Oral History Interview with
David A. Kessler, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
November 1990 – February 1997

FDA Oral History Program
Final Edited Transcript
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Oral History Abstract

David A. Kessler, M.D. served as Commissioner of Food and Drugs from November 8, 1990 to February 28, 1997. In his oral history, he recounts how he led the agency's response to the HIV/AIDS crisis; the development of the accelerated approval program; the implementation of the Nutritional Labeling and Education Act, including the design of the Nutrition Facts Label; and efforts to regain public trust after the generic drugs scandal. He also discusses the Agency's efforts to regulate tobacco in the 1990's, the establishment of the Office of Women's Health, the Office of Criminal Investigations and the Office of Special Populations.

Keywords

Food labeling; tobacco; women's health; nutrition facts label; HIV/AIDS

Citation Instructions

This interview should be cited as follows:

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Interviewer Biography

Catherine Copp, J.D. is former Associate Counsel for Foods and Policy Advisor in FDA's Center for Food Safety and Applied Nutrition. Prior to her work in CFSAN, Catherine served in FDA's Office of General Counsel for over fifteen years. She retired after thirty years at FDA, and joined the FDA History Office as an oral historian. She earned her law degree from the University of Michigan.

Suzanne Junod, Ph.D. is an historian in the FDA History Office at the U.S. Food and Drug Administration. Soon after beginning her career at FDA in 1984, Suzanne helped to organize the FDA History Office. She is a subject matter expert in FDA history and her scholarly writings have been published in *the Food, Drug, and Cosmetic Law Journal*, the *Journal of Federal History*, and the *Journal of the History of Medicine and Allied Sciences*, as well as edited compilations. She earned her Ph.D. at Emory University in Atlanta, where she studied under James Harvey Young.

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

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Interview Transcript

SJ: Today is November 24, 2015, and we are here with Catherine Copp and David Kessler to talk about his contributions to the history of the FDA. This is part of our continuing series of FDA oral history interviews. First of all, thank you so much for agreeing to sit down with us.

DK: Thank you for doing this. It's been how many years since I walked out of the Parklawn Building, as it was then called?

CC: Almost nineteen, but who's counting? Have you visited White Oak yet?

DK: I don't think so. I may have been there once.

SJ: Well, hopefully you'll get out to visit sometime. You're on the wall in several locations and some artifacts from your tenure are there as well.

DK: Remember, I took down all the portraits of the FDA Commissioners in the Commissioner's Conference Room.

SJ: Oh well, they're back up, but were relocated near the White Oak Great Room.

DK: There was something about how they were looking down at every meeting and that was somewhat intimidating.

SJ: Well, at one time, I was tasked with taking down all the pictures of the deputy commissioners that I had once assembled for a previous deputy.

DK: They deserve to be there.

CC: The deputy commissioners?

DK: Absolutely. I had great deputy commissioners.

SJ: We normally start these interviews with some background information, but because you have written about that elsewhere, I want to begin with your work with the Edwards Committee. As far as I know, that's when you became known to the people in FDA and the movers and shakers that are responsible for soliciting and convincing people to take the Commissioner's job. But, you know, obviously we—

DK: I'm sorry. Soliciting and—

SJ: Getting to know people who were candidates for Commissioner. As I understand it, this brought you, with your dual legal and medical backgrounds, to the attention of the people working on the Edwards Committee. At the time, that background was very unusual. What do you remember about that period and what do you remember about the Committee and your contributions to it?

DK: I actually don't think the Edwards Committee was key—I think it may have been somewhat more public but I think I certainly was known on the Hill. You may recall that I was —I was working for Hatch during my medical residency. I got paid $100 a month when actually employed. That barely covered my gasoline expenses, I think, to the Hill. But that was my real introduction to the FDA. "Hill staff" is too high a term to use for me— I was the most junior of the junior people on the Hill. So I was known to the Committee that had jurisdiction—the House Committee that had the jurisdiction. And that was probably more key to my becoming Commissioner than certainly the Edwards Committee. The Edwards Committee was a public committee, but I think it was my working with Senators Orrin Hatch and Ted Kennedy and their staffs.

I had gone to see if I could work with Senator Kennedy. Larry Horowitz – we were good friends—Senator Kennedy's AA [Administrative Assistant] and later his Chief of Staff. There was no room on the staff. I just wanted to volunteer. My resume was sitting there, then the Senate changed hands—the Republicans became the majority—and Senator Hatch became chair. They saw my resume and I got a phone call "Can you come down and help?"

There was always a history on Labor and Human Resources, there was always a person, usually a [Partially inaudible: DAA [Deputy Administrative Assistant?]], who would go between Democratic staff or Republican staff and would be sort of a neutral broker. Because when you focus on Republican staff and Democratic staff, they would get their backs up in the room. There is a history of Robert Wood Johnson fellows working on the committee. I wasn't a Robert Wood Johnson fellow, but there was sort of a neutral person on the Hill—really, to lean more than anything else. And so I became very friendly with both Democratic staff and

Republican staff. One day the Committee staff director for Senator Hatch came back and said, "Who knows something about FDA?" Being the sort of eager volunteer I was, I raised my hand and there were four of us. I said, "Well, I wrote a large article." And at that point, he handed me draft legislation and he said, "You're the Committee's expert on FDA for right now."

And I think that that was as much the defining moment in my career—that may have been a more quiet introduction to FDA than being known to the parties that had something to say about who got nominated. So I was, in essence, "favorite son." And I was "favorite son" by both Hatch and Kennedy and that was—and they were close. They were back and forth on issues. They didn't necessarily agree on everything but they were personally close. So I was known to them – I was a known quantity.

The real issue was when I was interviewed by the Secretary's Chief of Staff. This in the book. It was Michael Calhoun who was Chief of Staff of HHS for Louis Sullivan. He came in and he was very blunt. He said, "Are you going to be loyal to Hatch or are you going to be loyal to the Secretary?" That was the concern. Understand there was a Republican President and this was a Republican Senate Committee Chairman, and they were concerned about would I be too loyal to Hatch.

So by the time I was named to the Edwards Committee, I was already known. My name was probably out there. The Edwards Committee membership was just, I think—that was a piece of it but it was sort of the end of years and years of working with the Committee that has jurisdiction and I was "favorite son." That is why I ended up being confirmed, I think, in seven days without a hearing. But clearly, when I was put on the Edwards Committee, there was already serious, at least quiet discussion, of whether I would become the FDA Commissioner. That's the way I remember it.

The Edwards Committee was put together by, I believe, the Department, not the Hill, in the wake of the generic drug scandal. And I certainly got to meet—to know— Charlie Edwards well. Larry Horowitz was on the Committee, and a number of others. I think I chaired a subcommittee if I remember. It issued a report. I remember there was quiet talk about my being on that committee, whether that was sort of the easing into being nominated, as far as I remember.

SJ: What were your impressions of Charlie Edwards?

DK: I admired Charlie Edwards very much. Regrettably, at one point several years later, Charlie became paid by Phillip Morris and basically ended up attacking us on tobacco, hanging his head. That hurt a little because I had a lot of respect for him.

SJ: You talked about "a confirmation process" before it was actually what we know today as "the confirmation process." So you went around and—but you went ahead—you knew most of the people on the gathering, but did you go ahead and make yourself known to other people before you took office?

DK: I remember having been on the Hill and knowing how things worked and knowing what I was supposed to do. I think I said to the Department after I got named, "What's the strategy to deal with the Hill? I'm going to go see these folks." and the Department said, "You're going to do nothing." They wanted to be fully in control of that process. And you basically respect that

but you still have to do what [you have to do]—you have your friends talk to their friends. It's not that you can sit back and do nothing.

I certainly made the courtesy calls. I remember several of them very well. I remember my visit with Senator Gore who I then became very friendly with and very close with over the years. I became very close with the family. He probably won't admit to anyone else he carried the FDA regs into the President on tobacco years later. I remember with my conversation with Congressman Waxman, so I remember some of the calls. Abortion was a very big political issue then as it is now and certain members --- neither of them—but Metzenbaum on the left and one member, a Republican—was trying to push me to commit to what I would do on RU-486. I sort of had to just—I had none of that and just didn't commit what I would do because that would be improper.

In general, the visits were uneventful. I was "favorite son." I remember I got a phone call, it was the original phone call from White House Personnel that came in in the morning. It said, "The President wants to nominate you." Then that afternoon or soon thereafter, there was another phone call from White House Personnel. I thought the phone call would be "Never mind, they changed their mind" or something like that. I was in the Bronx and the phone call was, "And we want to get you confirmed before the session is out and there are only seven days left." And I had not even started my full field FBI background check. And so they did the full field very quickly, the FBI background check, and Senator Kennedy, I remember I was not there obviously. He called. Without a hearing—there was no hearing.

Senator Gore wanted to put a hold on my nomination. Actually one of the people who ended up working at FDA was staffing him and he was the one responsible for trying to put the hold on my nomination. Senator Kennedy committed to Senator Gore that they would have a

hearing that Senator Gore could come to even though Gore wasn't on Labor and Human Resources, but that he could come and ask questions but that would be after the fact. Senator Kennedy then held a Committee vote off the Senate floor literally the night as they were going out. Actually, that's not true—it was several days before they were going out. Metzenbaum, you know, at that point joked, "I would vote for Kessler but he worked for you, Orrin." It was all very friendly and jovial and very good natured and it was unanimous there. Then I remember getting the phone call somewhat after midnight that it was unanimous consent from the floor.

SJ: So you reported the next day or you gave it a few days?

DK: So understand I'm living in Westchester. I'm running a hospital. And I said I would start—I mean, literally this all happened very quickly. I had no place to live. Again, during the conversation with the Chief of Staff of the Department, I said I would start in several weeks. "No, you are an Article II officer under the Constitution and you are—because you are confirmed." I said, "Well, I'm not sworn in yet." "It doesn't matter." So he made this Constitutional argument that to this day I'm not sure is correct. But I didn't challenge him. So we worked out a deal, an arrangement, because I really wanted to get some time with the Agency. Jim Benson, if I'm correct, was Deputy Commissioner at the time.

CC: He was acting Commissioner.

DK: He was acting but I think he also had the position of Deputy.

CC: Yes, yes. He was the Deputy Commissioner but he had been appointed Acting.

DK: And I asked Jim if he would stay even though I was confirmed. Again, I still hadn't had my hearing but I had the votes. It's much better that way when you have the votes and then you have your hearing. My hearing was going to come after I came. I think it was to be in January. I asked Jim if he would stay as Acting. I had a very small office, I think, several floors down from the Commissioner's office and I just wanted to meet people. So I didn't walk into the Commissioner's office for several weeks but I was there in the Parklawn Building just getting to know people.

CC: Do you remember the first time we met?

DK: This is Ms. Copp asking a question.

CC: The record will reflect that. You don't remember?

DK: There are people that I met in that little office.

CC: We were working on the WTO talks. You, Jim, and I were in the backseat of his/your car because we been called to go downtown to meet with Michael Calhoun about this letter we wanted to send to USTR.

DK: That may have been one of the first issues, if I'm correct.

CC: You came into the conference room—we were meeting. Kay [Hamric] came in and said, "They want you to go downtown." We all piled in this car.

DK: They wanted me to go downtown?

CC: Not you—you came. But it was Jim, me, Walter Batts – no, Walter was in England. Linda Horton was there. There were five of us. And I was sitting between—my introduction to you was sitting in the backseat of your car between you and Jim. But we wrote a letter to USTR. We got Connie Horner to sign it.

DK: Who was the Under Secretary.

CC: Right. And you were involved in that. So maybe that was one of your first things. I wanted to ask you about some of the personalities. Do you remember who the Assistant Secretary for Legislation was that might have been telling you that you won't do anything on the Hill?

DK: No. That was Michael Calhoun—much of this was Calhoun. Calhoun was basically in charge of everything.

CC: Right. I'm just curious.

DK: The key players at the time were Boyden Gray who was White House Counsel. Boyden was the one person in the White House who actually cared very much about drug regulation. You never know how people get nominated. I didn't have any relationship with the President obviously at that time. I mean, I had taught food and drug law. I had written on it. As you said, I was on the Edwards Committee but I was staff. I certainly didn't know White House staff. Anyone on the White House staff really can weigh in on almost any nomination, and certainly Boyden, who was chief counsel to the President, could. And I had written these law review articles and he had read these law review articles and apparently he liked those law review articles or they passed muster. So the lesson is be careful what you write in law school because you never know who is going to read it.

SJ: Generics was one issue that I thought might have been settling down when you arrived. Did you sense it was time to learn from that and move on from that point, it had been hashed out, the Edwards Committee had certainly reported on it, and of course, Jim Benson was there when you came. What was your sense of legacy when you came into office during aftermath of the generic drug crisis?

DK: So generic drugs were still, you know, arrests had being made. Jim Benson had been Acting Commissioner for a long time.

CC: At least a year.

DK: It was a considerable period of time. When I was interviewed by Secretary Sullivan, because there was one other person I think in the running for FDA Commissioner, Kim Kaiser, and they were interviewing both of us. And the Secretary asked me, "What are you going to do when you're Commissioner?" I remember looking at Secretary Sullivan and simply saying, "I am going to enforce the law." He nodded and he had no idea what that meant.

At that time, certainly on the Hill, oversight was very intense and remained very intense for the Agency by John Dingell and Dingell's staff. I mean, they were vicious with the Agency. I don't think the reason I became Commissioner was because of the Edwards Committee. The reason I became Commissioner was generic drugs. The Administration was going up to the Hill almost weekly—if not more often—to defend themselves on generic drugs. At a certain point, the Administration, the White House, just simply said, "We need someone to come in and just fix this. Get this done. Get this off. Let's move on. We need someone who can fix it." And I think I simply looked at Sullivan and said I was going to enforce the law.

I have enormous respect for John Dingell and I love John Dingell. My last day in office, there were several people I went to see and one of them was John Dingell. I had enormous respect but Dingell did not believe the Agency was strong enough on enforcement, that it had the ability to take on tough – hard—enforcement questions. The strategy – this is a little cavalier and I don't mean it at all disrespectfully. If anything, I mean a great deal of admiration—I had to "out-Dingell" Dingell. I didn't quite know it at the time but the only way that I was going to build confidence in John Dingell was to show that the Agency was up to the task. So that was key. Once he saw that we were up to the task, he would let us alone.

SJ: Having been in ORA during that period, I think the entire organization was ready to have a nervous breakdown. The requests were simply overwhelming.

DK: That's exactly correct, and if Dingell perceived any weakness in the Commissioner or the Commissioner wasn't serious or the Commissioner wasn't going to do his job, he would have continued to decimate the Agency. I mean, his staff was very, very, very hard to deal with for the Agency. It was an unrelenting kind of pressure.

CC: There was one particular investigator—

DK: David Nelson.

CC: Yes. I'm sure you will never forget his name.

DK: Right. One of the first people I hired—there was always a tradition of the Commissioner going back to Don Kennedy—the Commissioner always hired, maybe not the best out of General Counsel, with due respect to the people around the table. Right? But they hired among the best out of General Counsel to bring up to the Commissioner's office. That was a tradition. At least Don did it. I think it was Stuart Pape.

CC: And Mike Taylor with Jere Goyan, Jess Stribling with Dr. Hayes.

DK: So I knew that tradition. A very close friend of mine from my prior job working with the Robert Wood Johnson Foundation was Bruce Vladeck. Every Thanksgiving, we would go to Bruce's mother's house. She was one of the great employment law pioneers, Judy Vladeck. And this is, you know, Bruce Vladeck who ended up being at HCFA [Health Care Financing Administration], David Vladeck, Consumer Protection Division at the FTC. At that apartment, I would meet Mary Pendergast, who was married to David Vladeck, and who was in General Counsel. And she was among the best. She was also very tough and she knew David Nelson and I think I hired her almost from day one.

SJ: One of the other things that you inherited was the AIDS [Acquired Immune Deficiency Syndrome] epidemic. I think that was certainly something that recommended you to the position. My most vivid memory of Dr. Young when AIDS moved to the forefront of his tenure, was that they started their research in New York, looking to their efforts as a model for how to educate gay men. I discussed what I knew of other educational efforts, based on Shilt's book *And the Band Played On* and they began to turn some attention to San Francisco as well. FDA was struggling to communicate in the area of AIDS. Soon, however, Dr. Young left and went to the Department for a while where he didn't have much influence on AIDS policy. Then the generics crisis consumed Jim Benson. How did you perceive the AIDS crisis when you arrived?

DK: Probably number one on my list was the AIDS epidemic. You have to understand I'm coming from a hospital in the Bronx. I dealt firsthand with one of the largest pediatric HIV clinics. And while it was not primarily gay men in the Bronx, it was certainly an epidemic. We took care of Ryker's Island, the Prison Health Service. I remember being in the Bronx when my

colleague—when one of my colleagues in 1984 said to me, "I'm seeing fever and lymph nodes. What is this?" So we were firsthand. We were very hands on in the Bronx. If I came with an agenda, there were probably two things. One was HIV [Human Immunodeficiency Virus] and the second was food labeling because the NLEA was very front and center on the Hill. And those were probably the two agenda things that I knew I would have to address.

CC: Could I interrupt you please? Could you, just for the record, tell me what you mean by you "were in the Bronx?" and what your position was?

DK: I was Medical Director of a hospital, the Albert Einstein College of Medicine. I ran, in essence, the medical operation. And I was also an emergency room physician at Bronx Municipal Hospital. So we were very much confronting this epidemic. I was also teaching at Columbia Law School. That was part time and my day job was at the hospital.

CC: Is that Montefiore?

DK: So I was originally in Montefiore. Einstein Hospital is run by Montefiore so that hospital is part of the Montefiore Medical Center. I mean, Einstein Hospital, Montefiore Medical Center, you can figure it's the same thing but the hospital is called a hospital, the Albert Einstein College of Medicine, but it was run by Montefiore. Montefiore's actual hospital was in the West Bronx and I started off there and then moved to the East Bronx.

SJ: Within a very short period of time you went from being a practicing physician seeing AIDS patients, to overseeing the Agency charged with approving drugs to treat the disease? What were your impressions and what did you see that you knew needed immediate attention, besides the blood issue, I presume?

DK: Well, there was only one drug available at the time that I came to the FDA. It was AZT. I knew Ellen Cooper. I think I had met her in the discussions of the Agency AIDS effort—I am not exactly sure where. She was running the Anti-Viral Division at CDER. I had a lot of respect for her. But there was only one drug on the market and it did not work very well. People were still dying. The drug had considerable toxicity. To Frank Young's credit, it had been approved in about 100 days, but that was the only drug and the epidemic was still in full force. And there was not a lot of hope with AZT.

SJ: There were a lot quack products as well, were there not?

DK: That didn't bother me. I was not very focused on quack products. I saw that—to put it succinctly—when we came, there was one drug on the market that didn't work very well. And, you know, by the time we left about seven years later, six years plus later, depending on whether you count drugs for opportunistic infections or just anti-virals, there were more than a dozen agents on the market, and some of them—there was evidence certainly by 1996, 1997, that the newer agents—were going to transform this disease. Not that they were going to cure this disease, but they were going to keep this disease, for a number of people, in check so they could live a normal life. That was a very big deal. So the—I think we had a half-dozen drugs also to

treat the opportunistic infections associated with HIV. Accelerated approval was a very big part of this along with PDUFA [Prescription Drug User Fee Act].

But at the end of the day, [inaudible] hit me with the hands-on management. I sat at advisory committees. I met with a new recruit, David Feigal. Carl Peck and I met with Tony Fauci and we developed the model that really allowed DDI an accelerated approval, even though there was no accelerated approval policy in place. I remember going to Bob Temple and saying to Bob, "You need to do conditional approval." He shook his head and said, "No." I said, "Well help me design this conditional approval," which was something that Senator Kennedy had advanced in the late 1970's – the idea that you could do some of the work up front. Bob deserves a lot of the credit. We worked together to develop accelerated approval.

We put those policies in effect in approximately '92, and the great thing was to see that the drug industry followed those policies exactly. We said if you show effect on a surrogate or surrogates, we will then allow you to go to the market. If you ever wondered whether policy makes a difference, we put those policies out. Drug companies followed those policies. We sat there in '96 at advisory committees with the data that came in. They followed those policies and those drugs were approved in some 42 days. And it was an historic period of drug development. The pharmaceutical industry deserves an enormous credit, the NIH deserves an enormous credit, the Anti-viral Division in CDER deserves an enormous credit. It was not easy by any means. I remember a meeting that I convened with the pharmaceutical industry for them to work together – I never went home with a greater headache than that night. But in fact, they did begin to start to do collaborative joint trials and multi-agents and it changed the course of the disease.

CC: I'm in the process of editing the interview with Rachel Behrman Sherman. I think she said that they got clearance—the drug companies got clearance—from the Antitrust Division to have a conversation and to collaborate. I mean, it was highly unusual.

DK: Yeah. I remember, we literally convened the pharmaceutical companies and people just sat there. The industry sat there, "What do you expect us to do?" It was a very difficult set of meetings but it worked. They deserve enormous credit.

SJ: One of the things that was a hallmark of your administration was the organizational framework that you created in the Office of the Commissioner. Prior to your arrival, the Office of the Commissioner at FDA was structured around a group of top officials that met regularly – known as the Policy Board. It included all of the Center directors as well as an assortment of other officials, including associate commissioners for legislation, press and public affairs, and medical affairs, as well as the Chief Counsel's office. As I understood it, they frequently met and essentially sorted out issues and, with the Commissioner's assent, made decisions regarding the Agency's course on most issues. When you came in, you had a different approach and the deputy system you enacted is not one that the Agency was familiar with. It seemed, however, that you knew exactly where you were going to go with it. Many in the Agency weren't sure about how to work within this framework. I would like to get your perspective on the respective choices and roles of the deputies you appointed—Carol Scheman, Mary Jo Veverka, Mike Taylor, and Jane Henney.

DK: And Mike Friedman.

SJ: And Mike Friedman.

DK: And Bill Schultz.

SJ: Ah – okay.

CC: But Bill and Mike [Friedman] filled positions initially occupied by Mike [Taylor] and Jane.

SJ: But they weren't deputies.

DK: Yes—they were deputies. They came second round.

CC: And we should not forget them.

DK: So there was one agenda item and only one agenda item. I was looking for very strong talent. I was looking to recruit strong talent –I didn't believe the Agency could be run by one person, a commissioner. You have to understand even at the time Carl [Peck] left, Jim Benson left, so that there were open director positions in the Center Director positions. And I don't think—you have the historical record but I don't think the Policy Board ever made decisions across Centers. The Director for CDER rarely gets involved in the food decisions.

SJ: They did, however, did they not, gather around a table to present issues, discuss them, and add their individual perspectives?

DK: Sure.

SJ: Regulation, especially within ORA, had to have some consistency.

DK: You have to understand, the Agency at that point was not heavily trusted by the public because of generic drugs. And I didn't think I could do this alone. I needed very strong talent – and I needed talent that probably the likes of which the Agency had not seen.

SJ: But you needed talent, or you chose talent, with very specific things in mind, backgrounds in mind, so that's what I would like to hear more about. Why would you choose one as opposed to somebody else?

DK: If you look at the record, if you look at Mike Taylor and you look at Bill Shultz, if you just look at two deputy commissioners, both Jane Henney and Mike Friedman, both went on to become Commissioner, one interim, one permanent. Bill Schultz has gone on to become General Counsel of the Department. Mike Taylor has dedicated his life to foods. These were enormously talented individuals. The strategy was very simple: The Commissioner can do X. If you have five very talented people, the Agency can do five X. That was my only goal. My goal was to recruit strong talent and then find the appropriate position. I made up positions. I needed people who could handle and move the Agency on a range of issues.

SJ: Are you saying that you were basically recruiting individuals and assigning them to areas that you considered important or were you seeing the areas that were important and choosing strong people already proven in those areas?

DK: I think it was a little of both.

SJ: Okay.

DK: The Agency didn't have a central policy. There was no real policy. There was always the tug between the Commissioner's office and the Chief Counsel's office. – here was a range of talents that I needed. There was operational talent in Jane Henney, who could be hands-on with the Centers. There was policy-forward/legal talent in Mike Taylor. There was managerial talent in Mary Jo Verveka. There was being able to understand how Washington worked and deal with the Hill, deal with the White House, deal with the Department, deal with the public, and that was Carol Scheman. Obviously there were areas that needed to be covered but I was on the lookout for superb talent—I needed to create a team, each of whom could become Commissioner and some did. I mean, any of them were as good as me and they were certainly as senior, and they were certainly as smart, and they were certainly as knowledgeable, and probably represented the intellect […]. I don't think the Agency has since seen a group of individuals. If you take Pendergast, Taylor, Schultz, Henney, Friedman, and Jerry Mande—you can keep on going—these are enormous talents. I think the Agency's always had very strong talent at any given time, but to have that breadth of talent and that team of talent.

There's so much going on at the Agency. Mary Pendergast's job was just to handle crises so that the Agency would not end up—I would not end up—like your kid playing soccer where there's a crisis where the ball is here and everybody runs to the ball. The goal was to have Mary handle the crisis of the day so that not everybody needed to handle the crisis of the day. In some ways, you can call it the Policy Board, we met equally often, probably twice a week. We met every morning on a phone call and it was just the beginning of cell phones at the time. But there was an 8:00 o'clock every morning. And the goal was it didn't matter who handled what. What mattered was whatever was on the agenda, somebody was handling it and handling it well. Bill Schultz could handle anything. Jane Henney could handle anything. Mike Friedman could handle anything. They were—these were all very senior people. That was the goal.

CC: What about, and you mentioned it a little bit, and I hope this doesn't sound parochial, but in this list of your arsenal of talented people, where's the Chief Counsel fit in? I mean, you didn't choose the Chief Counsel.

DK: The Chief Counsel doesn't report to the FDA Commissioner theoretically. I had enormous respect for Margaret Porter. Margaret Porter and I became close friends. Margaret Porter was key.

Margaret once said, I remember, before I came, in a statement that I disagreed a little with her. But she said, "Chief Counsel deals with the law, it doesn't deal with policy." You can't deal with the law without dealing with policy. But that was the way that she saw the world. And we were very heavy into policy: we were into accelerated approval, we were into food labeling, we were into tobacco. You can look at the number of policies. There must have been

some 50 major policies developed during my tenure. When I left a big, they gave me a huge framed thing covered with thumbnails, and each one represented a major policy. There must be 50 to 75 different major policies represented. All of those involved very complicated legal questions, very complicated policy questions. In essence, Margaret Porter was Chief Counsel I; the Deputy Commissioner for Policy, certainly when you look at Bill Schultz or Mike Taylor, they were Chief Counsel II. Or Chief Counsel A and B. We basically created in a Deputy Commissioner for Policy a means to bolster, to strengthen, to support the Chief Counsel's office.

So we had that legal talent and Margaret was signing or Bill was signing. They worked together well – exceptionally well. Margaret could deal with more of the straightforward legal issues defending the Agency in court, et cetera, and Bill or Mike—Mike Taylor and Bill Schultz—both of them could handle the legal policy issues. So we created, in essence, an arm of General Counsel in the Commissioner's office. We had enormous legal talent. Between Mike Taylor and Bill Schultz, I mean, there are not many FDA lawyers who are good at FDA, who you really respect and this is a real national resource. These were national resources. Bill Schultz, Michael Taylor, they all—and they came to the Agency and Margaret would work on certain things and Bill would work on others and Mike would work on others—there was nothing we couldn't handle. If you look at the productivity, there probably wasn't a major area that wasn't affected by these individuals. I mean, even probably to this day—I think this is overstating—but PDUFA, accelerated approval, food labeling, and tobacco, each of those areas required enormous talent and again, sort of we built equal talent in the Commissioner's office.

SJ: Did you think that they worked well together, as a cohort?

DK: Who?

SJ: Well, you said the legal talent worked together but Carol [Scheman] and Mary Jo [Veverka], and perhaps Jane [Henney] each had their own fields of endeavor. Jane was technically in charge, I guess, of the larger portion of the Agency.

DK: Well, the Center directors reported to Jane. So everybody worked well with me. I deliberately picked talent because I wanted to get things done. I didn't define boxes. Were there some elbows here or there between deputies? Sure. I mean, my goal was to get stuff done. I had very little use for that stuff, and I sort of ignored it. But I certainly think whenever you have very strong people in an intense environment where a lot is at stake and people are stressed, you're going to find that there are disagreements. That was certainly true here—these are highly, highly intelligent people who said what was on their minds and weren't afraid. And so there were times when there clearly were some sharp elbows between deputy commissioners, I think if you go ask them, but certainly not with me.

SJ: My first interaction with you was actually when you were looking to make that transition between Administrations. In those days, the Food and Drug Law Institute meeting was in the fall, and you were concerned that maybe this was your last talk to them. You were looking to put together a speech that would both explain what you had done, offer a kind of roadmap for the future, and not incidentally, you know, make a case that you would be certainly amenable, if not ready, to continue and keep the things that you had started moving forward.

DK: I'm not sure you and I see this exactly the same. Certainly I want to agree with my spouse because my spouse would have been only too happy at the time to leave.

CC: Did she have a particular place she wanted to go or did she just want to leave the rat race of Washington?

DK: No. We had done two years. We had done food labeling. We had done HIV. We had done a number of things. She would have been only too happy to leave. There was no desire to stay. We did not campaign at all to stay. There was no desire for the family. They enjoyed—my kids enjoyed—living in Bethesda but my wife made it very clear, she would have been only too happy to leave.

CC: So if you didn't campaign, what happened? How did you end up staying?

DK: I'm not sure I was fully aware of everyone's agenda in this situation. Right? Little did I know, the decision was made but I didn't know the decision was made that I was going to stay. I had no relationship with President Clinton. I do now. I worked closely with him on tobacco and certainly got to know him afterwards. I spent considerable time with him.

But I had no relationship with the Clintons whatsoever when they arrived. What I didn't realize, and it just didn't dawn on me for some reason, the die really was cast. I had known Donna Shalala. We had gotten an honorary degree at Amherst together. I sort of knew her but I was not close with her. In a minute, I will tell you the story of the day she calls. But what I was not aware of, and again, I don't think I've ever asked it point blank, but I think it was the Vice

President. You have to understand we had, by '92, FDA had become—someone joked—the Gore outpost. So Jim O'Hara, Jerry Mande. Mande was the one who put a hold on my nomination.

SJ: Oh, now that's news.

DK: And Jim O'Hara was married to Marla Romash. Gore had come to my confirmation hearings and we were both sort of science nerds. He was not very good at small talk. I wasn't good at small talk. It was always awkward at first but we became, I think, and to this day, I think it's fair to say we became friends, close friends. That was certainly in years subsequent. But certainly by '92, when Gore was Vice President, Gore had confidence that we could turn generics around, that the Agency had done some great things. It was working on HIV. But I have to believe it was Gore who said to the Administration "Keep Kessler," but none of that was said and I don't think anyone knew that.

CC: Did you actually tender a resignation?

DK: Oh, my resignation was pending. It was a little awkward because you have everybody sort of doing their own thing here and I'm not quite sure what's going on. No one is telling me anything. The White House Press Secretary would say, when he was asked, said, "Well, we're going to work with Kessler." That was the answer. He didn't know the answer either is my guess. So it was on a Saturday morning, all I know is a call came in and it was at 7:00. My wife is usually up earlier than I was. She had already read the papers by 7:00 and there was Secretary

Shalala (who had probably just been confirmed) on the phone, and she said to Paulette, "Just whatever David does, don't answer the phone because the *Washington Post* had a story that said Clinton reappoints Kessler and he did not do that for Bernadine Healy at the NIH." That was the story, I believe, of the day. I never asked President Clinton about the story or anyone else the story, but as I hear it and it may not be true, the President actually picked up the paper and said, "Oh, did I do that?" And I think it was, I believe, the Vice President and the Secretary who basically concocted it. That was the moment where it got settled.

You're talking about a period that was in limbo so people are talking. I'm giving a speech. I had no agenda to audition to stay on or not to audition. I was just doing my job, not knowing what the outcome was and actually not caring. I mean, I did nothing. Others under me may have wanted, you know, to keep the door open. Let's see what's going on. But I did not. At that point, I didn't know how it would play out. I mean, it was unusual at that point because I don't think anyone had done that. When was the last Commissioner who served Republican and Democratic Administrations?

SJ: I'm not sure there were any.

DK: Oh, I'm sure certainly there were Commissioners.

SJ: Not in the modern era.

DK: Well right. But going back in the 50's, you certainly had some.

SJ: I will double check but the whole tenor . . . at any rate, I count your administration as a turning point and I credit you (and user fees) with creating what we know of as the modern FDA, even though Dr. Henney was the first commissioner whose approval went through the Senate.

DK: I thought you would have said the modern era started with Charlie Edwards.

SJ: There's an argument to be made for that as well but the criteria would differ.

DK: I mean, it became shorter terms. It became tied to one President—you served the term of the President. Right? Don Kennedy, Goyan, Edwards. That was the way I saw it. Everyone prior to that, I thought, had served—

SJ: True, but to my mind, Edwards' tenure is closely related to the transition from Chief Counsel Billy Goodrich to Chief Counsel Peter Hutt that notably began to shift FDA away from case law into administrative law from strictly legal cases.

DK: Peter Hutt was never Commissioner. Can we put that on the table?

SJ: No, no. But Peter worked for Edwards and a lot of his work came through—

DK: He may have thought he was Commissioner.

SJ: That's another issue! Drafting the Freedom of Information Act policies that Dr. Edwards signed off on, along with preambles to Federal Register notices, and making some important changes in the Office of Chief Counsel – they all mark a very important turning point but also a prelude . . . But between AIDS, generic drugs, and some of the other things that were coming on when you came into office, I consider those issues to mark the modern era of crisis management.

DK: So you're making the case in some ways, and you understand now why I needed the talent that I needed. Not that I fully knew how many issues we would address—I mean we came with no agenda on tobacco whatsoever. Ultimately, there were many issues that I couldn't even dream of. But if you talk about real sophistication in administrative law, all right, not just on the enforcement. The General Counsel was always good on enforcement, but real sophistication on administration policy. The kind that a Bill Schultz or a Michael Taylor—

SJ: Yes. Absolutely. When I came to FDA, the generation before me, from the 70's in particular, were still preoccupied with discussions about whether the Agency's resources should be devoted more towards regulatory work or towards industry education, and those were the two choices people perceived. Do we govern mostly by educating or by enforcement, and Commissioner Schmitt had the famous quote that "of course we're an educational institution, we just put slow learners in jail." And so by the time I'm coming in the '80's, that dichotomy is starting to give way in favor of other options.

DK: I came in when the Agency was still an enforcement agency. At least that's the way I had taught it. That's the way I thought about it. I thought we regulated foods, drugs, cosmetics, and I told Secretary Sullivan that we were going to enforce the law so I thought we were an enforcement agency. What dawned on me, and I can't tell you exactly when, and I would disagree with you just in your terminology, respectfully. It wasn't a question of being regulatory enforcement agency or an educational institution, we were a public health agency. To me, that was the major shift.

SJ: Yes. I had been given to understand that that shift to "protecting and promoting public health" was closely linked to the AIDS epidemic, but when would you date that?

DK: There was a shift in my own thinking, a recognition that we weren't just regulating an industry but we could dramatically affect—and I don't think "dramatically" is too strong a term—and thus, you could have a dramatic effect on public health. That's really what you needed to measure.

SJ: In the short synopsis that we present at the new employee orientation, I say that the AIDS epidemic taught the Agency that slow approvals also had an effect on public health. Is that incorrect?

DK: See, I disagree with you a little.

SJ: Okay, good.

DK: I think this is not a question of delays. The drug lag thing was a debate carried on in the '70's.

SJ: We were past a lot of that?

DK: Well, but we were not. Understand the average drug approval time when I came in—drug review time, sorry—was 30 months. That was a long time for an application to be pending. I think it was a combination of things. I think that if you look at really affecting people's health and having an impact on people's health and what you can do to have an impact on people's health, certainly AIDS was, for an important segment of the population, it was life and death. So yes, no question – the AIDS crisis played a role. I mean I was very respectful and that's why we worked so hard and changed policies. But it became broader than that because food labeling taught us that you can affect public health and nutrition through the food label. Tobacco was the number one cause of death, certainly preventable cause of death at the time—

[Kessler, Tape 2]

SJ: We're resuming with tape 2. During the break I repeated a story that Peter Hutt tells about his experiences with the Policy Board. My knowledge of the major players comes from a giant photo of the group given to Peter when he left FDA by Paul Hile, the Associate Commissioner for Regulatory Affairs. Peter said that he usually achieved his aims by

persuading his colleagues—until someone came up with the idea of trying electronic voting handsets. After that, he says he lost some of his persuasive power.

DK: I can't even speak for how the Agency was run before I arrived, but I don't think anybody had a monopoly on developing policy. Maybe I'm wrong on that. I'm certainly respectful of people who thought that the Commissioner had perhaps more voting power than anybody else. And I think people understood that. But I think it was fair to say that nobody dominated the policy development. No one had that amount of clout. What had that amount of clout were the best ideas. And anyone who had those best ideas could speak up. We tried—I mean, it's always hard to do—to create an environment where people could speak up and share their ideas—no matter where they were in the rank and file. It was the best ideas and the smartest ideas that really governed. If you look at the range of things we did, they came from a whole range of people.

SJ: Yes. This was just an anecdote and you're right that is the way—

DK: One of the very early experiences right off the bat was the Sudafed tampering in the Pacific Northwest. There was a conference call that started at midnight or so on a Saturday night, we are getting to the bottom of this and I insisted on talking to the field. That was a no-no because everything was supposed to be filtered through headquarters, and I said no. This was real-time—a real-time investigation trying to put together the pieces. I wanted to speak to people in the labs. I wanted to speak to the field scientists and the field investigators. The conference call started off and then it kept expanding with more and more people by the following morning.

It was very clear that I was stepping on certain toes because I said, "No, put Seattle lab on the phone. We want to hear from them." That was just not the way things had been done.

CC: I wanted to intervene on two things you just said. I don't know if you remember during the olestra approval discussions, there was a meeting. It was probably January – I remember it got dark early. We were talking about the laxative effect of the product. This shows that not only did you not consider yourself to have a corner on the policy market, but you brought in people, some very smart people—Bruce Burlington and Bob Temple—to a meeting to talk about that effect. These were two physicians who had nothing to do with the product approval, but you respected their intelligence and wanted their insight. I've always remembered that as an example of your willingness to bring in talent. So I'm just affirming what you've said.

DK: I appreciate that. I think you felt—the people who had the best ideas and the best opinions got to speak.

CC: Well, having been in more meetings with you than I can count, I certainly did my share of speaking – and I was simply the staff attorney—and I hope that part of my being permitted to speak was because I had ideas.

DK: Well, that's what I'm talking about and that was very accurate – you know that – that was very much the case. Even though your boss is in the room and your boss's boss was in the room—

CC: And my boss wasn't particularly keen on me speaking up.

DK: Right. But that didn't matter.

CC: And you communicated that by the way you ran the meetings.

DK: The important thing was to get people—whoever understood the issue, whoever moved the issue forward—that was who should have commanded—and it was all about talent. I will admit I was not great at organizational boxes. I created an Office of Special Investigations, an Office of Criminal Investigations. That was to deal with John Dingell. We needed very strong investigative talent in order to be able to "out-Dingell" Dingell in a nice way. We needed very strong investigative talent.

SJ: Were you involved in selecting Terry Vermillion to head the Office of Criminal Investigation in ORA? That turned out to be a very good choice.

DK: I created the Office of Criminal Investigations. I certainly interviewed Terry—I don't think I hired him—I don't know who made the decision on Terry. I'm not sure where I got Vermillion's name from. I don't remember sitting there with Vermillion. There was a little bit of a complexity there because we were hiring a Secret Service person. Terry brought basically a Secret Service kind of mentality. I'm saying this in kind of a complimentary way. Every law enforcement agency has their own talent and their own way of doing things. We needed criminal investigations— I didn't realize how much I needed criminal investigations. Later, we broke the

Diet Pepsi can with syringes because Terry had hired two polygraphers. I didn't even know why I needed polygraphers but he took two of the people, they ran around the country, and quickly, within a day, people confessed on the polygraph that they had put the syringes in themselves. It stopped the national crisis and it was only because of that talent we had. That talent, also Gary Light and Tom Doyle, was critical to tobacco.

CC: Who was the first one? Gary who?

DK: Gary Light. He did the polygraphs on Diet Pepsi and then I asked him and Tom to help on tobacco. We needed to have very strong enforcement measures. That was why we created the Office of Criminal Investigations. It had some complexities. They didn't trust lawyers—they didn't trust central lawyers. They always had a mentality of bringing their cases to the U.S. Attorney and that created some tensions. They also didn't play well with some of our other investigative groups. We created a separate office with a different set of investigative talent, Hill investigators, in Jack Mitchell. Those were Senate investigators, Congressional investigators. They operated in a very different way than OCI. But we ended up needing all of them in order to handle what was thrown at us.

SJ: Well I would say that when you came in, you were viewed as an agent of change and we're talking about different areas of change. The two areas that I think we can probably discuss before we have to take another break are probably DSHEA [Dietary Supplement Health and Education Act] and your enforcement actions regarding heat processed orange juice and spaghetti sauces with "fresh" on the label. I guess start with "fresh" orange juice. Was this your

first enforcement action or just the most publicized? Was it a follow-up to your statement to Dingell and elsewhere that this law would be enforced?

DK: Right.

SJ: The moniker of Elliot Nessler.

DK: Elliott Nessler was simply a line that Jeff Nesbit cooked up with Malcolm Gladwell when Malcolm covered me. That was when Nesbit was head of Public Affairs.

SJ: But it was very influential in the Agency and with the public. No FDA commissioner since Harvey Wiley was dubbed "Old Borax" had been given such a distinctive public identity.

DK: Again, you have certain philosophies and you try to live by those philosophies and have them shape what you do. Food labeling was very much on the agenda. I don't remember exactly the order but I think I was asked at a Congressional hearing about tomato sauce, whether it was fresh. And so there were some goings-on about that entire manufacturing area. But once it became public, they put a disclaimer that said "means fresh taste," which meant that we had to go back and do consumer surveys. Margaret Porter came into my office one day and said, "We've been in discussions with Citrus Hill Orange Juice and we asked them to take the term 'fresh' off the label," and they [Citrus Hill] walked out of the room.' I said to Margaret, "Well, what did you tell them you were going to do?" She said, "We told them we're going to seize the product." She looked at me and said, "Well, what do you want to do?" I said, "Well you told

them you were going to seize the product so go seize the product." She said, "You want me to seize the product?" I said, "That's what you told me you told them you were going to do. Go seize the product."

So I'm the next day, I'm giving a speech to the GMA, Grocery Manufacturers Association, and Jeff Nesbit, who is head of public affairs, is with me. GMA was having some conference—they were playing golf or something. I was wet behind the ears. I was reading from a script. I wasn't a very effective speaker. I had very little experience. But I was reading what was said and you could see them. They don't care. They want to go play their golf. And in the middle of the speech I remember saying today I am having, on behalf of FDA, the U.S. Marshals Service seize X number of gallons of Citrus Hill Orange Juice.

SJ: And you knew it had already happened?

DK: Yes. Because Nesbit who, again, like a lot of people at the Agency, had enormous talent, had a camera in the back of the room and unbeknownst to me, he had it on satellite. So at that point, there were big satellite news broadcasts and the Agency took the feed out of it. It made it on every evening news show that we had seized Citrus Hill orange juice.

SJ: And was this totally a coincidence that you happened to be—I mean, had Margaret brought this to your attention in preparation for this meeting?

DK: No.

SJ: That seems an incredible coincidence.

DK: Well, Nesbit was very facile. Nesbit was working with Malcom Gladwell who was a significant talent. They were close friends. They developed a very significant relationship. Nesbit saw an opportunity. He connected the dots.

There were two things I remember the next day. One was there was a newspaper story, "Kessler Targets P&G." I turned to someone and I said, "P&G? I thought the company was Citrus Hill?" Somebody said, "Don't you know who owns Citrus Hill?" and I didn't—I said just go seize the product. Everything was ascribed that we had selected enforcement to begin with a big company to show that we meant business. I didn't know Citrus Hill was Proctor and Gamble. It was news to me. So people were reading in things that weren't there. The second was a phone call earlier that next morning when it was in the newspaper from Connie Horner. It was the first of several that would come.

CC: She was the Under Secretary of HHS?

DK: She was the Under Secretary. She said, "Would you mind next time you do something like that, to just give us a little bit of a heads up?" And it was what I learned to do. "Thank you very much for the call. I appreciate it. I certainly will try to do better next time," and I hung up. It was clearly not only Connie, it was Connie's bosses. I don't quite know who was pressuring her on what was going on.

SJ: I believe Denise Zavagno had a role in trying to –

CC: She was the staff attorney

SJ: She was the staff attorney working on it and there were some last-minute negotiations as I understand it.

DK: But they walked out.

SJ: I think I was told that they were surprised as anyone that seizure actually went through. Is that what you heard?

DK: That was how Margaret happened to ask me what to do. I told her to go seize the product.

CC: You mentioned Connie Horner, and I know this isn't in the flow, but who were you dealing with? Technically, wasn't Jim Mason the Assistant Secretary for Health and wasn't he your line authority?

DK: Jim Mason was a very decent and wonderful human being and a doc. When you're FDA Commissioner, you have a lot of bosses. Everybody thinks they are your boss. Everybody at the White House thinks they're your boss. Jim Mason worked in the Secretary's office. Anybody above you could get to the phone and sort of make those phone calls. So on the org chart, you are correct. The great Phil Lee, when he came back the second time, said, "There's no reason for

you to report me – you should report to the Secretary directly." He had been around the Administration in the '60's under Johnson, and he didn't need anyone formally reporting to him. He was very senior and very savvy, and he wanted Harold, David, and I – Varmus and Sacher—to report directly to the Secretary.

CC: I'm sorry, Harold Varmus?

DK: He was NIH. And David Satcher.

CC: Oh, David Satcher, who was the Surgeon General. And Phil moved aside and said report directly to the Secretary.

DK: Hundreds of people think that they're your boss when you're the Commissioner.

SJ: Words of wisdom. So talk a little bit about food labeling. It was a huge effort. What I recall of some of this period was certainly your willingness to be assertive and assert jurisdiction over some of this labeling but there was a lot of other labeling that was a cacophony—I think even at one point you described it as that—having to do with definitions of "light," and a host of other terms that lacked precise definition.

DK: So understand that the Nutritional Labeling and Education Act (NLEA) had passed. It created some framework, statutory framework. But it basically said to the Agency, "Go implement this."

CC: And do it by these dates.

DK: Right.

SJ: Now did you bring Jerry Mande in at that point?

DK: Yes.

SJ: Okay. To work on the implementation part of it?

DK: Well, again, I didn't bring Jerry Mande for a specific project—I brought Jerry Mande in because he was very smart and very talented. Jerry decided to take on the graphics of the Nutrition Facts Panel. Jerry basically, sort of, again, learned everything about leading and kerning and font and graphics and how to capture the eye. But there were also the regs. I think that is fair to say that the Agency had never before gotten something as complicated as the proposal out of here and got a final out, too. From beginning to end, we implemented it in about two years. So there was the task of getting it right. And there was the task of coming up with, I think you'll both agree, the iconic Nutrition Facts graphic.

SJ: It's the most recognized graphic in the world.

DK: Is that true?

SJ: It is.

DK: So that almost didn't happen. The jurisdictional products are processed foods under FDA. But we wanted to do program with Ag. Secretary Madigan, at the time, disagreed. We wanted to do a joint [kick-off? program?] between Ag and FDA. That was sort of the discussion, and the Secretary [Louis Sullivan] was very much on board. Madigan was not on board for whatever reason. I don't to this day quite understand why, but he took it to the President.

SJ: Well the simplistic version was obviously that the higher calorie count supports the meat industry since its products tend to be more caloric. But perhaps this is a bit too simplistic?

DK: I think Madigan had, and I want to be respectful here, but I think there was some experience – and again, I don't know this firsthand – but there was some experience with eating disorders. He understood eating disorders and understood if there was too much focus on nutrition, that people could become so focused that it could affect them and their eating habits. Madigan fundamentally didn't think this was wise. I remember I was at getting some award from amfAR—the Foundation for AIDS Research—in New York and this was going to the President. Mike Taylor and I were having private discussions about what we would do if the President didn't support us. My wife was wearing a little button that said "Free the Hostage Rules" because the rules were sitting in the OMB and we had to shake them lose. I remember the discussion with Mike, and also with Louis Sullivan whether the two of us – Mike and I –

whether we would resign if the President didn't support us. I mean, it had gotten to that point. We didn't tell anybody at the time but we had that private discussion of what we would do.

But the reason that we were able to require the Nutrition Facts panel is interesting. If you look at the proposed regs, they did not specify the format. I mean, I don't think the FDA lawyers believed that we even had the ability to require the exact format on the label. Jerry was very much focused on getting design format. There were a number of options we gave the President. We actually gave him the graphic and he actually pointed and said, "I like this one. I'm going to go with this one." When the President sided with us, when he decided between us and Ag, we then went to OMB and said "the President picked that one." And they said, "Okay." We said, "No, no—you don't understand. This has to be exactly the way the President picked it." It had to be in the exact font, in the exact box, and the exact print. At that point, OMB said "If the President picked it, the President picked it." I think it's fair to say we were—I'm not sure my lawyers would have been happy but the President picked it and that's what we said.

SJ: What would the lawyers have been concerned about? Mandating a particular format?

DK: Literally. Exactly. The regs didn't have it initially—but when the President picked it, we mandated it. We actually decided to mandate it.

CC: So it was more a question of whether we had actually proposed it or hinted about it enough that you could put it in the final rule?

DK: Yes. But in the end, we put it in the final rule.

CC: And nobody challenged it.

DK: No one challenged it. I don't know exactly how it happened – maybe Bill Hubbard had something to do with it—but the Nutrition Facts Panel received the President's Design Award from the National Endowment for the Arts. And I didn't quite understand why would we get the Design Award but if you really talk to graphic designers, in terms of how a graphic functions, the question was how do you convey information to people in an excessively small amount of space. And again, very much consistent with the theme of something with which you could affect public health. It could affect people's health. It wasn't just specific people getting a drug—obviously that's critically important, that's life or death—but here you could have an effect on an entire population, certainly those who wanted to read and use it. And you could advance the public health.

SJ: The research showed that people were reading it and still are reading it.

DK: We were fought very hard by the food industry. At that point, there was the Grocery Manufacturers Association and the National Food Processors Association and they were strongly opposed to the food label. They fought it. Today they would tell you that they would never dream of having anything else. But it was viciously fought. Go back and look at the news clips. There was, you know, the FDA was hitting you over the head with a 2x4.

SJ: Well as I understood, it was being fought on two levels. One side felt it was a ridiculous idea and nothing should be done at all. The other side felt it was fighting in the trenches against individual products and individual ways of portraying it. They were antagonistic but they didn't stand a lot of chance of prevailing. Both sides were negotiating specific provisions while, at the same time, opposing the whole thing. Center for Science in the Public Interest, where were they?

DK: We took on fresh and I remember sitting with CFSAN and saying after "fresh" "Okay, what's next? The reaction was—"What do you mean what's next? Enforcement actions don't just happen—what do you mean what's next?" "We've done 'fresh,' what's the next thing you're going to focus on? What was the next thing?"

CC: Who was the head of the Center at that time?

DK: Fred Shank. He was a very good—how do I say this?—Fred did what Mike and I asked him to do. Once we said, "What's next?" it was, "Oh, okay. We have to have something next?" "Yeah. You're trying to clean this up. You did 'fresh.' What claims are you going to do next?" And then we focused on "no cholesterol." I think we sent letters – they may not have been exactly "no cholesterol" – I don't remember exactly what it was. But we sent letters and then the industry, basically after 'fresh,' all we had to do was send a letter. We didn't have to go seize a product.

I remember going to CSPI and giving a speech. I remember the room was packed. We had done "fresh" and we had done "no cholesterol" or one of the more outrageous claims. I

remember giving a speech. I said, "The FDA is concerned about the following claim," and all I had to do was give the speech – I didn't even have to send a letter. We got the label changed. The industry responded. It was that the industry knew we were serious. Those were actions before the NLEA rules. The rules then implemented a number of those actions.

SJ: We did an interview with Peter Greenwald at NIH talking about Benefit cereal and All Bran when NCI created a panel.

DK: That was before my time.

SJ: Oh, that was before your time?

DK: Yes. That was during Dr. Young's time. I remember I taught it in my Columbia Law School class.

SJ: Well, I just find it interesting in retrospect that neither of those premises that the National Cancer Institute used to support their statement on All Bran cereal turned out to be true. Neither a high-fiber nor a low-fat diet was ultimately shown to be linked with cancer prevention. At least, not in a way that could be implemented across the board as a public health measure. There were some territorial issues as well, I think.

DK: At that time in the 80's, I think it's fair to say, FDA didn't know how to deal with those claims. Were they going to allow the claims or not allow those claims? There was no framework to deal with those claims. That's really what NIH did.

SJ: Hadn't FDA's position, or at least part of it, been that you just don't allow them?

DK: Certainly when I got there, that may have been FDA's position but that wasn't what the marketplace showed. The marketplace was full of these claims. Obviously it raises very complex, tricky issues with truthful, non-misleading speech, and First Amendment. You can't ban everything. It puts you in some kind of legal jeopardy as a matter of policy.

CC: The "no cholesterol" letters, were those "no cholesterol" claims on foods that inherently lack cholesterol?

DK: Yes, I think that was probably the second set of letters. I forget what the exact sequence was in the second claims—it's probably in the book. It was sort of like saying [for these products] "No nuclear waste" or "No radioactive material here." You wouldn't expect it to be there. But I forget what the sequence was. There was seizure, letters, speech. I remember that.

SJ: Some of this is overlapping so that's why I'm having trouble moving from one to the other. At the time same time that NLEA activities were underway, FDA was also looking more critically at dietary supplements. Now I want to hear from your own perspective, how you viewed these products. This represents a turning point for me in the Agency's approach to what

an earlier generation would have deemed, and labeled, "quackery." I do not recall during your administration ever hearing or using the word "quackery." What are your recollections on this?

DK: It probably would not be a kind of word that I would use. It's not, for whatever reason, a term I would use, whether it's my legal training. I would again say "false or misleading" or "harmful." "Quackery" is a little more imprecise and has certain pejorative sense but "false or misleading" was the Act. That was my job.

SJ: And that's a huge cultural shift for FDA.

DK: Meaning?

SJ: FDA's historical roots involved identifying and attacking quackery through legal means or scientific ones. Quackery was popularly associated with gullibility, I think. H. L. Mencken said that "quacks serve a useful purpose—they rid the world of people with no sense." Had you heard that H. L. Mencken quote?

DK: They rid the world—

SJ: Of people without good sense.

DK: Why do they rid the world of people without good sense?

SJ: It's a criticism of people who have been taken in by quacks and quackery.

DK: I see.

SJ: The whole concept seems foreign to you . . .

DK: No, I get it. It was certainly a big part of medical history but the fact is–that if you look at the report card of the Agency, if you look at the field, there was an endless number of dietary supplements on the market.

What happened in NLEA was that Hatch and Metzenbaum could not agree on the legal standard for claims for dietary supplements. It was a very technical point. It was part of the NLEA statute. They basically said to the Agency, "You go decide what the standard should be for dietary supplements." Mike [Taylor] and I, as part of the NLEA regs, said we couldn't find a reasoned basis to distinguish foods from dietary supplements. The statute said there needed to be "significant scientific agreement" before you make a claim about a food, and we thought the same standard should apply to supplements. We just couldn't come up with a basis that would make sense—stronger, weaker, level of proof before you say on a food label that this is going to have such and such effect. The same standard, we said, should apply to dietary supplements. We promulgated that in the [NLEA] regulation and that set the industry off. It was one of the largest campaigns to Congress imaginable. I did testify pretty extensively, I remember, in the House. When you testify, [inaudible: you're facing the Committee members with your back to the audience]. The table in front of me, the Congressional table, was filled with hundreds of supplement products. We issued a report, I remember, that showed that the marketplace was

filled with claims for which there was no scientific basis—products making claims for memory, cancer, again, without any scientific basis.

We just got killed – it made tobacco look easy. The votes were not there. The good news was that the industry spent millions of dollars. If you want to do the real oral history, go interview Tony Podesta. He led the campaign. There were billions of dollars at stake. All we were saying – we were very particular – we were saying before you go make a claim, have a scientific basis. On TV, the industry said, "The FDA is going to take away your vitamins." So it's always the big lie but it worked. The Members got more mail on supplements than any other issue. And even the Department basically sold us down the river—didn't back us because there were not the votes on the Hill. We stood up the best we could but the Administration wasn't [partially inaudible: in the same place].

CC: And I'm just trying to remember who was President then. Was that still Bush 41?

DK: No, this is Clinton. They would not stand up on this issue. And I actually think that this was Tony Podesta at work.

SJ: That's a good perspective because people are starting to write about DHSEA and realize exactly what was lost there. A new journalist, Catherine Price, just wrote a book, *Vitamania*, that you'd be interested in reading.

DK: I know. I did an interview on the book with her on Diane Rehm. People have been concerned about this for the last 20 years but you know, the good news is the vast majority of these dietary supplements don't kill anybody. There are some – I'm getting a dirty look here...

CC: No, you're not.

DK: Yes I just did. But the vast majority don't kill people.

CC: I think that's probably true.

DK: Some do. Ephedra and others, there have been deaths. We've lived through a number of those deaths. But in the end, the American people– through their elected representatives—get to set policy. As long as they understand that there is almost massive fraud. Actually, I didn't use the word quackery but there was massive fraud. I think we were very clear about the extent of the fraud, but on the Hill, we just didn't have the votes.

SJ: I remember talking to you about dietary supplements. Afterwards, you sent some staff members down to our office for me to brief them and I tried to—

DK: On the history?

SJ: I tried to explain to them the kind of foe they were coming up against and they listened but I don't think they believed me.

DK: We tried. We did the whole thing. You would think the country would be more sophisticated—the American people—you would think with that history, the Hill and everybody would care again about public health and public safety, but that was not the case. It was sort of the American way: I want what I want when I want it, and if then there is a problem, where was FDA?

SJ: But it's also a different kind of industry than the ones we had become accustomed to regulating. Scientific evidence becomes problematic.

Let's talk a little bit about your use of the media in a way that it had not been used before and in some cases, since then. What was your perspective on media interactions? Was your inventiveness deliberate? You were talking about the fact that you never used email.

DK: There are multiple answers to your question, multiple parts to it. So you can't be good, you can't be out there, unless you have people who are good at being out there and understand that. Both Jeff Nesbit and Jim O'Hara were very talented. They were real professionals. Media relations – public affairs—was not something I had any background in or you and I would do, nor was it purposeful initially. Now that's not obviously all of it. Nesbit and O'Hara – different views—but that's their world, and if you're not out there, you're not doing your job. That was their view. They grew up in public affairs. I had no experience. Before I became Commissioner, I was on TV once when there was a disaster at the hospital, a crisis. I had no experience. In fact, my first interview, a TV broadcast, was just horrendous.

CC: As Commissioner?

DK: As Commissioner. Nesbit sent me down. It was a Charlie Gibson interview and I had just come—it was very early on. I'm in the box. It's a remote camera. There's a red light and I had a panic attack. My hands are waving as if they're not attached to my body – you just see them. I can't get out a full sentence because I'm literally having a panic attack. Charlie Gibson asked a softball question but I interpreted it as basically why is the FDA killing all these people? That just began with the red light. The end of the interview, Gibson just says, "Well good luck, Dr. Kessler." I was not coherent then.

CC: Are you making this up?

DK: No, it's really true.

CC: Are you exaggerating?

DK: No, I'm not exaggerating. It was a horrendous interview. I had to train myself then to do these interviews.

SJ: Didn't they send you to school, some sort of training?

DK: I was not educable and I resisted any media training. I would kick any media training out of my office.

SJ: They tried to?

DK: They tried but I didn't do that. But how did I, when that red light went on, avoid having a panic attack? If I could look at you, I was OK. So I would fly up to New York if I wanted to do the morning show, first simply so I didn't have to look at the camera and I could look at the interviewer and not me. I made them turn the monitors around in the studio so I wasn't distracted and I would just do the interview.

But the question of media and the Agency … You have to understand, where was the Agency before I came on the level of public trust? We had just come off generic drugs. You're not going to win back public trust unless the public trusts the Agency. You're not going to do that if you're going to be withdrawn, reclusive, not explaining what you do. Whether you want to admit it or not, the public face of the Agency is the Commissioner. That's the way it's set up. That there's one person and it's the Commissioner. If the Commissioner does well, people have confidence in the Commissioner, and then people are going to have confidence in the Agency. We had to turn this around. We had to have a sense that we were able to do our job and the people in the public could identify this. That wasn't a verbal strategy but when I got off that first Charlie Gibson interview, I said, "I'm never doing TV again." The public affairs folks laughed. They knew they had to get me back on the horse. There were very specific roles in the media.

I have enormous respect for President Bush, the father—he sided with us on the food label—but being a strong enforcement agency, taking strong regulatory enforcement in a Republican administration did not go over well with other members, other than the President, in the White House. If you read Sununu's comment, people wanted me out. I mean, they wanted

to come after me after orange juice, after a number of these things. I would get these phone calls "The White House wants—there's a train wreck coming if you don't..." We were not listening. We were very independent and we were not going to be bullied. We were not going to pull any punches. I was given lists of people to put on the reproductive drug advisory committee who had a specific political position. There were pro-life [inaudible]. I never gave the list to anybody.

So we were independent even though we're not an independent agency. You could do a story about that. But we were acting very independent. We were trying to restore the public face and at the end of the day, the protection the Agency had in order to do that was to have the Commissioners out there. If you're out there and if you're enjoying public confidence, there is no way that they're going to be able to undermine the Agency. So it was the greatest form of protection we had.

SJ: That's a very good perspective.

DK: Let me just give you the second one. When the decision on tobacco—this was not just during a Republican administration—this was also true during a Democratic administration. When the regulation, the decision on whether Clinton was going to support us on tobacco and whether he was going to side with us, there was a discussion in the Chief of Staff's office—I wasn't there obviously—but – you know—what was the political calculus? Do we fire Kessler? I mean, is Kessler going to resign or are we going to support him on tobacco? And if you have a Commissioner who is well known, they did the calculus and said we can't fire him, we don't want him to resign, so we're going along. That's not the President's or Vice President's thinking necessarily but certainly the political focus of the White House when they're discussing that. If

you have a strong media profile that is positive, that's why they supported us. At the end of the day, there were a lot of reasons why we got tobacco. The President decided himself. The Vice President carried it through. It was also because the White House was afraid of taking on our public profile. Lloyd Cutler saw me one day in the elevator. I was in the West Wing. He said, "Kessler, I'm getting all these headaches about you. People are calling me and what you're doing."

CC: Was he White House Counsel at this point?

DK: He's Counsellor to the President. He said, "You know, I tell them, 'Look, Kessler's FDA. That's an independent agency. I have no control.'" This is the Counsellor for the President and I'm sitting there—

SJ: Did you take this as a compliment?

DK: I'm sitting there thinking—it's going through my head "This is the White House, this is Lloyd Cutler, the great Lloyd Cutler, and he thinks I'm an independent agency. I'm not going to dissuade him but we're not an independent agency by any stretch of the imagination." But if he thought we were independent, that's what I needed in order to do our job because then there was not going to be political pressure.

CC: I'm just thinking about maneuvering around the political minefields. Do you remember the hearing before Waxman—this was still Bush 41. This was when the Democrats were in

control of the House and there was an FDA enforcement bill. Eventually your testimony was whittled down to two pages. Do you remember the hearing I'm talking about?

DK: Yes, I remember the hearing.

CC: So tell me your version of it.

DK: So this was a request for additional enforcement of authorities.

CC: Right.

DK: And the Hill was supportive but the White House was not. I got revised testimony from OMB. It was not two pages. I got revised testimony that was extensive, but just the opposite of what we were saying. They were saying we didn't need additional authority. I said, "Okay, fair enough. What we can do is, you can restrict what I'm going to say but you can't put words in my mouth." So I basically said, "I'm going in there and my statement was going to be very brief – we cut all the stuff out, fine. But I'm not putting in anything you've written. I'm just going to read the testimony with everything cut out." It was very clear what was going on and I brought personnel from all the enforcement parts of the Agency. They were sitting next to me and everybody knew what was going on. But again, the reason it was short was because I didn't read what others, OMB, had written to be put in.

CC: My recollection, which is not inconsistent, was that we were at FOB-8 and you got back the testimony and you decided what you were going to do. I was pretty facile with a word processor and I decided you needed more than one page so I set really big margins, really wide margins, chose really big, speechwriter type, and created two pages. That's why I said you had two pages of testimony.

DK: Basically we cut out everything—they cut out everything.

CC: "Good morning, and thank you for calling me."

DK: Exactly. But that was done deliberately because again, I was not going to—you may restrict what I'm going to say—okay—but I'm not going to say something I don't believe. These were still key enforcement authorities.

SJ: Were there questions?

DK: There were plenty of questions.

SJ: That's what I thought. And you had your enforcement officials there to answer the questions and they hadn't been vetted. That was sort of my recollection. It was actually quite a famous hearing for that.

DK: Those were the inside baseball hearings.

CC: What do you mean?

DK: Those are hearings that are taking place that people care about inside the Beltway. Those are not the major hearings that the public sees. The issue is how do you reach—how does the Agency do its job by connecting with people who think that you're on their side and you have their interest.

SJ: What was your best strategy for that? We're talking about media is the point and that was one of the things you were quite good at. In case you were wondering, too, all of the tapes—you had Sharon Kuperman set up that whole office—but all the tapes from your Administration are in cold storage at the National Library of Medicine.

DK: We did it to be able to build confidence in the public and trust. There are complexities to it. The Secretary's folks didn't like it because the Agency is getting more press than the Secretary. There is that that goes on.

CC: Was that in both Administrations?

DK: No. The Secretary—Louis Sullivan—was a real gentleman, and it was only staff around him that cared about we were getting more press than he was getting. That's what they cared about. Donna—Secretary Shalala—she understood that if we were out there and we were doing a good job, then that would work well for HHS.

SJ: In addition to the electronic media, I guess, you worked with a variety of outside writers, I guess, starting with Herbert Burkholz of the *New York Times* article.

DK: Herb Burkholz wrote that—he did that independently.

SJ: Right. But then you brought him on board at some point.

DK: I brought him on as a speech writer, et cetera, yes.

SJ: And then he went on to author *FDA Follies*, as I recall.

DK: I forgot about that book until you just brought it up.

SJ: I remember when I worked with Burkholz just a little bit but when *Follies* came out, honestly, as far as I can tell, almost no one at FDA read any of it before it came out. So it was a surprise to a lot of people.

DK: I don't know anything about the book.

SJ: And you don't have any—

DK: No. I didn't work with him—he wrote the book.

SJ: And you really didn't?

DK: I can't tell you anything about the book.

SJ: You didn't? That will surprise some. The story of the grape episode, for example, cyanide in grapes, was a version that no one was familiar with and we just assumed that you had talked to him about it and allowed him access to someone within FDA. So that's a really interesting perspective.

DK: I'm sorry, cyanide in the—

SJ: In the grapes. The grape crisis.

DK: So what year was the cyanide in the grapes crisis?

CC: It was before you came.

SJ: It was during Frank Young's tenure but – I think it was '88.

DK: I was going to say I didn't do cyanide in grapes.

SJ: No, no. But what I'm saying is that the sense was that he had access to internal folks, certainly—

DK: He was a reporter from the *New York Times*. He worked for me for several years but—

SJ: But you didn't give him any particular access that you're aware of.

DK: I have no idea what you're talking about.

SJ: That is really interesting. That's good to get on the record, actually. Of course, Phil Hilts worked with you on tobacco. Herb Berkholz, I don't think, is with us anymore so we can't—so that's why it's particularly helpful to hear. You also worked with, I guess, Phil Hilts.

DK: Again, Phil Hilts covered us—I didn't hire him. Herb Berkholz, you're right, worked for *The Times* and then we hired Herb. Phil always worked—Phil was *The New York Times* reporter on tobacco, breast implants, and a number of other things. He covered the Agency.

SJ: And then he wrote the book Smokescreen. Did you have any—

DK: I'm blocking on that book, too.

SJ: Okay. I know we did provide him with some material for *Smokescreen*. Some of it came from research I did for you.

DK: Maybe. What year was *Smokescreen*?

SJ: I don't know when the book came out but it was before the *Brown v. Williamson* [This should be cited as *Brown and Williamson v. FDA*.] It was one of the books in a cascade of literature that turned the tide of public opinion . . .

CC: I checked – cyanide in grapes was 1989.

DK: Right, it was before my time.

CC: Yeah, yeah – right.

SJ: That was just part of my question about your work with reporters . . . I think we have time perhaps—one of the things on my list was to talk about Ruth Merkatz and the Office of Women's Health and breast implants. Of course, Jane Henney had a big role in that as well.

DK: Ruth Merkatz was a Senior Nurse Administrator at my hospital, the hospital I worked at. We both worked at the same hospital – I knew her. Her husband had a fellowship down here for a year and he was chairman of OG/GYN. Again, it was my search for talent and search for someone like Ruth. NIH had created an Office of Women's Health to look at certain issues. The NIH issues were in research. But I asked Ruth to come form this office. I don't think there was

an Office of Women's Health before Ruth. There may have been something on women's health. Maybe there was something—I don't know if there was anything.

CC: Was there an Office of Special Health Affairs? Randy Wycoff?

DK: Special populations. There was no shortage of important issues—there was the female condom, there were women in clinical trials, there were breast implants, as you mentioned. As for women in clinical trials, women were not allowed to be in clinical trials even if they were on an effective birth control. That didn't make sense. How do you approve a drug for a significant part of the population, but you have no data on that significant population and you say it's okay to take it but they can't participate in the clinical trials? There were complex issues so we had to work through those. There was RU-486. There were a whole host of issues that were very much central to women's health. The Centers were very capable and able to handle these kinds of issues on an adjudicatory basis. But I think that we tried to address these issues on a policy basis. Ruth certainly did grapple on women in clinical trials.

SJ: She and I co-authored an article using the history as background.

DK: So you understand that it was a very important period.

SJ: Yes. I particularly recall controversy over the Agency's decision on the breast implants.

DK: You're understating it.

SJ: Well, in fact, when Jane Henney left as Deputy, we did an oral history interview with her. I pushed her a little bit on that decision because I guess the argument of course is that if they're not safe enough for healthy women, why on earth would they be safe enough for women who had had cancer? We were talking about that kind of thing. She was honest in her answer but we had no idea, of course, she was going to come back and be a Commissioner so that oral history interview became more important.

DK: Did Jane make that decision or did I make that decision?

SJ: That's a good question. The assumption was that given her background at NCI as deputy to Marc Lippman, and as a female physician, that you may have been making the decisions but you were certainly listening to her.

DK: I think that's probably correct. I was probably in her office. I can probably tell you where I was sitting when we were discussing these issues. There are different risks and benefits. Again, I think if you study the issue—the effects of a mastectomy on a woman – it raises different issues than the effects of cosmetic surgery. Sometimes cosmetic surgery can be critically important. This is by no means disparaging or diminishing the importance if there is a body deformity and what's cosmetic and what's medical. I think with a major deformity, especially after surgery – actually, at any time—you have to be especially sensitive and I do think that's a special case. I don't think that is a hard—I don't think it's a hard [inaudible].

I think Jane and I did have extensive conversations, as you mention it, and we felt that there was a difference between the risk-benefit, at least in these issues. [Inaudible] the actual risk-benefit [inaudible] but when you're dealing with major chief deformity that you had—that you could distinguish that from cosmetic. So where is the overlap concerning individual instances where those things overlap and I'm sensitive to that. The problem was that the Agency called for data for these devices. These were pre-Amendment devices. The industry never had data – the industry never did develop the data. What we were saying was before you implant anymore of these, get the data. That was the story. That was not the way this necessarily played out in the press. If there was any lesson there, it's when FDA or the Commissioner says "These have not been shown to be safe and effective," for the public, that's too nuanced– because the public will understand, when you say it's not been shown to be safe and effective, the public will understand that to be "These are unsafe." Those are not quite the same thing. Those are not the same thing. But you can't make that distinction in the public's eye.

SJ: There were so many allegations of a link to auto-immune disorders. People felt that you were skirting that issue. To say it's not been shown safe and effective is perceived very differently by women who think they have auto-immune diseases as a result of implants – something that had not been shown and never was.

DK: We had published the data pretty extensively in that article. We had basically dismissed that evidence and said that a link to auto-immune disease wasn't there. We did say there was a very high rate of rupture and that, in and of itself, causes issues—silicone was leaking out and creating local complications. I think that was the key problem with the devices. There's a rare

form of cancer that obviously seems to be associated of late. But again, we said no one had studied these devices. No one had studied these for any extensive period of time. No one could answer questions but they were being used. We said "Time out, get the data, and the Agency will look at it." The fact is the devices that ultimately got approved were very different than the devices that were on the market when we had problems.

CC: Is there a way to deal with this misunderstanding—the public's understanding that the statement "having not been shown to be safe and effective" means that the device is unsafe? Is there a way to do that?

DK: Please don't put it on the market in the first place and then say oh .. Once they're on the market, you have to stop something that's been on the market for a long time. That's why you try to get data before you put it on the market. It's much simpler. People are using them, people have them in them, because you already let them on the market. That's the problem. Most of the time you should deal with these issues before they're on the market.

This was a unique set of circumstances because these were pre-Amendment devices, there were allowed under [section] 510(k), there were allowed on the market without any scientific data. The Agency was supposed to call for the data under the law. The Agency never called for data—put it off, put it off, put it off. People kept using these devices and no one had the data and then you had controversy about these devices that no one could answer. The Agency called for data and no one provided any data. What were we supposed to do when no one provided any data?

SJ: It really wasn't unique either. There were a lot of pre-'76 products on the market that hadn't been ruled on. Was this your first introduction to that larger project? Gingrich went nuts over our regulation of devices at some point.

DK: Gingrich, at one point and I still remember, I think there was an NBC story in which he called me "a bully and a thug." I think he'd just gotten off Phillip Morris's plane, if you go look at the clip. [Laughter.] I remember getting a call from NBC News—did I have a comment?

CC: And what was your response?

DK: I can't tell you my response, I don't know my response. But I can tell you it was in the fall and I can tell you who my son dressed up as for at Halloween. He dressed up as Newt. [Laughter] I met Newt years later and actually we had a very pleasant conversation but this was ... I don't know.

SJ: Well, by way of nothing, my major professor had Newt Gingrich as a student at Emory. He was known for coming up with his conclusions first and supporting them later. Historians tend to try to not prove our own prejudices.

CC: If we're done with women's health and breast implants, this is probably a decent time to wind up.

DK: Good.

CC: You must be exhausted.

DK: No, but I'm glad I have other things to do.

[END OF INTERVIEW]

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