History

of the

U. S. Food and Drug Administration

Interviewee: Charles Gorton

Interviewer: Ronald T. Ottes
and
Robert A. Tucker

Date: December 3, 1997

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBER(S) 1 & 2

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Administration

DATE: December 3, 1997 PLACE: Rockville, MD LENGTH: 90 minutes

INTERVIEWEE	INTERVIEWER
NAME: Charles Gorton	NAME: Ronald Ottes & Robert Tucker
ADDRESS: [redacted]	ADDRESS: Rockville, MD
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FDA SERVICE DATES: FROM: 1974 TO: 1997

TITLE: Director of Planning & Management Communications, Office of Planning & Evaluation
(Last FDA position)

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DEED OF GIFT

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Charles F. Gorton

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Chief, History of Medicine Division
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RO: This is another in a series of FDA oral history recordings. Today we are interviewing Charles Gorton, retired director of Planning and Management Communications staff in the Office of Planning and Evaluation. The interview is being held in the Parklawn Building in Rockville, Maryland. The date is December 3, 1997. Also present are Robert Tucker and Ronald Ottes. This interview will be placed in the National Library of Medicine and become a part of the Food and Drug Administration's Oral History Program.

Chuck, to start the interview, would you give a brief biographical sketch of where you were born, raised, educated, and any relevant experience--FDA experience--prior to coming to FDA, and what brought you to FDA.

CG: I was born on May 31, 1935, in Clarinda, Iowa. I was educated up through high school in that community. Part of the time my family lived on a farm, and I went to a nearby high school. After graduating high school, I found out that it was cheaper to go to school in Missouri, even with out-of-state tuition, than it was to stay in Iowa. I migrated south across the state line into Missouri and attended Northwest Missouri State University where I eventually took two degrees, a bachelor of arts in social science and a master of science.

Following that, I served in the U.S. Army for two years, then taught high school for another two years, and then in 1962 entered the civilian federal service. My first job was with the U.S. Civil Service Commission as an investigator in Kansas City, Missouri, and that's when I first became acquainted with FDA, other than being just another government agency.

At the time I was working as an investigator out in Kansas City, and some of my colleagues and I were approached by the Association for Federal Investigators (AFI). A chapter was formed there, and I was a provisional officer, and some of the other initial

members were from the FDA district office in Kansas City. So, I began to form acquaintances with FDA people and some of the programs.

Then later, in 1965, I transferred to Washington, D.C., still as an investigator, and became the national treasurer in AFI. At that time the AFI president was John Finlator, who was director of the FDA Bureau of Drug Abuse Control. So I learned even more about FDA at that point.

Then my association with investigative-type work and FDA slacked off some, because I went over to the Bureau of Training with the Civil Service Commission in 1966, and I worked there until I came to FDA in the fall of 1974. My reasons for coming to FDA were essentially it was the best offer available at the time. I didn't have any particular reason for choosing FDA over any other organization, except that the job was right and the location was right. I'd already bought a home just three miles from the Parklawn Building, so everything got better for me almost immediately.

That essentially is how I got to FDA, as well as by some of my previous knowledge about the agency. I did know a few people from FDA through the late sixties and early seventies through the interagency training programs at the Civil Service Commissions when FDAers would come through as training participants.

RT: Where did you come into FDA?

CG: I first joined the Bureau of Drugs in their Office of Management. Richard Terselic was the director, and the person who hired me was Dan Michaels, who, of course, is now a director of the Office of Compliance in the Office of Regulatory Affairs. I worked first for Dan until he moved on to bigger and better things, and then for Dick Terselic until 1980 when I was offered a position in the Office of Planning and Evaluation (OPE).

During my years in the Bureau of Drugs, I had some contact with the other programs in the agency, but a considerable amount of contact with the Office of

Regulatory Affairs, then EDRO, the field organization, primarily through the planning process, planning compliance programs and resource allocation.

RT: Were you doing planning initially with the agency when you first came in?

CG: Yes. I was hired to take over the bureau planning and budget formulation tasks. I was a branch chief.

RT: In your work for Civil Service Commission, had you gotten into planning activities there, too?

CG: Yes. The history of this is, to me at least, interesting. I joined the training operation in the Civil Service Commission at the beginning of the Lyndon Johnson administration, and he was instituting a new management system called the Planning, Programming, and Budgeting System. The Civil Service Commission had a prime responsibility in delivering training to government managers on how that system operated. So I found a niche in training because the senior cadre there were being drawn into the new training. So I was brought in to backfill for them in general management supervision and training.

Subsequently, I got more and more involved in the new management concept, and for the 1969-70 school year, I was sent to the University of California at Irvine to study these tools and techniques in greater detail. During that time I was also able to spend some time at the Rand Corporation in Santa Monica.

So that was how I really got my underpinnings in planning, analysis and budgeting. Then when I returned from school, I was put into the bureau planning function at the Bureau of Training in the Civil Service Commission. That was my credential that I used when I approached FDA to become involved in their planning operation.

RO: In the Bureau of Drugs, were you involved in strictly the bureau's aspect of planning? Or were you involved in the portion that had to do with the field?

CG: I was involved in the portion that had to do with the field. All of the planning activities were consolidated in my branch. So we prepared the programs or the bureau's response to the invitation from EDRO to prepare an annual field work plan, and we also worked with the planners in EDRO on developing budget justifications on an annual basis. There was a fair amount of involvement there. Some of the people on my staff also drafted compliance programs.

RO: Did you do any evaluation in that group, as far as the field's accomplishments?

CG: We did some compliance program evaluation. We were not as active as was the Bureau of Foods. They seemed to have a more effective way of getting that accomplished. We worked at it, but we weren't terribly successful in producing it. We frequently had problems with data. We'd find that the data that were available didn't necessarily match the questions that we were trying to answer. As a consequence, the process would stall from time to time.

RO: Who was the director of the Bureau of Drugs when you first came?

CG: Richard Crout, and I served under two deputies there, and in many cases the deputies were more active in the planning and budgeting process than was Dr. Crout, the director. They were Carl Leventhal, and then Jerry Halperin. Both of them were very good people to work for in that context. They had some interest in what we were trying to accomplish and gave it a great value added. It was a fun time.

RO: What prompted you to leave that and go into OPE (Office of Planning and Evaluation) then?

CG: A couple of things. One, sometimes there are not enough chairs for everybody who wants a seat, and I wound up without a chair in an organization shuffle. I still had a job, but it wasn't as high as I had hoped it would be. Simultaneously, Doug Sporn, who was then director of the Planning and Management Communication staff in OPE, offered me a job as a group chief of the Management Engineering Group.

I got that offer because of some experience that I'd had in the Bureau of Drugs involving zero-base budgeting. During the Jimmy Carter administration, zero-base budgeting was thought to be the answer to a lot of our problems on how to more effectively allocate resources, and the department, then Health, Education, and Welfare, in their wisdom, added a dimension to basic zero-base budgeting. They said, "We need a system that will identify the unit costs of all these things that are being done throughout the department. And by the way, if anyone wants budget increases, they will be obligated to install a system that will tell those people at the department who need to know what they will get for each additional dollar in terms of additional outputs based on different levels of increases."

I was responsible for implementing and operating that system in the Bureau of Drugs, which then connected to a system being operated by OPE that responded to the Office of the Assistant Secretary for Health. The person who had been in charge of that group in OPE moved. So I was invited to come in and take that over.

RO: What year was that, Chuck?

CG: Nineteen eighty. By that time, of course, Carter was on his way out and zero-base budgeting was on its way out as well, so I didn't do much more of that once I came to

OPE. But that was the primary reason that I moved in there. Plus, I had a lot of experience with the FDA planning process as it was being operated by Jake Barkdoll and his staff, and I felt very comfortable with the agency planners.

As I remember, when I first came to FDA, I felt like I was a stranger in a strange land. I didn't understand the language, and I didn't understand what most people were doing. There were only two places that I could go where I felt comfortable. One was to the training staff, and the other was to OPE where the planners and I spoke the same language. So I've had a long pleasant association with agency planners.

RO: What was your responsibility then when you first went to OPE?

CG: Well, the Management Engineering Group at that time still had primary responsibility for the Manpower Management Program--later called the Staff Resources Management Program, to be more politically correct. Like most government activities, it didn't die quickly; it died slowly. So we did that for about three years, prepared the annual reports that were necessary to accompany the budget submission and that sort of thing.

By that time other things had come into focus. I'd become more directly involved in the rest of the FDA planning process. One of the things that I did--or I supervised for seven or eight years--was the annual external discussion of priorities. As part of the agency planning process, an attempt was made to seek the opinions of outsiders, those people who would now be called stakeholders, about where the agency's priorities should go in the budget process, and my staff prepared and distributed the annual ballot and then analyzed and reported the results to the FDA Policy Board.

In order to avoid implications of conducting surveys without clearance from the Office of Management and Budget (OMB), we never said we're doing a survey; we're conducting an ongoing dialogue with our constituents out there, and annually we send

them a ballot so they can vote on some things. So we never asked, and we were never told we couldn't do it.

In some respects, this dialogue was an early form of stakeholder consultation that is now required by the Government Performance and Results Act.

RO: So you were the guy that was responsible for those things.

CG: For a while. I didn't start it. It wasn't my original idea, but I did have a major hand in it for quite a while. We'd prepare on the order of twenty-five hundred ballots to individual addressees around the country.

RO: As well as internal in the agency. Or were they different?

CG: Those were different. That's an interesting question.

In the seventies, the emphasis was primarily internal among the various leaders in the agency--essentially the Policy Board, as it was constituted at that time. A series of questionnaires would be sent to each of them. It was a delphi process. There would be one round of questionnaires, and the results would be recorded and sent back to all the participants, and they would be asked to vote again and register any changes of mind that they'd had as a result of having seen everybody else's ideas. Usually there were two or three iterations of this. Finally, one profile of priorities would be elected, and that would be presented to the commissioner as the consensus of the agency leadership. The budget process would flow from there. Normally the balloting wound up in December, so it was well in advance of the time when we had to write the budgets.

RT: Who was the commissioner at that period of time?

CG: Well, first Dr. Schmidt and then Dr. Kennedy. This practice overlapped the two. Schmidt would have gone out in late '76, early '77, and we were still doing that.

RT: So he was really the initiator or at least the concurring commissioner.

CG: Right, right. He was the first customer is another way to look at it. I don't think in many cases that the commissioners actually asked for some of the things that OPE did, but they were very receptive to them.

RO: OK. That's what I wondered, whether or not you prepared those questionnaires or whether there was input from the commissioner's office.

CG: No. It was grassroots up to the commissioner. The commissioner always had the final say. He could change any arrangement either in priorities or in or out or that sort of thing. But it was presented to him not as just a staff recommendation, but as the collective opinion of the people who were responsible for making FDA work.

RO: Was that supposed to guide the agency for short term or long term?

CG: It had a two-year time frame, because the focus was on the planning year. Traditionally, you have the operating year is where we are now; we have the budget year which is the very next year; and then we have the planning year which is two years out. So the focus was usually two years out. It was not strategic planning in the classic sense, but a little bit more than operational or budget planning.

One of the primary purposes was to decide on the priorities for budget requests, which were just beginning to be crystallized two years in advance.

RO: How did that differ from what you sent to the outside?

CG: It changed gradually. The framework for the questions for the inside process were the PMS projects, the Program Management System projects. Those were the cards, or sub-parts of programs, that managers had to play with to put in priority order. For a while, we attempted to get to use the same techniques for the outside. But there were some problems there, because some of the PMS projects are very difficult to explain in lay language. Biopharmaceutics, for example, so we had a choice, either to do a lame job of explaining or simply to leave those things off the list. Once you start eliminating things from the list that will be voted on, then you've impaired the system somewhat, because it's no longer a level playing field for all the program efforts.

We eventually decided that maybe we needed a different way of telling the story, so we shifted to functional descriptions of FDA work, such as inspections or research. We came almost a full circle back to the way that people looked at FDA before the PMS concept. We looked at research, pre-market review, compliance activities--a kind of standard bureaucratic set of activities that you'd find in almost any organization that has a function like ours.

RT: That outside audience, it covered cooperating officials and organizations industry, I suppose. What was the universe of that audience?

CG: About as big as we could make it. We went through the various external affairs offices in the agency. We went through health affairs, we went through consumer affairs, and, of course, regulatory affairs. We had on our mailing list consumer organizations, health professional organizations, including medical schools as well as all of the other professional organizations. We had intergovernmental regulator organizations, like

AFDO (Association of Food and Drug Officials) . . . Let's see. What haven't I covered here?

RO: Trade associations.

CG: Trade associations, right. Right. I'd forgotten about them. That were essentially speaking for the industry and its various subparts. We attempted to keep a balance. Like all systems of this kind, from time to time people would point out that the coverage wasn't essentially balanced. There was a time when veterinary medicine wasn't getting its share of air time. We simply didn't have enough vet medicine interested organizations on the mailing list. So we put on a special effort to make sure that that was pumped up a little bit.

We never got an overwhelming response to the balloting process. Fifteen percent was considered to be a pretty good year. But there was a certain validation over time. We changed the questions somewhat to keep the process interesting to the outsiders, but would be essentially asking them about the same things. There was a fairly consistent pattern of responses to the questions. Like, put more emphasis on pre-market review of new products, but don't make a big deal of research in FDA, because FDA will never be able to hold its own with your neighbors down the street at NIH. So these messages came at us fairly consistently.

RO: Was that the same delphi process that was . . . ?

CG: No, it was not. Thanks for asking that, because that's an important difference. We did publish a report of the results of this and sent it back to all of those to whom a ballot was sent. We didn't try to separate out who responded and who didn't. But they were not asked to vote again or anything like that, as we did inside. So this was just a one-time

what do you think? Thanks. And here are the results.

RO: Did you ever query them on that and what they thought of FDA?

CG: Indirectly, yes. For a couple of years in the early eighties, we used focus groups--not OPE exclusively; I think regional directors were involved in that--to go out and get a deeper level of understanding of what people were saying, why people were saying what they were saying. They were asked to explain their votes. Out of that came a variety of perceptions and opinions about FDA and what it was doing and how it did it. We didn't continue that indefinitely. It was a fairly expensive and cumbersome process.

RT: In that regard, Chuck, were you in consort at all with Alexander Grant's operation?

CG: Oh, yes. The first focus groups were with consumer groups. So his organization had something to do with orchestrating that as well as the EDRO consumer affairs operation.

Later on we expanded it to other interested parties. I don't think that industry was ever invited to those focus groups, but health care professionals were. One year--this may have been 1981--Dallas and Seattle both hosted focus groups for health care professionals. The attendees were heads of the medical community in each case, and the interviewer was the regional director.

RT: In a relatively recent interview with Alex Grant, he spoke of his assignment or mission being to get a better rapport with a lot of outside groups, which apparently had deteriorated about the time he came in. So part of his role apparently paralleled or complemented the . . .

CG: Yes, there was a strong complementary relationship. I don't think we were asking the same kinds of questions, but we were inquiring of the same people. We just had a different focus of what we wanted to hear from them. He was much more operational. He could respond to an article in this morning's paper that was published in Denver. We didn't try to get into that sort of thing at all.

RO: I got the impression from what you said earlier that this was very active up until maybe about the time that Commissioner Schmidt left. Did it continue after that?

CG: Oh, yes. Yes. To reconstruct the history a little bit, the inside discussion process continued pretty much through the seventies. But, as with all processes like this in a situation where there are not a great number of major changes each year, the answers became pretty predictable. The inside consensus essentially came to rest about the same place year after year after we had done it a few times. So the thought was, well, let's see if we can get another look at this same question of, What should FDA be doing and where should we be putting our chips?

For a very brief time, perhaps not more than a year, an FDA advisory group was engaged. I don't think that lasted very long. One group of advisors looking at the whole agency simultaneously. But they were invited to register their opinions about FDA priorities.

Then we went to the outside in a more extensive way, and the first outside was probably '78, '79. I can't remember for sure, but it was before I joined OPE. It was already underway when I took it over, and we thought we were improving it, and we tried to do some things differently. But that process suffered essentially the same fate as had the earlier one. If you asked the same questions of the outside groups for several years, you're going to begin to get redundant answers. "You know, we already told you. This is where your priorities need to go." The process was finally ended when Dr. Kessler

came in with a different perspective on how to do business. So OPE was invited out of this external communication process, and it never happened again.

RO: In some fashion was it done then by a different group than OPE? Or wasn't it done at all?

CG: Well, it's always been done in some fashion, in that there have been consumer exchange meetings, and later on there were grassroots meetings and things like that. The concept never went away, but the specific practice of an organized annual approach to our total stakeholder community hasn't been done again, I don't think.

RO: Jake Barkdoll was always very active in this. Maybe he wasn't the only one, but we always accused him of being the perpetrator.

CG: He was the primary cheerleader of it, you know.

RO: You know, he conducted go-aways for the top staff and things of that kind. So in that sense OPE had a very active role in at least trying to suggest what direction the agency should take.

CG: Well, that perception is very consistent with my own perception of OPE looking from the inside out, and I didn't have the term for it at first. One of my co-workers said, you know, "We're someday going to have to decide of whether we are primarily an organization development group," because that's what Jake liked to do best, and organization development essentially means change. You don't go into an OD operation if you're satisfied with everything the way it is. So that's really what we were about, trying to entice people to think about alternative ways of doing things, and how to gather

information and help them make those kinds of decisions. Yesterday, when I was trying to organize my thoughts for this, I made a note to myself . . .

(Interruption)

CG: OK. OPE and change. The thought that came to me yesterday as I was making some notes to myself, that without change, the planning process would consist of copying last year's plans and changing the dates. So if you don't have the element of change in planning, there's really not much point in putting a lot of effort into it. But once you do introduce change as a specific primary ingredient in planning, then that means you've got to do a lot of other things to make it work.

You have to have reliable, useful information. You have to have a group of people who are willing to put some energy into thinking about how to do things differently, as well as keeping things running on a day-to-day basis. So it's not cheap and certainly not a free lunch. But that was kind of the culture of OPE. You really ought to wonder if there is a better way, and we want to try to find it.

RT: When Dr. Kessler came in, you mentioned a moment ago that the former system kind of was retired with Dr. Kessler. How did he and his immediate staff operate in the planning arena?

CG: They didn't. They isolated themselves from it.

RO: I am curious what the role of OPE is under the current structure of the Office of the Commissioner and how it compares to earlier commissioners.

CG: So do we. (Laughter)

In all fairness, OPE has always had to stay loose and quick on its feet, because if you're in the change business, you can't get too set, because then you aren't able to respond to what really needs to be done. But this process of, "How can OPE be helpful?" didn't start with Kessler. The first major change was when Frank Young came in as commissioner.

Up until that time, we essentially had a pretty sweet life, because Jake had been successful in encouraging the Policy Board members, whoever they were--they came and went as well--of accepting the necessity and the value of some of these planning processes that Jake went through, the go-aways and the studies and all of this, as a useful way of managing the agency. Commissioners came and went. Dr. Kennedy accepted it; Dr. Goyan accepted it; Dr. Hayes accepted it pretty much in its existing form. So all we had to do was just keep the thing bright, and then we were on our way.

Then Frank Young comes in, and Frank Young had a different view of the world. Essentially, this is second- or third-hand information, I didn't hear him say it, but I understand that he said it. He said, "I am my own planner. I don't need a planning staff." Oops! What are we going to do now coach? That was the advent of the action planning era that Frank Young started.

So in the best, most complementary sense, Jake Barkdoll had to kick his way back into the mainstream on this, and he did it by volunteering OPE staff members as kind of executive secretaries to the various groups that Frank Young put together to come up with the initial action plan. Step by step, OPE began to get back into the mainstream.

The primary avenue was through the action plan reporting system called APRES (Action Plan Review & Evaluation System) which was labor intensive. A lot of information had to be collected on a monthly basis, and reports had to be prepared, and feedback meetings had to be set up where Deputy Commissioner John Norris presided to hear the reports of the various key managers who were responsible for the parts of the action plan.

So that's how OPE got back into the game. My group had the primary job of producing the APRES documentation and setting up the meetings. One of the major challenges was trying to deal with John Norris's calendar so we could get him pinned down for the meetings. But we also had a tremendous amount of documentation that we produced.

That was the era of the rabbits. The record document of action plan accomplishment was a kind of Gantt chart showing milestones and progress, and the symbol for motion was the rabbit. The rabbit was positioned at the right point on each report. The rabbits only lasted one iteration of the action plan. The next action plan we went on to something less interesting. (Laughter) And success in your action planning or meeting your goals in the action plan was recognized by a bunny pin, which the awardees were allowed to wear.

RO: I thought that action plan, though, was more of an operational plan.

CG: Yes, absolutely. It was not a longer term. It was there, so that's what we did, but all of OPE wasn't involved. But it was very much on my screen, and OPE got quite a bit of favorable recognition. Billy Don Weaver was the primary interface between John Norris and OPE on it. John Norris gave Billy Don a hug at an awards ceremony.

It was a way to stay relevant, although, as you very accurately pointed out, it was not a traditional program planning process. It was essentially resource neutral, and that was one of its flaws that Dr. Young and Mr. Norris simply would not allow discussion of resources to accomplish the plan. I saw a couple of fairly senior people embarrassed by the fact that they had overlooked that little nuance when they started making the presentations, when they started to say, "And, of course, you understand in order for us to do this, we're going to have to have an increase of about . . ." That was as far as they got. They were simply told to go back and rethink their presentation.

What's one thing that one can do to succeed in that environment when you can't get anymore resources? Simply to plan things that you've already accomplished, and at the right interval, come forward with it.

RO: In your analysis, how did the agency do as far as those action plans were concerned? Was it successful?

CG: Yes, but only if you accept that the targets that were set up were in fact righteous. Many of them were, but some were perhaps not as meritorious. But one of the things that OPE did, and I was a primary actor in this, was coaching the people who wrote the plans not to write plans that they couldn't win. Make it reasonable. Put enough starch in it so it looks like you're going to have to work hard, but don't make it so tough that you are in the fifty-fifty range of success. Build in some probability for yourself.

RT: Dr. Young apparently was reticent to add on expenditures or budget increases. Was his style, if a plan was to be approved, to then adjust within the current spending sacrificing something else?

CG: I'm not sure that I completely agree with your analysis of Dr. Young's approach.

RT: Well, this is just a question, not my analysis.

CG: OK. That's fair. It brings out some things that I hadn't thought about. Dr. Young didn't want any additional resource business in the action plan. But when it came to annual budget requests, he was quite aggressive, and he had some ideas that he was trying to peddle. He wanted to place FDA more clearly in the product development stream so

that FDA's participation had a value added rather than a neutral or a negative effect on the availability and value of new products to the American consumer.

I remember writing something--I don't know how far it survived in the food chain going up--but an analogy between a canal and a lock system and FDA's part in bringing new products to market. But at certain points, it's necessary to raise the barge to proceed, and FDA is part of that lock process. We enhance the product concept and design by our participation in it. He was peddling this.

One of the major market opportunities was in 1988 when it was clear that George Bush was going to be the, or was already the nominated candidate, and there was strong indication that he was going to be the next president. Dr. Young launched a campaign to impress the Bush group, who was beginning to draw the outlines of the new administration, so that he would have a place in there. That's where some of these arguments for FDA as part of the product enhancement process came from. But he had that idea in the back of his mind all the time.

So he was not at all bashful about going ahead and asking for more resources through the budget process for this sort of thing. I don't think he was particularly enamored of the post-market part of the agency operation. It didn't have the same sheen to him as it might have had to some others.

RO: In this whole process of the planning, other than for the questionnaires, did you have any personal involvement with the bureau planning people or the . . . ?

CG: Oh, yes, yes. A part of the OPE approach is to set up a process that creates the plan, but not to write the plan. The plan writing had to be done by the bureau people just as I did it when I collected the information from the office directors and the division directors in drugs, and then I combined this into a drugs program document.

here in veterinary medicine there were areas where they were severely under-funded. I'm struggling to remember specifically which program that was, but it really doesn't matter.

Everybody was pretty much in agreement that it would be a wise thing to do to shift some of those biologics field resources over to veterinary medicine. But nobody from the primary participating groups wanted to step forward and say, "Let's do that," because there were political reasons and others that would make it awkward. So OPE was invited to conduct a study to determine whether in fact it would be a good thing to do to do this shift.

We did the study; we didn't invent anything. The evidence was there, and it was pretty blatant. But we conducted the study, and Herb Hammond presented the results to the commissioner, and the commissioner in effect said, "So be it," and it was done. But, I say it was a set up. Everybody wanted it to happen, but we were the neutral agent that made it easier to bring about.

We didn't get involved in many serious tussles where the answers weren't already clear, at least planning did not. Now other parts of the OPE, evaluation got into some sticky wickets, and, of course, the economics folks have always had to struggle, because they're frequently trying to take people where they don't want to go.

RO: What's the communication aspect of your job?

CG: OK. For a long time, the P&MC (Planning & Management Communications) staff had the role of publishing a couple of documents that were pretty popular inside and outside the agency. One of them . . . Let's see. I made myself another note here. After looking at some of your questions, I had to rewind some tapes and remember things I hadn't thought of for a while.

The Executive Information Manual was one of the things that the staff published. It was essentially a directory to key agency managers, photographs, short bio sketches,

that sort of thing, and it was very popular. That eventually went outside the agency. It's now being published privately. That was part of the management communications function. A more visible and generally available document was the Quarterly Activities Report that essentially contained information about the whole agency--mainly by program area, but also by certain functional areas such as GC--on a quarterly basis, what had happened, and what its significance was.

RO: What was the audience for that? What was it intended for, internal or external?

CG: Primarily intended for internal. There was no distribution list for external, but there was always a fairly active FOI request, and it's probably no secret that a few people who were old friends of the agency who are now working for consulting firms managed to wander by and walk away with a copy without going through FOI.

RO: That first one, the management . . .

CG: The Executive Information Manual?

RO: Yes, was that also more internal? Or was that intended for external?

CG: I don't think it was intended for external. I think--and this is my own speculation about Jake Barkdoll--he was pretty sensitive about boundaries, and he didn't want to get too close to the external affairs function. So some of the things that he had a hand in producing may have had external appeal, but he didn't market it that way.

RO: I see. So that was primarily the communication aspect.

CG: Right. And there were various and sundry other special projects, but they would be one-time things.

RO: In later years then, as far as the query that went out, you know, to our constituents, that was no longer done? Is that right?

CG: That's correct. I think that was last done by OPE in . . . Dr. Kessler came in '90 or '91? Which was it? I can't remember. Anyhow, it was during his first year when it was time to decide to go again, that's when it was stopped.

RT: Were you talking about the Quarterly Activity Report?

RO: Well, I was talking first about . . . Well, both of them, in fact.

RT: The latter, the Quarterly Activities Report, also has been terminated now.

CG: Right. It was last published covering fiscal '95. This was a different set of circumstances that led to its discontinuation. Essentially it had become obsolete because there were so many alternative information sources that were much quicker that one could learn most of the things that the quarterly contained two or three months before the quarterly came out. Also, with the advent of the Government Performance and Results Act (GPRA), it was conceptually out of date, because it concentrated on activities--that's a euphemism for consuming resources--and GPRA concentrates on outcomes. So to have a primary agency document that says "Activities" was kind of counterintuitive.

So there were two reasons for discontinuing the quarterly. One was it simply wasn't quick enough anymore, and two, it was conceptually out of focus with what we really should be concentrating on.

The next generation of a periodic report, in one form or another, will be a quarterly results report, which may never appear in hard copy; it may be entirely electronic. But it will be focused on, "So what difference did it make?" And OPE, I'm sure, will play a central role in that, partly because of the PDUFA (Prescription Drug User Fee Act) connection. OPE has been publishing the annual PDUFA report on results. "OK, so what did we get for our money?" And that's been done by our evaluation staff. Planning and evaluation are going to probably over time become progressively less distinct and recognizable as separate parts. It's all part and process of the same thing, and there are no independent groups like planning and management communications in OPE anymore. Those have been abolished.

RO: Tell us a little bit about this Government Performance Act and . . .

CG: OK.

RO: I'm not real clear on that.

CG: I have a short version and a long version. The act was co-sponsored by Senator Roth and Senator Glenn. Senator Glenn was chairman of the Government Operations Committee at the time that the bill was actually passed in 1993. Both Senator Roth and Senator Glenn had a long history of interest in that. I mentioned I was a student of planning and budgeting systems clear back in the early seventies, and Senator Roth's name came up occasionally then. So this wasn't just a last minute thing with him. He put some time and energy into developing the idea.

But there are three basic parts to the act and to the idea. Number one, every agency should have a strategic plan. "Agency" wasn't completely defined, so as it's turning out now, sometimes the strategic plan is written at the department level and in

some cases not. Sometimes at lower levels, and they're brought together. But the strategic plan must cover at least the next five years, and it has to be revisited at least once every three years to make sure that it's still accurate, and it has to focus on strategic outcomes. What, in fact, is going to be different and better as a result of this agency following its strategic plan? There have to be measures, things that you can observe and record and compare, not just "feel good" kinds of evidence, about whether in fact differences are really being made, which means for FDA we somehow have to get into that chain of events that means people live longer, with fewer health-related complications along the way.

RO: These are somewhat quantitative then, the measures?

CG: More than somewhat. You'll get a low-grade first if you don't have any quantification in your plan. You may not say exactly how much it's going to change in five to seven years from now, but you'll say, "These are the things that you need to watch, because when that happens, other kinds of useful changes are going to happen."

Now we may not be able to in every case prove arithmetically a cause/effect relationship between what we're doing today and people living longer in the next millennium. But there has to be a strong logical connection, and you have to take the numbers as far as you can go. If you can, in fact, reduce the number of people who die for causes related to food contamination, then that's the kind of data we're interested in.

The strategic planning and the quantification is one part. The second part is each year there will be a performance plan prepared by each agency, and this does in fact mean agency down to the lower levels, FDA, and the like. The performance plan is made up of a kind of strategic overview that connects annual plans to this multi-year strategic plan.

Secondly, a set of performance goals is required that tell people in very specific terms what they can expect to happen over the next year and with what implications. There have to be data sources described. How are you going to know? Where are you going to collect your evidence? And how do you know the evidence is good? There's a validation, an audit implication there, too. Not only do you have to show your numbers, but you have to prove that your numbers are good numbers. All this is in the law. It's a by-the-numbers process. And, finally, it says at the end of each year, you've got to write a comprehensive report that describes exactly how successful you were.

So right now, OMB is looking at a performance plan that FDA prepared over the past year for Fiscal Year 1999. It was my last major effort. There are 157 different specific goals that cover most of the agency. The law explicitly says you don't have to cover every dollar, that the performance plan should concentrate on the keys things, and not just every little thing that you do. The cornerstone of the Performance Plan is PDUFA. That's where it all started for FDA. We were doing that not because of the Results Act, but because of another act. But it was a very good starting place, and we built out from there using that as a model.

RT: So in a way, I guess this is when the performance plan concept kind of came in. And I recall that you served as an instructor in the employees' performance plan development activity. These are just grandiose or larger level plans for agencies as well.

CG: Ultimately, it's hoped that all these pieces will be hooked together, that individual jobs will be hooked into organization performance plans, which will hook into agency performance plans, so that if you pull any part of it, it all moves.

RO: How was that different than what we had back in the eighties?

CG: The primary difference is that in the eighties and before, going clear back to the sixties, the primary emphasis was outputs. That's what was used in budget justification. The question of what difference does it make didn't occur. People obviously wondered about it, but there was no systematic way to capture that information. So our plans that we wrote in the seventies and eighties and the budget justifications that we wrote were all firmly grounded in changes in outputs. More applications reviewed, more inspections conducted, etc.

(Interruption)

RO: I noticed there was a little ad in the paper, in *The Post* this morning about FDA had just received some award or something for . . . I'm wondering if that had anything to do with this performance thing?

CG: I haven't seen the paper.

RO: Well, I wish I had the specifics, but . . .

CG: Was it a Hammer award?

RO: No, no, not a Hammer. It was a very complimentary award.

CG: Well, Hammer awards are complimentary, too. (Laughter) No, I'm sorry I hadn't seen that. I hope it's connected, but I don't know that it is.

RO: Well, what happens now if you don't meet these goals? This goes into OMB, and then OMB, what do they do? Give you a couple demerits or . . . ?

CG: It's supposed to go all the way to Congress, and Congress is showing direct interest. This is the first time in any of the history of any of these processes where Congress has been at least a participant from the beginning. All the others were essentially executive branch conceptions, and when they were carried over to Congress, the Appropriations Committee said, "Well, what do I do with this?"

But this time, at least in theory and to a certain extent in practice, the congressional staffs are getting interested and getting involved and asking questions or asking more questions than the law called for. So it ain't all good, you know. They're liable to be pestering people more than they have and more things to pester with. But OMB is now a middle person rather than the end person in this process, and they have to try to orchestrate it in such a way that the Congress will respond favorably, at least to that way of doing business.

There are two levels, I guess. First is will the Congress be willing to deal with this kind of documentation and presentation? And secondly, is the message the one that's most effective? So first you get the Congress willing to tune in on that frequency, and then you try to send the stuff that will be most effective.

RO: Going into Congress this way, I can just see that gets in there, and then the next thing somebody is going to say, "I wonder if that agency told the truth?" So they're going to send the General Accounting Office out and start a study.

CG: As a matter of fact, there's a piece of legislation floating around right now that calls for that. So you're clairvoyant.

RO: What did the agency do?

CG: You roll over and take it.

RO: No, but I mean how did the agency perform on that endeavor?

CG: Our plan is still a work-in-progress. Final votes aren't in. But since last spring, we have been getting favorable feedback from OMB on the work that we've done. Of course, we're working under the guidance of the department, and we get some coaching from them. They want to succeed too, and they can only be as successful as the component pieces are. So we can't claim exclusive credit. But Paul Coppinger made a presentation to an OMB team. I think it was March 29. This was in response to a requirement that each agency provide some kind of progress report to OMB. Originally, it had started out as a paper report and became just a lot of hard work and not much substance. So the department people are the ones who actually suggested this, that why don't we get together in agency-level meetings and talk about it so we can have some conversation rather than just having a lot of paper?

Paul Coppinger was the primary spokesperson for FDA, and Butch Bosin, my successor in the planning staff, and I were the backups, and we got very favorable feedback from OMB on the presentation. There were a couple criticisms too, questions that the OMB people thought probably should have been answered that weren't, which we may have ducked and dodged a place or two.

At that time we were just beginning to put together the performance plan, and we had a call out to all of the centers and ORA. Then we put together our performance plan and sent it downtown, and the latest feedback was in a form of the OMB passback, which just came in a couple of weeks ago. There was one short paragraph on FDA's participation in the performance planning process as a subpart of the entire budget presentation, and it again was favorable. We got compliments on the way we went about it, the heft of the plan, the coverage, and some of the specific goals that we had indicated were deemed to be good outcome goals. One of them had to do with food and

labeling and changing the number of people who actively use food labeling in planning their diets. There are some survey data about this.

Overall I'd say we got a strong B+, and it's all situational, because it's the first time for everybody. In the training that we presented on GPRA . . . We did that over about a two-year period, trained over five hundred FDA managers in twenty-six different locations, including most of the district offices. One of the things that--at least whenever I was on the platform--I said, "We have a unique situation here. Ideally in training you like to have the benefit of the experience of a combat veteran, somebody who really knows how to take care of themselves in this situation." I said, "There are no combat veterans in GPRA. Nobody's ever done it before. So we don't have that kind of experience to share with you. We're all neophytes, and we'll all be learning together." But apparently a lot of FDAers learn pretty well, because over all we were pretty darn successful, and I'm proud of that.

RO: That's a responsibility of OPE then to put together this assessment.

CG: Right. It's essentially the responsibility of the planning staff. We once again kicked our way in on it, and I personally chose the same approach. I wasn't just automatically included in that at the very beginning. This is essentially where I started thirty years ago, so I want to wind up doing that same sort of thing.

RO: Sure. Well, now, on top of that is reinventing government. Tell me about it.

CG: NPR (National Performance Review) is best described as, number one, good public relations with a fair amount of substantial change behind it. People are in fact doing things differently.

RO: This acronym you used . . .

CG: National Performance Review.

RO: OK.

CG: That's the organization that's behind reinventing.

RO: All right. Go ahead.

CG: And that's Vice President Gore's hobby. We've had close connection with them as well, primarily through ORA and Marie Urban and ORA 21. There have been a lot of favorable comments about FDA's reinvention activities, particularly in the field but not exclusively. We are designated as a reinvention site, and we were more or less strong-armed to contributing a set of multi-year reinvention goals that will be probably published in a month or so by the vice president.

Performance Planning and NPR are related, but not actually part and parcel of the same thing, and sometimes they're a little contradictory because of the PR dimension of National Performance Review. We're being asked to go further than anybody really wants to and make promises we aren't sure we can keep.

RT: Is that perhaps a part of the department's oversight of the agency? I'm wondering if it has anything to do with the political interest in the agency that's developing.

CG: To a certain extent, but not as clearly as it is in some cases when you're talking about politics within the agency and the influence of the administration and that sort of thing. Because the department's role in this set of reinvention goals that we have on the

table right now wasn't very clear. They kind of got involved later. The deputy secretary, Kevin Thurm, eventually got involved in signing off on the whole thing, but there wasn't a lot of top-down guidance on how to play that game. We kind of just had to figure it out on our own.

But an example of the type of goal they're calling for . . . And incidentally time frames are different, too, because they're most interested in things that can be racked up by year 2000. I wonder why. (Laughter) Of course, that's shorter than our strategic planning framework. But one of the goals that we eventually acceded to was shortening the total drug development time by one year, by the year 2000, which means exerting enough influence on the whole discovery process so that instead of twelve years or whatever it is, it becomes eleven years.

RO: That almost seems that that would be a part of the performance plan.

CG: Well, but . . .

RO: It's pretty hard to divorce it from reinventing government.

CG: It could be, but in the performance plan, which is part of the budgeting process, which is more reality, nobody is willing to sign off on that ambitious of a goal. So you have two different games going on here simultaneously.

RO: I thought reinventing government was to streamline your operation.

CG: That's part of it, yes.

RO: And really streamline staff.

CG: Yes, well, it kind of is what one chooses to call it. If you can prove with the same number of people you're doing things quicker, that counts, too.

RO: I thought part of the thrust was--as far as reinventing government--was to eliminate some of your mid-level managers.

CG: Oh, it is; there's no question about it. And the 250,000 total reduction, all that's part of it, too. But the last thing I think that anybody is going to step forward with is an offer to put 10 percent of their work force on the table. You know, they'll find other ways to talk about change and improvement and reinvention.

RO: Did your office then have a role in measuring how the agency was doing in this reinventing government?

CG: Not really, no.

RO: Not really.

CG: Indirectly.

RO: Did you put together the overall plan for the agency?

CG: No, no. That was handled in a variety of places. The deputy for operations had part of the responsibility. I think it was primarily handled through the office of policy, Mr. Schulz's office. I participated in the focus group process that related to that two years ago last spring, I think. I'm having trouble remembering exactly the time frame. But Susan Meadows, from the Office of the Deputy for Operations, and I did a series

of focus groups throughout the agency including the field on, How can FDA reinvent itself? We made a report back to Mr. Byrd and to Mr. Schulz, and I don't know where it went from then. But we, the planners, are not centrally involved in all of the reinvention things, but we tended to weave in and out of them at times.

RO: Would you care to comment on how you feel, whether this performance plan is going to continue? Or is it going to be short-lived?

CG: The answer is not known, but speculation is it stands a better chance than any of its predecessors--PPBS, management by objectives, zero-based budgeting, and all those others--because it is in law. Beyond that, there is at least some demonstrated congressional interest at this point. Not all that interest is necessarily viewed as being favorable from the administration point of view, because they talk about waste, fraud, and abuse, and this will be a useful tool for getting that out. That's not an encouraging word necessarily. But, nevertheless . . . And it will require a literal, actual culture change--people will have to think about the work they do differently than they ever have. We use the field organization as an example, but it's certainly not the only place where it has occurred.

People have built their careers on certain kinds of records of accomplishment, certain kinds of statistics. Over years I have been able to do this again and again and again and improve on it. Well, what if somebody comes along and says, "Well, those numbers don't mean anything. They don't have anything to do with real outcomes. Those are just outputs." Now how quickly is someone going to flip over on that and say, "OK, I'll play a new game"? It's going to be hard.

RO: You mentioned PDUFA a while back, the user fees. Were you involved at all when the agency started to justify its need for them?

CG: No. Just by chance, I was doing something else at that time. so I was not drawn into that. OPE was, of course, clearly, centrally involved. Paul Coppinger's been a main player all the way through. But I've only come in and out of it a couple of times.

At one point, there was a question of having a more elaborate scheme of fees for more than different kinds of services, and some of the people in the agency said, "This would be horrendous. It would unmanageable." So I was sent out to conduct some interviews with other agencies that had more complicated user fee systems and to see how hard in fact it is and whether they were able to manage it. The end result was they were all having a great time, because they never had to worry about money. All you had to do was make sure that it was invested optimally as it was rolling in. The Federal Grain Inspection Service has one full-time person that does nothing but make short-term investments of fees so that they don't waste any of the interest.

That's the kind of peripheral involvement I had with user fees, and, of course, when I was trying to help craft the performance plan, had to put the user fee goals in in the best possible way.

RO: I guess you've already answered one of the questions I had as to the role of the OPE, in then the current structure of the Office of the Commissioner, and I guess you've said that it kind of diminished from what it was under previous commissioners.

CG: It's not as predictable. I think it comes and goes. It's much more opportunistic and to look for opportunities to be relevant and find ways to get inside. The planning staff, at least right now, is behaving entrepreneurially, looking for things that will be useful to do and selling the ideas. They've always done some of that, but it's a different focus. Historically, we had the luxury of going out and selling essentially free goods to individual managers, maybe even only at the division level. They would say, "I've got something I'd like to have analyzed here and I need some help." And we'd say, "Sure."

Because that was an accepted line of work. But now in leaner, meaner times, you have to focus at a higher level. In most cases, if you're going to spend much money on it, it has to have agency-wide implications, and that makes it harder, because you've got a more varied cast of players that you have to work with to be successful.

RO: Bob, you have any other thoughts?

RT: As far as the commissioners during your tenure here, have there been any that have impressed you as being more adept planners? Not to compare one with another, but some have probably had more interest at least.

CG: Good question. Of course, you have to remember my involvement with the commissioner's role in this doesn't cover the whole period. When I was in the bureau, I attended some of the meetings that the commissioner conducted on planning and so forth, but I was only looking at it from the standpoint of just the drugs program. And then . . . So that cuts it down to about a five-year horizon until we got to Frank Young when he kind of changed the whole game. But I liked the way Dr. Hayes approached it. He really attempted to make use of what was available there.

I can comment somewhat on Dr. Kennedy, too. I think Dr. Kennedy was more interested in evaluation than he was planning though. One of the things that he called for was a series of PMS project evaluations on a fairly short-term turnaround. I think they had sixty-day time frames, and he just wanted them coming at him, like a movie serial, a regular schedule.

RT: Well, you aren't answering what I was after. You know, kind of an impression of the style, if you will, of some of these leaders.

CG: Dr. Goyan wasn't here long enough to really impress much on me.

RO: Kind of a caretaker commissioner.

CG: And I was too naive in Dr. Schmidt's tenancy to really get much real sense. I mean, he's just a very powerful person. (Laughter)

RO: Well, he's the one that created the Policy Board. Some of the bureau directors--now center directors--thoroughly endorsed the Policy Board and others didn't think highly of it.

CG: Yes, that was a long growth process. By about 1980, that was a pretty well established and accepted way of doing business. But it didn't happen overnight, I know.

RO: Very interesting. Anything you'd like to add, Chuck, to this?

CG: Oh, gosh! Not really. I think you've given me the opportunity to say what I needed to say.

RO: Well, it's clarified what your office was about and the operation of OPE now as compared to what it was under some of the other commissioners. Do you have any idea of what caused Jake Barkdoll to leave when he did?

CG: Yes. My idea, and I don't think it would be too hard to corroborate it. Mary Jo Veverka. The two of them just did not mix. You could almost see Jake wince at times, because her style was so dramatically different from his, and it was a functional demotion, too. He had been at the small table with the commissioner for many years, and all of a

sudden, he wasn't even asked into the room in many cases. So, what's going on? (Laughter)

Yes, I . . . Some of my recollections in getting ready for this, I remembered the old Policy Board days in the seventies. First it was a full room. There were really few limitations on who could come if they had any legitimate credentials at all, so ordinary analyst staffers could go visit the Policy Board meetings and listen to the discussions. There was a certain amount of excitement in that, because you were hearing about what's happening now at a fairly high level. The arrangement of seating assignments was always interesting to me. The deputy was at the left and at the right was ORA. I guess Sam Fine was there first, and then Paul Hile.

RO: Sam Fine was the first one.

CG: I remember at one time the room was just overly crowded, and somebody had taken Sherwin Gardner's chair and was sitting at his location. So Sherwin didn't say anything, and he walked back into his office and came back with another chair full-arm extended over his head and just set it down. (Laughter) I would not want to try to convince him of anything for a few minutes after that. (Laughter) He was thoroughly steamed.

RO: Well, in addition to the main Policy Board meeting, each one of the bureaus had their own staff meetings.

CG: Those are the ones that I got to sit on earlier.

RO: Of course, there aren't any of those under the current system.

CG: No, those were weekly events.

RO: Those were. That's right.

CG: The commissioner put in a lot of time. So if you say, "Were there commissioners who got more involved in some of the things that planning was interested in?" there sure were. The commissioners who made that commitment to spend time, travel downtown and meet with the foods folks and wherever once a week and listen to GS-14 project managers make presentations.

RO: You were gone from drugs when the merger with biologics was going on.

CG: Yes.

RO: Well, Chuck, we want to thank you for this.

CG: Well, I thank you. This has been a real pleasure. It's the kind of thing I like to do.

RO: We'll get this transcribed, and you'll have a chance to edit it. So thank you very much.

CG: Well, thank you.

(Interruption)