History

of the

U. S. Food and Drug Administration

Interviewee: Donald Kennedy, Ph.D.

Interviewer: Robert A. Tucker

Date: June 17, 1996

Place: Holiday Inn Golden Gateway
San Francisco, California

DEED OF GIFT

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Donald Kennedy, Ph.D.

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INTRODUCTION

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

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

INTERVIEW INDEX

General Topic of Interview: History of the Food & Drug Administration

Date: June 17, 1996 Place: Holiday Inn Golden Gateway, San Francisco, California

Interviewee(s): Donald Kennedy, Ph.D.

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Last FDA Position: Commissioner of Food and Drugs

FDA Service Dates: April 4, 1977 - June 29, 1979

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Number of tapes: Two Length: 90 minutes

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RT: This recording is another in a series of oral history interviews with former Food and Drug Administration employees. Today the interview is with Dr. Donald Kennedy, President Emeritus of Stanford University and currently Bing Professor of Environmental Science Institute for International Studies at Stanford University. Dr. Kennedy served as commissioner of the Food and Drug Administration from April 4, 1977, through June 29, 1979. Present in addition to Dr. Kennedy is Robert Tucker of the FDA history office. The date is June 17, 1996. The interview is taking place at the Holiday Inn Golden Gateway in San Francisco, California, during the Centennial Conference of the Association of Food and Drug Officials (AFDO).

Dr. Kennedy, in these interviews, we like to begin with some autobiography. Would you please start at the beginning of your life, or where you were born and so on, and carry it on through to the time when you were appointed commissioner of the Food and Drug Administration.

DK: Yes. I was born in New York City, went to school in various suburban schools during the first period of my life. My family moved from place to place in the suburbs; and then during the war, my father was in the military, and we lived in several different places. I lived for a while in western Massachusetts where my mother was teaching in a small, private elementary school, which I attended for a while, and in Florida, at several different locations in Virginia, when my father was reassigned to Washington. I then, in 1945, went away to a preparatory school in New Hampshire, where I spent four years.

During that time, my father was discharged from the military and went to work for the Ford Motor Company, and we then lived in Ann Arbor, Michigan, while I was attending Harvard College, from which I graduated in 1952 with a major in biology. I stayed on for a Ph.D., which I completed in 1956, then went to an assistant professorship at Syracuse University, where I remained from 1956 to 1960, and then moved to Stanford. I taught biology and ran a research laboratory in neurobiology at Stanford during the years 1960 to 1977.

RT: Doctor, your degrees were in what area? How did they relate to your later work?

DK: All my degrees were in biology. I was promoted through the ranks in the biology department at Stanford, was chairman of that department from 1965 to '72, and then served as chairman of a new program called the Program in Human Biology.

In 1976, I was loaned by Stanford half-time to the new Office of Science and Technology Policy in the (President Gerald R.) Ford White House, and worked there to help establish that new office from about the spring of 1976 through the early part of 1977. Early in 1977, I was asked by Joe Califano to become commissioner of the Food and Drug Administration, a job I started in April of that year.

RT: Doctor, the work or research that you might have been involved in at Stanford, was that related in any direct way to the interests of the Food and Drug Administration at that time, do you think?

DK: Well, I think anybody who does physiology, which is what I did, is getting some subject-matter knowledge. Much more relevant to my later work at FDA was participation in a number of different National Academy studies. I chaired a study on alternatives to the use of chemicals in pest control and public health applications, and I was on the executive committee of the academy's World Food and Nutrition Study in 1973 through '75. So those aspects of science and policy development were so much more relevant than the work I was doing in the laboratory.

RT: The academy you mentioned, was that the American Academy of Arts and Sciences?

DK: No, the National Academy of Science.

RT: The National Academy of Science.

DK: The National Academy of Science.

RT: When Mr. Califano, or Secretary Califano, approached you, were you given any particular priorities or mandates that you would undertake as commissioner for the agency?

DK: Not really. He had originally talked to me about the assistant secretary for health, and we both quickly concluded that he needed an M.D. in that job. He then came back to me and suggested that I might do the FDA, and that seemed very interesting to me. We certainly discussed problems of regulatory agencies in general, but I didn't have any explicit mandate. He just said essentially, "Get in there, and do a good job."

RT: Now that was during Mr. Carter's administration, wasn't it?

DK: Correct.

RT: Yes, (President James Earl) Jimmy Carter (Jr.). All right. As you came to the agency, Dr. Kennedy, and more or less assessed it or summed up what it was doing and so on, did you identify any particular needs that required your administrative attention at that time in particular?

DK: Well, I thought there were several problems. The first was that the agency had taken a terrible beating in hearings before Senator Kennedy's committee, and in an appearance by Commissioner Schmidt on *Face the Nation* or some such program. The nature of that criticism had been that FDA had not been performing

its regulatory function in a sufficiently aggressive way, and that it was allowing unsafe food additives and the like. So public image was a real problem for the agency--and that had serious consequences, I felt, for the morale of the very able people who worked in it.

The second problem was in the medical devices area. The Medical Device Amendments were then barely a year old--probably a little less--and the Congress had given FDA an enormous new responsibility without an equivalent appropriation increase. So there had been done a lot of quick reallocation of resources, and I felt that although the medical devices area was coming together, it needed strong support.

In addition, the agency was taking terrific heat for the announcement, just weeks before I got there, that the tests it had done in collaboration with the Canadians had demonstrated that saccharin was a rodent carcinogen. That had produced a real storm of protest, because people didn't want the only artificial sweetener then available to be taken off the market, and it looked as though it was going to have to come off under the law.

RT: That would have created a serious problem for diabetics, I'm sure. Did you hear from interests of that type?

DK: We heard from people who were managing diabetics, especially juvenile diabetics. We heard from people who were concerned about teenagers who were obese and suffered dietary restrictions, who wanted nevertheless to be able to enjoy a diet soft drink with their age-mates at the local fountain.

But I must say that the loudest outcry was orchestrated by the manufacturers, particularly Coca-Cola and Pepsi-Cola, who stood to lose a very substantial amount of money. It turns out to be quite a lot cheaper to sweeten a soft drink with saccharin than with sugar. So Coke's profit margin on a can of Diet Coke was significantly higher than on a can of regular Coke.

RT: As you also looked over the organization and its management team, did you see any particular changes in management personnel that you felt were indicated either in the leadership of the various bureaus or in your immediate office staff?

DK: No, I thought it was in good shape. I felt I needed a little more support in the commissioner's office, so I brought Tom Grumbly in. He had been at OMB, and I had gotten to know him as we were working on the last Ford science budget. Howie Roberts was at that time an acting director in Foods, and so one needed to either take the "acting" away from his name or find someone, because that was not a job we could keep in temporary leadership.

RT: Now Tom Grumbly, what were his particular responsibilities?

DK: Well, he was really my special assistant. I wanted very much to organize the Office of the Commissioner a little differently, and we brought in Ellen Williams as an associate commissioner, and he worked with her in sort of reorganizing the executive secretariat of the agency and trying to improve internal communications.

RT: Was Ms. Williams your associate commissioner for policy or is that the right term?

DK: Yes, yes.

RT: And what was her background prior to joining your team?

DK: Oh, she had a degree from MIT and had worked in the private sector quite broadly; she was very bright, and had done quite a lot of consulting work with government agencies before. So she was no stranger to the federal government.

RT: At that time, Sherwin Gardner was in place as the deputy commissioner as I recall.

DK: That's right.

RT: And he had served at least for parts of the two previous commissioner's terms, Drs. Edwards and Schmidt, I believe.

DK: That's right, and he had been acting commissioner in two different spaces between appointed commissioners.

RT: Mr. Gardner was a management engineer in his previous private sector experience. Was that and his prior stints as acting commissioner helpful to you as the new commissioner at that time?

DK: Yes, he knew the agency well, and he was one of the people that Charlie Edwards originally brought from Booz, Allen. So he had had considerable experience in management consulting. He knew how to make things work. He was thoughtful, patient, knew the agency well, interacted very successfully with people across the agency. I enjoyed working with him a lot, and he was very helpful.

RT: You mentioned that Secretary Califano had personally contacted you about taking this responsibility. Was your rapport with the secretary close and successful?

DK: I think we had a lot of respect for one another. I felt that he was very able, but he was not easy to work with. He had an array of bright young lawyers whom he instructed to kind of keep track of what was going on in the agency, and they would often cause us to need to do more explanation than I thought was necessary. I understood Joe's desire to keep the operating parts of the HEW (Department of

Health, Education and Welfare) elephant in close touch, but Joe probably could have given the agency a longer leash.

RT: Well, the Food and Drug Administration, among the family of department agencies, perhaps is one of the smaller in terms of budget, but yet I'm sure one of the politically sensitive parts.

DK: It's by far the most politically sensitive, and it needs a certain amount of independence, I always felt. Something I was convinced of from the beginning was that it was important for FDA to have independent regulation writing authority. Although I understood why the FDA chief counsel reported to the general counsel of HEW, it seemed to me important that the legal office at FDA be primarily accountable to the commissioner and the commissioner's staff, and I think in practice that's the way it actually worked out.

RT: Let's see, was Richard Cooper the counsel to FDA?

DK: Dick Merrill was the counsel when I came, and then Dick came back to law teaching at the University of Virginia, where he subsequently became dean. We interviewed quite widely for his replacement, talked to a number of people, and eventually persuaded Rich Cooper to come.

RT: During your tenure, you were as actively a participant in congressional hearings as any of the commissioners have been for a long time. In looking over the record, I saw about forty-three times where you had been a witness for the agency.

DK: I would have said forty-seven. I remember counting them up, because the Office of Legislative Affairs made me a wonderful diagram showing all those appearances at hearings.

RT: During that time, the agency was in an expansion mode. Were those hearings, as an overall assessment, helpful or encumbering for the agency?

DK: Well, obviously, appropriations hearings are important and necessary, and we, I think, prepared for those rather carefully. We were very fortunate in having good chairs. I worked hard to establish a relationship with Congressman Whitten, who wasn't always sympathetic to the agency's purposes. I found him a very enjoyable and friendly person, but he had a rather autocratic view of the budgets under his control. Of course, the agriculture budget was his favorite, and as we came under the Department of Agriculture for appropriations purposes, we were heard as part of the agriculture budget. So it was very important that we deal with Congressman Whitten.

On the Senate side, at least for most of the time, Patrick Leahy was chair of Ag Apps (Agriculture Appropriations), of the subcommittee, and he was terrific. I mean, just a very low-key, reasonable guy. So we didn't have a lot of trouble on the appropriations side.

RT: Now on oversight . . .

DK: On oversight, it was a different matter. Oversight came pretty much from the Health Subcommittees. Paul Rogers was a very experienced and very thoughtful Health Subcommittee chair on the House side. When he decided to leave the Congress part-way through my tour, there was quite a struggle to see who would succeed him. The more seasoned and senior person was Richardson Pryor from North Carolina. The relatively more junior contender was Henry Waxman. There was a considerable struggle, and Waxman eventually got that chairmanship.

Of course, we also got oversight from the Oversight and Investigations Subcommittee of House Commerce, chaired by John Moss. John Moss was regarded as a scary figure by people in the agency. I remember Dick Merrill advising me not

to jump out of my seat when I heard a sharp crack of California oak on Michigan maple, and he gave me my first rough hearing on conflict of interest in advisory committees.

But I thought John Moss was really a fine chairman. He was tough. He really believed in oversight--to him it was *the* most important function. Under him, there was a small professional staff. We didn't like them very much, but it was small, it was tightly organized, and it was kept within limits. When John Dingell took over that subcommittee, the staff exploded from about six to 125, and began to regard the whole universe as its domain. Probably they paid less attention to FDA than in John Moss's tenure, because they had such an enlarged agenda. But John Moss was a good chairman.

RT: Did I recall you mentioning that Mr. Moss was from California?

DK: Yes. He represented the Sacramento District that Bob Matsui has now.

RT: On the Senate side did Senator Kennedy have leadership there at that time?

DK: That's right. And our relationship with Kennedy was actually very good. He was extremely helpful on the Laetrile issue which was a very difficult matter for the agency. He held hearings and invited the advocates of Laetrile to appear and gave them quite a grilling. I think that his intervention was instrumental in keeping some balance in that thing.

RT: And that was an ineffective purported cure for cancer?

DK: Laetrile was the substance extracted from apricot pits that was supposed to be a cancer cure, and was being actively marketed by a few unscrupulous physicians.

There were clinics in Mexico, and Americans were going down to visit them. The House got 280 signatures on a bill to legalize it. Finally a case involving Laetrile went to the Supreme Court, and the Supreme Court reversed an appellate court decision. That decision would in effect have legalized it. The Supreme Court threw it out unanimously.

RT: In addition to Laetrile, there were other interests in drugs and drug clearances. Depo-Provera, an injectable contraceptive, was one. Do you recall any particular difficulties with that?

DK: Yes. Congressman McCloskey, whom I had known from out here in California, chaired a Select Committee on Population in the House, and there was a strong interest in the approval status of Depo-Provera in this country. Some representatives of USAID testified that if Depo-Provera were to be made widely available as a contraceptive in connection with family planning and population control exercises abroad, it was important that it be approved in this country; otherwise, people would think we were exporting a drug for others that we were unwilling to use ourselves.

I was awfully unhappy with that. I thought that to make the U.S. approval process hostage to a need for export was the wrong thing to do. The law plainly instructs FDA to approve or disapprove drugs in the context of the American health care system. Here we were being invited to ignore that provision and to approve something just so it could be sold overseas. In fact, I don't think there was at the time a good reason for approving Depo-Provera in the United States, although that was a different time.

RT: This may have occurred in part, at least, prior to your assuming leadership of the agency: the UGDP, the University Group Diabetes Program study, regarding Orinase. Do you recall coping with that problem?

DK: Well, the vestiges of it were still around, because the advocates for solving the diabetes problem through oral hypoglycemics and lowering blood sugar were extremely vocal and extremely aggressive about FDA approval of anything and everything that would do that. The doctors at the Joslin Clinic in Boston were especially zealous in their efforts. The controversy that you mentioned was largely before I got there. But there was some re-echo of it when we employed the imminent hazard provision in removing Phenformin which was another oral hypoglycemic.

RT: OK.

DK: Most of the controversy about the UGDP study, independent of the general issue of whether oral hypoglycemics are the right way to control diabetes, took place largely before I got to FDA.

RT: Now, with regard to alleged risk of cancer products, I believe that hair dyes presented that question at one time during your commissionership.

DK: The hair dye questions, most of them arose before I arrived. I did have one major cosmetic and hair dye hearing before Congressman Gore, now the vice president, and there were concerns about how closely the FDA was monitoring cosmetic products and so forth. I simply said that in view of the relative risks posed by food additives, and drugs, FDA really couldn't allocate large amounts of resources to the cosmetic problems and that although I understood what the chairman was getting at, it didn't seem to me the wisest use of FDA resources.

RT: Another item in the drug arena were veterinary drugs or antibiotics in animal feeds.

DK: Reuse of antibiotics in animal feeds was a really important issue, I thought. Eighty percent of the bulk sales of antibiotics in the United States were as growth promotants in animal feeds. There was already evidence that people who worked around livestock had resistant plasmids that had originated in those livestock. There was independent evidence that resistant plasmids could jump from those enteric bacteria to pathogenic bacteria. So we felt that the loss of vulnerability of human pathogens to antibiotics was being put at risk by the use of these compounds as growth promotants in animal feed. So we issued proposals to ban the uses of penicillin and tetracycline and chlortetracycline. They were fought bitterly by the meat industry. I felt that the evidence was plenty good enough to justify ruling them out, but we lost that fight then, although plainly we were right, and that's something that has turned out since to have been a real worry. I'm glad we tried to take action on it and at least got it on the table as a scientific issue.

RT: In the food area, there are a number of things that occurred. Food labeling public hearings were something that I think you were active in.

DK: We tried to push food labeling. We held hearings around the country. We tried to work with the food industry to promote more informative nutritional and more complete ingredient labeling on food. I think that was a very useful forerunner to some of the efforts that Commissioner Kessler has been making on that issue during his tenure.

RT: I recall that ice cream became an area of interest. Would you care to comment on that problem?

DK: Well, it became an area of interest only because of a regulation that had been started in the agency long before I got there. It would have triggered ingredient labeling on ice cream by allowing manufacturers to substitute casein and whey

protein for nonfat dry milk solids at no nutritional loss and no effect on the taste of the product, or so I was assured. I even went to the Bureau of Foods and taste-tested the food, the ice cream, and couldn't find any difference.

I was warned by Secretary Califano that some congressmen from agricultural states were pretty mad about this, and I soon discovered why. It was that nonfat dry milk solids were a price-supported surplus commodity and that casein and whey protein were byproducts of cheese manufacture largely imported from Europe. What the dairy industry was seeking was for FDA to kill this regulation, so that there could continue to be what amounts to a nontariff trade barrier against the imported product.

Well, I didn't think that was what FDA regulations were for, and so I told the industry that we were going to proceed with it. They then persuaded their friends in Congress to have a large hearing in which they tried to beat me up for a couple of hours. The newspapers then accused us of trying to put foreign chemicals in ice cream, and eventually, with the secretary's encouragement, we decided to wait to fight that battle another day.

RT: Doctor, you've mentioned the economics factors. Initially, did the problem come to light because of economics or another concern about ice cream as a food?

DK: Oh, I think it was strictly economics. The ice cream manufacturers very much wanted to be able to do this, because they could lower their costs a little bit, and consumers would benefit because they could get ice cream a cent or two cheaper a gallon. But the industry obviously didn't like it, because if the draw-down of nonfat dry milk solids stopped and they accumulated more rapidly, somebody was going to notice and challenge the support price.

RT: Commissioner, I believe that saccharin with regard to food safety became a very hot item. Would you like to mention something about that?

DK: Well, saccharin was hot because about two weeks before I came to the agency, a Canadian/American joint study had shown that it was a weak rodent carcinogen. It produced an excess of bladder cancer in rats at high doses, but not unreasonably high in terms of good protocols for animal testing. There was a public outcry because it was the only artificial sweetener available on the market, and for reasons that we've already discussed in this interview, various groups were strongly opposed to it.

What happened in the end was that Congress got so much mail and so much constituent pressure that they simply passed a special law exempting saccharin from the food additive provisions of the law, but requiring that saccharin products contain a warning label--which, as far as I can tell, nobody reads.

In the end, it turned out that although saccharin is undoubtedly a carcinogen in certain rodents, there's every reason to believe that it isn't a carcinogen in humans, because it doesn't form the calculi that it does in the rather peculiar bladder of the male rat. It therefore doesn't lead to abrasions in the wall which then produce hyperplasia and lead to cancer. So that's a case in which the provisions of the food safety laws didn't leave enough room for saying that not every animal carcinogen is a human carcinogen. That's one of the reasons the zero tolerance provision of the Delaney Amendment ought to be modified, in my judgment.

RT: The Delaney Amendment continues to be a controversial concept. As a scientist, would you care to expand a little bit on your views of that provision of the act?

DK: Well, I think zero tolerance is a mistake in that case. I think there ought to be some kind of de minimus standard that leaves room for a demonstration that, for example, something that's a rodent carcinogen may not be a human carcinogen. In other words, it leaves it open to those who wish to add the food additives to the food

supply to demonstrate that it isn't a problem for people. They'll need to do science to do this, and that's fine. The law ought to be an incentive for good science.

RT: In California . . . Let's see. Is it Proposition 65? I'm not sure whether I recall the number correctly.

DK: Yes.

RT: California has something similar to Delaney, I think, and that's been rather troublesome.

DK: Well, not quite. Actually Proposition 65 left the state free to set a standard of acceptable risk, in effect, and it chose a rather bold standard, 10 to the minus 5 lifetime. That's an order of magnitude more risk than the 10 to the minus 6 that FDA chose to implement in the sensitivity of the method regulation.

RT: We've mentioned chemical residues and nitrites and nitrates in poultry which was another area of interest, was it not?

DK: Well, the big one was nitrites in bacon and other meat products where it's used not only as a preservative, but also as a colorant. Bacon wouldn't be red without it. We got a study from a very good laboratory at MIT that suggested that nitrites were carcinogenic, and we announced that there might be a necessity to take some regulatory action against nitrites. There was an outburst from the meat industry, and we were castigated for it. We proposed a rather slow withdrawal that would have permitted the industry to substitute. The Department of Justice wrote us a letter and said we couldn't do that. They'd never heard of a dance called the slow Delaney.

So in the end, nothing was done about nitrites. Ultimately, some questions were raised about the study, and in retrospect, I jumped out a little too fast on nitrites. What we probably should have done is to commission a new evaluation of the study, say, in effect, "We don't think the evidence is strong enough to proceed yet against a substance that's really a major item in the American diet, and we'll see."

Now somebody would likely have taken us to court on that, but then you just see what happens.

RT: Another food that's ubiquitous in the diet is milk. Do you recall a concern about aflatoxin in milk?

DK: A lot of concern about aflatoxin, but only a little bit of it having to do with milk. Aflatoxin does sometimes get through if there is contaminated grain or feed that's being used to feed dairy cattle. But the real problem with aflatoxin occurs in peanuts and corn and crops like that. One of the years I was commissioner, there were relatively high aflatoxin levels in corn, particularly in the southeastern part of the United States. Aflatoxin is a natural contaminant; therefore, it's not a food additive; therefore, it's subject to tolerances that are set by FDA. FDA had set a tolerance for aflatoxin, and it seemed like a reasonable tolerance.

The problem we had was that we kept getting requests to blend. Somebody who has a silo in which the corn is over the tolerance and one that's way under, thinks that if he can blend them, the resulting corn will be well under the tolerance. But if you let them start doing that, then everything's going to be right at the tolerance. So we said, "No." That seemed very unreasonable to some people, so we had some strong arguments about blending--but we never permitted it.

RT: Blending or laundering could certainly have been expanded to other foods as well and set a marked departure from tradition. Now, with regard to interagency

cooperation, you took an initiative with the IRLGS. I think that was the Interagency Regulatory Liaison Group. Would you like to cover that a bit, please?

DK: It's just IRLG, and, yes . . . Doug Costle, who was the administrator of the Environmental Protection Agency, really took the lead in getting together the people who did health and safety regulation. Initially, John Byington and then Susan King at the Consumer Product Safety Commission, Doug, myself, Eula Bingham, who was assistant secretary for Occupational Safety and Health in the Department of Labor, and then later on Carol Tucker Forman, who was the assistant secretary of Agriculture for Food and Consumer Services.

RT: And that group met periodically for what reason? What was the objective?

DK: We wanted regional collaboration so that there was better communication about actions that would affect the agencies. For example, EPA and FDA are linked together in terms of pesticide regulation issues and so forth. We wanted closer regional cooperation. We also wanted cooperation in the development of regulations. Doug and I insisted that the good laboratory practices regulations by EPA and FDA be done together and that there be a single regulation on good laboratory practice. That was hell to get. The people in FDA wanted it their way; the people in EPA wanted it their way. You'd shut them up in a room, and soon you'd find them in two rooms. Costle and I finally had to yell at everybody until they got it done.

RT: Was there a person from FDA as chair of the group?

DK: The chairmanship, a functional chairmanship, rotated.

RT: Was there any interest in developing a network of intelligence violations that one agency might find and call to its cooperating . . .

DK: Well, where it was appropriate, but it wasn't primarily designed for that purpose.

RT: Do you think that the effort really came to fruition in terms of its early expectations?

DK: I think it was a big success. I don't think that we would have gotten those agencies together, for example, to encourage the beginnings of the national toxicology program; you wouldn't have a single set of good laboratory practice regulations; and I think we established a tradition of regional cooperation that survived our administration. However, the IRLG itself did not survive, and I think that's really unfortunate. I wish that the EPA and FDA had kept that going. I think probably it was a victim of Ann Gorscheth in that very unfortunate period when EPA essentially had a mission to self-destruct.

RT: It certainly was a rather pioneering effort, and just recently, Dr. Kennedy, there was some exploration by Commissioner Kessler's staff about this, possibly with the idea of reinventing something like that now. Now I might ask you also something about the device area. IUDs (intrauterine devices) were device that you had some interest in, as I recall, in terms of patient information about them. Is that correct?

DK: Yes. There the challenge as I recall was to encourage the manufacturers to include patient information. I don't have a very clear recollection of how that all turned out though.

RT: As I recall, there was some interest in either the physician discussing with patients or providing a brochure of some sort so that they would be fully apprised of what they should know about the device's use.

Were there any other devices? You mentioned earlier, Doctor, that about the time you came in, only the basics of implementation had occurred with regard to the device amendments. During your time with the agency, were specific initiatives taken to further that implementation?

DK: Well, the Medical Devices Bureau was growing. They were taking on new personnel. They had to because they had to go classify that whole universe. So classification was the first big issue; then, once they were classified, we were dealing with pre-market approval--either IDEs, individual device exemptions, or 510 (k)s. So there was a monumental workload, and the Devices Bureau kept taking on people to meet it. It was a very difficult challenge, because it's a much more heterogeneous universe than drugs. You've got all kinds of manufacturers, big and small, some of them very innovative and out on the fringe, and some of them large companies. Some of them make band-aids and some of them make pacemakers. I mean, it's a huge range of things. So . . .

RT: This was an industry that had not experienced regulation by the Food and Drug Administration, so there was a lot of pioneering work to be done with that group.

Do you recall any particular experience with regard to the press or the media? Were they kind or not kind to the agency, as you recall, during this period?

DK: Well, it depends on who they are. The person that everybody in the agency feared when I came on board was a reporter for the *Washington Post* named Morton Mintz. Mintz had been partly shifted to cover the Supreme Court but still had an

interest in FDA. It was believed in the agency--and I don't know whether this is true--that Morton had had a relative who was quite close to him who had had some unfortunate iatrogenic illness, and that he was really a hawk on unsafe drugs. In any event, he was pretty hard-charging, and he got after the agency. I actually found him pretty fair-minded once you settled down and had a long talk with him, and I thought our coverage from Mintz wasn't too bad.

Victor Cohen also covered us at the *Post*. The . . . And Christine Russell for the *Star*, who later went to the *Post* after the *Star* folded. But Christine Russell was a very capable science and health writer, and Morton Mintz and Victor Cohen were good as well.

The *New York Times* had a singularly lazy reporter named Richard Lyons, who I think was the least competent of the major journalists who covered FDA on a regular basis. He just didn't seem to get it.

RT: As a scientist, science-based administrator, did you feel the need to advance, or did you advance science as a basic criterion for regulator actions?

DK: Well, I think so. I mean, we certainly tried to make good strong scientific appointments and to promote good scientists where we could. I went to MIT to recruit Sandy Miller when Howie Roberts left the Bureau of Foods, and I think he reached out to others. I thought that the Bureau of Drugs was pretty strong scientifically at the top levels, and . . .

RT: Who was the director?

DK: Dick Crout was the director, and there was a very smart woman named Marion Finkel in charge of the drug approval process, and, you know, several very

good kind of division directors in the bureau. Bob Temple, an especially talented guy. Still with FDA, I think.

RT: Yes, he is, I think.

DK: And Ron Kartzinol. There were some . . . I thought there was some very strong talent there. On the other hand, I thought the run-of-the-mill medical review officers were more uneven than I would have hoped, and I was a little bit appalled at how difficult it was to get rid of the ones that were bad, that Kennedy had "projected." After a Kennedy inquiry, a special committee had been appointed by the secretary of HEW under the chairmanship of Norm Dorsan, professor of law at New York University. There had also been a special counsel who had investigated some reassignments and firings that had been done by a previous bureau director and Dick Crout.

The findings of the special counsel were such that I had no choice but to reinstate a man called John Nestor--later famous for driving fifty-five miles an hour in the left lane of the Beltway, but then famous for driving fifty-five miles an hour in the left lane of the new drug approval process. There was no question that Nestor had his own agenda and his own set of beliefs about drug approval which were, in effect, that none should be approved. At the time I had to reinstate him, I called him and told him that I thought that he had not been properly treated at FDA--but also that from everything I read, I really didn't like the way he went about doing what he was doing, and that I hoped that he would change. Well, I don't think it did the slightest bit of good.

RT: Probably not. Drug lag, of course, was one of the areas where a hearing or two had been held, and I think you provided a good basis for why that was probably scheduled.

DK: Yes. I thought . . . I mean . . . No matter how fast it is in the new drug approval process, unless it is terribly lax, it will always be the case that there are some drugs approved in the United Kingdom, or Germany, or France that are unavailable in the United States because FDA hasn't approved them yet. Some doctor or doctors will be deeply convinced that they should be available here, and they will holler like nobody's business that their patients are being deprived. It is simply a fact that every country has a drug lag.

I thought that the so-called studies of the FDA "drug lag"--particularly by the Rochester Group--were very shallow. It was also plain that the Rochester Group was heavily supported by the pharmaceutical industry and might be tempted to say what they thought their sponsors wanted to hear. So I had some debates with them in JAMA (*Journal of the American Medical Association*) and other places in which I tried to say, "Yes, there's a drug lag, all right, and we *are* a little slower; but we're not a lot slower, and who's to say what the point of optimum social utility is?" The argument went back and forth, and it got a little bit personal, but I thought it was an argument that we should have.

RT: I think we've covered a rather broad array of the activities. What would you assess as perhaps your principal contributions to the agency as its commissioner?

DK: Well, I have to tell you that we certainly didn't change the world. But I think agency morale and the pride that people in the agency took in their work, was higher when I left than it had been when I got there. That may be the most important contribution that a political appointee can make in a government agency over the period of time he has. The administrative organization was pretty good when I got there. I think maybe it was a little better when I left. Who knows about that? But the agency took some strong positions; it got a lot of the key issues in regulatory science on the table; and we did a little better job of educating the American people

about what's at stake in those differences of opinion. I tried to be very active and very public.

David Kessler has been even more effective in those regards. It is necessary for a commissioner to get out there and make sure that people understand what this business is all about and why we're doing it.

RT: Certainly, to the Congress, as well as to the public at large, the commissioner is a real focal point for whatever agency image is presented.

DK: A focal point for resentment on the part of people who feel that regulation is hampering innovation. Every once in a while somebody would ask me, accusingly, "Do you think that the new drug approval process retards the rate of innovation in the pharmaceutical sector?" The answer to that is, "Yes. What the hell do you *think* it's for?" The problem is that sometimes innovation moves too fast, and that inadequately tested products get loose and do some damage. What we should do is to slow things down just enough that careful evaluation can be done so that new products are getting to market and the rate of innovation is good, but its costs don't exceed the benefits. The trouble is the costs and benefits are very difficult to evaluate. You're always debating where the social optimum is in that process. But to say that regulation doesn't retard innovation is ridiculous, because that's what it's supposed to do.

RT: Advisory committees, of course, have been impaneled, I suppose, by each commissioner. Did you derive any particular advantage through that system?

DK: Yes. I thought the advisory committees were very helpful. For one thing, they really do mobilize some very strong academic experts into the process, and they also give the agency, the bureau, and the commissioner some useful external cover

for actions that might otherwise not go down very well. But if a clear outside group with no conflict of interest is saying, "Yes, we think this is good," and it's obvious that they're bringing to bear some seasoned, respected academic judgments, then people are apt to say, "Well, OK. That makes a little more sense."

RT: Do you have any particular thoughts that you'd care to share, Dr. Kennedy, regarding kind of where the agency has gone since you have returned to academia or where you might feel it needs to go in the future? That's a very open question, I know.

DK: Well, what I hope mainly is that it can survive this little spasm of regulatory reform and move forward to continue to . . .

(Interruption)

RT: We're ready now.

DK: I would hope that FDA can survive the current regulatory reform spasm, which I think will produce some modifications in its statute--and perhaps even for the better. The original appetite in 1995 to get rid of the FDA or to substantially weaken its capacity to regulate food and drugs and devices was wrong; however, I think the Congress soon discovered that people really want consumer protection in these areas.

I would hope that the Delaney clause could be softened.* We don't need a zero tolerance provision. We need to be able to use scientific good sense, and we need a comprehensive risk standard. Once we've got that, I think things will be a lot better.

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* Note: This was done at the end of the 104th Congress.

My sense is that most of FDA's problems in the past--ten years, say--have resulted from the congressional appetite for giving FDA more mandate and no more money. You don't get something for nothing in this world. Although much was expected of user fees, my impression from a distance is that user fees haven't, and aren't going to, make up for what the agency doesn't get by appropriation. So obviously, one of the things I'd like to see, along with a clarification of FDA's statutory mandate--is an appropriation program that makes it possible for it to carry out that mandate.

The proposals in the Kasselbaum bill to tighten the regulatory deadlines in 1996 were meaningless proposals. If FDA doesn't have the person power and the capacity to meet the current statutory deadlines, there's no way that increasing the height of the hammer is going to help them meet those deadlines now. So what's needed is a certain realism in pursuing the path of reform.

RT: Well, those are good thoughts. Are you active, Doctor, in any kind of an advisory or counseling capacity to either members of the Congress or members of the administration where you are now?

DK: Well, the assistant secretary for health, Phil Lee, is an old friend, and he's asked several of us to look at some of the congressional proposals and to give him our views about them. Every once in a while I get a call from Ted Kennedy's staff about a provision here or there, but I'm not a regular advice-giver.

RT: Well, anyway, they're calling on you, and that's appropriate.

Now, you mentioned earlier that when you left Stanford for FDA in 1977, you kind of had a planned absence. Was that primarily, the conclusion of that time period, the factor that brought you back to Stanford, or were there other considerations?

DK: The fact is that the provostship at Stanford became vacant, and the president asked me to come back and do it. I knew that wasn't going to happen again. By that time, I had enjoyed administration enough at FDA so that I knew that I wanted to do some academic administration when I got back. So I said, "Yes."

RT: *Well, certainly that wasn't . . .*

DK: I was actually a little sad to leave when I did. I would have liked to have gone through the remainder of the Carter term, of course. There was no way in the world that Reagan would have kept me on. But it would have been nice to finish out Carter's term.

It would have been a little awkward, however; it was only about a month after I left that Carter fired Califano and replaced him with Patricia Harris. I would have had to then get used to a new secretary and so forth. I might have been fine; might not have been. You never know. But although he was sometimes a trying taskmaster, I had a lot of respect for Califano and a pretty good personal relationship with him. Had I turned Stanford down and said, "I want to stay another year," and had Califano then left, it might have made me question my own wisdom, but I didn't see the handwriting on the wall at all.

RT: Well, it worked out, I guess, best for you . . .

DK: It worked out fine for me, yes.

RT: Is there anything in summation that you care to put on the record, Doctor?

DK: I don't think so. I concluded my term of service with really enormous respect for FDA people, and I feel good about the people that I appointed and promoted. Tom Grumbly, whom I brought to the agency at the age of twenty-eight, is now the

undersecretary of energy. I think that others have had really good careers, and I think the agency is in good shape. I wish the American people would recognize what a treasure they really have.

RT: Currently the agency's under some criticism for undertaking regulation of tobacco or tobacco products. Is that something that you have a thought about?

DK: It's interesting. I used to get petitions from John Bansahoff, but it never seriously occurred to me that we could do anything about tobacco, because it was so plain that Congress had left it out of our hands. Now, fifteen years later--seventeen, eighteen years later--there's an interesting opportunity. In the first place, there's an enhanced national appreciation that children are being persuaded to smoke. And second, there are new revelations about how companies regulate the nicotine content of cigarettes. So my guess is that this effort, whatever happens to it, will raise everyone's consciousness of the hazards and result in substantially greater regulation of sales to children. My guess is that the idea of regulating cigarettes on the basis that they're medical devices may not stand a court test--but my belief is that the matter may be settled on the courthouse steps with substantial concessions by the industry, and that's what I hope happens.

RT: Well, Doctor Kennedy, we certainly appreciate your participating in the FDA Oral History Program, and thank you very much.

DK: Thank you, Bob. It's been a pleasure.