

History
of the
U.S. Food and Drug Administration

Interviewee: Morris R. (Butch) Bosin

Interviewer: Robert Tucker
Ronald Ottes

Date: July 29, 2003

Place: Rockville, MD

DEED OF GIFT

Agreement Pertaining to the Oral History Interview of

Morris Robert (Butch) Bosin

As a conditional gift under section 2301 of the Public Health Service Act (42 U.S.C. § 300 cc), and subject to the terms, conditions, and restrictions set forth in this agreement, I, Morris Robert (Butch) Bosin of [redacted] Fairfax, VA 22032 do hereby give, donate [redacted] Library of Medicine, acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at Parklawn Bldg. Rockville, MD on July 29, 2003 and prepared for deposit with the National Library of Medicine in the form of recording tape and transcript. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

Title to the tapes and transcripts shall pass to the National Library of Medicine upon their delivery and the acceptance of this Deed of Gift by the Chief, History of Medicine Division, National Library of Medicine. The Chief, History of Medicine Division shall accept by signing below.

I place no restrictions upon the use of these tapes and transcripts by the National Library of Medicine.

The National Library of Medicine may, subject only to restrictions placed upon it by law or regulation, provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, description, exhibition, display and servicing of the tapes and transcripts as may be needful and appropriate.

Copies of the tapes and transcripts may be deposited in or loaned to institutions other than the National Library of Medicine including the U. S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The National Library of Medicine may dispose of the tapes and transcripts at any time after title passes to the Library.

Date: 7/29/03 Signed: Morris A. Bosin

I accept this gift on behalf of the United States of America, subject to the terms, conditions and restrictions set forth above.

Date: _____ Signed: _____
Chief, History of Medicine Division
National Library of Medicine



CASSETTE NUMBERS: 1,2

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

DATE: July 29, 2003

PLACE: Rockville, MD

LENGTH: 90 minutes

INTERVIEWEE:

INTERVIEWER(S):

NAME: Morris R. (Butch) Bosin

NAME: Robert Tucker
Ronald Ottes

ADDRESS: [REDACTED]

ADDRESS: Food & Drug Administration

FDA SERVICE DATES: FROM May 1979

TO: August 2003

TITLE: Director, Planning Staff, Office of Planning

INDEX

Tape	Page	Subject	
1-A	1	Personal History and education	
	2	Early work experiences	
	3	Entered FDA service	
	5	Strategic planning	
	6	Operational planning	
	7	More on strategic planning	
	8	Commissioner influence on planning	
	11	9/11 influence on planning in FDA	
	12	Commissioner Young's Action Plan	
	14	Mary Jo Veverka	
	1-B	16	Administration /Congressional planning influences
		21	FDA Modernization Act
		22	Planning and the Budget
		23	Counterterrorism planning
25		Dr. McClellan	
28		Importation of drugs	
29		Commissioner McClellan's regulatory philosophy	
30		Workload balance among the Centers	
32		Shared services	
35		History of FDA Planning processes	
36		Wrap-up and end of interview	

RO: This is another in the series of taped interviews in the FDA Oral History Program. The interview is being held with [Morris R.] “Butch” Bosin, retired director of planning staff in the Office of Policy and Planning. The date is July 29th, 2003. The place is the Parklawn Building, Rockville, Maryland. Interviewing Dr. Bosin is Robert Tucker and Ronald Ottes. The transcription of this interview, together with the tapes, will be placed in the National Library of Medicine and become a part of the FDA Oral History Programs.

Butch, to begin this interview, would you give us a brief biographical sketch of where you were born, educated, and any relevant work experience prior to coming to FDA.

MB: Thank you, Ron. I was born March 6th, 1941, in Washington, D.C., actually in Columbia Hospital, which is now a hospital for women. My parents moved to Arlington, Virginia, a couple of months before I was born, and so I was raised in Arlington, Virginia. Went to Washington Lee High School in Arlington, Virginia. Graduated in 1958. I attended Virginia Tech [Virginia Polytechnic Institute and State University], 1959 through '61, and then I ran out of money and went to work with the Department of Defense [DOD]. My first employer was the Bureau of Ordnance, what was then called the Bureau of Ordnance at DOD, and they were down on Eighteenth and Constitution Avenue in what used to be called temporary buildings. I worked for the Bureau of Ordnance and then Bureau of Ships during my summers.

I then re-enrolled in American University in 1962, and while I was at AU, I worked part time at the State Department in their Foreign Service Institute. I got my bachelor's degree in

business administration from American University in 1963, and my M.B.A. from American University in 1964, and I actually began as an adjunct instructor at American University starting in 1965 through '69.

RO: What were you teaching then?

MB: Marketing and marketing research at AU. I had my bachelor's and master's degree, and I worked for the air force as a statistical analyst in the summer of '66, I believe it was.

Then in 1967, I went to work with the Department of the Interior, in what was then called the Bureau of Commercial Fisheries. I stayed with them from 1967 through 1979, for about thirteen years. But in 1970, NOAA [National Oceanic and Atmospheric Administration] was formed, so my whole bureau got transferred from the Interior Department to the Department of Commerce under NOAA. So from 1970 through '79, working for the same agency, but they were now called the National Marine Fisheries Service.

RO: What were you doing there?

MB: I started in '67 as a marketing specialist. I was really helping the industry develop their underutilized resources. For example, everybody demanded fish like shrimp and cod and the well-known species, but those were being overfished, and it was causing economic hardship for the industry.

So part of our job was to encourage the development and the marketing of underutilized resources like pollack and some of the lesser known fish that didn't have a good name with the

U.S. public, but which were perfectly healthy fish. So as a marketing specialist, I helped work with the industry to help them develop their resources and to market them.

Then I became an industry economist with that same agency and produced situation and outlook reports, which were forecasts of what was likely to happen with prices, imports, and domestic production and all together with the economic factors that affected the industry. Industry used to appreciate the reports that we put together, forecasting what's likely to happen over the next six months or year. It was a quantitative analysis type of job.

RT: I was just going to ask you, at that point in your career, what grade level were you?

MB: Well, I started off as a GS-9. In my earlier jobs, I started off as a 3 with the defense department, and I moved up, 3, 4 range, while I was in school, working for State Department. In the air force, as a statistical analyst, I jumped up to a GS-7.

Then in the Bureau of Commercial Fisheries, I started as a 9, and then I left there as a 13. So while I was working as a marketing specialist and industry economist, I was at a GS-13 level. Then finally, I spent the last five years there, working in the planning office. So we did—very similar work to what I started off doing here.

And I left there in April of 1979. I applied for a job at FDA and started in May of '79 in the planning staff.

RT: Was that under the directorship of Jake Barkdoll at that time?

MB: Right. Jake was the associate commissioner for planning and evaluation at the time. I came in under Don Kennedy in May of '79. It was like two months before he left, in June of '79. The head of the planning staff at that time was—the person who hired me, my direct supervisor, was Ken Durham, who's now down in CFSAN [Center for Food Safety and Applied Nutrition].

RO: Ken is still in FDA?

MB: I think Ken is still there, and he's working in education and consumer outreach. Then I had a series of bosses as the staff director. Ken, followed by Doug Sporn, who left to go to industry, I think, a few years ago. Then Billy Don Weaver, who unfortunately passed away this past year. Then Bob Navazio was my boss. Then I became staff director in 1997, so I've been the staff director for six years.

That's sort of employment history. I guess, from an academic background perspective, I obtained my doctorate from GW [George Washington University], in public administration, in 1984.

RO: You've been involved, then, in what is called strategic planning.

MB: Yes.

RO: Would you describe, for the record, a little bit about what strategic planning is, and how it varies from what is traditionally considered planning. Or is it all strategic planning?

MB: Well, strategic planning is basically looking at the long term, five to ten years into the future. It usually has two dimensions. One is, it's longer term planning, and the other one is, it's usually broader. Broader in directional type of planning, as opposed to operational planning or performance or tactical planning, which focuses in the shorter term and is much more specific in terms of specific targets and specific actions. Strategic planning is usually starting off looking at what is our mission, what is our vision for the future. Any major changes in direction, like moving from—in the inspectional area, making the basic decision to move from statutory focus to high risk, which is like big, broad changes.

RT: Would strategic planning be what Mr. Barkdoll used to refer to as a plan to plan? That was a term that he sometimes used.

MB: Yes, I think that term, a plan to plan, really referred to any kind of planning, and it was talking about you have to have a process in place, regardless of what the plan is. And when you're planning to plan, you have to think about and plan the steps in the process, regardless of what the plan is. I think that's what he meant.

RT: I see.

MB: Decide on the process that you're going to go through. Whether it's planning to move your furniture or planning to move into a new scientific arena, you still have to have a process in mind and who gets involved in that process. So that's what I think he meant by a plan to plan.

RT: So that would be more of a generic reference or term?

MB: Right. Regardless of the kind of planning you're doing.

RO: You're familiar with the way that the agency plans field operations. That's more of an operational plan, then?

MB: Right. Well, they do their work planning, and, when the centers prepare compliance programs, that's more a year ahead of time. That's much more operational and much more focused on the specifics. How many resources, what do they have to specifically get accomplished.

RO: How many inspections to make. How many samples to analyze.

MB: How many inspections. How many samples to analyze. I would call that operational. But the operational should be aligned with the strategic direction that you're moving in, so if, for example, in the strategic part of the planning process, they decide they want to move toward focusing on high risk as opposed to statutory in the future, then the specific kinds of inspections would change to focus on high risk.

For example, for the past two years, the Center for Drugs has decided that they're going to put all their emphasis on high-risk drug firms, and they're defining them as those who produce sterile drugs, those who produce prescription drugs, and those who have been in business less

than a year. So they've defined what they mean in their strategic thinking. Then that guides the specific selection of establishments that they want to inspect.

RO: How is that going to impact on the statutory drug inspections?

MB: Unless we get more money, it's going to cause us to not meet our obligations. In drugs, for example, we're already not meeting our statutory requirements of inspecting those firms at least once every two years. I think we're at about 20 to 25 percent a year, rather than 50 percent a year. And the reason that Dr. Woodcock, our current center director, has offered is that we have to divert our limited resources to focus on the highest risk problems. If that means sacrificing meeting statutory goals, then so be it.

RO: What are some of the strengths and the weaknesses of strategic planning?

MB: The sort of traditional strengths that are associated with it are that you anticipate the future rather than react to it. You're preparing for change. It looks at the whole agency rather than just pieces of the agency, so it galvanizes the employees together and maybe unifies them to move in certain directions. It sets a framework, a frame of reference that everyone can follow. Those are the strengths.

There are a lot of weaknesses, particularly in the public sector, because in the public sector, for one thing, all of our stakeholders don't want us to move in the same direction, necessarily, so, particularly in federal agencies, there's tugs in different directions, and if

strategic planning is supposed to unify you, it's hard to do it in an atmosphere where different stakeholders want to push you in different directions.

RT: In this era of more frequent changes in commissioners or top-level managers, does that complicate the strategic planning process?

MB: Very definitely.

RT: When a new commissioner comes in or a new administrator, you then have to apprise them of the plan and get their concurrence and support?

MB: Right. And it often means direction changes. Like when Dr. [David A.] Kessler came in or Dr. [Mark B.] McClellan. Whether it's their agenda or whether it's the administration's agenda, it doesn't necessarily pay homage to the current directions all the time. So operating in a political environment also means changes in direction, and change is hard enough as it is for the people in the agency. Strategic change is really hard. When they finally start moving in one direction, and a new administration, a new Congress, or a new commissioner has other ideas, the change is simply hard to implement.

RT: A little frustrating for the planner, then, isn't it?

MB: Yes. And Jake, who is my mentor, supreme mentor, has always said that we operate with one foot in the careerist camp and one foot in the political camp. You sort of stretch, and it's difficult to keep it all together.

RO: Since you've been here in FDA, what changes has the agency undertaken as far as the enforcement philosophy and as far as planning is concerned? I suppose that changes with the commissioner?

MB: I think that they're more like cycles than changes, at least in terms of the approach to planning. I mean, we could be talking about two types of changes. One is the way we plan. The other one is the new issues that come up, so do you want me to talk about the way we plan as opposed to the issues, or like when AIDS came along or when all the new genetic—

RO: I guess I was thinking more if there has been a change in the philosophy of the agency, but I guess that will depend a lot on the commissioner.

MB: I jotted down five different dimensions that I've seen cycle back and forth over the twenty-five years.

One of them is whether the planning process is driven primarily by the commissioner as opposed to driven by the centers, and we seem to have cycled back and forth. In some years, it's mostly the center directors and the field directors who's got the power and the influence over which direction we take. In other years, it's been the commissioner.

Like, for example—and this is all impressionistic, but—when Dr. Kessler was here, it was very much a commissioner-driven process, and it looks like Dr. McClellan is driving it from the commissioner’s office more so than in other years, where the center directors or the field had more influence. So that’s one aspect of planning that seems to cycle back and forth.

Another dimension is whether the planning tends to be more along organizational lines within centers, or whether it’s crosscutting, and we form these crosscutting teams that consist of representatives from all the centers in the field and the Office of the Commissioner, and that cycled back and forth, too. Some years, planning takes place strictly within center lines and within the Office of Commissioner. Other years, they form these big interactive teams when they’re dealing with agencywide issues.

A third dimension is whether the planning process tends to be focused on getting the money for the agency or legitimately concerned with strategies that we’re going after. So in some years, it’s all about how much are we going to ask for and how much are we likely to get, and then having the budget drive the plan. In other years, it’s the plan driving the budget.

And a fourth dimension is what I call—at one end of the spectrum, it’s a go-for-broke kind of budget, and the other years, it’s a minimalist budget. Nobody’s getting anything. And I’ve seen years, for example, where Dr. [Michael A.] Friedman—and a couple of years when GAO [General Accounting Office] said, “Tell us all you need to be an ideal agency.” In those years, we planned for the ideal agency, and it was a sky’s-the-limit kind of a budget.

In other years, like this past year and the year before, it’s a very minimalist budget. The signal is, you’re not going to get any more money. Nobody’s getting any more money, so when you plan, you’d better plan with the resources that you now have. And that’s varied over the past—at least since I’ve been here.

RO: You're doing more of a long-range plan, you know, five years out. And what I think you're telling us here is that this was almost on a year-to-year basis.

MB: Yes, in each year that we plan, there's a period of time where we look longer term, and then there's a period where we just look at the budget. I guess what I'm saying is that in some years, we more or less abandon the longer term and look and focus on the next year. Some years it's a balance.

RO: After 9/11, what changes were made, as far as the agency was concerned, in their strategic planning?

MB: Well, for one thing, it called for the development of a counterterrorist strategic plan, which was not in existence before.

RO: Before 9/11.

MB: Before then. So a big change was that the agency focused a lot of its resources on getting people together to develop a counterterrorist strategic plan, and that called for cross-agency planning, and we developed one. Thank God, we haven't had to implement it. But that was a big change, and it caused people to work across organizational lines to do it, and now it's part of Dr. McClellan's—what he's calling the strategic action plan, which is a combination of strategic and operational planning. But counterterrorism is one of his five major goals in his plan.

RO: I remember when Dr. Young came in, he put together an action plan. What was your involvement in that action plan? Because that was a mix of short term and longer term.

MB: Well, at that time I was heading up the planning group, and Billy Don Weaver was the head of our planning staff. We got the job of helping to form action teams all around the agency. Then we got the job of—these teams developed narratives for the future, and then our office got the job of taking those narratives and translating them into specific action plans with milestones, and then we set up a tracking system.

I'm not sure whether you were here at that time, but there was a whole series of—there was a big monitoring system and a whole series of meetings that Dr. [Frank E.] Young and his deputy, John Norris, held with each of the center directors to check on the progress of his action plan. And our office ran the monitoring system and prepared the materials so they could have their discussions.

RO: Dr. Young was big on biotechnology.

MB: He was big on biotech.

RT: Were you involved in trying to see what the impact of biotechnology developments would be on the agency?

MB: Yes. As a matter of fact, during that era we did two biotechnology forecasts. One was covering medicine, and the second was for food biotechnologies. We actually have the publications here. I believe they were both under Dr. Young's watch. He was interested in that and wanted us to do forecasts. The forecasts were mainly asking the experts all over the country and internationally, which developments do you think are most likely to be emerging over the next several years.

Most of what I've been talking about up to now is planning processes, but particularly in the eighties, a lot of our work were studies where we were looking at factors in the environment that may be moving in a different direction and examining them a little more closely and then giving the information back to the agency. And biotech was one of those.

RT: Dr. Young, I think, showed a greater interest than some commissioners have in some of the operations of the agency, particularly emergencies. Did he have a particular interest in planning and a desire to be involved in that operation?

MB: When he came on board, we heard that—the quote from him was that he said, “I'm a planning nut,” and that turned into a pretty famous statement. He was more hands-on involved in planning than a lot of the commissioners we've had. Almost a complete contrast to Dr. Kessler, who, from my view, wasn't interested in formal planning processes at all. He had issues, tobacco and orange juice and those things. But as far as planning processes, that was probably not very important in his mind.

But it's interesting. Both of them, both Dr. Young and Dr. Kessler hired consultants to come on board and run the planning operation. Dr. Young hired John Norris, who I guess he had

worked with up in Rochester. John Norris was the one he relied on to run—there was a sort of a clash, somewhat of a clash between Jake and John, because Jake was the quintessential planner for the agency, and he'd worked with the leadership for years, and then John Norris came on board and said, "I'm taking charge of this planning." There was a little bit of angst, I would say, between those two.

Dr. Young left in December of '89, and Dr. Kessler didn't come on until a year later, November of '90. And Dr. Kessler brought a planner with him, who was Mary Jo Veverka from I think Booz Allen [Hamilton]. So both of them actually brought in their planning consultants. But Dr. Young seemed much more interested in the process than Dr. Kessler. Dr. Kessler sort of turned it over to Mary Jo, and we supported her. By that time, Jake had gone to USC.

After Kessler came in with Mary Jo Veverka, Bob Navazio and I worked for her and helped her put together the agency's strategic plan at that time, which was from '90 to '92 era. That plan never really went anywhere. It wasn't really owned by the agency.

RO: There was a rumor that Jake and Mary Jo didn't get along very well.

MB: That's right.

RO: I can understand that.

MB: Yes. She was very top-down, and he was very participative and consultative and that didn't work very well, either.

RT: Of all the commissioners through the years—usually we ask this question more near the end of the interview, but you've discussed both doctors, Young and Kessler. Were there other commissioners in your tenure who were particularly noteworthy in terms of their interest or involvement in the planning aspect of the agency?

MB: Well, this happened early in my career at FDA, but Jake had a great relationship with Sherwin Gardner, who wasn't a commissioner. I guess he acted periodically. But from my understanding, Sherwin must have brought Jake in. He brought in a lot of ideas from the private sector on planning approaches, and Jake implemented a lot of those approaches, and Sherwin endorsed all of them and supported Jake completely, and he sort of gave Jake a platform.

I didn't come in until Dr. Kennedy came in, but apparently Dr. Kennedy had a lot of confidence in Sherwin Gardner, and Sherwin Gardner had a lot of confidence in Jake, so Planning was in a heyday during that period. And I think Dr. [Jere E.] Goyan and Dr. [Arthur Hull] Hayes [Jr.] expressed confidence in the planning and basically turned it over to Jake.

So from the time I first came on board, from May of '79 until September of '83, Jake really enjoyed a lot of autonomy and a lot of close working relationships with the leadership. And he did before I came, too, in the seventies.

[Begin Tape 1, Side B]

MB: Then in '84, when Dr. Young came on board, for those five years from July '84 through December of '89, that's when Dr. Young brought his planning specialist in, and Jake's influence began to get a little diluted. Then when Dr. Young left in '89, and Jim Benson took over for

about eleven months, January '90 through October of '90, he and Jake were very close and had the same philosophy, so Jake's star sort of rose again, and when his star rose, our star rose.

But then when Dr. Kessler came in, in November of 1990 through February of '97, the planning processes, per se, were not considered terrifically important, even though Mary Jo did develop the strategic plan during that time. There just wasn't as much agencywide simpatico for planning. Mary Jo tried to strategic plan, and my impression was that it was hard to get buy-in, both from the agency and from the department, who actually killed it. They didn't want to publish it, because they hadn't endorsed it.

RO: You mentioned the impact the different commissioners have, but what about the administration?

MB: The administration has had impacts, too, definitely. I mean, if we can go back to—in terms of the administration having an impact, it is maybe getting a little aside, but for two or three years after I first came into government, we started having this series of governmentwide planning and management reforms.

The first one I was involved with was PPBS, Program Planning Budgeting Systems, the series that's usually referred to as PPBS, brought in under President [John F.] Kennedy; and then Management by Objectives brought in by Lyndon [B.] Johnson; and then Zero-Based Budgeting brought in by [James E.] "Jimmy" Carter.

Then there was some minor reforms, but the next major one that was brought in was GPRA, Government Performance and Results Act, was brought in around '94, '95. This was the

first one that was legislatively mandated, but it came in under [William J.] Clinton and [Albert A.] Gore.

All of these have been governmentwide reforms that the administration has been pushing, so when you ask the question, what about administration's influences, these are like periodic eruptions that the administration is pushing governmentwide, and the current version of GPRA is PART.

RO: PART.

MB: Which is also part of the president's management agenda, which is what came in under President [George W.] Bush.

RO: So PART stands for?

MB: Program Assessment and Review Tool. But PART is part of the president's management agenda, which has five chapters, and this is Bush's plan for making government streamlined and more citizen-responsive. And the parts of that agenda are, to improve our use of intellectual capital, our human resources, is one aspect. A second aspect is e-government. A third aspect is making sure our financial management systems are efficient, and a fourth aspect is outsourcing, making sure that whatever jobs are being done, are being done the most efficient way, even if it means outsourcing them to the private sector.

RO: Is that the same as sharing? Outsourcing is sharing, or are they different?

MB: Well, now there's a term called shared services, which is different than outsourcing, but they're all—shared services is part of us making better use of our intellectual capital. And A-76, this competitive sourcing is another chapter.

And the fifth one is performance and budget integration. That's where the PART comes in. They want to make sure that agencies can connect what performance is being realized for what level of dollars. They want to hook dollars into results. That part of the president's management agenda, performance and budget integration, is where PART is active, and that's also the successor to GPRA, which was brought in by Congress under Clinton.

So that's a long-winded answer to the question, does the administration have influence over the planning, and it very definitely does. For about the past ten years, GPRA and performance and performance budget integration has been the big administration influence on our planning approaches, because we now have to produce performance plans each year. We've done it for the past seven years, and we have copies of all of that.

RO: Is the agency measured against those, then?

MB: Yes, our staff is responsible for producing those plans, but we have to cooperate within the centers.

RO: Are those plans rather broad?

MB: Well, the performance plans are specific, where you set specific targets. For example, we had about seventy performance goals in the plan. One of them, for example, is to review 90 percent of all priority drugs within six months of the time that they're received. Or to inspect 95 percent of all of high-risk food establishments.

RO: Is that Congress-driven, or is that an administration's initiative?

MB: The idea that we need to measure things is congressionally driven by GPRA, this Government Performance and Results Act, and they mandated that all agencies have to prepare performance plans, and we've been doing it ever since, for the past seven years. Our first plan was produced in the fall of '97.

RT: Those planning cycles, do they involve congressional committee interest and oversight hearings?

MB: There have been a series of hearings by the Senate Government Operations Committee and the House Government Reform Committee. Those are what usually we refer to as the good-government committees. They have a lot of interest in implementing things like GPRA and PART. The ones that we've had a hard time getting their attention are the appropriators. The appropriations committees make their decisions based on what they're used to making their decisions on, like things that would interest their constituency, but are not necessarily performance goals and things like that.

But the good-government committees have commissioned GAO to do studies to determine how well our agency's doing in implementing these reforms like GPRA and PART, and you've seen in the paper, they give scorecards for—red lights and green lights for how well agencies are doing in implementing these things. So they get a lot of press. But the appropriators are—been hard to get their attention on this.

RT: That's interesting.

MB: Yes.

RT: Well, the Congress seems to have fallen into the practice of giving the agency additional responsibilities without commensurate funds, but usually the requirement for absorbing the expenses within the current resources.

MB: Right.

RT: I suppose that's what you mean by the difficulty in getting appropriations committee attention to plans?

MB: That's part of it, yes. I mean, unfunded mandates is part of the problem, but I've got to think about that one, because we're still being asked to identify specific results, but it's usually results with our base money. But it's also often the case that they expect us to achieve results without having the money to do it, and that's a problem.

And also without funding our cost-of-living increases. Recently they've started doing that, but that's been hard to do, too, because we have to stay committed to goals and at the same time divert some of that money to pay for pay raises, which is money, taking it away from programs.

RO: What does this FDA modernization act refer to? Is this a part of GPRA?

MB: Well, this was actually going on parallel. The FDA Modernization Act was—I'm blanking out on the year, but it was in the nineties. That was an attempt—and this is just my interpretation, but—an attempt on the part of a Republican Congress to make FDA more responsive to its stakeholders, industry and consumers, I guess.

But as part of that act, there was a section in the act, Section 406(b), which required the development of a plan, and when Dr. [Jane E.] Henney came on board, and Linda Sydam was her right-hand person, we worked with Linda to prepare an FDA Modernization Act plan. It was called FDAMA for short. That was produced in November of '98, and it was basically responding to how we can become more stakeholder oriented. In part it was acknowledging to the world that FDA can't do it alone, that we have to rely on lots of partners, domestically and internationally. And they wanted to see a plan for how we were going to implement all of the reforms that Congress put on us.

RO: Is the agency monitoring their performance against this plan?

MB: Well, not—we had to produce one report and give it to Congress, and that was done the next year, and then—it's passé right now. A lot of the results, though, are still under way.

For example, some of the specific provisions on compassionate review processes for certain medical devices, or indirect food additives, the way they're handled now, where—it was sort of deregulatory, in a way. It was, in some cases, allowing industry to give advance notification rather than getting permission to market certain indirect food additives.

There are a lot of subtle and not-so-subtle changes in our regs that were mainly spearheaded by the policy office, that got implemented in the agency, and some are still being implemented.

But modernization really meant regulatory reform, and it's still happening. That was happening at the same time we were implementing GPRA. The difference between the two, I think, is that FDAMA actually had an ideologue in mind to move us toward a more deregulatory stance, whereas GPRA wanted us to make sure we could measure what we were producing. So this didn't have a philosophy, other than a good-management philosophy. This actually pushed us into a more conservative deregulatory approach.

RO: How closely do you work with FDA budget office?

MB: Very close. Particularly when we get into the annual planning, like performance planning. The performance plan has to be integrated with the budget.

RO: Performance planning, then, is more on a short-term basis than strategic planning?

MB: Right. All of these GPRA plans are annual plans. Performance planning is not strategic planning, but in these performance plans, in the front end, we usually sort of have a strategic framework to frame it, and then when you get into the details of the performance plan, it—this document tries to align strategic directions, which are outlined up front, with the specific performance goals that will move us in that direction.

For the past several years, the front part of the planning process is supposed to be strategic. It's supposed to be broad and directional. Then it's followed by the performance plan, which is specific targets to carry out those directions. Then it has to be coordinated with the budget, because the dollars to achieve the plans have to be identified, and that's where we tie it to the budget. Then it gets submitted in parallel with our budget, but the budget is prepared by the budget shop. A lot of processes.

RO: I guess so. What was your involvement in the counterterrorism plan?

MB: I and a few members of my staff sat on the planning group that actually developed the strategic plan that had to be converted into action items. It was chaired by Janet Woodcock, to begin with, and we were more or less providing planning support and database support to that group.

But the real experts in the centers and the field were the ones to think about what we needed to do, emergency preparedness plans, and primarily a field effort, where the people in charge of our emergency operations in the field, Ellen Morrison and people like that, spent a lot of time thinking about the emergency preparedness plans, and people in what used to be Larry Tidmore's shop.

Barry Smith was concerned about protection of FDA assets and physical property. Then people in the centers, particularly drugs and biologics, were concerned about the development of medical countermeasures; in case an attack happened, do we have enough drugs and vaccines. So that all became part of this counterterrorism plan.

RT: That whole operation, then, was reported to the Office of Homeland Security? Is that correct?

MB: Well, I think they communicate with them, but none of us got swept up into that office. But the department has a counterterrorism coordinator that the folks in counterterrorism communicate with to coordinate department counterterrorism policies and planning with the agency.

RT: I see. It would logically follow that the department would gather from all of its subordinate agencies' input.

MB: Yes, particularly CDC and FDA and a few other agencies, but CDC is a primary participant in the development of medical countermeasures. But I think we both worked together in encouraging industry either to develop novel, new countermeasures where we don't have any drugs or vaccines for, or modifying—or getting something going on permitting the use of vaccines or drugs that are already in existence, for emergencies. So I think they also work with the defense department on the stockpile of vaccines and drugs. A lot of reaching out to different stakeholders in that counterterrorism effort.

RO: Do you see from where you sit any difference in what the agency's direction might take in the next five years? I'm sure you've looked at it, because you've got a five-year plan now.

MB: Well, what Dr. McClellan is calling a strategic action plan is for the period, fiscal year '03 through about '07. And when he is looking out with his leadership, he has established five goals. One of them is to make sure that FDA is strong for the future. By *strong*, he's putting a lot of emphasis on recruiting the right kind of professionals in the future who have state-of-the-art science expertise. Making sure that we have the right IT capability and making sure that all of our processes are running efficiently. That's all strong FDA.

His second goal is risk management, and I think his big emphasis there is that he wants to make sure that we analyze—this probably doesn't sound new to you, but he's putting a lot of emphasis on making sure that any decisions that we make, the risks are analyzed, the costs and the benefits of the risks of making that decision are analyzed, both from a scientific perspective and also from an economic perspective. He's a world-class economist, and he brought on a lot of economists to look at the benefits and the costs of all of our regulatory decisions. He wants to make sure that whatever decisions we make, the net benefits exceed the costs, and he's put a lot of emphasis on that second goal of risk management.

As part of risk management, he's also looking in the pre-market area for studies, seeing how we can reduce our review time. Why do we take so many cycles to review? And on the post-market side--this is all risk management—he's looking at, particularly in the drugs area, are drug GMPs outmoded; do they need to be modernized to recognize the technologies that are

coming along. And also trying to ensure that the drug manufacturers have quality processes in place.

So he wants to reinvent us, and he wants to help industry in the GMP side, and he wants us to make sure that we're ready to handle the new technologies on the pre-market side, to make sure that we have an efficient review process in place, and make sure that we analyze the benefits and costs of all the risks. It's all part of his risk management package. That's his second goal.

The third goal, which is a new emphasis—maybe everything is cyclical. You remember when Alex Grant was in the Office of Consumer Affairs, and that had sort of seen its heyday. Well, now Dr. McClellan is resurfacing consumer information as a very important priority for him for the future. His objective is to make sure that the information that consumers have is the kind of information they can use to make good decisions with emphasis on communication to consumers, understanding the impact of our communications, and—because he feels that when consumers have the right information, they can help to manage the risk along with us.

RO: Does that include product labeling, for example?

MB: Yes. Making sure that the labeling is accurate. Some of our recent rules on like getting information out about trans fats to make sure that people understand that they're dangerous. And so that's the third.

The fourth goal is patient safety, and he's trying to do whatever he can to reduce the 100,000 or so deaths from medical errors in this country. One of his big initiatives in that fourth goal is to make sure that we're linking up with other surveillance databases, like healthcare provider databases, other health agency databases, to make sure that we are getting as many of

their reports as possible on a real-time basis on adverse events and doing something to correct those problems.

The fifth goal is counterterrorism, and it's not so much a change, but it's a continuation of what we've been planning since 9/11.

So strong FDA, risk management, consumer information, patient safety, and counterterrorism are his five key goals, but probably the ones that he sees the most change in are risk management, consumer information, and patient safety. Those are the ones that he wants to be more active.

And I think he believes more than any commissioner that I've seen on board, he wants to make a material difference in reducing healthcare costs, because he believes FDA can be a major player in reducing healthcare costs. By getting the products out there quicker, by having consumers understand their usage, and by correcting patient safety adverse events as quickly as possible, he thinks he can have a major impact on healthcare cost reduction. I think he's espoused it more than any commissioner that I've heard. Maybe that's partly because he's an economist, and he's done a lot of his research on the impact of health policy on healthcare costs.

RT: I see the FDA was sued—according to the paper this morning—for not getting some of these drugs out in a prompt manner. A lot of the new drugs that they're still working on; a group wants to have access to them.

MB: Right. Right.

RT: This new legislation that is working through Congress now that would permit the reimportation of drugs and perhaps importation of uncleared-by-FDA drugs, is the strategic planning taking cognizance of that possibility?

MB: There is an import section in the strategic plan, but I don't think that the strategic plan touched that issue, because it was such a hot potato. The agency's official position was to be opposed to it, because we couldn't guarantee the safety of these finished drugs coming back across the border, so we didn't have it in our plan.

But what we did have in our plan, as far as imports were concerned, was to strengthen the information that supported decisions at the border and to automate it, to get information from a wider variety of sources on imports, and also to make sure that the people looking at the domestic inspections had import information available to them, so that they may be able to start seeing which products on the market were imported. And so part of the strategic plan is to have a closer linkage between the domestic and the import monitoring, and to have a lot more automated and real-time information available to make decisions at the border, whether to let things in or not.

Then Matt Wampkin has a big initiative on strengthening the capacity of international producers, so that we can stop the problem upstream before it gets to the border by helping them to build the capacity to have good regulatory systems in foreign nations. So we're sort of attacking it in the strategic plan from an upstream, at the border, and even after it enters domestic commerce, to make sure that internationally furnished products have a better assurance of being safe.

RO: When Kessler first came to FDA, he decided he was going to show industry that he was a regulatory commissioner.

MB: Right.

RO: I remember he took on some of the big cereal manufacturers on the labeling of some of their cereals and things like that.

MB: Right.

RO: What do you see this commissioner as?

MB: Well, I think his emphasis is on smart regulation as opposed to more regulation. Carefully weigh the benefits and the costs of each new regulation that comes out, and he's really serious about it. In that sense, I think he's sympathetic with John Graham, who is the new head of the regulatory machinery at OMB [Office of Management and Budget], who is a big benefits-costs type of person. I even think they might have written some articles together.

But it's this calculus of, you know, we're not going to get another rule out without carefully weighing whether it does more good than harm. So that's why, I think, his emphasis is on smart regulations based on an analysis of the risk.

RO: I wonder if that goes to smart compliance actions, like seizures or injunctions, and what impact that's going to have on the industry, and FDA?

MB: Right. And of course, counterterrorism is driven into the new legislation. That gives us a little more authority to demand that firms are registered and that we have the right to turn them away, and they have to give us advance notice.

[Begin Tape 2, Side A]

MB: So anyway, the new bioterrorism legislation has given us a few more teeth to make sure that products that could be suspect have controls in terms of registration and record keeping. And I was going to say, that's in keeping with Dr. McClellan's desire to put emphasis where there's legitimate serious risk.

RO: Twenty years ago, the big emphasis was on foods, and then all of a sudden it shifted to drugs, and then, of course, medical devices and radiological health came in. Where do we stand now as far as a kind of workload balance with the centers?

MB: Among the centers?

RO: Yes.

MB: Well, certainly PDUFA 3 [Prescription Drug User Fee Act] still puts the emphasis on drugs in that respect, because that's a crucial piece of Dr. McClellan's plan to reduce healthcare costs, is to make sure the drugs are there on the market.

In medical devices, with the Medical Device User Fee Act, MDUFA, they're trying to follow suit by getting critically needed medical devices on the market. The problem there is that the funding from Congress is not as forthcoming as it needs to be to keep the act implemented. So from the drugs and the medical devices and the biologics side, it's still important as a healthcare reduction strategy.

From the foods side, foods has maintained prominence, particularly since 9/11, because food safety is associated with food security and counterterrorism, so the agency has been able to get Secretary of Health and Human Services (Tommy G. Thompson) definite interest in food safety as a major part of protection against terrorist acts.

So if you look at the driving forces, healthcare cost reduction and the threat of terrorist attack, healthcare cost reduction has kept pre-market review for drugs and devices and biologics prominent, and the threat of a terrorist attack has propped up the food safety program—and CBER [Center for Biologics Evaluation and Research], too--to an extent.

And the field, particularly in the counterterrorism arena, has gotten a shot in the arm because of their laboratory capacity that needs to be developed and their participation in emergency preparedness. So they're sort of an integral part of the counterterrorism effort, too.

NCTR [National Center for Toxicological Research], I think, may be harder pressed to make the case that they're an urgent and critical part of these two environmental factors, you know, healthcare costs and counterterrorism. They still can do supporting things, but they're not quite as much in the limelight as the other centers. I guess that's been the case for a while, because they can't quite make the connection that we're a research agency. We need the research to support our regulatory decisions.

RO: Would your staff or the whole planning operation fall by the wayside if the shared resources emphasis of the administration continues?

MB: So far, planning hasn't been included in the definition of administrative services. In one sense, the shared services organization doesn't include planning, so when they're creating a shared services organization, we're excluded from that. It includes facilities and HR and all the other administrative tasks.

So we're sort of immune from the shared services part, but what we're not immune from is the president's move to streamline government agencies, and one of our goals is to reduce the ratio of administrative-type positions to mission-critical positions in the agency. And when you look at that goal, we do become part of the administrative support positions, because it includes planning and policy types of functions as support. So that may put us at some risk for being downsized, because they have to meet this ratio of administrative to mission-critical positions.

So we're not in danger from shared services. We may be in some danger from this overall streamlining.

RO: Mission-critical positions, I suppose, are the reviewers, the drug reviewers—

MB: And the inspectors.

RO: The inspectors and analysts.

MB: Epidemiologists, who look at all the adverse events. People who develop standards. So anyone who's called a consumer safety officer or a chemist, etc. But us folks who are in the softer disciplines like policy and planning get grouped in the administrative category. Not for shared services, but for ratios.

And actually, the planning staff, over the years, has been reduced in size somewhat. When I first came on board, it was more like twenty, and my staff's fourteen now. So it's been reduced a bit over the years.

RT: Has it been reduced commensurate with the reduction in available staff?

MB: No, we're just like the agency. More work and—

RT: Less resources.

MB: Fewer resources to do it.

RT: I've covered some of the questions I had.

RO: I think we've pretty much covered the things that I had, too.

RT: Are there still some things, Butch, that you want to add?

MB: Well, I think it's been a very enjoyable experience working for FDA. I'm going to miss the agency terribly, particularly the people. I hope to keep following what's going on.

RT: Do you have plans to continue in some professional capacity in the private sector?

MB: Yes, I do. I'm going to take a month off in August, and then the day after Labor Day, I start with a small planning consultancy. It's a small firm here in Maryland who does planning and performance contract work with federal agencies. So I'm going to try them for a while.

RO: You might be back planning for FDA.

MB: Could be. Could be. Maybe broaden my contacts with other agencies. But there's so many agencies that are in the same boat.

One thing that has changed over the years, as far as I'm concerned, is that in the planning community, there seems to be a lot more reaching out to other agencies to share experiences and learn from each other, and it's much more of a sharing environment.

I think that's also the difference between the government reforms of—the management reforms in the earlier years and the management reforms of the 1990s and the first few years of the twenty-first century, is that in the earlier reforms, each agency was on its own to do—and they had to meet deadlines to have these new planning approaches in place, and there wasn't any reaching out.

But with the passage of GPRA in '93, there was encouragement from Congress and the administration to form interagency groups to learn from each other and get better across the agencies. And that's been a big difference, and that's helped.

RT: In the whole area of intergovernmental cooperation, the 9/11 and subsequent events seem to be generating that philosophy, that government needs to be more inclusive—

MB: Right.

RT: —rather than exclusive.

MB: Right. And even in the directions that FDA is moving, there's a big emphasis on we can't do it alone. We have to work with our stakeholders.

This package that I gave you has—maybe I can review it real quickly. In the short-term history, one page talks about generic FDA functions, reviews, inspections, etc. Then there is a page that takes the last seven years and identifies FDA strategic goals over the last seven years and how they've changed.

But what's noteworthy is that we can't get away from our basic functions, so we may word them a little differently each year, but you'll see repeating—the goals really haven't changed that much over the past seven years, with the exception of counterterrorism. Other than that, you see a lot of repeating each year in slightly different words.

There's another page on ranking the priorities, and the ranking has changed a little bit over the years. For the four years in the late eighties and into the nineties, pre-market review

seemed to be the number one priority. Then you'll see in later years, when we became budget-poor or needy, being a strong FDA internally became the number one priority. Then starting in '04, counterterrorism became the number one priority. So the goals haven't changed, but the priorities have changed.

Then I have another page on how the planning themes have changed emphasis over the past six years. The themes, though, haven't really changed. The themes, the sort of crosscutting themes are, we have to establish risk-based priorities, we have to have strong science, we have to collaborate with external stakeholders, and those have been—and more recently, we have to look at the whole thing as a system. But you can see some of these if you want to augment—

RO: You refer to stakeholders. Are you referring to the regulated industry or the consumers or both?

MB: Both, as well as health professionals. You could even consider Congress and OMB to be stakeholders, too. Academia. I mean, all of our stakeholders. Our sister health agencies.

Agriculture. It's just that almost every important thing we do, we seem to have to—but for a while there, Dr. Henney was emphasizing the initiative of leveraging, which is the same thing as saying that we can't lift this big, heavy rock ourselves. We've got to leverage it with other people—

RO: Butch, thank you for the time you spent with us.

MB: Thank you.

RO: It was very enlightening. I learned a lot about strategic planning this morning.

MB: Glad to be of help. Thank you very much.

RT: Thank you.

[End of interview]