

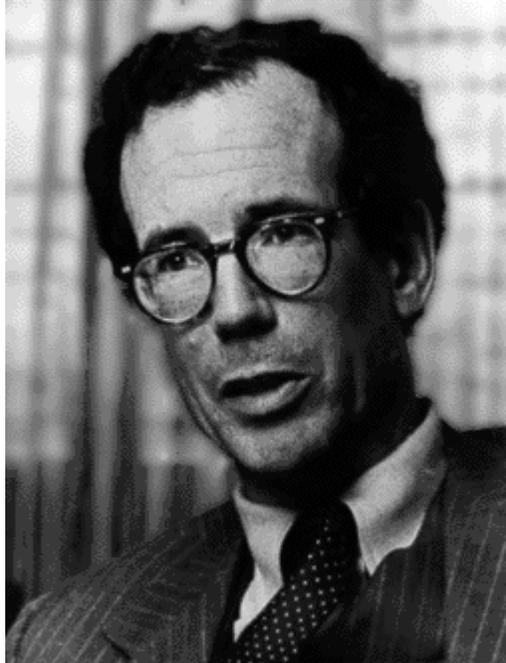


**Oral History Interview with
Donald Kennedy
Commissioner of Food and Drugs
1977-79**

**FDA Oral History Program
Final Edited Transcript
September 17, 2014**

Table of Contents

Oral History Abstract	3
Keywords	3
Citation Instructions.....	3
Interviewer Biography	4
FDA Oral History Program Mission Statement.....	4
Statement on Editing Practices	4
Index	5
Interview Transcript.....	6
Deed of Gift	56



Oral History Abstract

Donald Kennedy was appointed Commissioner of the Food and Drug Administration in 1977 by HHS Secretary Joseph Califano Jr. He served for just over two years in this role, during the Carter administration and was integral in attempts to ban saccharin in food products, halt the use of antibiotics in medicated animal foodstuffs, and develop legislation that would become the Drug Regulation Reform Act. Prior to his service at the FDA he was both a scientist and academic, and used his experiences in teaching to facilitate engagements with Congress, increase consumer knowledge with the public, and increase the scope of regulatory policy.

Keywords

FDA Commissioner, saccharin, medicated animal feeds, antibiotics, food labeling, Delaney Clause, Drug Regulation Reform Act

Citation Instructions

This interview should be cited as follows:

“Donald Kennedy Oral History Interview,” History Office, U.S. Food and Drug Administration, Department of Health and Human Services, September 17, 2014.

Interviewer Biography

John Swann, Ph.D. is an Historian at the U.S. Food and Drug Administration. He is a subject matter expert in the history of the FDA, with a specialization in the history of pharmaceutical and biologics regulation. He joined the FDA in 1989, after earning his doctorate in the History of Science and Pharmacy from the University of Wisconsin, Madison, and researching a centennial history of the University of Texas Medical Branch at Galveston. He is the author of *Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth-Century America*, as well as numerous articles on this history of therapeutic products published in scholarly journals and edited compilations.

FDA Oral History Program Mission Statement

The principal goal of FDA's OHP is to supplement the textual record of the Agency's history to create a multi-dimensional record of the Agency's actions, policies, challenges, successes, and workplace culture. The OHP exists to preserve institutional memory, to facilitate scholarly and journalistic research, and to promote public awareness of the history of the FDA. Interview transcripts are made available for public research via the FDA website, and transcripts as well as audio recordings of the interviews are deposited in the archives of the National Library of Medicine. The collection includes interviews with former FDA employees, as well as members of industry, the academy and the legal and health professions with expertise in the history of food, drug and cosmetic law, policy, commerce and culture. These oral histories offer valuable first-person perspectives on the Agency's work and culture, and contribute otherwise undocumented information to the historical record.

Statement on Editing Practices

It is the policy of the FDA Oral History Program to edit transcripts as little as possible, to ensure that they reflect the interviewee's comments as accurately as possible. Minimal editing is employed to clarify mis-starts, mistakenly conveyed inaccurate information, archaic language, and insufficiently explained subject matter. FDA historians edit interview transcripts for copy and content errors. The interviewee is given the opportunity to review the transcript and suggest revisions to clarify or expand on interview comment, as well as to protect their privacy, sensitive investigative techniques, confidential agency information, or trade secrets.

Index

- anti-substitution laws, 42
- Califano, Joseph, Jr., 7, 9, 12
- Calorie Control Council, 9, 11, 31
- carcinogens
 - Delaney Clause, 11, 31, 34
- career
 - FDA Commissioner, 23, 38, 54
 - Medical Director FDA, 7
 - Office of Science and Technology, 6, 9
 - Stanford, 6
 - White House representative, 7
- congressional affairs, 24, 27, 46, 54
 - Agricultural Appropriations Committee, 25, 26
- Dorsen Report, 19
- Drug Price Competition and Patent Restoration Act, 38
- Drug Regulation Reform Act, 31, 43
- FDA
 - food labeling, 49, 50
 - Mini-Sentinel Program, 46
 - Office of Chief Counsel, 22, 23
 - restructuring, 21, 22
- Federal Trade Commission, 15, 48
- Food Safety and Inspection Service, 48
- Gardner, Sherwin, 8, 10, 22
- generic drugs, 30, 38, 39, 42
- Grumbly, Tom, 6, 7, 8, 13, 48
- Interagency Regulatory Working Group, 15
- Kennedy, Ted, 9, 25, 31, 44
- Kostel, Doug, 15
- Laetrile, 11, 12, 31
- Lily, Eli, 39, 40
- liquid protein diet, 14, 15
- medicated feed, 35, 36, 37
- National Milk Producers' Federation, 26
- nitrate, 34, 35
- nitrite, 34, 35
- nitrosamine, 34, 35
- Orange Book, 41
- saccharin, 8, 9, 10, 11, 31, 33, 34
 - Saccharin Study and Labeling Act, 10, 11, 31, 32, 33
- Supporters of Agricultural Research, 48
- Vodra, Bill, 43, 44, 45, 47
- Waxman Hatch Act, 38

Interview Transcript

JS: This is an interview with Dr. Donald Kennedy at the Stanford University Campus. The date is September 17, 2014, and my name is John Swann. This interview with Dr. Kennedy will cover his time as Commissioner of Food and Drugs from 1977 to 1979.

So, Dr. Kennedy, first of all, thank you for agreeing to do this. We very much appreciate it. And the focus here is going to be your time at FDA, of course. But I wondered if we might start out with just a couple of questions dealing with your time leading up to when you came to FDA. You obviously had an abiding interest in science per se, certainly by the time you left Harvard, if not before. But it's the interest you had in science policy that I find interesting too. And I wondered if you might say a few words about where your interest in science policy came from and how that developed over the years before you came to Food and Drug.

DK: I was chairing and teaching in an interdisciplinary program at Stanford called The Program in Human Biology. And one of the things that we did with our students was to try to cultivate an interest in what issues confronts science in terms of regulatory policy and questions relating to that. So at about the same time, when I was doing that teaching at Stanford, I was going to Washington on occasion to work for Guyford Stever, who was then the Director of the Office of Science and Technology Policy in Washington.

And at that time, several of us got interested in what we might do to create a more interesting and alert scientific program within the Department of Agriculture, which had a rather different tradition from the NIMH (National Institute of Mental Health) tradition of having competitive peer review. So that actually introduced me in the first place to Tom Grumbly who was a food policy expert that we wanted to consult on some of those questions. And, lo and

behold, Tom Grumbly later agreed to come on with me at FDA as the only Schedule C (political) appointment I could have.

So it grew out of an early scientific interest that he and I shared. And at the time that I was asked to consider some kind of post in the Department of Health, Education, and Welfare. I was certainly interested in the science policy aspects of that when I was briefly attached to the Office of Science and Technology Policy. I had actually been White House representative on a committee that looked quite hard at some of the issues that we were later to confront at FDA.

So I was interested in something in HEW and at one point, someone who was sort of recruiting me for that kind of interest said, “Well, there’s a job out there called something Medical Director,” and nobody would confuse me with anybody who could save their child if they had croup. So I said, “No, be more serious and think about having somebody who really is interested in science and science policy and maybe even in regulatory policy.” And so I was asked about FDA. I was asked quite directly by Joe Califano, who was the Secretary of HEW. And I was very enthusiastic about the appointment and took it right away.

JS: So what was your sense of FDA even before you had that glimpse when you were working for the Executive Office of the White House? What was your sense of the agency before then?

DK: I thought it was interesting. It was important in a regulatory sense. Somebody, when I started inquiring about it, told me it actually regulated about 25 cents out of every consumer dollar that’s made in the United States. Probably everybody at the FDA knows that as a matter of
—

JS: Well, I even know the person who found out that figure, by the way, but that's another story. Go ahead.

DK: Well, that's interesting. But, of course, there was an issue with which I was introduced to FDA, and I was introduced to it well before I got to Washington. In a telephone call to the Program in Human Biology I was told by Sherwin Gardner, the Acting Commissioner -- great guy -- "Oh, you'll be interested to know that we and the Canadians have some interesting information about saccharin." Wonderful.

JS: Well, yeah, that's definitely on the agenda here. But that certainly was an introduction to the agency.

DK: It was an introduction. And, of course, introduction to an agency is actually probably facilitated if there's an interesting and challenging issue right up. So you walk in as Commissioner and you meet a bunch of staff people who've been there for some time. And they want to welcome you, but they all want to tell you a little bit about what you want to do for them. And so I walked in with Tom and with Sherwin and was introduced to a larger group of people than I had seen before. And pretty soon, we were talking about saccharin. And pretty soon I was at a hearing with lots of television cameras talking about saccharin and why it might be a problem for us.

JS: I definitely want to talk more about saccharin, but you just mentioned something and I have to ask you about it. So before you came to the agency, before you became Commissioner of

Food and Drugs, did you have many opportunities to appear before the public, appear in front of cameras in any way, shape, or form like you did once you became Commissioner? Was that sort of a new way of speaking to people?

DK: It was pretty new except for my rather brief tour with Office of Science and Technology Policy, which didn't attract much attention of that kind. So, no, it was a fairly novel experience.

JS: Okay. Now you mentioned -- Secretary Califano's name came up. And I wanted to ask just a couple of questions about the Secretary. I guess, first, how well did you know him before that invitation was forthcoming? I assume the invitation came from the Secretary.

DK: Yes, we had had a discussion. I was sworn into that office. I think actually Ted Kennedy came to the swearing in because he, obviously, had very significant responsibilities for the regulatory dimension that the FDA occupied. So we then confronted a variety of interests. One set of interests were from the people who were using saccharin as an artificial sweetener. It turned out that if your Coca Cola and your Diet Coca Cola each cost a quarter in the machine, it costs the people who make the diet cola a lot less because sugar's a little expensive.

And so the Calorie Control Council, which tried to tie up our office in comments on a proposed regulation, were very much against that regulation. Oddly enough, we also heard from some people who were mothers or family members of teenagers who liked to be able to go down to the corner store or the drugstore and join some of their friends for a non-caloric drink that wouldn't make them fat. And so a little argument that we heard at hearings was this is not a fair

thing to young people, to rob them of an alternative that obviously is of some importance to some of them.

JS: Well, when we came to deal with saccharin, I believe we had provided for making it available perhaps to those who needed it for medical reasons though, is that correct?

DK: That is correct. It was available to those who needed it for medical reasons. But they had to go through some hoops to certify that it really was a medical reason. So the Congress was, nevertheless, deeply concerned because it was an issue that involved a potential cancer agent in human beings by comparison with what had happened to the rats. At least speaking strictly to the male rats, although not the females, in those early tests.

So the Congress understood the rules about this, that if something had been shown in animal studies to be carcinogenic, it was presumed to be a carcinogenic risk for you and me. And so the Congress ultimately dealt with the problem by passing the Saccharin Study and Labeling Act, which asked for more of a hard look at the whole problem and required, as a consequence of that hard look, that there be carried a label on the animal products to demonstrate that they were warned against human use.

JS: Here's something, since we're talking about saccharin, I guess I'll go ahead and ask you now. Sherwin Gardner had made this statement about the whole issue. He said, "Well, here we have a law that's unequivocally clear. And here we have data from the Canadian-US collaboration, the study of the 200 rats, whatever, that was equally clear about what to do." And,

of course, Congress turns around and takes a very different take -- takes a very different route in dealing with this.

So when you have what the law says is clear and the evidence seems to be clear, does this create sort of a perfect storm of confusion in science policy or something?

DK: It could be quite confusing in science policy. The Delaney Amendment is absolutely clear, that goes without saying. And so Congress needed a fig leaf and the Congress found one in the Saccharin Study And Labeling Act. We're going to look harder and we're going to put a label on the bad stuff in case people aren't satisfied with labeling. And, of course, some of them weren't. Some of the people who were economically hurt by that requirement weren't very happy about it. And so the Calorie Control Council continued to be busy, continued to flood our comments on the proposed regulation.

I was also feeling a little concerned because in addition to the saccharin issue, there was—instead of a possible cancer causing agent—another compound that was widely advertised and attended to by the Congress called Laetrile that was made from apricot pits. It was visited enthusiastically by numbers of Americans who sought an alternative way of dealing with a probability that they may have cancer. And at one point, there were something over 280 signatures in the House in support of a law that would have legalized the production and sale of Laetrile in the United States.

JS: Was it Steven Symms in Congress who had come up with some idea to legalize this?

DK: Well, yes, that's right. Congressman Symms did. Everybody was frustrated with that, but nobody quite believed the FDA. In the long run, I think even Secretary Califano believed that the only way to deal with that problem was to conduct what some people call the first political control clinical trial, because that's what they in fact did. I mean, they went through the motions of doing a control clinical trial with Laetrile against some placebo. And that was just a political way of putting a damper an enthusiasm that didn't really mean anything.

JS: These in particular are two huge regulatory issues that you faced early on. In fact, some of these had obviously started even before you came to Washington, came to FDA. I guess along those lines I wanted to touch -- if this is okay -- on a couple of other issues . . .

DK: Please do.

JS: . . . before we start getting into the meat and potatoes of what you faced—what the agency faced—in these years. When you came to the agency—now your predecessors, your immediate predecessors at least, had all been physicians. Clearly, you brought these impeccable scientific credentials to the position. But I wondered, did you sense any reservation from anyone in the medical community. That here you were speaking directly to issues that would have a huge impact on medical practice? Do you think people expected that position to be occupied by an MD or did that just never materialize?

DK: John, I can't tell you how many times I conducted grand rounds in major medical centers and didn't get much of any pushback about what's a scientist doing running the Food and Drug

Administration. They had been conscious of some of the ways in which the regulatory status of FDA could be a terrific assist for wise medical practice. For example, antibiotics in animal feeds is a huge issue and they all knew it. And they all knew that the FDA had the regulatory authority to deal with it.

Of course, we tried to do that back in the day and never got anywhere with it in the end. Now, once again, it's a problem that is getting people's attention. But in the beginning, it was very hard to do the order that would have removed penicillin, chlorotetracycline, and tetracycline from their use in growth promotion in animals.

JS: So at the time you arrived, I wonder if you could characterize what you sensed? Because I think things by the time you left, things had changed substantially. But when you arrived, what was your sense of the public's perception of the agency,

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the perception that consumer groups had of FDA, and maybe even what impression the people on the Hill had? With the people on the Hill, you could have 535 different ideas about FDA, I guess. This kind of sets us up for what you had to deal with when you came to the agency. There were a lot of issues that needed attention. But perception of the agency was something that perhaps needed immediate attention.

DK: I thought and so did Tom that one of the things that we would need to work on is to find quite convincing ways of upgrading the science leadership in the agency, in different parts of it. That's when we went out to MIT and made a major recruitment for the head of the food area. You'll remember his name.

JS: Howard Roberts?

DK: Yeah. And that was reasonably convincing, I think, to many people that the agency was serious about making good appointments and making certain we were going to speak strongly on regulatory issues that are really important. You may remember the liquid protein diet. There's an instance of something that plainly was a menace, a medical menace. And people in significant numbers had died after having been on liquid protein diets. And that's a particular case in which a regulatory agency head has to talk straight to the public and use a bully pulpit if necessary and say, "This is not safe. And there's a strongly added medical risk if you mistakenly use it."

JS: Toward the end of 1977 CDC tracked something like almost 30 fatalities that were connected to these. Most of those on these protein diets that died did not have any cardiovascular preexisting conditions, if I remember right. And there were dozens -- scores of illnesses, I think.

DK: Yes.

JS: One of the things that you said about that was the importance of going out to do inspections to make sure we understood how these companies were making these products, looking at the labeling, making sure and instituting mandatory warnings statements on these diets, and communicating with doctors. But there was one other thing though that sort of made me wonder about this--and you yourself said it--part of this problem was the promotion and the advertising of these liquid diets. Obviously, we didn't control advertising of foods. But there was

an agency that did. And it kind of made me wonder, do you know if the Federal Trade Commission was roped into this at all?

DK: I knew the Federal Trade Commission and I had had some personal contacts with Mike Pertschuk. And I think perhaps what I should have done is to lobby them a long time to take action. But it turned out that -- I mean, that's a regulatory commission with not just one commissioner. They've got four or five. And they have to get that gang together before you get an action. Well, in the case of the liquid protein diet and the information that you just mentioned from CDC, probably better not to wait, but rather to tell people it's really bad stuff and they should stay away from it.

JS: People outside of Washington and a lot of people inside of Washington don't know how things work like this. How would it work if there were a couple of agencies that have a real important interest here and they aren't in the same department?

DK: Well, you know, Doug Kostel and I—he was Head of EPA (Environment Protection Agency)—realized that there was very little bonding between the federal regulatory agencies. And we founded something called the Interagency Regulatory Working Group. And one of the things that we did there was to discover that the laboratory evaluation protocols in EPA and FDA were largely similar. I mean, they could have been put right together. Well, they got the bureaucrats to sit down and decide to make a standard piece of protocol for both of them. Well, the turf consciousness in that room was terrible.

JS: I can imagine.

DK: Finally, there had to be some semi-abuse inflicted before it was put together. But one of the issues is should a federal regulatory agency be led by one person or led by a consortium? And we tried to create a kind of consortium through the IRWG and like that. But there wasn't a single feature that characterized all of them, that Consumer Product Safety Commission was four or five people. We liked them, but it was hard to pull them together to get some kinds of agreement.

JS: Right. Which was a function, I think, that was transferred not too terribly long before you came to FDA when the responsibility we had for consumer products was transferred to CPSC.

DK: Yes.

JS: Right. So continuing on the theme of sort of the upgrading of FDA scientific infrastructure . . . This was clearly of huge interest to you when you came on board, given the variety of scientific questions we had to deal with and using the best tools we had to, first of all, ask the questions and then answer them. There were then and certainly still are many laboratories in FDA all over headquarters, all over the country. Did it strike you when you came on board that there were innately different roles for the scientists in the headquarters laboratories and those in the field laboratories in terms of their research endeavors?

The reason I ask this—and it might have been in the first year when you became FDA Commissioner—the former Executive Director of Regional Operations, Don Heaton, had come

to you to get your feedback on his proposal to establish research centers across the country dedicated to seafood, total diet, and other things. And I think in this process, his office, the EDRO, as it was called, had met a little resistance from some of the bureaus or certainly one bureau in particular. And you did sign off on that. And I wondered if you caught any reaction from those in the headquarters bureaus once those field centers were established?

DK: I don't remember any. I don't remember any. But there could have been some. I mean, there are a couple of functions that would be hard to integrate with a central thing. But you would have to have a peripheral effort localized and resonant with that. X-Ray crystallography isn't just practiced anywhere. And so there was a certain amount of independence given to that one as I remember. It was in Los Angeles. That would be one illustration of a function that's so special and so not practiced in every single location.

JS: Right. Many if not most of those labs, of course, are still around and others as well. Another lab that started not too long before you came to FDA wasn't part of the field structure, but this was the National Center for Toxicological Research. And I wondered if you could say something about how the work at that lab was cultivated? There was another laboratory, part of the National Institutes of Health called the National Institute of Environmental Health Sciences, not on the main NIH campus. I think this is in North Carolina. But I didn't know if there was work there that might have been overlapping or not. But what kind of role did they have in the work, their scientific role in the agency?

DK: they did large-scale experiments, trying to establish hazard levels, and they had huge mouse colonies and were doing lots of very fundamental toxicological research finding thresholds for various toxicants. And I remember the Director for a while was somebody named Morris something or other.

JS: I don't remember. I can't recall the name myself. [Morris Cranmer, Ph. D., headed NCTR from 1971 to 1977].

DK: Anyway, I paid a visit down there once or twice and I never got quite confident about the work that was going on there. They were at such a distance from everything else that we were doing. And so affiliated with one another, rather than engaging particularly actively with other elements of the FDA. And certainly, not at all with National Institute of Environmental Health Sciences in North Carolina.

JS: Well, that's a good point because this was and is a fairly isolated laboratory. Although there are academic centers that are, I suppose, closer. But in terms of interacting with fellow scientists at FDA, that becomes a difficult thing to do, doesn't it?

DK: Yes, yes.

JS: Well, among the many other challenges you faced once you came on board was having to deal with a large variety of internal management issues. And one of the things—and here I'm quoting—you mentioned that the most troublesome and the most painful duty you had in your

first six months was dealing with something that started before you even arrived here. And that was dealing with the fallout from the hearings, the Congressional hearings, that featured over a dozen different dissenters, FDA-ers and some consultants, who had leveled a number of accusations that the drug approval system was just not carried out in the correct way, that FDA was too cozy with industry. And there was a panel, the Dorsen Panel.

DK: The Dorsen Report.

JK: The Dorsen Report that repudiated some of these. The reason I bring this up is this must have had a huge impact on morale in the agency, on public perceptions of the agency. So how did you deal with this?

DK: Well, I don't think that we were terribly damaged internally by that. I did say a lot of things to my colleagues about that. We can't not pay attention to the Dorsen Report. It's asking us to do some things we may find a little painful. It asked that we reinstate a couple of people who were skeptical of what we were doing and, in the view of many people, a nuisance.

One of the ones that I had to restore to activity because he had been unfairly treated became a legend inside the Beltway because he, to express his resentment over this, that, and the other thing, decided on a personal campaign that he would undertake, not anonymously at all, of driving at exactly 55 miles an hour in the fast lane in the Beltway. And he became famous. He became famous by his own name. He was a celebrity. And I can't remember his name.

JS: I think you're referring to John Nestor.

DK: Nestor, yes, yes. Nestor the Protestor. Well, we did have to give him his job back.

JS: Well, what was he assigned to?

DK: He had been demoted at some time from his role in the new drug approval process.

JS: Okay. So what happened once he was reassigned? Did he continue to just –

DK: My recollection is that he continued to express his distrust of the way things were being done.

JS: Okay. But there were others that also were in the same boat, right?

DK: Yeah. I thought, by the way, that the new drug approval process was favored with really pretty good leadership. I thought that Dick Crout was a very, very effective guy. And among his senior specialists, I thought Bob Temple was just without many peers. He was really, really excellent. And the institution was retaining some of its leading people and letting the Nestors drive slow on the Beltway to express his annoyance.

JS: I believe Dr. Crout brought Dr. Temple over from NIH. Perhaps it was during the time that you were there or shortly before. I know it was in the 1970's. Of course, Dr. Temple is still there.

DK: I think that happened before I got there, so I would love to take credit for it but I can't. Dick Crout did that.

JS: I understand that when Dick Crout retired, that was the point at which they brought the Bureau of Drugs and the Bureau of Biologics together. And I'm told in part because they had such a difficult time replacing Dick Crout. But regardless, that union of bureaus lasted a few years, but not much beyond that.

DK: Biologics and Drugs came together. Now are going to have some new pressures generated around that problem because the people who are deeply into

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biotech and systems biology and so forth are watching very carefully what kind of regulatory structure is set up to deal specially with the new kinds of products that are coming out. And so I watch the headlines, but I—

JS: Oh, they, of course, now are independent entities, independent centers, although some years ago, a number of biological products were reassigned to be evaluated by the Center for Drugs. But that, of course, is much later, much, much later. Toward the end of 1977, and this I think was finally made effective about midyear of 1978, you restructured the Office of the Commissioner. And I think one of the things you were concerned about was sort of facilitating advisory and analytical functions within the centers, and within places like the Office of Regulatory Affairs and the Office of Legislative Affairs and Health Affairs.

And then, I think, you reassigned more management functions to entities like the Office of Management and Operations and Planning -- the Office of Planning and Evaluation. And no doubt, having someone like Sherwin Gardner there, must have been a help in that.

DK: Yes.

JS: But I mean, was there something that led you to restructure the agency like -- I mean, the Bureaus were left out, so let me correct myself. The Bureaus were left out of that. But what led you to restructure the office, your office, like that?

DK: I just wanted a small group of people to whom I could delegate particular specialized functions. Planning evaluation is one example. And legislative affairs is also a critical one because that person has to do most of the difficult work on the hill if you're going to try to explain agency practice and justify it.

JS: What about the Chief Counsel's Office? What kind of relationship did you have with your Chief Counsel during those years?

DK: Desperately dependent is the answer to that. When I came, Dick Merrill was the Counsel. He's brilliant and, of course, when the time came, he went back to be a professor of law and, eventually, Dean of the Law School at the University of Virginia. I mean, very distinguished guy. And then it was a problem. How could we replace him? We sought a lot of suggestions from people and so forth and got Rich Cooper, who turned out to be absolutely outstanding.

And I guess I was closer to Dick because we had developed a lot of sort of parallel interests. But I like working with lawyers and, in fact, very often I would eat with the lawyers as often as I ate with the scientists. And I thought there was some really outstanding ones—Mike Taylor, who is still now a food expert here, there, and everywhere.

JS: Technically the Chief Counsel reports to the department. But how would you characterize the way the Chief Counsel works with the Commissioner of Food and Drugs?

DK: Well, very closely and gives lots of advice to the Commissioner. If there are occasions in which there are potential conflicts of interest, the Commissioner's opinion may be guided by lawyers who are relatively independent from those who are preparing to deal with the opposition that might come up if the Commissioner delivered an opinion or a public proposal that couldn't be supported. So you would always have a blue team and a red team -- the blue team being the Commissioner's team, the red team being the ones that are preparing to deal with possible alternative views of the proposal or how the policy should be shaped.

JS: Okay. You had more than four dozen appearances before Congress during your slightly more than two years in the agency. I don't know this for a fact, but I can't imagine any Commissioner that has gone before Congress as frequently as you did in that time span. So there's a good reason why I think you're recognized as an outspoken leader of the agency from that extent. Do you think the time you had to spend doing things like that, appearing before Congress, appearing in front of so many other groups—and that's part of what a Commissioner

has to do, I'm sure—but do you think that would take you away from administrative leadership over the staff, the troops, so to say?

DK: The troops are very often involved in preparing your testimony. And you ask for it and you read it carefully and you—

JS: One moment. Let me just flip this over if you'll just hold that thought. And if it's okay, we're going to do about maybe 15 more minutes and then we'll call it a day, if that's okay with you.

DK: That's fine.

JS: Okay.

DK: You ask your staff people to prepare your testimony. You then read it and you change it if you want to. And one of the things that you learn in appearing before Congressional committees on the Hill is that it is okay to have a sense of humor and let it loose. You don't offend people by using some humor largely in a positive sense. You can't kid them, but you can make them laugh. You can soften the experience by trying to create more of a connection between the witness and the interrogator.

JS: That's interesting. And you obviously had quite a lot of experience at doing this. So that's one of the things you try to do, regardless of the committee. Even in testimony before members that maybe had a reputation for being really hard on their witnesses.

DK: Oh, we were lucky. We were lucky in that regard because on the drug side, which is largely related to urban issues and so forth, we had, you know, Paul Rogers, a sweetheart. And then on the Senate side we had Ted Kennedy. And I knew several at the Kennedy staff and had reasonably good relationships with them.

On the other hand, if you had to appear before Agricultural Appropriations, you might have had a less friendly time. Certainly, I had people question me about the order that would have eliminated the use of antibiotics in animal feeds for growth promotion. That didn't go down well with the meat industry. And so I had some testimony before those committees.

But there were cases in which you had a difficult and contentious relationship with a Congressional committee that had been put together sort of for a particular purpose. And I really must tell you the ice cream story because you may remember that in the recipe for characterized things like ice cream, there are lists of ingredients that are part of the federal recipe for ice cream. And then there are safe and substitute ingredients that can be substituted one for the other. And so we had the idea that it might be sensible to substitute casein and some other proteins from –

JS: Whey, maybe?

DK: Whey, yes. For non-fat dry milk solids. Well, when you think of non-fat dry milk solids, you have to think of a huge silo somewhere that is filled with non-fat dry milk solids. And

people who make ice cream are trooping up to that and trying to use the non-fat dry milk solids as they are making the ice cream. But that substitution would have foiled that effort. So I got a visit from the head of the National Milk Producers' Federation and he's the only guy I've ever seen who could make his cigar trail from one side of his mouth to the other while he was trying to argue with you about a position.

And so finally I said, "Well, we have to agree to disagree." So I had then a mass hearing before several of the Agriculture Committees and I said, "This is a perfectly reasonable measure. It does not damage the taste or the quality of ice cream in any way. And what the National Milk Producers' Federation is trying to make you guys do is to create a special avenue for the milk producers in the United States to defeat the imports from Europe. And you need to decide whether you want --I said, "You need to decide whether you want to be an agent for that kind of trade policy manipulation."

Of course they were unconvinced, but I think the thing went through. What I love was that The Times did an editorial about the whole thing and I think Nick Wade was on the editorial board of The Times and he wrote it. He wrote the editorial. And it describes the whole thing and says what the National Milk Producers' Federation wanted to do. It closes with the single line, "We wish them a rocky road." That was really precious.

But it was sometimes fun to lose those battles if it seemed as though you had a reasonable point to make—and if by taking the right position and talking with your agency leadership that they understood it. The best thing you can do for agency morale, oddly enough, is to lose respectively and make the agency's point effectively.

JS: The losing part, that's an interesting observation. But that helps the morale.

DK: Yeah. If they know you've done the right thing, of course they will cheer when you do something well. I had some difficult challenges from reporters and I was on "Meet the Press" a couple of times and on other programs in which I was very conscious of the fact that if I performed well, my agency would gain from it and the morale of my colleagues will be better.

JS: You obviously did well in circumstances like that in front of Congressional Committees, in front of fairly high-pressured programs like that. Other Commissioners sometimes did this and didn't fare so well. So I'd like to kind of just go back quickly here because I want to reference one more thing before we break up for today.

But before I do that, you've raised an interesting point, which is you've mentioned a variety of skill sets that help a Commissioner in different situations, whether you're talking to a Congressional Committee, in front of newspaper reporters, or broadcast media people. What do you think it was in your own background that prepared you to do this so—I don't want to say effortlessly, because plenty of effort went into it. But it might have had that appearance to people who didn't appreciate. But it came off as something that might have been effortless.

So was there something in your scientific background, do you think? Or just the way you approached situations like this?

DK: You know, everybody talked about -- some people talked about my scientific background and my scientific skill set and what did I know about science and isn't that great? But that didn't have anything to do with those skills. The thing I brought to those confrontations was not, "I'm a

scientist.” It was, “I’m a teacher.” I mean, I was pretty good at that. And I think it was a more important ability for me as Commissioner in a way than the hard rock side science.

JS: Well, this gave you the experience in relating to people, a wide variety of people, whether it was a seminar, whether it was a lecture, right?

DK: Yes.

JS: Okay, I wanted to ask about one more thing. I tried to divide this up into different areas, whether it’s arriving at FDA, dealing with scientific integrity, building that up, dealing with internal management issues.

[01:00:00, DR-100_0046]

And the more high profile regulatory issues. And we’ve already talked about some of those, but I would like to continue that tomorrow. But the last thing I wanted to explore with you about the sort of internal management issues was that famous memo you wrote in 1979. “Our dealings with regulated industry and with one another.” This was a pretty expansive memo in which you laid out a number of points. And it may or may not have been an outgrowth of what you had mentioned, a code of ethics, not long after you arrived at FDA. You mentioned this was something that was under consideration, under development.

But, of course, here it is almost a couple of years later and this 13-, 15-page memo comes out, which, of course, the trade press picked up on it. This was directed to FDA employees, but, of course, others found out about it. And so I wondered, I don’t know what memories you have of that memo and I didn’t have any specific things to ask you about what was in the memo. But

was there any reason why it came out at the time it did? This was in March of 1979 and this was about three or so months before you ended up moving back to Stanford.

So was there anything to the timing here? One of the things you talked about dealt with the whole issue of how do we deal with industry? How do we do meetings with industry? And you brought up things like these without being pedantic. You said simply that “these are some ideas to consider.” And in fact, you mentioned this as an informal statement, nothing to be considered etched in stone. I see the teacher at work here, you know, in this memo that you mentioned.

But I was curious what kind of a feedback -- if you recall, what kind of feedback you got from this memo, both from people on the inside of the agency and on the outside. I wish I would have brought it with me. I have that back in Washington.

DK: If you would sometime email that to me, I'd love to reflect on it and tell you something about why I did it. I think I knew I was going, but it was only three months. I'm not sure I had really settled on that. But I did think we needed to say something about our own ethical and practical structures for dealing with our relationships with industry and for our relationships with each other and with other government agencies.

JS: Exactly. One of the things you mentioned in this memo was we can disagree. And here the scientist and the teacher were both sort of coming into play in this memo and I could see that. But you were recognizing that we don't have to always agree here, but the way policy is formulated, a variety of inputs can be taken into account. That doesn't mean we always have to

agree. And so it was speaking to the importance of respecting these dissenting views on important policy areas.

DK: And that's an important point and I have one thought about that and it probably isn't a legitimate part of this record. But the thought is the following: that often the desire to create agreement, the objective, which is agreement demands so much sacrifice on the part of one side or the other, that the objective becomes a catalyst that drives too much change on either side. And makes the convergence less valuable than it otherwise would have been. You just put too many chips on the table to get an agreement.

JS: Okay. Well, let's leave it at that. Perhaps what I could do if you're willing, I can send this to you when I return to Washington.

DK: Love it.

JS: And perhaps you can send an email or something in writing and we can include that in the record.

DK: That would be great.

JS: Okay. We'll go ahead and close for now, but pick up tomorrow and revisit some of your favorite topics, including antibiotics in foods, the generic drugs, the Drug Regulation Reform

Bill, maybe a little bit about liquid protein diets, and our favorite topic, Laetrile as well. So I'll looking forward to picking this up again tomorrow. Thank you.

DK: Well, you've been terrific. Thanks a bunch, John.

JS: That was great.

[End, DR-100_0046]

JS: So we are here again. It's the morning of September 18th with Dr. Kennedy. And we're going to resume kind of where we left off. We were talking yesterday about some overriding issues, but also some of the selected high-profile regulatory issues, one of which was saccharin. And you had mentioned a bit about this yesterday, but I thought we might revisit that and see what else you might want to add to the story of our regulation of saccharine under the Delaney Clause.

DK: I think everybody remembers that the Delaney Clause essentially said that anything that produces cancer or that can be characterized as a carcinogen in mammals or humans shall be subject to regulation. The Senate, the Congress knew that it had to deal with saccharin. Accordingly, it instructed the agency to call hearings where both the Calorie Control Council, which didn't want to see action against artificial sweeteners, was represented, along with some mothers and young people who were concerned that if there were no artificial sweeteners, young people would not have the opportunity to engage in trips to the drugstore.

So we heard a lot of things. In the interim, of course, the Congress had to do something under the Delaney Clause. And so what we got was the Saccharin Study and Labeling Act. We

need to study it more and then we need to provide a label so that consumers will know that it has been found to produce cancer in experimental laboratory animals. But that was a pretty limited labeling exercise and it turned out not to scare a lot of people, I think. I don't think there was much of a revolt against FDA on account of what had to be done under the Delaney Clause.

So the Saccharin Study and Labeling Act emerged. And while that act was in process and everybody understood what the situation was like, more scientists started to get interested in the question whether the rat, and in this case in particular, the male rat was an ideal organism in which to evaluate conditions that would lead to bladder cancer. And after a lot of study, it turned out that, in fact, the rat is a uniquely bad organism for testing for bladder cancer. Other mammals—mice, other kinds of experimental animals—could be significantly more reliable. In fact, the study had just happened to pick an animal that was unusually subject to the kinds of things that happened when you fed a particular artificial sweetener to them and it produced bladder cancer.

JS: But rats themselves have this long history in work of this nature, don't they?

DK: Absolutely. Rats were thought of as excellent models, excellent subjects for analysis of what kinds of circumstances led to cancers. But in this case, that animal species was so cancer prone anyway and so unreliable in terms of what the relationships would be between a deliberately induced dose of an artificial sweetener to produce it. So finally, a clear scientific consensus developed, which said this was a wrong call. And it provided some guidance for future use of selected experimental animals for that kind of analysis of what causes cancer.

JS: Did we develop because of this finding any formalized regulations or even informal recommendations on the types of species, types of animals, to use in the study of cancer for Delaney purposes?

DK: Except for a decision that the rat is not the best one, I don't think that there has been an order issued to specify what alternatives should be used.

JS: Okay. But the outcome remained the same even after the 18-month period expired under the Saccharin Law. I believe, is it not the case, that the status quo continued after that 18-month period? Is that right?

DK: That's exactly right. It did not happen soon enough that the analysis of carcinogenesis in the rat on account of artificial sweeteners was produced in time and in convincing enough fashion so that the Congress might have been tempted to change its rule.

JS: Okay. I believe someone whom you worked with fairly closely—not only on saccharin, but also on many food issues, such as nitrites and nitrates—was Stuart Pape.

DK: Yes.

JS: Can you tell me a little bit about that and how he came to be involved in this and what his role was?

DK: He's a very good agency lawyer, has gone into private practice since leaving FDA. He was clearly one of the senior lawyers who we would consult in cases where there were rather strong implications that certain compounds would be subject to regulation as potential food hazards. And so nitrites and nitrates both fell into that category and, among other lawyers, Stuart Pape was prominently involved in that work.

JS: Right. So in 1977, the agency had requested some additional safety data from manufacturers who used nitrates and nitrites.

DK: They were used as preservatives in food items like bacon.

JS: And poultry products.

DK: Poultry products.

JS: Right. And then an interesting development occurred from studies at MIT about the possibility of cancer that came not so much through the formation of nitrosamines, but resulted in lymphatic cancer. And I wondered if you could say a little bit about how the nitrite, nitrate story unfolded and the public policy dimensions that we didn't see—well, actually that we did see perhaps to some extent with saccharin. That is, there were problems with these products. Saccharin being that it was a violation of Delaney. Yet on the other hand, there was a role for saccharin in certain populations. So with nitrites—

DK: It was a generally recognized as safe thing and had to be pulled off the grass list in some sense because of what happened.

JS: In the case of nitrites, these had a role in helping to prevent botulinum toxins in food products as well. It was a coloring agent, but it did have a functional role.

DK: Yes.

JS: So that, it seems, must have created some public policy concerns, a combination of that role in protecting foods, yet on the other hand, maybe creating some problems.

DK: My memory of that is not as clear as I would wish. It was clear that nitrosamine was a potential carcinogen. I don't remember how convincing the data were that nitrosamines were produced from either nitrites or nitrates as generally used in food coloring or food preservation. So there is not a settled status on that issue as yet as far as I know.

JS: Okay. We talked yesterday also about the use of medicated feeds, the antibiotics in animal feeds.

DK: Yes.

JS: And I gather one of the things that we had proposed was to insert into the business and the trade in medicated feeds an order involving licensed veterinarian. And this wasn't received very well, was it?

DK: The problem is that in large part, the addition of antibiotics to animals, particularly to cattle that are being fattened as beef cattle, the purpose is to use these compounds to remodel the biota in the digestive tract. So that, in fact, the animals now gain weight significantly faster than they otherwise would have. So that led to an agency order that would have prohibited the use for that purpose of antibiotics in the feed. And we wanted to eliminate the use of penicillin, tetracycline, and chlorotetracycline as the most prominent antibiotics that were being used for production purposes in animal feeds. And we failed in that effort. There was very strong opposition from the meat industry. And so that is certainly an effort that went along for quite a while and now 30 years later or so, the central member of the cast is not the cow, but the chicken. And so the problem with using antibiotics in animal feeds is much more serious in the poultry industry.

In fact, there's a really quite brilliant investigative report from a group from Reuters that has looked at feed orders. Big, organized firms produce chickens with a bunch of growers scattered around who actually do the management of the flocks and are responsible for their feeding. The Reuters people examined the feed orders, the feed tickets that are handed out by Perdue or a major chicken manufacturer to all the people who are doing the raising of those chickens. And it turns out that many of those feed orders contain antibiotics, used for promoting the growth of the mature chickens at the pre-hatchling stage and then a different formula for the hatchlings.

So they've been able to get the feed ticket orders from those companies and show that there are still prescriptions for the addition of antibiotics to those mixtures that are fed to chickens, either in the rapid growth stage or as hatchlings.

So they have a major report out. It will, I think, surely change the politics of antibiotics in animal feeds, but this time from the point of view of what's happening in chickens. Whereas the whole start of the question of how we use modulation of the biota of the digestive tract in cattle by feeding them antibiotics so they gain weight faster. It's quite a different story.

JS: Right. I wonder, what do you think the role was or could have been at the time you were at FDA on this policy issue of those in the healthcare community? Because clearly, one of the concerns with this is the proliferation of antibiotic resistant pathogens, right?

DK: Yes, it is.

JS: And I wonder if healthcare organizations might have been behind us more, helping support an issue like this that had such an impact on really a public health problem.

DK: I think there has been at least sporadic support

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from the physician community to what FDA has tried to do to limit the use of antibiotics in animal feeds for production purposes. There are circumstances under which disease potential is high in a flock of organisms used for human food. You certainly want to be able to treat those

diseases and you may have to use a treatment that involves an antibiotic, but it ought to be used under the supervision of a veterinarian who is capable of judging the severity of the problem and judging the appropriateness of the remedy.

What I've done in periods since I was Commissioner is to editorialize frequently in *Science* and elsewhere about the problems of producing antibiotics in animal feeds and the problems that they cause the human health industry. And I think a lot of support from physicians' organizations has come about in part because they recognize that a substantial part of the problem comes from the animal foods industry.

So Congress has started to pay a little bit of attention to that. Louise Slaughter and one or two other members of Congress have vowed to support legislation that would limit these uses. And it's been a slow process. It's been a very slow process.

JS: Well, it so often is when it comes to legislative initiatives involving what FDA does. There are so many interests involved.

DK: Yeah.

JS: I wanted to change gears here a little bit and talk a bit about generic drugs and some of the developments that came about in the period you were Commissioner. Now many people look at the 1984 Drug Price Competition and Patent Restoration Act and Waxman Hatch Act as a turning point in generic drugs and certainly it was. However, there were initiatives launched during the time you were Commissioner that promoted the use of FDA approved drugs, including generic drugs.

DK: Yes.

JS: And you worked closely with a number of states. And I wondered if you could describe a bit how that initiative came about? If there was interest and support from the department, from the administration? And how that fared and what some of the obstacles were that we faced?

DK: Well, generic drugs had to pass the same approvability tests that those drugs that were originally issued on patent by the primary research firms. So there was a competition between the makers of generic drugs that had been released from patent and the manufacturers of drugs that are patent-protected. And there has been strong competitive interaction between the generic drug manufacturers and the research firms that operate to produce their drugs on patent. There was a very long argument between the Commissioner and Eli Lilly. And Lilly claimed, I think without adequate evidence, that more generic drugs failed recall tests when done at FDA. That is, that it more often happens that a generic drug is found to be less adequate than it should have been, given its approval by the FDA in tests that the FDA performed on both the patented drugs and the generics.

We had no evidence, in fact, that the generic drugs were recalled more often than the primary drugs of the leading research firm manufacturers. And so Eli Lilly kept hounding us with that and we would argue on the basis of the data. And I was convinced that public opinion was pretty strongly for the use of generics. My God, they cost less—compare the price between a drug that's on patent and the generic version that jumps into the marketplace as soon as it comes

off patent. The people who are dependent on Drug X love it when it's available in generic form because it's cheaper.

And so I think the outcome of that debate is probably a little bit inconclusive. I think Lily will make some claims about generics failing recall. But FDA will continue to say that, no, it doesn't. The statistics show that those are recalled no more often than those marketed by the primary research manufacturer.

JS: I think at the time, the agency had suggested that perhaps Lily was cherry-picking some of their data, that they were perhaps leaving out, for example, some research firms who had significant recalls and that they were kind of lumping recalls into one boat. In other words, not differentiating between a major recall and one that wasn't quite as significant. So there were some issues, I think, with what the Lily study was contending, right?

DK: We looked as hard as we could with what Lily offered us with respect to recall data on the leading research firms. And we weren't quite convinced that they were being consistent with the grouping of recalls either for the primary manufacturers or the generics. I think if you select your data, it makes it a little easier to make a case that you're anxious to make. We did not accuse Lily of deliberately making phony statistics, but the way in which the recall data were jumped as to their application to research firms and drugs that are on patent and the case of drugs that are generic and, therefore, not on patent . . . They were saying that FDA recalls of generics are more frequent than patent-holding research manufacturers drugs. We didn't think that they could show a legitimate difference of that kind.

JS: Okay. One of the things that came out of this story, it seems, was a source that we're all very familiar with now. And that's the Orange Book. It seems that we were asked by the State of New York to construct a list of approved drugs, including approved generic, therapeutically equivalent drugs. How did they come to approach us for this assistance? And is it true that the Orange Book, the compilation of approved drugs, kind of came out of this development?

DK: I don't recall exactly. We would certainly have been very responsive to any state government requesting a list of approved and not approved drugs. They have every right to know what FDA has actually concluded about efficacy and safety of the drugs that are available on markets to which those states have access. And so it's a perfectly legitimate request that a state would make, in this case New York, to prepare a complete list of drugs available, the indications for those drugs, and what the approval process was. It could have access to drugs, for example, that were in the midst of a controlled experimental trial to compare that drug with placebo or whatever.

But it would probably list only those drugs that had passed those tests and were approved for prescription, either as generics or as patented drugs. And, from what you're saying, I gather that New York had compiled a rather large list. I don't remember it having been called the Orange Book.

JS: Well, in any case, it seems that by the time you left the agency, there were more and more states that were asking FDA to provide such a list, which of course had to be updated from time to time.

DK: I think that was from a genuine desire on the part of states who really wanted to serve their population of consumers well. And also to maintain the least costly possible health system for operation in its own boundaries. They, I think, showed some appetite for the clearly approved generics because they cost less.

JS: Right. Of course a majority of the states by this time had done away with their anti-substitution laws. And I think they wanted to be able to have pharmacists in the state have a list available to see what drugs might be available if the physician's prescription so allowed to substitute a therapeutically equivalent drug. So it seemed to be an important service that the agency was providing to New York and these other states.

DK: Obviously, Medicare is an issue. There are states with programs designed to help the least favored of their populations of consumers. They're under some equivalent of Medi-Cal—or whatever it's called in the particular state—that's designed to particularly provide some benefits to poorer consumers. And so a state that has the equivalent of Medi-Cal would have an expanded interest in making sure that the proportion of generics is as high as it could be made.

JS: Right. I think at the time you and the Secretary had both argued that the high cost of drugs was particularly damaging to those that were least able to afford it.

DK: Yes.

JS: People like you just mentioned, the senior citizens, for example, who are relying on Medicare or the state version.

DK: Yes.

JS: Right. Not necessarily along the same lines, but certainly an important part of the endeavor during the Carter Administration to promote changes in healthcare, was the Reform Act, the Drug Regulation Reform Act. It was the legislative initiative that came up during your time as Commissioner. And I wonder if you could speak a bit to that -- its inspiration, if it might have been tied in to some extent with this whole drug lag debate, how it was carried out within the agency, the assistance you had from people, the bureau directors, your immediate staff? And what happened with the bill, which in the end did not pass. But I wondered if you could share some insights into why that might have happened and if it might have had an impact at least later on some regulations.

DK: The key player in developing that act was a very experienced and capable attorney

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then working for the FDA named Bill Vodra Just a terrifically able person. I think he played a key leadership role in the development of that.

JS: If you can pause just a moment. I think I'm going to have to close our window because we have some construction going on. Sorry. Please continue.

DK: That's good. The idea was to review and reform the new drug approval process so that it was better understood and more effective for both the regulated industry to see and understand and conform to. And to make some contribution to driving the cost of healthcare down. So the fate of that set of efforts looked somewhat promising when we got a good hearing at the Senate level. Senator Kennedy was helpful in making sure that we could at least present a hearing with the basic features of the plan and get it discussed. I think there was real hope since it had a hearing from a major Senate committee that in general was respected by almost everybody. But, in fact, it went through some careful questioning in the committee hearing. But it never got to the floor at all, and the question of whether the House Committee could have gotten more excited about it if we had concentrated on that branch of the Congress . . .

But, in fact, it remained as a very thoughtful proposal and a lot of people have read it. It's been well distributed and I think Bill Vodra, in his capacity as an independent health quality expert and lawyer, has caused a lot of people to read it and look at it and perhaps be influenced by it. But I think the problem of really changing a new drug approval process is so large and it affects so many interests that lots of the big firms in pharma were, I think, awfully hesitant to make any move toward adopting a change. After all, they've learned their way around the present character of FDA regulation of new drugs. Why should they fool with an obviously intelligent and thoughtful effort to change the system that they've been dealing with? But I think they eventually decided that they had had too much of a success dealing with it as it was and didn't want it to change.

JS: This was a wide-ranging bill, no doubt about it. But were there some provisions that you particularly felt would just be of immense value to the way we regulate drugs?

DK: I think it did somewhat clarify the claims of the research intensive firms and what they did. And why their opposition to generics was not a fair evaluation of FDA's recall process. My recollection is that there was some careful attention given to recall data and how bioavailability is measured. I mean, my recollection of the details as a proposal has been a little bit dulled by time. But I remembered it as a way of seriously attempting to make that process much more understandable and much less capable of being manipulated.

JS: It seems like there were provisions there that I would have thought—it seemed like these were provisions that pharma might have really been attracted by. For example, you had mentioned on several occasions your interest in—and this was part of the bill, I think—giving particular attention to approval and speeding up the approval for particular therapies.

DK: Yes. Of course, nobody knew about AIDS yet. But it was obvious to Vodra and to the rest of us that there had to be a mechanism for doing something about really serious health needs in terms of encouraging development. So we ought to give them a break in the process, there ought to be careful recognition of an important category of drug that was needed by a growing population of conceivable users. And so the new proposal would pay some attention to orphan drugs or to conditions that were increasingly important in the national healthcare system, that would provide some advantages for developers, including pharma members to do that.

I think their fear was maybe the people that have authored this new procedure are people who are really conscious of the kinds of health problems we have and are interested very much in new regulations that would favor those who are most in need in terms of their financial

capacity or their personal health conditions. So it could have been regarded by some members of pharma as another way of promoting generics, but as providing a new set of mechanisms for identifying particular indications that would receive favorable treatment.

JS: And that was a concept ahead of its time because eventually that was embraced by the agency.

DK: Yes. I would love to see that come back, but it's hard to resuscitate something that's been left alone and not presented to the Congress in its full form. But the Senate hearings did do some things to improve it and make it more understandable.

JS: Well, some of those provisions keep coming up for debate, don't they? The concept of giving FDA greater authority to pull bad drugs off the market—either ineffective or real problem drugs, using administrative powers to do that outside of the imminent hazard provision of course.

DK: The FDA Mini-Sentinel Program. It has finally become recognized that the measures of safety and efficacy that are used in the approval process create a universe of treatments that is being used by some large number of people to gain approval. But that in actual practice, given the size of the target and how many prescriptions are being written, the number of people that are affected by that drug is now characteristically many multiples of the number of people that were considered in the approval process. That's a great wakeup call. And FDA now must recognize it.

I don't know how many past Commissioners have seen that problem and offered the most telling and thoughtful explanations of why it's a real problem that we have to deal with in the future.

JS: You know, as this initiative was developing, I know you launched hearings for agency officials, for people in the agency, to discuss the proposal, people like bureau directors and field personnel to come in and talk about this. Do you have a recollection of that and to what extent people were supporting or maybe not so much supporting what was in the bill.

DK: I thought that in these meetings EDRO (Executive Director for Regional Operations) and some of the regional units and certainly the reorganized Commissioner's staff were given very clear explanations of what the purposes were and how it might work. I think we had good support from the people who were in the drug approval process at that time. And Bill Vodra was a very effective advocate for the new plan. My impression is that we did not get severe obstacles put in front of us by any particular group. Inside the House, I think it was a pretty popular move.

JS: Well, again, this was a proposal that at least elements of which keep coming up from time to time.

DK: Yes.

JS: A final issue like this that I wanted to talk about very briefly is something similar that had been plans for foods, and that was the food labeling initiative that came up during your tenure at

FDA. And I know there was work that you did collaboratively with the Federal Trade Commission and with the Food Safety and Inspection Service of USDA. This was sort of a tripartite effort to improve labeling, I suppose, to help consumers make better decisions about the nutritional choices they were making through the food label. I wonder if you could talk a little bit about how that unfolded during the time you were at FDA and what the result of that was by the time that you left the agency?

DK: I had long conversations with both the new and experienced people in the food sector at FDA. It's clear that food safety and its quality and the demand for food is determined by a whole variety of features. I mean, in the communications business, there's the Federal Trade Commission and I got along reasonably well with them. I knew Mike Pertschuk and I thought that commission was good, although I think as a multi-party commission, it was a little hard sometimes to get everybody together.

The Food Safety and Inspection Service and USDA is very important. And I made pretty good friends with Carol Tucker Foreman. She was really a fine person. We work together now occasionally with a new organization called SOAR, Supporters of Agricultural Research. We're trying to push hard for a new competitive grant system at USDA that would be more like NIH and peer reviewing and so forth. We tried that once before and it didn't last very long, but it may again.

So there are lots of people who are knowledgeable in this area and that I got a lot of help from. I mean, Tom Grumbly most of all, and Carol Foreman. And at that time Mike Taylor was just coming along. So there were lots of people having some involvement in this. I don't remember that there's a particular set of decisions or documents that comprehensively pulls together Department of Agriculture food dietary advice and food labeling and the Trade

Commission. I don't recall that the whole food labeling project emerged with a single, easily digestible outcome.

JS: It sounds like we did not at any point have a chance to float the idea of a regulation that would mandate the labeling of certain food components, certain nutritional components on the food label. Is that your recollection?

DK: Well, we had a very complicated set of rules about where the recipe for a particularly characterized project rests in the government.

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I think I bored you with the long discussion of the ice cream adventure, but that was a particular case in which an agency move initiated with respect to the use of alternatives between two safe and suitable ingredients that were regarded as equivalent at the time. That was certainly an issue that involved food labeling. But I don't remember that we had initiated a brand new food labeling policy and won.

JS: It did seem that on the minds of the group were things like fat content or sugar content of foods—things that consumers had a right to know about on their food labels.

DK: Yes. I think we insisted on a lot of that. There is some state initiative in this area, too, so you may have to do some compromising. Science magazine used to have repetitive pieces, particularly by Gary Taubes on the dangers of salt, or fat and the dangers of paying too much attention to fat. I mean, food has become enormously complicated. And there are gurus

everywhere who have their own ideas about the food and food safety and health. I don't remember that it was anything like that at the time we were worrying about food labeling.

JS: The agency launched pretty wide-ranging studies about food labeling, but what the outcome of that was I don't recall immediately. And those may or may not have been done at a time when they could inform the work that was going on then.

DK: So we would go out and take polls or do some kind of analyses, do something that could inform them about the utility of food labeling of a particular kind.

JS: I know we went out and recruited, solicited information from the public, information that would be hopefully constructed into the proposals for food standards, which goes back decades, I think. And so we certainly have this tradition of getting this information from the public, whether or not it makes it into a rule is perhaps another issue.

DK: Well, I certainly think that we had a responsibility to make sure that if there was public confusion about a particular kind of food labeling, or if there was a powerful sense on the public's part that the priorities that are set out in our plan for labeling foods didn't include things that were important to some of the people, then we would respond.

JS: This does though seem to be consistent with a theme that really permeated your tenure as Commissioner, which is improved communication, back and forth with consumers on so many different issues, whether it's with drug information, or perhaps food information. Getting

consumers involved in a formalized way in advisory committee meetings, which I know is one of the things that you championed during your time at FDA; not only making greater use of those committees, but getting consumer representatives on them.

DK: We had some wonderful people who were powerfully interested in the work of FDA and in public policies for them. I remember I got to know several of them.

JS: Were these individuals in our public affairs –

DK: Well, no. Marjorie Guthrie, Arlo Guthrie's mother.

And the widow of her husband who had Huntington's.

JS: Oh, Woody Guthrie?

DK: Yes. She was fabulous. She was a livewire. You reminded me yesterday of something in the context of talking about my support for communicating effectively with consumers and working out processes for dealing respectfully and sensibly for regulated industry. And you referred to something that I wrote to the staff.

JS: I promised to send it to you. Unfortunately, it's in my office in Silver Spring, Maryland. But I will do that because I would love to get your reaction to this. This was a memo from 1979 laying out primarily the ideas that you had about proper ways to communicate with regulated industry and what could be perceived as acceptable ways. But also ways that we in the agency

deal with one another, particularly in instances where there is disagreement over findings, over policy, and so on, which of course has always been an issue in the FDA.

It's always interesting to talk to people on the outside who have this idea that FDA speaks with a single voice, that there is just an FDA voice. And how in the end that might be how it seems, but those of us in the agency and probably any agency like that, know that there are many different voices. But this memo was an informal statement. And really I don't think you casted it as anything other than that, as an informal statement on how we might consider doing that. And I know you had mentioned, probably not in the memo itself, but I had seen elsewhere that you based this on conversations with just a wide variety of people in the agency, not asking them what should go into the memo, but rather what their ideas were about these themes. And, perhaps, that's one of the things that I had wondered about was why this memo came about at the time it did.

DK: Yes, yes. Was it that I had it in my mind that I was going to move back?

JS: My impression was that what was happening back here at Stanford perhaps had not been clear at that time. I don't know. Although that was a question I wanted to ask you about: when it was clear that the position of Provost and Vice President for Academic Affairs was going to be vacated? But we can talk about that in a moment.

DK: I think it wasn't clear then, but somebody from the President's office at Stanford did contact me. But it was certainly much later than the release of that "Let's talk together about" letter.

JS: That's what I thought. I will absolutely send you that copy of the memo and I would love to hear what you might have to say about that as you revisit it. It's a substantial memo, by the way. It's about a 10 to 15-page memo, single-spaced.

JS: First of all, I can't thank you enough for sitting down with me over these last two days to talk about these things. It obviously happened a long time ago but it's been wonderful. We've talked about so many different issues and policies and your role as just an outstanding spokesperson for the agency in these years, something we really needed. But so many issues, complicated public health issues, came up.

And I wonder as you look back on our own tenure there, what do you think are just really crucial skill sets for a person to bring into the position of Commissioner of Food and Drugs? Because one faces so many different kinds of issues and you deal with so many different kinds of groups and individuals that it almost seems an impossible position. I talked to one former Commissioner who said his colleagues, when he agreed to accept the invitation to be Commissioner, wondered why on earth he would do something like that, because of the difficulty of the position. So what strikes you as some of the most important things a person could bring to that position?

DK: Well, I think in the first place, the position and the opportunities connected with it ought to offer somebody from an academic background, first, a really deep and passionate interest in how science is used in making public policy. Unless you thought with some of your students about how that happens, unless you've talked about how science is used in the making of public

policy to students, the Commissionship of the FDA is an opportunity to turn that kind of knowledge and that kind of understanding into positive outcomes. And one should be aware that you need to establish a kind of personal rapport with your colleagues in the agency, with the variety of interests in public health that you must encounter, with the members of Congress that care about the agency and are likely to be thoughtful critics of what it does.

My own impression when I came to FDA, is that it was very much more interesting and a very much more real world environment than the kinds of government appointments some of my academic colleagues were thinking about. For example, I really liked going to a couple of Congressional districts and finding out what their problems were and taking some heat from a large number of people in a meeting in Iowa in which there were both hog farmers and cattle growers and others who had very little use for some of the provisions that FDA was applying to what they were doing.

So rather than having gone into some regular government position that didn't involve contact with real people, I felt lucky almost every minute of my service at FDA. I thought it was fun, even when you got knocked around a little bit by some people who were critical of what we were doing. I felt the most valuable tool I had was my curiosity and interest in different people in government and why they're doing the things that they are—what a regulatory agency needs by way of thoughtful understanding of its regulated industry and its public health critics. You need to be able to manage a broad array of things. And if you can't satisfy some curiosity in the process and employ a certain sense of humor about the process, you're not going to grow as much as you probably should.

[01:20:00, DR-100_0047]

JS: That's a very nice and succinct way to bring this to a close. It's been a memorable conversation. And I think we particularly like to hear from our former Commissioners who can inspire a lot of us at FDA, and perhaps future Commissioners. So this has been extremely helpful.

DK: Well, thanks, I've enjoyed it a lot. I must say, I'm thinking about the current Commissioner who I've known since she was a small person because she grew up on this campus. Her father was Chairman of Psychiatry and Behavioral Science at Stanford.

JS: So, Dr. Hamburg was here in Palo Alto?

DK: Yes, yes. And I encouraged her a lot about taking the job. I have enormous respect for her. I think she's so able today.

JS: Well, again, thank you so much for sitting down these last two days.

DK: Thanks so much.

[END OF INTERVIEW]



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