious when one of these evaluations was being done of their program. After we had done a number of them and had demonstrated that we were there to help and not there to embarrass, I sent Tim Hegarity off to talk to, I think he talked to forty program managers. He said, "Look, we all work for the taxpayer. Your program is going to get evaluated. Here's the kind of work we've done in the past and here's what we've done for those program managers. When do you want your program--not if--but when do you want your program evaluated?"

And he came back with more business than we had evaluators to handle. In some cases it was a brand new program manager, who said "Hey, this is the best way I know to learn about my program with some professional help." Or others would say, "You know, I think there's an analysis of my program that I would love to do, but I don't have the time or talent or whatever to do it. Would you guys do that for me?" And we'd say, "Yes,". So Tim came back with more business than we could handle immediately.

What that meant was when our evaluator went in there instead of saying, "Hi, I'm from the Commissioner's Office, and I'm here to do an evaluation," which is a white knuckle kind of meeting, he could say, "I'm here to do the thing you requested." I knew it would be good for program managers, but until we had a discussion with our analysts, I never realized

how valuable that was to our analysts, too. So involving the program managers in deciding the timing of the evaluations worked great.

Can we take a little break? I'd like to get a drink of water.

RT: Yes.

(Interruption)

GB: All right. Let me comment on one final thing about the planning process itself and then about two commissioners who had an impact. This period of planning was when we were doing team building and some of the touchy-feely stuff. Stuff designed to help the agency run better and the Policy Board to coalesce. Dick Crout and I talked about that a couple of times afterwards. Dick would always say, "Was it as good as we thought it was?" And I'd say, "I think it was, Dick." So there was a very special feeling about that period, and a lot of it had to do with Mac Schmidt and his establishment of the Policy Board. That momentum just carried on for quite a number of commissioners and other key staff folks.

All right, I want to talk about two commissioners that had a big impact on planning. The first one was Mac Schmidt, who I think was the most management-oriented commissioner we ever had. Up until that point the planning staff felt as though it was pushing against a door trying to get these planning concepts and planning activities and time for planning in the agency. When Mac arrived it was like he suddenly opened the door, and the trick was not to fall flat on our face because of this great opportunity. I can remember him commenting several times, "I am looking for these kind of planning activities. I've been looking for this effectiveness in planning in lots of places, and this is the first place I've found it." He knew good stuff when he saw it, and he made it very easy to happen.

I have to tell you a story about the very first day he created the Policy Board. He first described his responsibility. He actually got up to a blackboard and wrote out, "What's the

role of the commissioner?" And he had it right. I mean, we just all looked at it in amazement. He had not been at the agency very long and he had it right...at least from my perspective.

Then he described this thing called the Policy Board, and when he was all done we were all sort of dumbstruck and in awe, but he said, "Are there any comments?" At that point I was a smart aleck kid and so I had to say something, I couldn't stifle myself. I said, "Gee, my feelings are like W. C. Fields, who says, 'There comes a time in the life of every man when he must grab the bull by the tail and face the situation.'" And there was a long pause after that, and then Mac smiled, so I knew I wasn't fired. (Laughter) But he was that kind of guy, and he was very sensitive. Personally he had good instincts and had good management skills, but he was also sensitive to the folks working for him.

We had a go-away one time, and he said he would not attend because he wanted the managers in the agency to review what we had been doing, to look at the management processes we had in place, and to make suggestions without being influenced by his presence. And they came up with some suggestions that I knew were counter to his preferences, but he accepted them because that's the kind of manager he was, an effective and beloved one.

One way to describe the planning process is to think of a funnel. We would always start at the widest end, and we would always try to find out what was on people's minds. That's where the phrase "Plan to plan" came from, because if you lay out the structure too quickly and you decide what you're going to do too quickly, you can be doing things that are irrelevant to the folks who are participating in the planning process.

I remember plans that focused on new presidents coming in. When Reagan came in and there was a lot of talk about deregulation, there were some people in room who weren't going to be in the agency in a few weeks. There were a lot of people worried about the FDA. So the go-away that year, through dumb luck or good judgment, focused on the agency strengths, why it originally had been established, what was apt to survive through a deregulatory period and a very popular president. We learned that although these concerns had been on everybody's minds, we hadn't had a chance to vent till the go-away. We came away from that a lot stronger and feeling a lot better.

Let's see. Let me talk about the other commissioner who had a big impact on planning. The very first time I met Frank Young, he came into my office, introduced himself, said he was very happy to meet me because I was the planning guy and he was a planning nut. I didn't know what that meant, but I found out that he had in mind this thing called Action Planning. It was something he had used previously.. John Norris, of course, came along with Frank Young as deputy commissioner, and Action Planning was a management approach they had used other places.

I think the agency responded well. Action Planning included a forced march through a whole bunch of issues, and trying to get agreement. I think Frank Young probably brought some of the issues with him, but others just evolved from the group. The group was very willing to engage these tough issues and do a bottom-up rethink. I think that was because we had all worked together for a long time and we had had go-aways, and we had had arguments, and we knew there were legitimate perspectives other than our own.

So we worked through the issues OK. The thing that worried me most was, how are were going to implement this Action Plan, because it had milestones and due dates and monitoring. I knew that if we made it look anything like what had been laid on us before by what I always call Management by Objection and its variations that had been laid on us by the department and the Public Health Service, that folks would do it. Nothing good would come of it and it would be a waste of time. John Norris said he wanted it to be a positive thing, and we held him to that, and he held himself to that, which was fortunate.

So we said, "What can we do? We don't want circles and squares, because everybody had seen these circles and squares that represented goals you didn't meet. You were punished or publicly embarrassed if you didn't meet a goal. So we went down to the FDA artists and said, "Can you draw a little cartoon character of something that's getting ready to run, and that's running while the project is going on, and then crossing the finish line. The very first character they showed us was exactly what we asked for, a little figure starting to run, running and finishing. Unfortunately it was a slightly overweight, sort of round caricature

that wore glasses and looked just like the commissioner. (Laughter) And we said, "This isn't going to work."

So on the premise that it was sexist to have a male character, we said, "How about an animal of some kind?" and that's how we came up with the little bunny who ran. From that we invented the bunny buttons, which were handed out to people who met their goals. John Norris thought it was great fun and handed them out with great ceremony. When people didn't get a bunny button and they thought they should have gotten one, they would come to us privately and complain about it. So we'd sometimes go back and give them a bunny button. That process worked extremely well--so well that other agencies wanted to know about it. But everybody was embarrassed to say we were running the FDA on bunny buttons, so we changed the characters a little bit. They became images rather than characters. It was something that was talked up around town and the agency was proud of.

RT: I think there's a Gantt chart. Was that something you used for Action Plan milestone progress?

GB: Well, there was a Gantt . . . The chart with the bunnies on it looked very much like a Gantt chart.

RT: Now, a Gantt chart, is that descriptive of a certain type of illustration?

GB: Yes. I have a story about a Gantt chart, and . . .

(Interruption)

RT: OK, we're set.

GB: OK. I think there are three other things I just want to touch on quickly. One is quarterly activity reports. There's always been a sense that the agency is doing very important things and a wide, wide variety of things. It's unbelievable. When I first came into this agency from industry, I said "If you took a company this size and you expected it to have all the technology that this agency is supposed to have and do all the things this agency is supposed to do, it would be bankrupt in a year. FDA is really spread over a lot of things. So one of the reasons that quarterly activity reports were important--they were established in OMO and then they came over to OPE--was because they maintained a record of the important activities going on on a quarterly basis. We produced quarterly reports for a lot of years, and we worked hard at it, and I think they're a wonderful record for those folks who want to look back.

In some ways it is the beginning of an idea. I don't want to call it a total management system, because it's all historic, but it was a total information system if you wanted to look back on where the world had been. It had everything in there: regulations, inspections, major decisions, activities, all of those things. Each one of the centers, and the field, and the associate commissioners all contributed to it.

RT: Do you happen to recall, Jake, about what span of time? When were they implemented or initiated?

GB: They actually . . . I don't know when they were started, because they were started in OMO and came over to us in one of, probably Don Kennedy's reorganizations. So they go back beyond that. They were here when I got here, so they were here before '70, '71, and I don't know how far they went back. Ray Penry came over from OMO. Actually, the whole staff came over. It was a good staff.

RT: Now they've really been terminated. Did that occur after you left?

GB: After I left, I think, as best I can recall. Yes, because they were challenged a number of times, and we always fought and kept them, but I think they got terminated after I left. And I'll be very surprised if something like that doesn't get reestablished sometime in the future. It's a good idea, and it probably will be restarted.

Two quick stories. One of the things we discovered during one of the planning processes. We were going through hard times; it was downsizing. I think it was in the mid-eighties. People were feeling glum, and we said, "Look, let's look a little beyond this." So we interviewed the Policy Board, and we interviewed a fair number of agency employees, and we said, "If we look back on these hard times three years, five years from now, and we want to say, 'We're proud of what we did then, back when times were hard,' what would we be proud of?"

People had all kinds of ideas. But one of the most important ideas was that we would have treated our people well; we would have treated FDA employees with the respect they deserve. There was a related topic, a thing we frequently heard, employees at all levels said "My boss needs better interpersonal skills." Now, of course, everybody was pointing at their boss and other people were pointing at them. So it was a universal feeling that here we are an agency full of doctors, and regulators, and lawyers, and what the hell have you, many of which haven't had any interpersonal skill training per se.

So members of my staff did a literature search and identified a list of fifty-two topics, subjects like change management, or conflict resolution or communication. Fifty-two things you have to know how to do if you're going to be a good manager. I never knew the list was that big, but we did a pretty thorough search. Then we talked to . . . We did several surveys inside the agency saying, "Which of these are most important?" and we managed to get it down to some groupings, and we developed four immediate workshops, because those were the ones that people said they wanted. They wanted motivation, they wanted communication, they wanted leadership, and they wanted team building. So we, for the agency, spent a lot of money and had ten outside experts put together those programs for us. We started to offer

them to all managers. The last I heard there were 1,400 people who had taken one or more of the courses.

There were two topics which weren't very high on the list in the beginning. One was managing change, and one was managing your career and your employees' careers. Those didn't get a lot of votes in the beginning, but as the world began to change more rapidly and people got more worried about their careers, those two started to get to be much more important.

Just about this time David Kessler came on the scene. I think he was my seventh commissioner, not counting intermediate acting commissioners. I had heard other people say, "I can't take another new commissioner . . . I can't do it again. I can't go through the 'breaking in' of a new commissioner again." I also realized, just intuitively, that David Kessler was an issue person. He was an issue-oriented person, whether it was tobacco or some other issue, and he really wasn't "management process" oriented. He will agree with that. He and I have talked about that. So I knew my world was going to be tough, because that's what I'm all about, and I'm not an issue person; I'm a management process person.

So I went in to him, and I said, "Look, . . . I need a break. The University of Southern California has offered to take me on as a distinguished practitioner in residence. I'll be doing some teaching there. I'll be doing some things for them, and while I'm there I can do something for the agency. I can design these last two workshops--one in managing change and one in career management--and I can get the faculty there to help. We costed it out, and it was going to be a wash, because if we had gone out and contracted for those, it would have cost exactly the same, or actually a little more, than my salary. So the agency continued to pay my salary. I delivered back those products to them, with the help of the faculty at USC. Meanwhile I was down at USC teaching courses and advising folks working on their dissertations and that sort of thing.

David Kessler was nice enough to agree to that. He said, "I don't want you to go, but if that's best for you and best for the agency, I'll do it." So he did it. I've always been grateful of that, and I thanked him for that. I subsequently retired at the end of that IPA.

So I'd like to do a little summary. This is a summary of how the agency has been willing to try new management things. Whether it was the PMS system that Sherwin had, whether it was Action Planning that Frank Young had, whether it was Type III evaluations a brand new approach we developed to meet Don Kennedy's expectations, whether it was reaching out to consumers and others with our surveys, our "illegal" surveys, or Agency Impact Analyses we invented for another commissioner . . . Those were all new and unique, and they were supported by the agency, and the agency was willing to try them, and not all of them, but most of them worked well. Our successes produced interest from other agencies.

Almost anything we did here was different enough and creative enough that I could write an article and it would get accepted because people would say, "Wow, you really are doing something different. You really are doing something neat, and it's really working." So I think the agency ought to not only be proud of the new management initiatives that it took on and did, and a lot of people had hands in that, but be proud of the fact we had an impact beyond the boundaries of the agency that we'll probably never know about. We did a great number of unique and different things.

RT: You've mentioned, Jake, several of the commissioners that were particularly significant in the planning and evaluation arena. You also worked with a number of other associate commissioners. Were there any particular experiences at that level that are worthy of mention?

GB: Yes, two that I want to mention. I have mentioned Mickey Moure before, because he made it possible for the planning and the budgeting shops to work together. He insisted on it. Sherwin Gardner insisted on it. Then when I took Sherwin's job, I insisted. So it always worked, and if you didn't have that, it wouldn't have worked.

Later when Gerry Meyer came along and took over that job, he just picked up right from there, so the working relations . . . And there's lots of opportunities for conflict between

the planning shop, and the budgeting shop, and the evaluation shop, and some other things that were in Gerry Meyer's or in Mickey's shop. I'd say those were special kinds of relationships that could have been very difficult but were not . . . In terms of the line managers, and whether that's a bureau director, or Paul Hile and the field, or others that came after him, once we had demonstrated that we were here to help and support and we believed in the agency, you couldn't have found a better place to try new things, and do new things, and be successful at it. It was . . . As I said lots and lots of times, "Hey, guys, the enemies are all on the outside. Let's not have enemies on the inside."

RT: Well, from what you've spoken earlier of the go-aways, I assume that you are very much convinced that those were worthwhile, the go-away type meetings. For better understanding and conflict resolution or whatever, they were effective.

GB: Right. They did two things. First of all, we did deal with strategic issues, but the second thing is there was a lot of team building. The culture of the Policy Board, I think, largely got established at those.

RT: Let's see. You said you actually retired or resigned after the work out at Southern California.

GB: At USC. Right.

RT: Was there any particular reason you had for leaving the agency at that time, other than perhaps just having completed what you wanted to accomplish?

GB: Well, I knew there was no coming back. It was time to move on and do something else. I actually spent the major part of my professional career at the Food and Drug Administration, and I couldn't ask for a better place to have done that. I spent thirteen years

in industry before that. I've now spent a few years at academia afterwards, and I've just come back from New Mexico where I spent two years working for a public utility out there back in industry again. There's nothing that compares with the dedication, and the spirit, and the esprit de corps that I felt on the Policy Board. That's the conversation I've had with Dick Crout several times. We ask, "Was it really that good?" and we always answer "Yes, it really was that good."

RT: Good. Well, unless there's something else that you want to add, we've probably covered most of the scope we earlier considered.

GB: Right, right. And some we didn't think about. We just thought about it as we went along.

RT: We certainly appreciate your participating in this Oral History Program, Jake, and wish you well in what you pursue in years to come.

GB: OK. It's my pleasure.

RT: Thank you.

GB: Thanks.

(Interruption)

GERALD BARKDOLL

Associate Commissioner for Planning and Evaluation, United States Food and Drug Administration, 1971-1992

Developed and managed agency-wide, performance monitoring processes and rapid feedback evaluations. Determined organizational needs and established strategic planning at the Policy Board level, and Action Planning at all agency levels. Acted as in-house Management Consultant. Developed culture changing training for 1400 managers. Directed planning, evaluation and economic analysis functions of FDA. Developed and managed staff that produced over 100 studies and publications that precipitated substantial organizational improvement.

Central Region Manager, On-Line Decisions, 1970-1971

Directed Chicago office of consulting firm that provided computer based modeling and simulation services to major corporations.

Controller and Chief Financial Officer, The Englander Company, 1968-1970

Managed financial, planning, marketing research, and performance monitoring functions.

Senior Economic Analyst, Union Carbide Corporation, 1965-1968

Conducted acquisition, profitability, investment, pricing, distribution and other studies.

Senior Industrial Engineer, Firestone Tire and Rubber Company, 1964-1965

Conducted operations research analysis for production and distribution improvement.

SERVICE AND CONSULTING

Member, Editorial Board, *Evaluation and the Health Professions,* 1980-present.

Player/Manager, Mid-Atlantic Club Masters Volley Ball Team (1992, 1993, 1994, 1995, and 1996 National Champions), 1988-present.

Member, Visiting Committee, School of Business and Administration, Drexel University, 1973-1993. Chairman of Curriculum Review Committee, 1992.

Member, Board of Editors, *Public Administration Review,* 1989-1992. Chair, Brownlow Award Committee, 1991.

Editorial Advisory Board, *New Directions for Program Evaluation,* 1986-1991.

CONSULTING

Department of Health and Human Services, Office of Planning and Evaluation
Egyptian Government (Food and Drug Regulation)
Iranian Government ((Public Health)

Pan American Health Organization (Jamaica, Barbados, and Trinidad and Tobago...Planning and Performance Management)

HONORS

Presidential Rank of Meritorious Senior Executive, 1988 and 1980.

Distinguished Contribution Award, National Council for Patient Information and Education, 1987.

Food and Drug Administration Award of Merit (Highest FDA Award), 1986 and 1974.

Gunnar and Alva Myrdal Award for Government Service, Evaluation Research Society, 1985.

Department of Health and Human Services, Honorary Award for support of Federal Women's Program, 1974.

Registered Industrial Engineer, Ohio, 1968-present.

PROFESSIONAL AFFILIATIONS

American Evaluation Association

American Institute of Industrial Engineers

American Society for Public Administration

American Society for Training and Development

Senior Executives Association

EDUCATION

DPA, University of Southern California, Dissertation: "Increasing the Impact of Program Evaluation by Altering the Working Relationship Between the Program Manager and the Evaluator."

MBA, Drexel University

BS (Engineering), Drexel University

SELECTED PUBLICATIONS

Books and Book Chapters

Gerald L. Barkdoll and James B. Bell (eds.), *Evaluation and the Federal Decision Maker: New Directions for Program Evaluation,* Vol. 41 (San Francisco: Jossey-Bass, 1989).

Gerald L. Barkdoll (with Douglas Sporn), "Five Strategies for Successful In-House Evaluations." In Joseph Wholey (ed.), *Improving Government Performance* (San Francisco: Jossey-Bass, 1989).

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Articles

"Targeted Planning: A Paradigm for the Public Sector." (with Morris Bosin), *Long Range Planning,* August 1997.

"Standards and Their Use in the Food and Drug Administration." Paper commissioned by the Office of the Assistant Secretary for Educational Research and Improvement, United States Department of Education, January 1996.

"Managing the Predicted SES Crises in 1994" (with Nina Mocniak). *The Public Manager,* Vol. 22 no. 1, Spring 1993.

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"Scoping versus Coping: Developing a Comprehensive Agency Mission." *Public Administration Review,* July/August 1992.

"Predicting the Payoff from Earlier Drug Approvals." *Pharmaceutical Executive,* Vol. 7, no. 11, November 1987.

"Type III Evaluations: Consultation and Consensus." *Program Evaluation: Patterns and Directions.* Eleanor Chelimsky (ed.), 1985. Public Management Forum, *Public Administration Review,* March/April 1980.

"Concentering: A Useful Preplanning Activity." *Public Administration Review,* November/December 1983.

"Involving Constituents in Agency Priority Setting: A Case Study." *Evaluation and Program Planning,* Vol. 6, 1983.

"The Downside Risk to Program Evaluation." *The Bureaucrat,* Vol. 12, no. 2, Summer 1983.

"Cost-Benefit Analysis and Other Promising Utensils." Across the Board, *The Conference Board,* December 1979; *Evaluation and Program Planning,* Vol. 3, 1980; *How to Evaluate Education Programs,* December 1980.

"The Perils and Promise of Economic Analysis for Regulatory Decision-Making." *Food Drug Cosmetic Law Journal,* Vol. 34, no. 12, December 1979.

"Evaluating the Evaluators: The FDA Experience." *Evaluation and the Health Professions,* Vol. 1, no. 3, October 1978.

"Making Planning Relevant to Public Agency Management." *Long Range Planning,* Vol. 9, no. 1, February 1976.

EMPLOYMENT RELATED RESEARCH/PUBLICATION

Supervised and contributed to the publication of over 100 studies/publications by the FDA Office of Planning and Evaluation, including:

National Survey of Prescription Drug Information Provided to Patients (with Louis Morris, et al.), September 1983.

Receipt of Prescription Drug Information (with Louis Morris, et al) September 1983.

New Animal Drug Applications: An Analysis of Approval Rates, Approval Times, and Deficiencies from 1972 through 1981, May 1983.

Regulatory Measures of Drug Quality, January 1983.

An Historic Look at Drug Introductions on a Five-Country Market, March 1982.

Forecast of Emerging Technologies, June 1981.

Approvals and Non-Approvals of New Drug Applications During the 1970's, December 1980.