History

of the

U. S. Food and Drug Administration

Interviewee: Paul L. Coppinger

Interviewer: Robert A. Tucker

Date: June 30, 2001

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

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

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INTERVIEWEE:	INTERVIEWER(S):
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FDA SERVICE DATES: FROM: 1970 TO: 2000

TITLE: Associate Commissioner for Planning & Evaluation
(Last FDA Position)

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RT: This is another in the series of FDA oral interviews for the history program. Today, April 4, 2001, the interview is being held with Paul L. Coppinger, Associate Commissioner for Planning and Evaluation, prior to his retirement on June 30, 2001. The interview is being conducted by Robert A. Tucker, FDA History Office.

Paul, we like to begin the interviews with a brief personal history of your background, education, and any pertinent professional experience prior to your joining the agency. So if you begin in that way, we can proceed.

PC: I graduated from the University of Maryland in 1963, went into the Navy for three years of sea duty as an officer immediately after that, and when I finished that in 1966, I both went back to graduate school and accepted a position as an executive intern in the Office of the Secretary of Defense. For my first three years of government service, I worked in the Office of the Secretary of Defense at a time when Robert [S.] McNamara and Melvin Laird were the secretaries. The Vietnam War was also going on during that whole period.

The Department of Defense was embarrassed by the fact that its Office of the Secretary was approaching 1,000 people, and so it said, "We can't have 1,000 people in the Office of the Secretary." So it was more or less clear that there wasn't going to be a future and that organization wasn't going to grow for political reasons, and most of the positions were going to military careerists in the organization. So most of my colleagues were leaving for the civilian agencies.

Of course, in 1970, EPA [Environmental Protection Agency] was formed, and there was a general interest in civilian agencies in my peers, and I think all but one or two of my colleagues left with me. Of course, the Vietnam situation went on, and that wasn't a real good management environment to be working in.

So I had a choice. HUD [Department of Housing and Urban Development] had a very good offer, and FDA [Food and Drug Administration] was way out here in the sticks. At the time I lived in Virginia, next to the Pentagon. It was kind of a coin flip between whether to go with HUD or FDA. FDA was forming a new planning group in the Office of Administration. Mickey Moure was the associate commissioner at the time. Everybody in the organization was new. They were looking for four staffers, and they had one supervisor that had the financial management. So four of us came in from four different agencies and had to do a real quick study of what's this thing called FDA. So that's where I was and how I got here.

RT: Paul, before we proceed, your degree from the University of Maryland was in what?

PC: It was a bachelor's in economics. I went back to grad school at the University of Maryland for the three years I was at the Pentagon, but I never got another degree.

RT: At the Pentagon, I think your remarks indicate you were in planning?

PC: The way their intern program worked, you took a bunch of long-term assignments in different parts of the Office of the Secretary, and then you took up the best of the opportunities you had. I wound up in the Office of Manpower, doing staffing, career incentives, retention. In fact, we were the people who controlled all of the statistical surveys in the Department of Defense, so we got to see a lot of information-gathering and the quality of that. We got to go out and do some of the surveys ourselves, so it gave you a nice overview of a lot of different pieces, really the human capital part of the defense establishment.

RT: Sounds like it would have been good background for you when you came to this agency in

terms of overall oversight.

PC: The thing that I think was most valuable was seeing the high command of an Office of the Secretary from the rest of the organizations and kind of the relationships between them.

The one thing I decided at that point was that I would never again work in an Office of the Secretary. I never wanted to be that far away from—because we saw a lot of the kinds of tension that happen, and lack of communication and different agendas that those Office of the Secretary kind of organizations wind up working on, and the political influences of all that. A lot of the studies we did, the data indicated one answer and the decisions somehow or other were different than that. So whenever I'm reading about the Defense Department now, I have fond recollections of how the data and the decisions didn't always meet up.

RT: That's good background to move on to the FDA. I just wanted to fill in some of those details. You were about to say that you had joined the unit that Mickey Moure was administering at that time. Is that correct?

PC: Right. Kind of the challenge at that time, the Nixon Administration had a "management by objectives" scheme of planning, and we more or less had to staff what were these intermediate-term objectives of the agency, and we had to have quarterly meetings at that time that very much involved the principals. The commissioner and the secretary and deputy secretary would sit down and negotiate those plans and report on the progress of them. Of course, in the early days, that was Charlie Edwards and Elliot Richardson. Mickey would be there, and we'd be shuffling the papers and making sure there were enough copies.

Compared to the way it is now, that was a very personal form of oversight by the secretary. There was an understanding of problems and empathy for what your situation is, and

many of the proposals, the objectives were, by present standards, rather foolish and reckless objectives that we couldn't get to, but wanted to. It wasn't a punitive environment at that time at all. We could come back three months later, and Peter [Barton] Hutt would explain, "We couldn't do that. We changed our minds."

I remember some of them were wildly ambitious when we were starting the OTC [over the counter] Drug Review. I saved one plan we had, and we'd convened the group to look at this class of drugs. In June we published the tentative final monograph in September, and we'd get all the comments, and by December we'd have a final monograph out. So it was four to six months, start to finish. When you look back on the OTC Review now, you realize how we just thought we could snap our fingers and do that, and no lawyers from the other side would ever quibble about anything.

All of that got revised and changed. It was a period of a whole lot of ambitious proposals and more reasonable executions, but nobody felt bad about being ambitious at that time. I mention that only because things are so different the way everything is very studied and cautious today in anything you would propose to a political level.

RT: Did you see this change or metamorphosis as the result of political administrations or of the administrative process of the Department and FDA?

PC: Well, it's probably a combination of things. One thing is, the Department has become enormously more bureaucratic over the thirty years. There it was the secretary and the deputy secretary. My funniest recollection of Secretaries and Deputy Secretaries is [Caspar W.] Weinberger and [Frank] Carlucci. They were still in that Nixon era. Because Carlucci was so sure that only his—and they never fixed the chair for him—that only his head would show, and it was almost—every time I would see them, it would remind me of the ventriloquists, you know,

just the talking dummies. Weinberger would be sitting up, very imperially, and Carlucci, because he didn't fix his chair, was just this head on the table. And yet everyone was very serious. Everyone overlooked his shortness of stature, but the contrast with both of them there. And the thing that's so odd about both of them is, we never, in the nineties, met with the secretary and the deputy secretary, and never in this inofficious understanding of the problem, talked about it.

So there was hilarity in a lot of this, with just the arrangement of things, but it was a very intimate group. There wasn't a lot of staffers that tracked the FDA from the secretary side. And all that's changed so much. They're a lot more institutionally bureaucratic than they are now.

But the other thing that changed is, we didn't really have the same relationship between the executive and legislative branch at that time. I mean, while it's turned out for altogether different reasons that the Nixon era is kind of viewed villainously, the relationships between the executive branch, Republican at that time, and the Congress, Democrat at that time, were a whole lot different than anything we've experienced in the modern era. That meant we weren't always looking over our executive branch shoulders at the reaction or the political consequence in the legislature, the reaction or the political consequence in the legislative branch, the budget decisions and all the rest of that.

The money and the funding of the agency was really separate from this enterprise of managing what we were doing, and the agendas were very different than I think the modern agendas. Those were proactive agendas, on what we wanted to do with our programs and our futures. They weren't the kind of reactive crisis management or fix-it kind of problems we were involved in.

The other distinction of the seventies is you could take FDA out of the rest of the government as a nice clean slice and deal with its problems. We weren't all tied into health care reimbursement, Privacy Act, all the other macro problems, everything that's connected to today, and all the international complexities. It was a pretty simple set of things. So we had a less

political environment, we had a personal department, and we had this simplicity of the executive branch and legislative branch.

I keep looking back on this and saying, is this just old eyes looking at the bright shining era of youth? Is everything simpler, cleaner, and brighter? But everything looks shinier back when it was new and young. And I don't think that's the case. Just because I can see more of the subtlety now, that it wasn't simpler and cleaner, more doable, and a place where new initiatives and new ideas. It was a better environment for those things than the current environment.

RT: Later, as you're suggesting, many more congressional oversight circumstances for the agency, apparently, right?

PC: Right.

RT: In other words, some of the committees were very interested in the operations of the agency on matters that more or less politicized some of the concerns.

PC: Remember, too, that the early seventies, we were still implementing the '62 Kefauver-Harris Drug Amendments. Everyone understood that that whole DESI [Drug Efficacy Study Implementation] was going to take a long time, but that was a profound change in the standard for approving products to introduce efficacy. And when it started to happen there, the first kind of philosophical attention that showed up was in the late sixties, around '67, the academics started publishing the articles on drug lag, and that was kind of the other side of "Let's make sure drugs are efficacious."

So that storm was starting to take shape in the early seventies, and every year there were more articles about, "Gee, was this the right thing to do, to set this high bar on efficacy?" So we

were headed into a whole decade of arguing about whether we were regulating too much or too little.

When I look back, and I've read it many times, the history of the debate over the '62 Amendments, what strikes me is how many prominent senators' names I recognize in the debate, and how bipartisan the personal involvement in that legislation was. That's another contrast. So I think there was a kind of political commitment, an understanding of what we were doing.

I particularly remember that Senator [Hubert] Humphrey even pointed out that, "You know, this is going to cause an awful lot of paperwork. Do we know what we're asking for here?" Of course, little did he know how much paperwork he was asking for. I mean, they were kind of aware where they were going, and I think everybody realized on the political spectrum that it's what they wanted to do. There was patience. Sure, there was a lot of criticism of the NAS [National Academy of Science] in the sixties and all, but when we got into the seventies, we were starting to see the counter-reaction to what had been a consensus political decision.

RT: Was that during the tenure of George [P.] Larrick that this was happening?

PC: Larrick was before my time. '67, I guess those articles started in his era, because they had enough time from '62 to '67 to start observing historically on how many European drugs we weren't getting, and that's what started all that.

I mention this one issue because I think it's one of the first threads that started to come out of the political consensus on FDA. If you go back to the Citizens Advisory Commissions in the fifties and early sixties, we saw enormous consensus about where people thought we ought to go. I think the '62 Amendments were the same sort of thing, when I see the personal commitment of the prominent politicians of the era. I don't think we've had that kind of ratification of the other major changes or changes that we didn't make and we've kind of finessed and stumbled over.

We've never had that kind of consensus again.

So, again, it's these old eyes looking back at youth. Is it just youth or was there really a different political environment for deciding where we were going strategically? My judgment is, yes, there's a very, very different environment today.

RT: Of course, Larrick was the last of the so-called career commissioners, and thereafter it was a political appointment or an administration appointment and Senate confirmation. Do you think that was at all a factor in changes that you're speaking of?

PC: See, I didn't know about the Larrick era. I came into all of this enthusiasm of the Edwards era, and yet I could understand very quickly, talking to people, the few that were left, because that was another period of very great turnover in the people in the Office of the Commissioner, I could understand how much change the organization had gone through. The creation of the product centers was only in '68, and so I was here two years after that.

The relationship between the centers, young as they were at the time, and some of them destined for outplacement because they didn't fit into the scheme of FDA, and the Office of the Commissioner was totally different than the relationship that's kind of evolved. Because they were so incomplete, because they were so embryonic at that point, there was a very tight bond. If a center director was trying to do something, it was understood that all of the Office of the Commissioner was going to help them and not critique or compete with them.

So there was a oneness of effort between the operating units, young as they were, and the Office of the Commissioner at that time, that has really changed radically in what I kind of call now the adolescence of our structure, with the centers kind of acting like eighteen-year-olds, still dependent in ways on the Office of the Commissioner for political cover and understanding and legal assistance, but wanting to stay out as late as they want to. So we don't fit together quite the

way we did when the kids were always under the benign control of the Office of the Commissioner.

RT: I think it was Commissioner [James L.] Goddard who really delegated a lot of authority to the regional or district managers, which wasn't the history heretofore. I think some of those administrators welcomed that, and a few may have felt more protected by the old lateral direct-line obedience or conformance to the commissioner per se, or his immediate staff. So that was a marked change, and these others, of course, have really charted new ways of the agency's operation.

Not to lose entirely your role or your career track, let's pick up on that a little bit. You came in and worked initially in the Office of Administration?

PC: Yes. I came over as a GS-9 in this new Office of Operational Planning Staff, and it was attached to the Office of Financial Management at that time, then the Division of Financial Management. So for my initial years, I got to see this interface between the agency and the Department, and we had to go out and rustle up all of these planning goals, because they weren't articulated anywhere else. So that was getting people to commit to them. As I say, there was less fear in committing to something you were going to fail to do, because there wasn't all this linkage with the budget and GPRA [Government Performance and Results Act] and everything else. You'd propose something and give it a good whirl, and when it didn't work, you'd revise it.

That was a very good interface and a very good way, as an outsider, to see the agency, and it was a good way to understand the Department and the whole political setting we were in. Very, very different, I might add, than the Department of Defense that I left. So I had the feeling I was in a young organization. Of course, it was growing very rapidly, so there were other things to make you think it was a young organization.

The other thing we were doing that kind of gave a counterpoint to this is we were the focal point for the GAO [General Accounting Office] investigations. There weren't too many of them back in those days, three or four, maybe five a year that were under way, so it was a minor account, but you got to see the other side of all this, let's do this, and here are these people nipping at our heels.

A lot of that, since at that time GAO had no experience in program reviews, as they called them. They were all people who were accountants looking at procurement contracts, basically, to find out the government was getting its money's worth on largely defense contracts. So they were in the process of trying to train themselves on how to look at programs and soft non-accounting kind of studies, and we were in the position of trying to understand how these people were going to add to the equation. Of course, as the gulf divided between the executive and legislative branch, the demands from both minority and majority members in the Congress in the late seventies just mushroomed that criticism via GAO.

So in my first years, I could see two faces of the FDA: the defensive face and the offensive initiatives of the agency, and sort of the disconnect between those two. You almost had to speak in two different voices on that. We could never say, "Well, here's what we're trying to do. Stop looking back, criticizing us for the way something was piecemeal executed. That's not today and certainly not tomorrow." We kind of started to develop different voices on our defensive posture, and it was less and less, of course, as we went forward.

I think the Nixon [era] and probably through the seventies, through—I was going to say through Jimmy Carter, there was kind of a break in 1980, not only with the Reagan Administration coming to office, but there were other things that I see kind of an era ending in the seventies, and the eighties started a very different period, particularly with this defensiveness and our reactiveness. We weren't in control of our management environment, and it wasn't as benign as it was in the seventies.

RT: Was Reagan a kind of turnaround on regulation, a trigger for that, do you think?

PC: That was just one of the manifestations of it. That was a manifestation of the lack of accord in regulatory policy made by the administrative rule-making process. I wouldn't personalize that to say that was Reaganomics. Of course, it kind of was. We see even now here's another administration [George W. Bush] issuing its edicts as soon as it comes into office, the spending, all the rule-making under way, and all.

That kind of started then, but no we know that wasn't Reagan in particular; that was the lack of legacy between the administrative rule-making or regulatory philosophy of the prior administration with the next one. . We didn't have those kind of junctures between Nixon, Ford, and Carter. There was an understanding of the continuity in that. All of this has become more politicized now, Reagan on, that every administration sort of disowns ceremonially anything that was done before. And yet that's not the way administrative rule-making works.

So in that sense, the executive branch has disabled its own rule-making integrity by each one kind of exercising political whim to criticize that of the last, and that just weakens the executive branch relative to all of the legislative restraints that have been put on it by a series of statutes in the nineties. And yet no single executive branch can rise above the urge to criticize what went before and say, "I have to stick together with my predecessors and successors and create executive branch continuity in all of this." There's no understanding of that now in any one single executive branch tenure. That's where we've lost an awful lot in continuity.

Now, on the other hand, you can look at FDA and say, boy, do we understand that kind of continuity, because we're struggling to paste it together and hold it together in so many ways, when the facts of the situation, the culture we're working in maybe don't make that possible. So we almost err on the other side that the presidential level, the executive branches have gone, in

disowning regulatory continuity. We try and hold onto it when we don't have all the cards to do it. That's an interesting contrast, particularly in the nineties.

RT: When Peter Barton Hutt was counsel for the agency, he went into quite an administrative rule-making crusade during his...

[Begin Tape 1, Side 2]

RT: ...tenure, that's been pretty much eroded away. Is that correct?

PC: Well, I think Peter had a very simplistic view—Peter himself hadn't thought where it was all going to go and sort of where he was going to go, because he certainly doesn't hold the same views about administrative procedures today that he did when he was a youthful, zealous general counsel. I think one of Peter's short-sightedness was, I don't think he saw what—and I mentioned it earlier—what Hubert Humphrey saw in the legislative debate about the amendments about how paperwork and burdensome it was going to get.

I don't think Peter saw any of the dark side of his vision of administrative rule-making. I mean, he thought that he could tie a silk ribbon around all of the different and contrasting points of view in the perfect forum of administrative rule-making, we would bring it all to, if not a perfect consensus, at least as near perfect as humanly possible, and everyone would understand it.

I think he was kind of harkening back to that era that I describe, where there was a general political consensus about the right thing to do in the regulatory environment, that just because some special interest wanted it some particular way and had its agents afoot, that they wouldn't skew the whole thing to make it come out that way. There was a level playing field in Peter's idyllic world of even the 1970s, as jaded as we might be about the history of those years.

And it just didn't turn out that way. When everyone took to their factional corners, it wasn't possible to execute what Peter and his idealism wanted to do. Peter himself abandoned that notion of self-driven consensus around all this ugly discord. So the world got too complex for that solution. It wasn't wrong; it's just that we didn't keep up with how the world was developing bumps and unevenness in the political process. And yet for too long I think in the agency there is still a Camelot of that. "It's supposed to be done right. Why doesn't it turn out that way?" And we struggle a lot with a Camelot that isn't anymore.

RT: I think earlier in your career, Sherwin Gardner was an interim commissioner, or acting, as I recall. Didn't he have you do a facilities study that looked at what was happening out in the field? *Do you recall that or am I reaching for something that—*

PC: You're reaching for a detail that isn't at the first order. Let me talk a little bit about Sherwin Gardner and the role of deputy commissioners, first of all. My first deputy commissioner was Charlie Edwards' deputy. Help me out with his name.

RT: Jim Grant perhaps?

PC: He really was serving, and was appropriate for the kind of person Charlie Edwards was, as kind of the chief operating officer, the guy that had to keep up on the details, because Charlie wasn't always awake at the point in the meeting when we were dealing with the details. He was a high-level commissioner. That tradition of a deputy that handled all the details and was able to step in, in the interregnums, I think was one of the strengths of the agency. I don't know how well Dr. [Bernard] Schwetz is doing, but he didn't come from the same training position that Sherwin Gardner and Mark Novitch came from, on having been the principal deputy and then all

of a sudden having to step over.

I think that was one of the strengths of the agency, that we had an alter ego, because as it has come to pass, we have these long periods of "Who's the next commissioner going to be?" and big parts of our life, particularly when commissioners were turning over at the rate of one every two years in the late seventies and early eighties, we really needed that interregnum continuity. I think we've lost that because of the change in our senior management organization.

Anyway, I think Sherwin was one of the good examples of that interregnum, and the advantage was that while they were the chief operating officer, they could dabble in some of the longer-range questions. They didn't have to be reactive managers to whatever the next headline was. The commissioner could do most of that with the center directors, and they could work on longer-term management questions. It was kind of their job. There's at least one deputy we won't mention in this regard, but most of them did a very good job of that longer picture.

And that's where a lot of my business and my satisfaction in the late seventies, under Mickey Moure and then in '79 when I switched to being Jake Barkdoll's deputy, came from, because Jake had a very close and good working relationship with Sherwin, because Sherwin was interested in planning. Sherwin was interested in the future, not just "What do we do today with this situation?"

So a lot of our business, and I can't remember if I got into that facility study when I was still—I might have still been in the Office of Management under Gerry Meyer then, when we got into it. Sherwin would ask for that kind of longer-view stuff.

I didn't like going into facilities at all. When I did the field piece, it was as the second leg. The first study we'd done in facilities was of the Headquarters Plan, and at that time, that must have been around 1976, we, of course, had a plan to all move to Beltsville [Maryland], it was all funded, and Jamie Whitten took all that money and helped pay for the Vietnam War sometime in the early seventies, kind of the opposite of the situation we're in now. We had the funding, but

not the A&E [architecture and engineering] work, and now we have lots of A&E work, but no funding.

But we were trying to reconstruct that, and what we did was very photographically as we went around to all of our old—that is for the headquarters, and took lots of photographs of how inadequate our buildings are, because we decided the congressmen couldn't understand an inadequate building unless you showed them the trivia, plaster cracking and old shabby-looking stuff. So it was kind of a photo album study of the Headquarters, and it was from this that Sherwin said, "Well, I should do something with the field, too."

Of course, the field situation was very different, and the field probably struggled more than the Headquarters with a lack of understanding and long-range view of the facilities. What we got into very fast was the manpower implications, that I don't think we've ever figured out the right mix. At what level do you consolidate and have an expertise? Of course, back in those days, we didn't have the possibilities of Federal Express and other things we have today. Even then, it seemed like the specialization of laboratory work was too diffuse, and so we were headed even then for the consolidations that we're more drawn into now.

RT: That was, again for reference, about what period?

PC: I think that was around '76 also. And yet we faced all of the internal angst of people being moved and "What do you mean?" And so it was a very difficult thing. We couldn't say everything that was on our minds because you couldn't tell people that we wanted to shut down. That's where the world started to get complicated, because they had congressmen, and we already started to have a number of GAO studies by the mid-seventies about facilities this, facilities that. So things were getting much stickier just to say "What's the right answer to this problem?"

Of course, the right answer in those days, and I think most of the field studies, is what did

the senior management of the field organization want to support and feel it could get its managers to buy into. We've always been dealing with highly political, both internally and externally, evolutions of physical attributes of the field.

The field studies, I think, and the results of those, were a precursor of what's happening to use facility-wise in this Headquarters Plan. I see the headquarters consolidation at White Oak as one of the bigger disasters in our future, because it was a political solution. That location was a political solution. Yet I can go back to those field studies and all the agonizing. "We can't say that, because this delegation has really staked out the whole—why don't we put this part of the lab in their district?"

That's where we wound up with the whole facility thing now. It's not a management decision of the agency. It's not geared to the efficiency or consideration of the employees or even the industry positioning of it. We've got a site that straddles two congressional districts, which makes it twice as good as any other site. And that just shows the change in the political environment that we've undergone in facilities. I wouldn't want to do another facility study. It isn't a rational exercise anymore.

RT: Certainly that type of oversight or investigation creates morale problems and, as you've said, people who seek out redress from congressmen and whatever.

PC: Right.

RT: To avoid transfers and to avoid closing down their facility.

PC: Right. And they're taking a very short-sighted and personal viewpoint—but that's where their power is, and if a congressman can make enough, or in the case of the whole Maryland

delegation, they can decide that's important enough, they can slip very quickly over the fact that the biotech industry of Maryland is not located along the White Oak corridor. They've missed it. Their map is—they threw the dart on the wrong space on Maryland. And they don't care about that and the dislocation from NIH [National Institutes of Health] and the other health agencies.

The other thing that we're obviously very much more entangled in, whether we like it or not, is a much closer dialogue with some of the other health agencies. You can't bring that into this agenda. When you realize how large and how many peripheral expertises there are going to be around the NIH that has eternally generous funding, we should seek to be close to and in proximity to that, because we're never going to be able to create the parallel expertise.

So once we get out closer to where the animals are over there in P.G. [Prince George's] County, we're moving away from many of the things that if we thought about what our issues were today, who it is that we need to be mixing it up with and close to and borrowing their expertise and synergizing around, our facility's future is one of our most ill-planned and disastrous courses we're on now. It's hard to tell how that will work out.

RT: Back in earlier times when I joined FDA in the early sixties, there were many diverse units. We seem to be moving at least to larger clump consolidations now.

PC: Yes.

RT: When this building [Parklawn] was selected, did you think that had some relationship to the NIH proximity?

PC: I think that was kind of dumb luck. I don't think we've exploited the NIH relationship as well as we should have. We have a very provincial view of that. Folks in Biologics want to stay

-on the campus because they have a lot of linkages, but I think at the agency level, never mind the number of principals that understand the relationship very well—Ruth Kirschstein certainly understood it well, and I think Dr. Jane [E.] Henney understood it well—we haven't really thought a lot about capitalizing on that. We haven't thought about the joint appointments possibilities and the merger of advisory committee expertise. Still we do it as a separate agency barely in the same department.

The same problems, we're not close enough to HCFA [Health Care Financing Administration] today to address many of the problems we have in the real availability of new medical products, because the reimbursement questions are the next step. Our piece of paper means little if it's not going to be reimbursed. And we hide from those integrations of public policy that we're not familiar with. That's where we want the old clean—the FDA slice that we can go talk to the secretary about in a Camelot environment that's simple and clean.

I just see our physical dislocation to a place where our employees can't get to and has lots of public transportation difficulties and isn't near anybody that describes themselves as biotech. It's kind of an ill-fated political adventure. If they had enough money to do it right, that would be different, but we all know we're going to wind up with half the campus there and some funding misadventure that leaves us not quite whole.

That's not good, because this experience we've had in the seventies and early eighties, even, we had all of the center directors, save Foods and NCTR [National Center for Toxicological Research], that could pretty well meet physically here in this building. It wasn't much trouble for John Villforth to walk across the street. Biologics wasn't very far away.

Part of the personal intimacy of the senior management that we had when most of them were close enough not to have to kill a whole half a day, as happens now, to come here, most of that's kind of dissipated. I mean, it's a chore even to get from Devices now to here. You have to plan on it and lose an hour on each side. So our executive coming-togetherness has steadily gone

downhill, and we try the straddle of getting to the utopia of a campus.

We're going to suffer ten years of not having that intimacy, and if we get more turnover, which we probably will—we're lucky right now to have a fairly stable cadre of center directors—when that shatters and we're not together, I see us even further from that all-getting-together simplicity of the Camelot when we were all close together and met regularly, to hold the agency together at the top. So we have to realize we're maturing into a very different kind of bureaucracy, separate physically and separate in terms of shared experiences in senior managers.

I don't think we've had enough introspection. No one here at the moment wants to think about that and how much that's changed, but that's changed our management environment, as I see it, for at least the next ten years. It will probably get worse in terms of the shared intimacy of the corporate problems.

RT: Back a few years ago, commissioners had initiated the Policy Board concept. I assume that from what you're saying, that was a medium for closer liaison than exists today.

PC: Yes, and part of that was not only because we had people that wanted to manage that way and, indeed, folks like Commissioner [Alexander M.] Schmidt and Commissioner [Jere E.] Goyan really seemed to enjoy that kind of consensus management. That was a style they were very comfortable with. We can't physically do that anymore. You carve out one part of—I think it was Thursdays, and they have the force together, but it was very different when that was on Friday afternoon and they'd stay as late as it took for whatever problems had accumulated, or whatever the commissioner or deputy commissioner wanted to bring up.

That kind of "However long it takes," and "We're all in this together" feeling, I think everybody's so busy. We ought to have some very thoughtful almost a clinical psychologist come and look at how we torture our center directors and senior managers in the positions the way

we've created them. It's almost impossible to ask those people for anything more or to care more about something off in the future or something of consensus agency importance rather than their impossibly full plate of reactive management.

RT: To put it in perspective for the record here, the Policy Board concept was implemented by which of the commissioners, do you recall?

PC: I don't know when we coined the phrase, but it's something I recollect. It was, in fact, a Charlie Edwards kind of practice, whether we called it that or not.

RT: I think it did come in about that time.

PC: Yes. One of the things I marveled on is everybody who had to be there in senior management fit into the old conference room. There was a chair for each one of them, and everybody was there. We can't do that anymore, the way we've got this complicated management structure.

RT: The picture on the wall shows that.

PC: Right. Absolutely. It was starting to grow then, but it still fit in the room. There's something about being able to get everybody who's important in the organization in one room and have enough air time that they can reach a consensus. Once you have to have thirty-five or forty people to represent every constituency and discipline of the agency, there's not enough air time. You can never get them all. There will always be a third of them missing. That was the reason why most of those people were in the same building, or proximate to it. We had possibilities

there that maybe in the future of a consolidated campus we'll enjoy, but it's beyond your and my lifetimes.

RT: Dr. [David A.] Kessler implemented a new type of top-level organization. Do you have any observations about his style and his successor Dr. Henney? At one time they've interposed a level of deputies.

PC: I'm thinking a little bit about what would I want to be on record for.

RT: I understand.

PC: Yes.

RT: It changed, for example, the configuration of the Associate Commissioner for Regulatory Affairs, who I suppose technically, in previous times, was about third in command. Now, of course, that isn't the situation.

PC: Yes. I see more harm than good in the reorganization of the senior management that Kessler implemented. As I've said earlier, I saw the value in the primary deputy, the chief operating officer. Again, that's part of, to me, the job engineering of what the commissioner had to do and what somebody had to do as the commissioner inside. It takes a singular deputy that is working intimately with the commissioner to do that.

When he decided—and I think probably in Kessler's mind it was a decision that that job was so big it could no longer be handled by any one person with one set of experiences or disciplinary expertise, and he had to create multiple deputies, he fractured the authority line and

certainly the succession path that we understood from prior times.

All of those multiple deputies, in my mind, had overlapping jurisdictions that they to this day haven't straightened out. That means they're always a little bit somebody else's business, and yet no single person is in charge of the decisions in that jurisdiction. Sherwin Gardner wasn't expert in science or law; he was just the guy who said, "Everybody talk and I'll tell you how it sounds to me on what we ought to do." And we've kind of lost that not only by the fragmentation, but each of these people have a slightly different disciplinary orientation. So we don't come to the consensus on anything that's bigger than something that's cleanly within one of those jurisdictions. Loads of things fall between the cracks.

Kessler, I think, made his own job simpler because a lot of the issues took care of themselves to fit within one of those disciplines, but an awful lot didn't, and those are the things that were undone or messily done in his era.

He also, of course, faced extraordinary change in the external world that probably prompted him to do some of that reorganization. Certainly the divisiveness between the executive and legislative branch was rising to historic levels. International questions were really getting messy, and it turned out he didn't deal with those in his reorganization. That was kind of an orphan category. And we had things like the DSHEA [Dietary Supplements, Health and Education Act] and other legislative assaults on our traditional view of the Food and Drug Act. I think he just thought he needed more players, more politically astute players to deal with what was an uncontrollable world. He may have been absolutely right on that, but the internal consequence on how we managed ourselves and how we understood where we were going suffered in all of this, trying to cope with this complex external environment.

Dr. Henney, I think, tried to not have another radical reordering of things, but tried to patch that up, to take care of what was missing. I think she knew that the international orientation wasn't strong enough. As a member of the team that helped her with her

reorganization, I know she very much wanted to restore the regulatory affairs stature to something more like its historical position as being—when we talked about the order of succession, I think she saw it as the number three position between the commissioner, whoever was the principal deputy. That was the next position, kind of the combined role that it had when Paul Hile was in charge of both regulatory affairs and the field organization.

She didn't really get there, because we didn't have the principal deputy and we didn't articulate a clear succession line in the traditional sense. I think that she understood that as long as the head of the field organizations was just seen as one vote against the multiple center directors, that half of the agency, or 40 percent or whatever it turns out to be, was unrepresented in the consensus deliberations of the agency.

We didn't get all the way to fixing that, because Kessler's change was so radical that I think in our future we're going to have to go back and look at how a non-geographically co-located senior management gets together and doesn't have gaps between the roles that both of them can either say, "That's mine," or neither party wants to do with it, and yet it can be representative of the whole agency more than just whose crisis we're reacting to.

Because basically the way we've allocated resources and priorities—and I'll try not to mention the tobacco distortion, but that's kind of the grandest distortion of all, but it's illustrative of kind of our reactive management, that we have so little management capital and reserve resources, people and dollars on anything, that as long as we're captured to the headlines of going from one mad cow disease to the next drug recall, whatever, there's no capital left in order to do the kind of proactive traditional management that we once enjoyed.

[Begin Tape 2, Side 1]

RT: Picking up from the other side of the tape, I think you've experienced many organizational

and personnel changes. Maybe you'd like to cover that area in whatever direction you wish to take.

PC: Two very profound changes in our work force over the thirty years. One I mentioned, Ruth Kirschstein [Deputy Associate Commissioner for Science], earlier. Back in the seventies, in the senior management circles of the agency, she was the only woman at those meetings. Of course, now the gender composition is very different in our senior management, and that's reflective of what's happened in the work force as well. Women play a far, far more prominent role in the composition of the agency, and that's changed our workplace culture to a far larger extent than we probably appreciate.

At the same time, especially in the nineties, we've had a far more significant influx of nontraditional minorities in the agency. That's been very dramatic in terms of the supervisory challenges and getting team efforts to work smoothly together.

The other influence besides gender and cultural change over these thirty years, and here again it's a question of whether I'm looking through old eyes, but I know this from statistics, that the agency of my youth was younger and at a different point in its career than the peers I've worked with in the nineties. When I tracked my organization in the late seventies and mid-eighties, supervisors were in their early forties Second-level supervisors were around forty-five, and first-level supervisors were around forty, and the work force was distributed in the thirties.

Because there was growth not only in FDA, but government as well, there was an enormous amount of mobility, both lateral and promotion, in that work force. People could move to where they wanted to go, try something different, and everybody was just making the random stepping stones of their career.

What's happened in the nineties, because opportunity in the government has certainly slowed down and all sorts of institutional barriers between promotion opportunities across

agencies and even across centers, have locked almost everyone into whatever position they found themselves. With the decline in mobility and the decline in the influx of new people, I've lived in an organization of older workers who kind of know what their retirement year is, a surprising number, and aren't really that adventuresome, particularly about another job in another zip code or organization. That has a profound impact on the dynamic thinking and energy of any organization, when everyone feels this whole movement kind of thing of the work force is slowed down.

I have seen very little help from government-wide policies to deal with that. Everyone now talks about this human capital crisis of the government, because so many people are retiring and who's going to replace them? That's not the issue I'm talking quite about; that's the first cousin of the issue I'm talking about. I'm talking about kind of the lack of invigoration of any one organization or because everyone has too difficult a job finding the next development step, or doesn't even think about the development step because this vacancy announcement is only for the people in that center or that organization.

In that sense, I despair to what's happened to the federal civil service. It isn't very federal anymore except in the uniformity of benefits. It's not federal in terms of its opportunity for mobility or development.

RT: Paul, based on the comments you've just made, would you say the historical old way, where people were told to report somewhere the next day was any better in that context? It certainly upset a lot of people in terms of their personal lives being shifted here and there and somewhere else. It did however provide a cross-section of experience that perhaps not so many people are getting now.

PC: I would certainly prefer that world, but remember that my experience in the military was in

an era when enlisted men below E-4 were told they couldn't marry because they didn't make enough money. So in our society, a lot of that wisdom of the elders that is imposed on individuals, we now have the reverse world where there is so much freedom that no individual is guided in their career. In fact, we've erected a lot of barriers against someone finding their way in this highly restricted and regimented personnel world. So we haven't figured that out at a strategic level.

I'm criticizing the government at large here, but the point I want to make is that I don't think FDA—and this is a part of our lack of proactive management—I don't think FDA's realized that it has had an enormous opportunity to counter these forces that the government world at large imposes on us. Most dynamic private-sector organizations as large and complex as we are have something close to what you speak of, Bob, as kind of a forced career development, "You're going to learn the whole business so that some of you will be our future senior managers."

When I look at that record of where we get our senior managers from, I make a rather harsh judgment in the nineties that we haven't done a good enough job finding the best and most able people inside FDA that can step into our senior positions. I can go down a number of positions in this agency and say, "Why did we go outside and find a financial manager or a personnel manager from another agency?" Not once, but successive times. Don't we think we have anyone that three job steps from now can be our senior manager?

Along with that, part of the Balkanization of our centers has been fostered by this lack of a corporate mobility and personnel development policy. We have a lot of idiosyncrasies in the management of the centers. Some may be good and some may be bad, but we don't have a way of finding best practices, because everybody goes to that center and spends the rest of their career there.

So I would be a proponent, looking retrospectively on what's happened to us, of a lot more forced management interchange and a lot more development of standardized understandings

of the agency and practice through personnel mobility. And I think this would force us, in the course of doing that, to sort out the excellent from the good, and develop more of our own senior managers.

RT: I think a lot of the field personnel have looked with favor on less dictatorial transfers.

PC: Well, the field certainly has a unique problem in this, since that kind of mobility involves geographic sacrifice on their part, and certainly from the family viewpoint. But I'm saying we've passed up a lot of opportunities in headquarters, where you didn't have to change the zip code that much. It's a messy commute any way you do it, and we haven't taken advantage of that.

I think to the extent the field has done it and people have suffered all that inconvenience, the field has benefited. It's been one thing that has held a structure which would otherwise have even more differences between districts than it has. It would be worse if the people hadn't had the common shared experience of, "Oh, this is the way we did it in two other regions. Why don't we do it this way here?"

So I think we have to push that way. I think we have to understand that people's career is bigger than their satisfaction with the single job they're in now. I don't quite know how we get there, but that's not something we're trying to do at all now.

The other problem, of course, there are two other aspects of this I want to mention. One is, we have some undesirable relationships between the Office of the Commissioner and the centers in the past few years. A lot of people I have known have taken flight from the Office of the Commissioner to go to a job in the center, and they kind of say, "Boy, it's better here."

Well, if that's the prevailing view—I know what they're getting away from. It is all this reactive management and you don't know how much of your work is just going to be set aside tomorrow because all of a sudden the Office of the Commissioner's charging off in another

direction. It isn't good to have your senior management structure a place where people don't want to go and take flight from, and particularly as they're older, they can see, "If I can go to that center and do a job that isn't so disruptive, it's more satisfying, I've only got six years left." That means they've already written off contributing again at the corporate level, and that means we're hiring more and more people without FDA experience into positions of policy-making and management direction in the Office of the Commissioner. That's not good.

And no one seems to be sitting down looking at the dynamic of this outflow. We do debriefs of people when they retire, in a very perfunctory way, but inside the organization we haven't looked at why don't people enjoy, why aren't more people gravitating to come to the Office of the Commissioner to do something of a higher order of importance. This is a very, very serious cultural blindness we have to why don't people want to and enjoy working there.

In fact, some of the people that enjoy it don't really have a career aspiration of where they're going. They enjoy the one thing they're doing with a passion, so they aren't the material that I speak of for, "Well, you've enjoyed this, but now you're going to go do that because you need to be cross-trained if you're going to do more than just this single thing."

So we have a lot of technicians of high energy and high competence in the Office of the Commissioner, but not much executive development. And no one's worrying about that. We worried about that back in the eighties. In fact, we were doing succession crises studies when we really didn't have a succession crises. And now that we have it, we only kind of deal with it in the most superficial kind of ways of saying, "Oh woe is us. Yes, we're a part of this federal aging process." But I'm saying there's a lot of opportunity even within the parameters of an aging work force we're living with to have a different energy and a different consensus sense of the Office of the Commissioner.

RT: The Executive Development Program that's been in place for some time isn't necessarily

placing at the commissioner office level many of their graduates?

PC: Well, that's a very good start, but that's kind of at the beginning of the process I'm talking about, turning a GS-13 into a GS-14. What we've got to worry about is the people that have already shown they can be supervisors. How do we get them to the next level of competence?

I think all of us have seen in our FDA career certainly people who couldn't move from the technical expert to the first line of supervision, but we see a lot of people that can't get to the second-level supervision, and they get stuck at the first level of supervision. And that's where they have to have different work experiences in order to go up to the next level and say, "Now I'm supervising supervisors." How is that different? That's where we're not thinking. And they have to learn all that on the job.

There isn't some kind of course you can create for that. Some people can adapt to that and others still want to control, like a first-level supervisor checking the work of each person. I'm saying that's the level of development that we have to work on after we find those managers of managers. And there isn't any effort to do that.

The beauty is that a forced natural rotation gets you people who can deal generically with any situation. Some of our best managers are ones that through accident had that experience. Ron Chesemore is an example of that, moving across the agency in different positions, but that's an accident of Ron's career that he directed financial management and that experience was very valuable to him in being the manager of the field organization. But we ought to intentionally try and find that kind of cross-training.

It's such a world of *laissez faire* in everyone's career that I don't think we can go back to not allowing the enlisted men to marry, or directing assignments, but we have to find something in between if we're going to take the work force we have and build a corporate management out of it that's better than what we've got.

The other aspect of all of this is how the different disciplines interplay in making our decisions, and we've had an interesting history in this regard—there were studies back in our reflective era on how the disciplines of science and law combine to make decisions. It isn't just science and law anymore; it's really science, law, health policy in a broader sense than science, economics, and certainly politics. They all come together on all of our issues, but we don't necessarily properly balance all those disciplines. So sometimes we produce a decision that is really dead on arrival in the real world because we made it too often from solely a legal construct or solely a science, medical judgment standpoint. And we're too comfortable with the traditional internal balances of those disciplines, to say, "We can't stop the lawyers. We don't want to lose the case, so that's why we've given them the front seat in this decision."

But when you look at what's happening in society today, this is the same problem we're talking about on how are we going to direct people and tell them what to do. We have a very controlled mentality about the officiousness of our decisions, and yet in the past decade a lot of them just haven't played. If we were accurate about the counterfire that ensues either in society as a whole or the political environment, it's not playing. And that's why we need to have inside the representation of all of those perspectives and to have more balanced debate on, "Yeah, you can do it, and, yeah, it'll be legal and it'll stand as a regulation, but we're going nowhere with this."

RT: Maybe tobacco was an illustration of that.

PC: Well, tobacco is. And all of it's nobleness to save lives and do the right thing. It didn't have the right mix of the political and the larger viewpoints on that. It should have been done. I'm not going to prescribe what should have been done. But if we had had a different mix of disciplines, we'd have still been a player in that, but we wouldn't have used so much of our own energy, our own capital.

You see, where tobacco has wound up has actually hurt us in a lot of other regulatory areas, not solely by the diversion of that energy that could have been spent on other things, but we've sent a signal to other industries that we're going to go right down the legal construct of what the act says, and we're pushing to the maximum extent that we can declare is legal and we can hope for a favorable decision. Hopefully we won't go to the Fourth Circuit Court of Appeals, but we'll find a sympathetic court and we'll be right.

Well, we're not right unless we can implement it, and in many cases we've lost what should be a very strong natural bond between us and the good guys in industry, because we're all the time trying to push a policy that maximizes our strength against the bad actor, and that's become our template because that's the way the lawyers think. "I never want to lose a case against a firm that's really doing us and society dirty."

But we don't realize what we've lost when we've turned it into that kind of maximize our own power, not solve the biggest problem with the largest consensus. And from my economic point of view, I am greatly stressed by the number of alliances in the good parts of industry and academia that we haven't bonded with in more effective ways to do our job, because the legalistic view always assumes that the FTE [full time equivalent] will be there to do the job that we have prescribed in the rule.

And yet our failures in that area are very evident to me. I don't know how many other people see them. I'll just mention two of them. One failure is in the seafood HACCP [Hazard Analysis Critical Control Point] breaks, and another failure is in all of this international regulation, particularly the MRAs [Mutual Recognition Agreements], where we imagine that we have resource and capability to execute designs that we don't have. And yet legally, if you only look at it from the discipline of what we're saying we can do and where our powers are, we have a half of a solution to many of the problems of the nineties, because they are based on imaginary troops. No general ever won a war with imaginary troops. He had to have real troops in addition to a

battle plan.

I think we're disconnected from the troops, and we don't ever want to admit that. Every new administration, we pray that they will restore the FDA to a glory it never really had. It always was kind of aspiring to this. And that's kind of the legalistic view of this. If we build the legal structure, all the rest of it will come into play, because they will understand that is required, but not with the political discord we have about regulatory policy. This is not the 1960s. That's the part that historically I anguish over the agency unable to understand what a lack of societal consensus means on our ability to execute a strict legal construct of what we want to do.

RT: The legal purist, or the legal adherent from the earliest times of the agency, of course, has followed that track, and whenever there is a move to do as you're suggesting, to reach out, a lot of people get very concerned, "Well, were losing our status as a regulatory agency."

PC: Right. There's this terrible anguish, and I've seen that reaction so many times on these particular issues, when you try and say, "What's the problem we're trying to solve? Can we solve it a different way?" There's a retreat. This is as "FDAish" as it is American to be anti-communist, even if there aren't any communists left. So it's just in a part of our gut that seems to reproduce itself on anyone that comes to the agency from the legalistic perspective of what does the Act authorize us to do and how can we twist that authority to achieve our objective.

It's interesting how we morph on this, too. When I go back and look at the history of some of our regulations—I'm going to pick on the seafood regulations a little more. We started out with HACCP saying it will free us from inspectional burden because it's self-executing. And yet we didn't really believe that, because the real belief, as it's turned out, is we have to go back every year and see if they self-executed. So we have an enormous regulatory cost for a tiny part of the food industry. We have about a third of our assets in 2 percent of the sales of the industry,

because we didn't follow through on our own design that this was going to liberate us. We're doing the same thing internationally.

So I see the legalistic view as very foolish today. I think that our future is in a much more interdisciplinary view of building an internal consensus that can make sense and is executable when we make it public. I don't see us on that course quite yet.

RT: Do you see any move or any inclination that way in our more recent commissioners, perhaps not Dr. Kessler, but how about Dr. Henney?

PC: I think if Dr. Henney had been here for a longer time, she would have gotten there. I remember her reaction to the briefing on bottled gas inspections, and when the facts were laid out there, most of the recent errors in dealing with bottled gases were janitorial employees of hospitals hooking up the systems wrong, and yet all of our inspectional effort is focused on the original manufacturers. So there was a major disconnect there, where all our resources are going, and I think that's an example where more technology can make fail-safe valves that nobody can screw them up at manufacturing, particularly the number of people dealing only with oxygen so there's no mix-up of different gases, but the problem's made at the hospital. This is part of our health care orientation they don't think we have. Just because we have the authority to inspect those manufacturers and it gets real messy on who inspects the hospital and certifies them, well, we don't need to keep inspecting bottled gas manufacturers if the problem isn't in their plant, since all the deaths but one incident in ten years, I think, are at the hospital.

This is the kind of thing I think she would have gotten to, because I could see her clicking on that. How are we working with the hospital associations? As far as I know, nobody's pulled the plug on our resource drain on inspecting the wrong thing at the wrong place, and that's where a different discipline, a different mix wouldn't go just to where our traditional authority is, it

would go to where's the problem and what's the cheapest way to fix it.

That culture hasn't taken over. You can't just have a commissioner aware of that; you have to have a different mix of problem-solving people. We can't solve all the problems. How do we solve some of them? Stop doing things that don't solve problems, that are only an exercise of our traditional authorities.

RT: Do you think Congress would be a critic if innovations of that type were developed? The biennial inspection, a small percentage of those, the bean count concept again.

PC: Right. I think it will take a very dedicated management effort to change because we know that in any single budget cycle, the quickest way to argue for resources is to point to a statutory mandate and say, "We're not doing it." And as long as we go for that reflex, it hasn't been answered in the last decade, so it may not be a useful reflex anymore. That may be because the public understands more than we do that whatever that statutory mandate is, isn't the fix to the problem.

I mean, look at all the on-the-fly regulation inspection we've had to do in mad cow disease that wouldn't have been a part of the statutory mandate at all. Well, you have to relax that mandate. That was one of the great failures of the FDA Modernization Act, that we didn't step in and have certain things we wanted to do to move us away from this lockstepped, fixed, traditional activity agenda. I think we could have fit more of that in and we would have had more flexibility. Never mind most of what was about in that act was mischief from political agendas.

We didn't have things we wanted to force into that. We were in a reactive mode to only take out things that were objectionable to us. We didn't have a proactive agenda of what do we want to put in there that absolutely makes good sense and we want to get it. It wasn't there. We were in a totally—

[Begin Tape 2, Side 2]

RT: As we move on, one of the issues faced by the agency for a long time is that of user fees. I'm sure you've had to deal with that issue during your tenure.

PC: For years, OMB [Office of Management and Budget] used to write, in the eighties, magic language in our budget that would say, "Well, here's a big increase next year, but it'll all come from user fees. Go out and get user fees." And it was their way of dealing with our budget requests without really funding them with real money. Of course, because the Congress realized that was requiring separate authorizing language, we were never able to do that in a budget cycle, so it was always very frustrating to have that be the answer to a budget request.

Yet in OMB's mind, and this is under both political parties we've enjoyed this understanding of things, that our work could somehow or other be apportioned out to industry parties that would pay for a benefit. Of course, regulation doesn't quite fall with that kind of distribution of the effort based on deciding how you can get people to pay for it.

When we got into the early nineties and it was apparent that the Clinton Administration was going to be no more friendly to the agency than Republican administrations had been with regard to funding, the situation presented itself where the drug industry wanted user fees because it saw this budget gridlock and it didn't want a further deterioration of approval times.

Dr. Kessler turned out to be the right commissioner for the times to negotiate the first user-fee deal in 1992, because he could say very convincingly that he didn't want to dilute the standard any, and yet he could see taking this user-fee money to enhance it.

Other commissioners probably weren't in the right political position to pull that off, even though we needed the money back in the eighties as well, so there was a certain congruence of

commissioner viewpoint and a need for the money that made '92 the year we started off on something that was a fairly big experiment for us, but, frankly, the rest of the industrial world had already come to grips with this and had been dealing with user fees for some time. So it's not quite as novel as it may sound.

It got us more money, but it had an awful lot of downsides in its first five years. The highly formulaic allocation of the resources and having to predict across the first five years exactly how much we would get each year caused a lot of difficulty, particularly with the two centers of drugs and biologics wrestling over a fixed number of positions that didn't necessarily apportion the way the work load did. So it was a further tension between the organizational components and it was a highly labor-intensive budget exercise to execute it.

It actually cured the longstanding problem of drug lag that we had dealt with from really 1976 up till the early nineties. The program was so effective that, of course, now we never hear the drug-lag debate with the Europeans anymore. In fact, a couple of years ago when we last measured it, on average I think we were eight months faster than they were in introducing a new drug. So we had swung from being a year or two behind them to actually well ahead of them in introducing new therapies. So in that sense, dealing with the problem, it solved that. Internally, it was a terrible arithmetic mess to administer.

It also drained on the rest of the agency, because the government share of user fees had to be kept whole in inflation-adjusted dollars, and those weren't provided in the appropriation. So every other center was indirectly kicking in each year to subsidize the base of this program, and this was a fairly unhealthy factor, particularly as it compounded itself.

When it came up to 1997 to reauthorize that, unfortunately the user-fee reauthorization was bundled into the whole Food and Drug Modernization Act debate, and so rather than being able to deal with this as a "How do we fix it" user-fee question, it just kind of got pasted on with very minor modification into the larger political debate over all of the modernization. Of course,

anytime you use the word "modernization," I've got quotes around it.

There were several modernization acts passed in the nineties. I think IRS and one other agency enjoyed the words "modernization" in statutes that were basically reform to congressional specifications, not necessarily modernization. Ours was the only modernization act called "modernization" that was not accompanied by a separate appropriation increases to achieve the modernization effort.

So that part of it is one of the reasons why there was such an inattention to making the user fees any better in the second cycle. There was no effort made to improve the agency implementation of the other parts of the Modernization Act either. It was a kind of "do it yourself" modernization.

The second five years of user fees has been plagued with some of the same structural problems we had in the first five, namely it's drained the base of other agency programs to fund an inflation-adjusted contribution to this formulaic program, and it went into a whole bunch of trivial monitoring of how many meetings we had with industry and how quickly we wrote the minutes up to those. It's gotten down to micromanagement level that's even more onerous than the first five years.

So we're now on the threshold, next year of the third user fee act, and the agency has done some good things to lay the groundwork for a more enlightened third round of this than they got in the second. But the political environment and the industry interest in simply Xeroxing something that looks like the old one is very dominant, and no one wants to deal with a return to actually funding this expensive program with appropriated dollars, because they don't want it to show up that way. And fixing a lot of the problems that are in it, there's no constituency other than the agency for wanting to do that.

So this entire history, where consensus public policy, to come up with a right answer, both in the executive and legislative branches, hasn't been there probably means we won't achieve fixing

all the parts of this which aren't working right and are creating disincentives, and yet we're tied to that money. Neither the public nor FDA can survive a program without continuation of this. It's just one more example where we're not in control of the management variables that I think the public thinks that any agency has at their disposal to make sense out of the resources and the directions they've given to do it in a sensible way. We're tied down to a lot of nonsensical kinds of things that no one outside the agency will ever appreciate, and yet they're enormously difficult things for us to execute and build a core and consensus on inside the agency. So it looks like it's going to continue to be very difficult, very misunderstood, and very unappreciated on what we have to do.

Another thing I might mention, getting near closing here, is the role of deputies in the agency.

RT: In that connection, we've had an administrative program of reinventing government with the apparent objective of reducing the numbers of interim managers. Would you say that has come in with what's happened in our agency in that regard?

PC: I guess it would seem to be. I've already mentioned that I think a principal deputy to the commissioner was very important in terms of the interregnums of the Sherwin Gardner and Mark Novitch eras, but the same thing holds true for subordinate organizations. When my Office of Planning and Evaluation was moved in Dr. Henney's reorganization into the Office of Policy, I observed at one point in our early deliberations about the future structure of that organization that all three of the principals of that organization, Bill Hubbard as the Director of the Office of Policy, and myself as the planning and evaluation component, and Mel Plaiser as the Office of Legislation, all came into our positions having served as the deputy to the principal in those positions. They took that as kind of an interesting—which, to me, was convincing evidences that

deputies not only provide continuity, but in many instances where the best qualified is the successor, particularly when you're looking for inside candidates to the position. Yet Mr. Hubbard does not have a deputy and is the first Director of the Office of Policy since the creation of the position who doesn't have a deputy. I lost my deputy in the reorganization, as did the Office of Legislation.

We have a very recent case study, and it would seem the benefits of deputies, and yet the total absence of us to be able to continue forward with that kind of continuity. One small consequence, I'm now nine months away from my retirement, my position has just been filled with an inside candidate from my organization who wasn't my deputy, and the costs of continuity in the past nine months not having that continuity of management with somebody that could have, in the in-between, carried on, whether they would have been the new associate commissioner or not, I think are lost to the organization.

I note, too, that up until the 1990s, the Kessler reorganization key positions such as the associate commissioner for management always had deputies, and they often filled in during the interregnum between appointed associate commissioners as the acting. That position does not have this benefit now and we have yet another instance of the person departing from that role and the succession not being clear.

So I think generally at the second levels of management and even below, we have generally unappreciated the benefit and value of deputy positions, both for continuity and for successor candidates to the principal position.

RT: Actually, the agency has brought some people into high-level positions from either the state governments or other organizations. Presumably that's been necessary because of the lack of well-groomed successors, would you say? Or do you think there are other factors in outside selections?

PC: There's always value in getting outside candidates and fresh blood into the senior positions. Ideally I think we ought to always be in a position of having a very well-qualified inside candidate as well as looking at outside candidates, and I think when we select an outside candidate, we actually owe them a principal deputy with some institutional memory of their function when they come into it. We're now in a position, without deputies in many of these key positions, when we bring someone in from the outside, they're going to be very alone or else dealing with an on-the-fly deputy appointment. I think that weakens the ability of outside managers to come in and do an effective job.

I'm not advocating we should always pick inside managers. I remember looking at this only a year or two ago, that out of about 400 of our senior positions, GS-15s and up, I think it was 98 or 99 percent of them were filled with inside candidates. Now, that would make it appear as though we have a viable pool of inside candidates. I think we probably hired too few outsiders, maybe not to the principal jobs, but just generally into the senior management positions.

We probably need more outside blood. I would think 10 to 15 percent of those positions ought to be outside blood, but that speaks generally to the point I made earlier, the lack of mobility across government agencies and all of this very siloed Larrick promotion eligibility rules that all agencies have engaged in, and yet we are all the losers from that kind of highly siloed promotion eligibility.

RT: Paul, you actually became Associate Commissioner for Planning and Evaluation—

PC: I served as Jake Barkdoll's deputy from March of 1979 until he went on more or less a sabbatical assignment in 1991, and so I took over as acting while he was at the Washington campus of the University of Southern California, and then he subsequently retired from that

position. So I served as an Acting Associate Commissioner for Planning and Evaluation from 1991 till 1993, when he formally retired, and after a considerable search for an outside candidate, I wound up assuming that position formally in 1993.

RT: During the time that you've been in the planning and evaluation function of the agency, there have been a lot of initiatives undertaken. Are there any that were rather successful ones that you might want to mention?

PC: Is this a deliberate prop for something?

RT: No, I'm just wondering if there were any of these initiatives that occurred that seem to be very successful in their objective.

PC: Well, as I've already said, user fees were successful in one respect. It's just that they fixed the problem. We're approving drugs faster and there's enormous benefit in that, but it's a very messy, imperfect solution. I think most of our successes recently are probably that kind of imperfect solution. I think we've addressed a lot of the real regulatory problems of the 1990s with pretty good on-the-fly solutions. People have not been injured or dead in the streets because we didn't know how to deal with unusual problems that have come up. Certainly mad cow disease is a good reaction, where the United States took a posture that was better than what we realized other industrial countries did.

The problem in all of these, though, is that we're draining our internal resource bank account. We never get in the political process proper repayment for those kind of reactive solutions to things, and we strip away from other regulatory programs to do them. So every success we have in the reactive mode is at the same time a failure of the strategic mode, because

we don't make the political process pay the bills for that. When you realize that we've suffered however it is, 150 or 160 million dollars in inflation erosion of our programs over the rather unsupportive years of the Clinton Administration, we're stripped awfully bare. Every time we achieve a success, we stand a little more naked with what's left of the agency to handle the next response.

So I have a hard time applauding each success, because there we are literally down to our skivvies in terms of our ability to react the next time.

RT: Paul, we've covered quite a lot of areas. Are there any other comments that you'd like to make as we move to closure?

PC: I've told you I didn't put this in the script, but I guess I will add it. One of the other benefits of being a young employee in FDA, and a young single employee in FDA, is I did meet a fellow employee who I could get along with fairly well, and I am one of many folks that met their mate in FDA and probably owe the agency or can blame the agency for more than just what happened on the job.

RT: That's interesting. I'm sure that you at least had a common interest that not every couple has, an interest in the Food and Drug Administration and its mission.

Paul, we really appreciate your giving us this interview. We'll look forward to getting it to you and getting it over to the National Library of Medicine in the FDA Archives for researchers' review.

PC: Thank you, Bob.

RT: Thank you; Paul.

[End of interview]