



**Oral History Interview with
Nancy L. Buc
Chief Counsel
Office of General Counsel
1980-1981**

**FDA Oral History Program
Final Edited Transcript
August 12, 2015**

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Oral History Abstract

Nancy Buc was the first woman to serve as the Chief Counsel of the U.S. Food and Drug Administration. During her brief tenure (1980-1981) she directed the agency's legal response to public health concerns linking super absorbent tampons to toxic shock syndrome, the use of diethylstilbestrol as a growth promotant in cattle, nutritional standards for infant formula and the development of prenatal alpha fetal protein test kits.

Keywords

Food and drug law; Office of General Counsel; departmental relations; congressional affairs

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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.

FDA Oral History Program Mission Statement

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

Statement on Editing Practices

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

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Interview Transcript

CC: This is another in a series of oral history interviews for the Food and Drug Administration. Today is August, 12th, 2015 and we are interviewing Ms. Nancy L. Buc at FDA's White Oak Campus. This is Catherine Copp and I am conducting the interview with the assistance of Cindy Lachin of the History Office.

Okay, Nancy. Let's start as we usually do by having you tell us a little bit about your background and early history and how you decided to become a lawyer and how you came to FDA.

NB: I was born in Orange, New Jersey, in 1944 and my family and I lived in New Jersey, mostly West Orange, until 1954, we moved to the suburbs in Pittsburgh and then when I was in a senior in college we moved to Northern Virginia. I went to Brown University (Pembroke College in Brown University), and got my Bachelor's degree at Brown. I worked for a year between college and ultimately going to law school as a management intern at the Department of Labor. This was my first exposure to working in the government, and I decided early on that I was not meant to be a GS9 employee of the Department of Labor.

And so I went to law school. I went to the University of Virginia School of Law There were I think six or seven women in my class of 250, which as we always joke was a quantum leap from the previous high of three. So that was an exposure. Brown had been nothing like that. Not that there wasn't any sexism. But the University of Virginia was a very special place, at the time they didn't even have women in the undergraduate arts and sciences college; they had sort of, if I can use the term, a separate but not equal institution down the road at Mary

Washington. It wasn't until I graduated from law school in 1969 that they admitted women to the undergraduate arts and sciences college.

How did I decide to become a lawyer? The only things ... I'd started out in college as a premedical student and I wasn't good enough with the science and the math to pursue that so I switched over to American Civilization. And the only things I knew to be were to go and get a PhD or to go get a law degree. Maybe if I'd graduated yesterday, I'd have gone and been an investment banker. But I didn't know how to do that and I knew I didn't want to be a PhD. I couldn't fathom spending that much time in the library learning more and more about less and less.

And what really appealed to me about the law was that it was so embedded in every aspect of, you know, the country's policy. And at the time I was thinking about, maybe someday I'd run for office and I thought law would let me do lots of things, which turned out to be very much the case. So that's why I went to law school. As I was graduating from law school, it wasn't, 1969 wasn't a great time for women to be applying to law firms. I had a couple of interviews.

Some people would interview me and say but we're not hiring women. I never could figure out why they interviewed me if they weren't hiring women. But anyway... And I was interviewed by somebody from the Federal Trade Commission and they were hiring women, I think in part because they were having some difficulty hiring at all. But in any case, they did hire me, and I spent three years at the Federal Trade Commission. I spent a year in Truth and Lending and I spent about a year in National Advertising, worked on toy cases and cases against the over-the-counter analgesic people.

And then I worked for the chairman – I was an attorney advisor to Chairman Miles W. Kirkpatrick for about a year. Did a short stint in consumer education and then was hired away to a law firm in New York, Weil, Gotshal and Manges. I worked in New York and became a partner at that firm in New York in 1978, I guess, and moved back to Washington shortly thereafter to open a Washington office for Weil, Gotshal. Then I was hired away to become the Chief Counsel of FDA by Jodie Bernstein with whom I had worked on both the toy cases and the OTC analgesic advertising matters and who had become the General Counsel of HHS [the Department of Health and Human Services]. When Secretary Patricia Roberts Harris came to HHS, Secretary Harris hired Jodie Bernstein away from EPA where she'd been the general counsel.

And Jodie asked me if I wanted to come to FDA, and my first reaction was I don't know. So she called up Peter Hutt and assigned him, asked him to see if he could talk me into it. And he and I were together at a, I think, at a cosmetic trade association meeting in Florida or somewhere, and he took me out for I guess a drink after one of the sessions and explained to me why I should want to be the Chief Counsel of FDA – because it was the most interesting job I would ever have. And he persuaded me. He also turned out to be right.

So that's how I got to FDA. But first, of course, I had to be interviewed by not just Jodie but by Secretary Harris, who was very involved with the lawyers all over HHS and certainly FDA. You may remember that at the time, maybe still, but at the time, the FDA General Counsel staff was part of the Office of General Counsel of the department. We technically didn't work for FDA at all. And the tradition had been, and was certainly true in my case, that in some respects the Chief Counsel was the Secretary's representative – eyes, and ears – whatever you want to call it – at FDA.

And that proved to be very much the case. Secretary Harris was very interested in what FDA was doing. And so part of my job was to, you know, not just represent FDA and work with FDA but, in a sense, represent FDA to her and in many cases, her to FDA.

CC: Let me ask a couple of questions about what was a wonderful story of your journey to FDA. Now I mean this in a positive way: why was Weil, Gotshal interested in hiring you? What was it that you had done that made them want to hire you?

NB: I had sued one of their clients.

CC: Oh, well that's interesting.

NB: As I said, at the FTC, I worked on the toy cases. The two toy cases were against companies called Topper Toys and Mattel. And Topper was represented by one of the senior partners at Weil, Gotshal, Ira Milstein, who was later my partner. At the time I was a relatively young lawyer at the FTC, and Ira Milstein called me up one day and said "This is Ira Martin Milstein and I'm not at all happy with the way you're dealing with this case. I want to go see Bob Pitofsky," who was my boss in the Bureau of Consumer Protection at the FTC. I said fine.

So we set up a meeting, and Ira and his colleagues Irv Scher and I guess probably Michèle Corash for Topper, and Jodie Bernstein and I went over to meet with Bob Pitofsky. And Bob said to us well, you should go back across the street and settle this case – go back across the street and see what you can work out. So we go back across the street to our offices, and Ira starts in on me saying I had misstated or lied, misstated some of this and had lied to Bob

Pitofsky. You know, I'm like 28 years old or something. I stand up I say to him look if you want to talk, I'm happy to talk; if you want to settle, I'm happy to settle. But if you're calling me a liar, I'm leaving. I started to walk toward the door and Ira said no, no, don't do that, come back. And so we started working on a settlement, which we ultimately reached. Although he stopped pretty much working on it and left it to Irv Scher and Michele Corash to negotiate with Jodie and me. So they hired me because ...

CC: You stood up to him?

NB: Well – yes – and because I knew what I was doing. We had a great case. And later, I think he said in an article that the *American Lawyer* wrote about me at one point, well, [Nancy] did such a good job all I could do was hire her, so I did. And I was the first woman partner at Weil, Gotshal. I had had some experience with these issues.

CC: I'm interested to know maybe how old he was at the time – I mean just roughly – you know what the disparity might have been or the age difference.

NB: Maybe 20 years. Let's see, it was 1970. So I was 26 and he's about, more or less 20 years older than me. So he was 46. He seemed, you know at the time, he seemed like a big deal to me. And he was a big deal.

CC: So when you went to Weil, Gotshal, what kind of work did you do?

NB: Well, the first thing I had to do was clear up conflicts with the FTC, so for a while, what I did was work on the Consumer Product Safety Act, which was new. Weil, Gotshal had a lot of clients who, one way or the other, had to deal with the Consumer Product Safety Act and all sorts of products. So I started working on that while we were sorting out my conflicts from my FTC days, because I'd been high enough ranking that I had to file something with the Commission. It took a while.

CC: Right.

NB: And so, for a while, I did work on the Consumer Product Safety Act and also, of course, the Hazardous Substances Act, and the Flammable Fabrics Act. Some of those statutes had come from the FTC and some of them had come from the FDA. And I learned, after I got here, the FTC always referred to the transfer of its people to the CPSC as the Federal Trade Commission Improvements Act of 1972, and that FDA had referred to the transfer of its people to the CPSC as the FDA Improvements Act of 1972, whatever year that was.

CC: So by getting rid of people, they improved the Agency?

NB: Yes.

CC: That's interesting – I never heard that while in OGC.

NB: And that was ... it was a joke ... all those people, but there was something to that. Once we got my conflicts sorted out and new things started to arise that hadn't arisen when I was at the FTC, I did a lot of FTC-related advertising work for clients. We had an advertising agency as a client that we reviewed all of their copy before it ran. I think I handled a couple of things at the FTC where the FTC was pursuing these people. I mean I was deeply into the federal regulation of advertising at the FTC, so that's mostly what I did.

CC: You mentioned already that you were the first woman partner at Weil, Gotshal – what was that like? Were you surprised? Were they surprised?

NB: No. Weil, Gotshal had had a few women lawyers, not a lot, but actually Michele Corash who was on the other side of Topper Toys had been there, and there were a couple of others. But there was no question that a lot of the older lawyers, the older partners, at Weil, Gotshal were sort of startled by the whole thing and some of them were not very happy about having a woman lawyer. But Ira Milstein, Irv Scher, and many others I can name in what we called the trade regulation department really just – I mean it's not that they were unaware that I was a woman – but what they wanted was a really good associate and ultimately, a really good partner. And I was able to be that.

And I got mentoring from many, many of them – Ira and Irv and Paul Victor and Carl Lobell – many of them. And I was pretty good – I was good. And one of the things, one of the things that I handled in those early days was a client that had some televisions that were allegedly in violation of the Radiation Control for Health and Safety Act. So my first introduction to FDA was actually dealing with John Villforth, and Bob Britain, and Bob Elder,

the radiation guys. And nobody knew anything about the Radiation Control for Health and Safety Act and so, it was sort of similar in some ways to the Consumer Product Safety Act, so I was basically put in charge of this.

It was a client that I'd worked with a lot, and I'd lead these delegations of people from the client and usually Irv Scher came with me, to meet with John and the two Bobs, you know, in that old Twinbrook building that they used to have. So that was my introduction to FDA. The client recalled those televisions and fixed them. I don't know that they were – they weren't actually radiating – the issue was whether they had a dual capacitor to prevent them from radiating. So they got them all back and they fixed them and then started to ship them again.

That was my introduction to FDA. It was one of FDA's largest recalls to that point and, as we'll talk about later, it was ultimately exceeded only by the Rely tampon toxic shock recall. So at least at the time of toxic shock, I held the record for the two largest recalls in FDA's history – one on each side.

CC: When you were appointed Chief Counsel, one of my colleagues and one of the lawyers who worked for you, Bob Spiller, pointed out that there were three women between him and the President – you, HHS General Counsel Jodie Bernstein, and Secretary Harris. You were the first female triumvirate. I hope we're going to talk more about that mix a little later in the interview, but do you have any initial thoughts about it? Going in, did you understand that it was unusual?

NB: Of course I understood that it was unusual. People thought that, a lot of people thought that Mrs. Harris was the first woman Secretary of HHS (or HEW as it was then), but she wasn't. Oveta Culp Hobby had been Secretary of HEW in the Eisenhower Administration. But memories

are short. And I think Jodie Bernstein was the first woman General Counsel of HEW, and I was, of course, the first woman General Counsel or Chief Counsel of FDA.

I think everybody sort of noticed it and to some people, it was just sort of interesting, sort of a fact, but to other people, the assumption was that Mrs. Harris had hired Jodie because she was a woman and not because of her qualifications and that Jodie had hired me because I was a friend and a woman and not because of my qualifications. And those people were making a mistake. I mean, Pat Harris was one of the smartest people and smartest lawyers I ever knew.

And in fact, before I came to FDA, one of my colleagues in the Washington office at Weil, Gotshal took me aside one day and said you know you're going to hear a lot about how Pat Harris is a token, she's not only a woman but African American. He said, I was on the Law Review with her at GW and I'm here to tell you she's no token, she is really, really smart. And he was right. Mrs. Harris had to break all sorts of barriers to get to where she was. Her testimony and confirmation hearing was before Senator Proxmire, I think, and he would ask her some question and her line was Senator you mistake who I am, I'm the daughter of a Pullman car porter, a sleeping car porter.

And she had gone I believe to Howard University for undergraduate school and then to GW for her law degree. She was really smart. And with all the things that she had to fight to get to where she was, she was no token. And ironically, a lot of the complaints about her later, which we can talk about more, were that she mixed in too much, she was paying too much attention, she knew too much. I mean there's an irony there.

CC: Yes.

NB: Jodie Bernstein had been on a *Yale Law Review*, she was also really, really smart and a really, really good lawyer. I didn't claim the academic credentials that those two had, but I can hold my own. I'm a good lawyer period. And neither one of them would have hired me simply because I was a woman, but both of them were open to hiring not just women but minorities and all sorts of diverse people who simply hadn't been in most of the previous pools. So in that sense, I'm a beneficiary of being a woman because the people who were hiring me were open to hiring me. But I wasn't hired because I was a woman. And neither was either of them. Not by President Carter in the case of Mrs. Harris and not by Mrs. Harris in the case of Jodie Bernstein.

[DR-100-0032.wav at 00:20:16]

CC: A couple more questions about stuff that you've already related. First of all, it's curious to me, I never heard about Peter Hutt convincing you to take the job as Chief Counsel, and I have to say I wouldn't have thought Peter would have promoted a woman. So set the record for me.

NB: Well, that firm and Peter had all sorts of women – they had women earlier than most of the New York firms. Peter has had a long string of women protégés. So I don't know what he was like you know when he was here FDA, but at least at his law firm, there was no doubt about it. I'm not sure how he knew Jodie and how Jodie knew to call Peter, but ...

CC: It's Washington.

NB: Well, yeah.

CC: But I'm trying to think when Peter was the Chief Counsel, which was 1972 to 1974?

NB: It was longer than that – it was more than two years. And he started before 1972 because I left the FTC in '72, and I remember going to a meeting with Miles Kirkpatrick about an Abbott recall of some kind with Commissioner Edwards and Peter Hutt when I was working for Miles, which would have been 1971 to 1972.

CC: While Peter was here, I'm trying to think about how big the Chief Counsel's Office was, maybe 35 lawyers?

NB: Right. I think Joanne Sisk may have been here.

CC: Joanne Sisk was here. Margaret Gilhooley. Cookie Poplin, who came and left pretty quickly.

NB: Linda Horton I think had not joined the Chief Counsel's Office.

CC: I think she came when Richard Merrill was the Chief Counsel.

NB: Yeah. And Selma Levine had worked in the Chief Counsel's Office, but that had been years ago. She worked for Billy Goodrich.

CC: Right. Well, anyway that's interesting. Now I'm thinking about ... well, now I can't remember the other question I was going to ask you. So when you came to FDA when was that?

NB: February 1st, 1980.

CC: You've said that you had one experience with FDA with one of the Bureaus, and you talked to Peter obviously, Peter Hutt. So what did you expect?

NB: I didn't really know what to expect. At some point in the process, I came out and spent an hour or two with Rich Cooper, who gave me a tutorial about what the Chief Counsel was doing and at the time probably ever since. Rich was fascinated with the way that FDA used sensitivity of the method to navigate around the Delaney Clause. That's the only thing I remember that we talked about. But that's something he was very into at the time. I don't remember what he was working on.

And I also met with a committee from the Chief Counsel's Office. Jodie had asked them, I don't know if she asked them to interview all the candidates or just me when I was getting close, but I met with a committee from the Chief Counsel's Office. I don't remember everybody who was on it – the only one I remember was Joanne Sisk. But you know I started studying up a little bit on FDA. But I really didn't know what to expect. I mean I know, I remember getting off the elevator and looking at the directory, we were on the sixth floor [of the Parklawn Building], right?

CC: Yes.

NB: On the sixth floor, some of the directory was for the Chief Counsel's Office and a lot of the rest of it was for the Bureau of Veterinary Medicine. And I remember the entry for the Bureau of Veterinary Medicine "minor species." And it's always tickled me – I mean I didn't know FDA had a Bureau of Veterinary Medicine. And it always tickled me that there was that minor species. I was, ironically, I was criticized by people in the Bar and sort of in the FDA community on two counts.

One was that I had all these alleged conflicts because I'd represented people who were deeply enmeshed with FDA. And I think except for the radiation thing, which was important to that client and important to FDA, but it was hardly central to most of the things that FDA did at the time. And I think I had worked with retailers on how to handle the saccharine warnings that were required for saccharine, but retailers, you know, it's not as if I were representing the saccharine people. I mean they were in Brooklyn but I didn't know that at the time.

So I was criticized both for having all these conflicts and, on the other hand, I was criticized for not knowing anything about FDA. So that's fine, you can get me both ways. All I could ever think of was that old joke about English history – Elizabeth the First wanted to be known as the Virgin Queen and the Mother of her country, and she really should have made up her mind. Here I am caught between these awful conflicts and knowing nothing, and I used to think well, they really should make up their minds.

What happened was that the Office was organized to give me tutorials and briefing books so I got tutorials both on you know specific things that were pending and on the generality of the law. I mean I remember Mike Taylor, now Associate Deputy Commissioner ...

CC: Deputy Commissioner for Food and Veterinary Medicine, yes.

NB: Including minor species I guess?

CC: Yes.

NB: I remember Mike Taylor explaining to me the concept of a food additive. Okay, so you have beans and you have corn and then standing alone they're not food additives, but when you mix them they're both food additives...

CC: I'm not sure he would agree with that today, but...

NB: I'm not sure I have it right either. Maybe I wasn't such a good student. Something like that.

CC: Do you remember who else briefed you?

NB: No. I'm guessing probably Don Bears because he was so involved in all the generic litigation with Premo, and Pharmadyne, and all those people.

CC: Right. And by then Bill Vodra had left.

NB: Yeah, Bill Vodra had left. Tom Scarlett had left.

CC: Right.

NB: And I think Michael Peskoe.

CC: It's interesting ... I think actually wasn't Mike Taylor Executive Assistant to Commissioner Goyan?

NB: No, not yet.

CC: Not when you came?

NB: No. He was still working at the Chief Counsel's Office.

CC: But eventually?

NB: Yeah. He did go do that at some point.

CC: So what contact did you have with the staff attorneys and how was that? Do you remember?

NB: Well, I tried ... I mean I met many of them just as part of the work process. I mean, various people are working on various things and I had to get involved in the various things and

just kind of got to know them that way. I often went to lunch down in the cafeteria. I remember the Chief Counsel's Office often went to lunch together in the cafeteria and I was also a big fan of going out to the Chinese restaurant, the Far East.

CC: It's still there.

NB: Well, in a different location.

CC: Yes, in a slightly upgraded location.

NB: And some of us went out to lunch at other places around the area. So I got to know people a little bit that way. I've always been somewhat of a walker-arounder, I mean I would just go walk around and meet people. I remember Phil Derfler was usually in the office very early, and I often spent a few minutes chatting with Phil in the morning before the work day started, because I had to be there early for various meetings with the Commissioner and what not and Phil was often there. So I got to know him a little bit that way.

It seems to me I got to know people relatively quickly. We occasionally had staff meetings, I think.

CC: Those were a rarity in the Chief Counsel's office until Margaret [Porter] became Chief Counsel. I mean, you may have had some meetings but like regular staff meetings, those were established during Margaret's tenure.

NB: We had some.

CC: Yes – I meant it as a joke.

NB: Yeah. Well, we had some. But as I said, I did get to know people as we worked on things. No question about that.

CC: And what about your management team?

NB: Jeff Springer was my deputy and Arthur Levine was in charge of litigation and Jeff Stribling was what? – the Administrative Deputy. And there was one more ...

CC: Linda Horton. She was the Deputy for Regulations, Program Review, or whatever. I'm not sure what it was called at that time.

NB: Right.

CC: So as far as I'm concerned you struck gold in one way because you had June Stevenson as your Executive Assistant. So what can you tell us about meeting June, about her role in your year as the Chief Counsel?

NB: I must have met June when I came out to meet with Rich Cooper and also when I met with that staff committee, because she would have been the one who was organizing it. I talked

to her on the phone some to get organized the day I was going to start and I don't know I may have even had to come out to Parklawn to fill out paperwork and stuff, I don't know. But what I mostly remember is walking in the door the first day, and she'd gotten here ahead of me, of course. I guess she'd arranged a parking place and she handed me an index card that had the list of places I needed to be that day, which were, you know, sort of institutional things where the Chief Counsel had to be, I mean it wasn't personal to me, she would have handed the same card to Rich I guess.

And I thought well, this is pretty organized. And I started talking to her and of course, I figured out – it didn't take even a small part of any brain power I have to figure out – that June Stevenson was the best secretary anybody could ever have. Period. The end. She knew everybody at FDA. She never practiced law but she knew pretty much about what was going on in the office and at FDA and where everything stood. She knew a lot of the people downtown as well because she'd been at FDA for a long time. So she knew Jodie Bernstein's secretary and she knew a lot of the people in the Secretary's Office and she knew lots of other people. And she knew her counterparts in the Chief Counsel Offices, whatever they called them, at NIH.

She knew everybody. And she's so smart and so nice that you know everybody loved her, and I just signed up on the first day. How could I not? I had had some very good secretaries both in the government and in private practice – I do no disservice to any of the ones I had had before I met June – but she was the best. And I mean there are things that happened to Chief Counsels that you can't necessarily discuss with your staff or you have a good day or a bad day, and June was also there, you know, for that kind of stuff.

I mean she wasn't worried about you know the substance of whatever it was, she was worried about me. And in turn as best I could I worried about her because ... and I think that's the general opinion.

CC: Do you recall, did you ever ask her to leave with you?

NB: I did. And Rich Cooper's never forgiven me for that. Rich Cooper always says that the best thing that he ever did for FDA was not take June Stevenson with him. So he was never happy that I asked her. She just said no. She always thought that her place ... what she wanted to do was to be the secretary – later she had other titles – but when I was there, secretary was a perfectly fine title, and she wanted to be the secretary to the Chief Counsel. And she was for many years. And with one exception, we're [the Chief Counsels] all grateful for it.

CC: And she somehow managed not only to take care of the Chief Counsel but a lot of the staff.

NB: Yes, she did. I mean one of the things that she was really helpful with ... I mean I think Jess Stribling was also attentive to staff, not just to lawyers. But June knew which of the staff people were really good and which ones weren't so good and how we could optimize the assignments if we had to juggle the assignments.

CC: Do you mean on the support staff?

NB: Yes.

CC: Because I was thinking both the support staff and the professional staff.

NB: I'm thinking both. I'm thinking both. And sometimes she would say to me, such and such a person on the professional staff could use – she didn't use this term but – TLC, you know, and go take him out to lunch or something. Basically, I always did what June told me to do. It was only sensible. I can't remember anything she ever wanted me to do that I didn't...

CC: In some of our discussions in the run-up to this interview, I said to you – what did I know? The second person I worked for was a woman, and the first real executive assistant I knew – secretary, not just somebody who did the copying or the typing – was June. And I guess in some ways I didn't realize that, one, women weren't always in positions of authority and power and, two, there were some secretaries and executive assistants that weren't competent because June was so incredibly good.

NB: There's another part of it, too, that we should mention. June was always happy and even thrilled that a woman had been put in the Chief Counsel position and was doing what I was doing. That wasn't universally true of support staff in that era. There had been a lot of secretaries at Weil, Gotshal, office managers, people like that who weren't so happy about having women in the ascendancy – they were threatened. An office manager in a place like Weil, Gotshal that had, I don't know how many – maybe 150 lawyers – when I came to FDA, was a big deal. That was the highest thing in the firm to which a woman could aspire. And

women lawyers threaten a lot of people like that. Not that we ever threatened them, but they were threatened by us.

CC: Yes – I understand.

NB: And one of the things that was so much fun about June was that she was always so happy for me, she was happy for Jodie, she was happy for Secretary Harris. It was wonderful. And she looked out for the women lawyers on the professional staff. No question about it. She looked out for everybody. She did look out for everybody. But there had been secretaries, executive assistants, in my past who would not have looked out for the women while they were looking out for the men.

I mean it was really extreme in some cases. I remember one secretary to a Weil, Gotshal partner – I think he was a bankruptcy lawyer – who initially refused to put through calls from me to him. She didn't think I was legitimate, you know. Those days are happily long gone.

CC: Yes.

NB: Not as if they didn't exist.

CC: Early on in OGC, when I answered a phone early in the morning, I was asked if Joe Levitt had received something that had been mailed to him and I said ...

NB: Why don't you ask him?

CC: More like: guess what, bud, it's a new world here in OGC, and just because we are female and answer the phone we still might be something other than a man's secretary. Yes – you'll have to ask Mr. Levitt.

So what do you remember early on about the FDA organization? You've been at the FTC in several different positions. You'd been at a New York law firm, you were in the Washington office of a New York law firm, and then you come to FDA. What do you remember about the early days of the organization, its culture, the people?

NB: Well, FDA was and is very different from the FTC in lots of different ways. For one thing, by then, FDA was really several different organizations. There was a huge, I think about half the people at FDA worked in the field when I was there – roughly half. And they had been organized and reorganized and, as my grandfather used to say, re-disorganized, in all sorts of ways from the beginning of the agency on up to 1980. And they've probably been reorganized ten times since then.

But the whole field operation is by and large things that are brought to them or that they discover by inspection and then decide what to do and whether to do anything about it and whose relationships with headquarters were largely uneasy, or often uneasy. They just lived in a different world, appropriately I guess, but they lived in a different world from most of the rest of FDA that was in headquarters.

[DR-100-0032.wav at 00:40:35]

I mean, there was a whole operation in headquarters – at various times the Executive Director for Regional Operations and then the Associate Commissioner for Regulatory Affairs and then various incarnations – whose job it was to deal largely with the field, although the Associate Commissioner for Regulatory Affairs had headquarters’ responsibilities as well. But that whole world is different from the headquarters world, from the Bureau of Drugs, from each of the Bureaus.

And for enforcement purposes, and sometimes in the case of new drug applications – for example for approval purposes – there has to be interaction between headquarters and the field, but a lot of that was uneasy too. I’m not sure which statute actually had it but one of the more recent ones had to prescribe whether the field’s decision on an inspection in an NDA had to be binding on headquarters or not and basically, the law said it couldn’t.

So that was one whole piece of FDA, which the Chief Counsel’s Office dealt with largely in the context of enforcement and whether to bring a case and how to bring a case and what the case should be about and so forth and so forth. And that was in an era when the Chief Counsel still had to approve all of the regulatory letters. So there was that.

Then there was, there were each of the Bureaus, which differed considerably from each other. The Bureau of Biologics had a very different history and culture than the Bureau of Drugs. The Bureau of Foods had its own thing and its own history, and its history was in many respects the original history of FDA – I mean they were sort of the legitimate heirs of Harvey Wiley, much more than anybody else.

The Medical Devices Bureau was brand new when I got here. The statute had been passed in ‘76 and so four years is brand new in government time.

CC: Yes.

NB: And most of the Bureaus didn't talk to each other except Veterinary Medicine and Foods because of the intersection of milk, meat, and drugs in terms of human food. And they really didn't, they hardly ever seemed to me to talk to each other. And to some extent, they didn't need to. But I always used to, when I was here, I used to joke that it would be good to take some small fraction of the senior people in each Bureau and move them to another Bureau every so often just so that the experiences could be generalized in perhaps new ways for each of the Bureaus. And that was an anathema and to some extent still is.

And the Chief Counsel's Office had different relationships with the different Bureaus, depending on what they were up to. I mean because of the generic drug stuff, we dealt a lot with the Bureau of Drugs. I mean we were constantly doing that. Depending on what Congress was interested in, the Chief Counsel's Office would often get involved with one Bureau or another to do whatever it was that needed doing, either in terms of legislation or oversight or whatever.

One of the things that I was really struck by, though, was that the FTC was very much a headquarters place. I mean, they did have field offices, but they didn't typically do very much; occasionally, a lawyer would surface out there in the field who was really good and who would do something, but it was uncommon. And the percentages of FTC people were much more heavily in headquarters.

But the FTC used to think of a lot about what was important to do and what it wasn't important to do. FDA had an Associate Commissioner for Policy and Planning, Jake Barkdoll, but even so a lot of the field stuff, as I've said, was reactive, and even a lot of the headquarters stuff seemed to me to be reactive. I'm not sure I want to say it that way, but there wasn't a lot of

thought, and there still isn't because there can't be, about should we really be spending this much money and this much time on – you know, fill in the blank – dirty warehouses? I mean, I understand that dirty warehouses were illegal and I understand that in some cases they can be real health risks, but I'm not sure, compared to other things that you could be spending money on whether that's ... I don't know.

But mostly what I know is that FDA couldn't think about it because, institutionally, they had X number of people whose job was to do that [develop dirty warehouse cases?], so there wasn't much thought of that [whether we should really be spending this much money and this much time in a given area.] And, of course, the other thing that affected a lot of that was that for historical reasons, a lot of FDA's Congressional interactions were with Agriculture Committees rather than Health Committees or what not, and that also had an effect on budgetary things and so forth.

But mostly FDA, FDA seemed to me to ... there were some issues where – and we'll talk about this specifically – there were some issues not just ... The outgrowth of DESI [Drug Efficacy Study Implementation] and the outgrowth of Medicaid reimbursement for generic drugs put FDA in the position of having to be, and it was, a careful, thoughtful thinker about how to regulate generic drugs and how to approve them or not approve them, what the policy should be. We're going to talk I know about the Orange Book, the Therapeutic Equivalence List, but in that area FDA, both at the Bureau of Drugs and on up to the Commissioner's level and its interactions with FTC, was heavily into big time policy and the relationship of FDA to those kinds of issues.

But that was in sharp contrast to a lot, of course, to what went on in the field. So there were some areas where FDA was, you know, the intellectual leader and that's one of them. And

that occurred over a very long period of time. By the time I got there, DESI was, I mean, the '62 amendments were 18 years old. But Billy Goodrich contributed a lot to how to think about how to do that, Peter Hutt certainly had, and all the Chief Counsels in between.

Caspar Weinberger, who had been the chairman of the FTC and was an antitrust competition policy thinker, was the one who at HHS put FDA in the business of ... in order to be able to reimburse for generic drugs and save money, he had to have a way to make sure that those generic drugs were high quality, because otherwise Medicaid was second class medicine, second class quality. It was that that put FDA in the business of – maybe it had already been thinking about it – but that put FDA into the business of thinking really hard about how to regulate generic drugs so that FDA could assure the Secretary that they were of the same quality and therefore, could be reimbursed. I mean, that played a big role in a lot of FDA's generic drug thinking. But the Agency rose to the occasion, handsomely.

CC: FDA rose?

NB: FDA did. Absolutely.

CC: I know we are going to talk about the Orange Book, but while we're talking, are there particular people that you thought were instrumental in this effort?

NB: I don't know actually. I came to this relatively late. I mean, the Orange Book was one of the last steps before the [Hatch-Waxman] amendments. But I don't know who at FDA ... I mean I know that the Chief Counsels had played big roles in this because they had essentially been the

ones to help construct DESI, the Drug Efficacy Study Implementation program, and I know from reading his oral history that Billy Goodrich was one of the key thinkers there. And he and Peter [Hutt] both worked on the cases that led to the four or five Supreme Court cases that laid a lot of that foundation. But I don't know which of the other Commissioners were particularly into it.

CC: Did you have a sense that you had to prove yourself because you were young, because you were female, because you either had too many conflicts or had no background in FDA?

NB: I think so.

CC: And what was that like?

NB: Well, you know, I was sort of used to it. My whole career ... I think I was the first woman in almost every job I ever had. I wasn't the first female associate at Weil, Gotshal but as I said, I was the first woman partner. I think I was the first woman to be an attorney advisor to the FTC chairman, although there had been other women attorney advisors. I did a short stint as the Assistant Director of the Bureau of Consumer Protection for Consumer Education, and I was the first woman to be an assistant director of the Bureau.

There were a lot of people who were dubious about having women Chief Counsels of HHS and FDA, and there certainly were a lot of people who were dubious about having women [Cabinet] Secretaries. And I want to come back and talk about that some more.

But I think I dealt with it mostly the way I essentially dealt with it at Weil, Gotshal, at the FTC, which was to do the work. The work was fascinating and most of the time you could do the work without that stuff ...

I don't remember that it ever surfaced directly, it was always there with some people. But it wasn't there with lots of people. There were plenty of people at FDA who were willing to, you know, they were skeptical ... I think part of it is that they didn't much like all lawyers. And so the fact that you were a female lawyer, you know, made it a little worse, but not really worse.

I've been thinking about this a little bit in preparation for this interview, and I think one of the things that happened was that because Secretary Harris was very much involved in a lot of issues with FDA and because she was tough, she was resented by a lot of people at FDA. It always used to fascinate me that Secretary Califano – of the Joseph Califano male variety – was famous for yelling at people, and everybody said “Oh, that's just Joe.” And when Secretary Harris sort of lifted an eyebrow to be tough, everybody said “Oh, she's a bitch.” They didn't say it, but that's what they meant. And the contrast was really striking. I mean, Secretary Harris had a zone – and women are very familiar with this – she had a zone of [acceptable] behavior that was very narrow... and Califano's was much wider.

CC: And his was tolerated more or less?

NB: Right. Oh, yeah, from what I can tell, I mean he misbehaved more, but everybody said “That's just Joe.” He was a very powerful figure in the Carter Administration until he wasn't, until he got fired basically. But everybody at HHS, I guess, really liked Joe and was mad that Joe had been fired. And here comes Pat – besides she's a girl – it's a problem. And as I said

earlier, part of my job was to represent the Secretary to FDA. And so pretty much from the time I got there, I don't think the Commissioner much met with the Secretary without my also being there with them. And usually, Mrs. Harris brought Jamie Studley, who was the person in her Exec Sec who was responsible for FDA.

And I think part of the resentment of me as a woman, of which there was some, was not only, or not even, because I was a woman but because people resented the involvement of lawyers in general and me in particular in the work of FDA. And I don't know much about Califano's involvement with FDA, but I know that he was involved on some issues like the imminent hazard case that Sid Wolfe engendered. I can't remember the name of it.

CC: Phenformin?

NB: Phenformin, thank you. And I'm sure he was involved on other stuff. I'm sure Rich [Cooper] kept him informed. But as the Secretary's person and sometimes the one to execute the maneuvers, I think I was resented for that as much as for being a woman except that they were inextricably linked when it came to Mrs. Harris and me.

CC: Right.

NB: One of the things I remember, for example, is advisory committee membership. I don't remember how or why, I think this had preceded me, but the Secretary had to approve the nominations to advisory committees at FDA. And they would send up this list of white males and [Secretary Harris] would send it back, often to me rather than [FDA] or at least copying me,

saying “Ah, um, we’re not going to do it this way anymore, you got to find some women, find some minorities. They can’t be all white males.” And people didn’t like that. And all of us, I mean that’s happened to me my entire life, you know, “we don’t know any.” Well, she’d say “You can find some.” And they did of course. They always miraculously could find a fully qualified woman, African-American, sometimes an African-American woman even, to staff advisory committees. But often those things – so I’d be, for example, at an FDA Policy Board meeting – I don’t remember a specific instance of this, to some extent I’m creating this, but ...

CC: No – please continue – you’re sketching your impression ...

NB: And the Commissioner would say “We got to do better on women and African-Americans and minorities on advisory committees” after Secretary Harris had given him a tongue lashing for the failure to do that. And you know I’d be the only woman in the room and I was very much in favor of that and I would say so and I would explain to them, usually politely – but you know probably not always – that the time had come to stop all this white male stuff, they had to do this. And they didn’t like it. And so I don’t think it was only that I was a woman, it was that I was mixing into stuff that had been the province of FDA which happened to be all white males except for Alex Grant.

CC: Was he Associate Commissioner when you were there?

NB: Yes, he was.

CC: And I'm trying to think – maybe Ellen Williams was there?

NB: I didn't know her.

CC: She was one of the early few females at a high level, but she didn't stay at FDA very long. I think she was a Donald Kennedy appointment.

NB: The more I think about this, the more I think that, yes, there are people who just couldn't believe they were having to deal with a high level and high powered woman. That might have been somewhat true in the private bar as well, although they got over it because they needed to, because if you're going to see a Chief Counsel, you better not say we hate you, you know, at the outset of the meeting.

CC: Oh, you're referring to members of the private bar while you were Chief Counsel, not when you were in private practice.

NB: Yes, when I was Chief Counsel. I mean, I'm sure there were some people who needed to get over whatever they thought about women lawyers and fast. But at FDA, I think it was a combination of the way in which Mrs. Harris and I, as her representative, interrupted what had been the only method of communication between FDA and the Secretary in the past.

CC: Before we move onto focus on some substantive issues that you handled when Chief Counsel, is there anything else about your background, about coming to the agency that I either haven't asked you or you haven't?

[DR-100-0032.wav at 1:00:15]

NB: No. Let's draw this to a close and do something else.

CC: Okay. Let's turn now to the substantive issues that you addressed or some of them. Do you remember what the first substantive issue was that you had to deal with?

NB: The first one I remember is I'd been here about a week when one of the staff lawyers came to me and said that the Agency had received some credible information that Marvin Seife, who was the head of the generic drug program, had been taking bribes or gratuities or something like that. And the lawyer who brought this to me was a very serious, sober, solemn, sensible fellow who would not have done this lightly. I think maybe he was scheduled to defend Seife's deposition in a case the next week or so, and was uncomfortable defending him. He thought, and rightly so, that Seife should get his own lawyer in case any of this were to come up.

So I went to see the Commissioner, and I don't remember who else we consulted with, but we agreed immediately that [Seife] needed to be suspended. I think we suspended him with pay. But our view was emphatically that you couldn't have allegations of bribery – serious allegations of bribery – running around for the head of your generic drug operation. Of course,

that operation wasn't as big then as it was now, but it was relevant to much of what was going on then in the Agency and certainly to all this litigation.

So we did and my staff lawyer conveyed to [Seife] that he needed to get his own counsel, which he was very unhappy about. We thought we were doing him a favor because if he was going to get asked in a deposition about bribes where he was testifying for FDA, he should want his own counsel, but he didn't view it that way. And the next thing I know, I get a call from a Congressman – who was then a Congressman – Gore's staff, accusing me of retaliating against Seife for some testimony he'd given on the so-called Man in the Plant issue the week before and telling me that this retaliation was utterly inappropriate. I think Gore must have also called the Commissioner directly – I don't remember. Well, I knew that I hadn't retaliated because I didn't know that Marvin Seife had testified on the Man in the Plant issue. I'd been there for a week. I didn't know what the Man in the Plant issue was and I don't know that I'd ever heard of Marvin Seife before the lawyer came to me with these allegations. So the next thing that happens is you know he's been suspended...

CC: So when you got the calls, had Seife already been suspended?

NB: I don't remember.

CC: Oh, okay.

NB: I think so, because that must be what triggered the calls ... [Seife] must have gone to Gore. But the next thing I know, Gore and his staff are investigating the Commissioner and me for retaliating against Seife for his Man in the Plant testimony. And I couldn't believe it.

CC: What position did Gore hold then?

NB: He was a Congressman. He was on the Energy and Commerce Committee.

CC: Okay.

NB: He'd been presiding with these, he'd been very involved in the Man in the Plant issue. I have since learned, most recently in preparing for this, and then of course then, what Man in the Plant was about. But I'm here to tell you that [when I received the staffer's call,] I had never heard of Man in the Plant. I certainly didn't know Seife had testified and therefore, I am confident that I wasn't retaliating. And I was just furious. I couldn't believe it because – really – a regulatory agency ought not to ignore allegations of its people taking bribes. It just shouldn't. The right thing to do was to suspend Seife, and he was lucky it was with pay.

But instead of seeing it that way, Congressman Gore – who of course went on to a stellar career as America's Vice President, and I will say I didn't vote for him for President – I never forgave him for investigating me and the Commissioner. You know he investigated us. We had to produce documents, and meanwhile, I think Seife was being investigated by the Inspector General or by the Bureau of Drugs. I actually don't know, because I was essentially cut off from it.

At some point, finally, there's not enough to do anything to Seife, and I know from reading the Pink Sheet in preparation for this interview that he was reinstated – I guess I knew it at the time but I had forgotten. And Gore summonsed – Congressman Gore summonsed – the Commissioner and me to his office and he sits in a big chair and puts us in these little chairs and sort of tongue lashes us and then says but you're free to go. He didn't say that, but that's what it felt like. So good, we were free to go.

And as you can tell from, it won't show up in the transcript, but as you can see, I'm still mad. This is 35 years ago and I'm still mad because [Gore] had this great image as a great consumer protector and a great friend of honest government, and he should have been outraged at the allegations. And, of course, as it turned out in the generic drug scandal later in the '80s – after the [Hatch-Waxman] statute passed – there were new allegations that [Seife] had been taking gratuities. I recognize that they weren't terribly serious and they weren't as serious as the allegations against others that resulted in prison terms for some of the people in the Agency, Seife served a prison term for perjury. I've always wanted to know whether Gore ever understood that his, in effect, preventing us from doing a really tough investigation of Seife in 1980, was in any way relevant to the scandal that happened later.

CC: Let's just paint a little bit of the context for this. My recollection is that at the time you were Chief Counsel, there was a Division of Generic Drugs. Or was there an Office? But Seife basically ran the generic drug program.

NB: And if you see [Dr. Richard] Dick Crout's oral history, he did it pretty much independently. It wasn't huge. But there it is.

CC: So that was the first thing you remember doing after arriving at FDA?

NB: Yes – that’s the first thing I remember. I mean I must have done something else in the intervening week, I hope I did.

CC: There were those index cards that June gave you.

NB: Yeah, right. I mean June sent me off to meetings. But that’s the first thing I remember. And it was such a bizarre introduction because it wasn’t really an introduction to FDA – it was an introduction to Congressman Gore.

CC: Unfortunately, he’s not the only one that picked on certain FDA people historically. I’m not minimizing it.

NB: It’s one thing to pick on FDA for disputes over policy. I mean, I knew something about the Representative Fountain hearings even when I was at the FTC, because he picked on the FTC as well as the FDA. It’s one thing ... I mean, oversight is one thing, but calling up and making that kind of accusation and being unwilling to listen to – or his staff being unwilling to listen to – the answer angers me and saddens me, especially in light of who [Gore] was and became and who he thought he was and who he thought he became.

CC: But my larger point was that there's a long history, at least in my own experience, of difficult relationships with the Hill – at least some people on the Hill, whether it's a staffer or a particular Congressman – and I know I would not want to be between the cross hairs of any of those people.

NB: There's no question that some hearings and some interactions like that are over issues of policy and not personal and there's no question that others are personal. And there's no question that FDA, like most agencies, has not been totally free of wrong doing and there's no question that not all the inquiries are well placed, that there isn't wrong-doing, and that Congress can't always tell the difference. The only thing that distinguishes this one from any others probably is that it happened to me and that I knew that I hadn't been retaliating.

CC: Right.

NB: And that I thought – this isn't capable, susceptible of knowing – I thought that regulatory agencies should act quickly in cases of alleged bribery, that kind of misconduct, to take the person out of the line of fire. As I said, I always thought I did him a favor telling him to get his own counsel, because our people couldn't have defended him against those kinds of questions nor forced him to answer.

CC: Right.

NB: So, you're right, of course. I mean, FDA is one of the many agencies that's often the subject of that kind of stuff, but to me, this isn't like the others.

CC: No, it's not. My point is not to minimize what happened to you. Rather, as you said, you learned about Congressman Gore, and I'm thinking you also had a very unfortunate, personal, in-your-face experience about what it's sometimes like to be in a Federal agency and deal with the Hill.

NB: I went to lots of other hearings and testified at lots of other hearings that weren't too much fun. But they weren't like that. They were debates about how FDA institutionally should have behaved. And some of the most unpleasant hearings that FDA's gone through were of that kind of question – how's FDA supposed to behave?

CC: Right.

NB: Although I will confess I did used to joke when I was back in private practice, I always said that I would never do anything or refrain from doing anything in representing a client that would help me or hurt me in terms of an ultimate, a later confirmation hearing, although it never happened. I just had to play it straight. But I was not sure I would want to take a job where the oversight was done by [Congressman] John Dingell, who was famously unpleasant. I've seen him beat up people at FDA, you know not lately, of course, but you know in the last ten years or so, that are just ridiculous and unfair in every way. So I take your point.

CC: How did Commissioner Goyan react because he was equally accused, and I assume maybe you were counseling him in a number of ways?

NB: This was the kind of thing where [Commissioner Goyan] really had no experience. I mean, any lawyer would have had pretty much the instincts I had in terms of counseling the Agency and in counseling him as the Commissioner. And I don't remember his reaction particularly. I don't know if he knew anything about Man in the Plant, he might have, because he'd been around longer than I had, but he wasn't retaliating in the sense that he wasn't the one who made the initial recommendation, the initial decision. I was the one who recommended to the Commissioner that we suspend [Seife], and he agreed to that. I remember Paul Hile, who was the Associate Commissioner for Regulatory Affairs, being involved. And I think Gerry Meyer was involved.

CC: Gerry Myer would have been, I think, the Associate Commissioner for Management?

NB: Yes, I think that's right. But he had also been the legislative guy and probably, I guess, maybe Bob Wetherell.

CC: Yes – I think Wetherell by then was head of OLA [Office of Legislative Affairs].

NB: I don't remember Bob Wetherell's being at these meetings, but I do remember Gerry and Paul and I being at meetings. I mean Gerry Meyer, not Jere Goyan. And Jere Goyan then

hearing from the three of us what we wanted to do and saying okay. I mean Paul and Gerry Meyer and I would have been in a fox hole for a little while there.

CC: Did you have to pull them along or did they see it the same way, because they all strike, the two of them strike me as pretty strong and principled individuals?

NB: My recollection is that they had no doubt that we had to suspend [Seife]. They took my word for it that I wasn't retaliating because they knew how long I'd been there and how ignorant I was of everything, like Man in the Plant. And you know, we just worked it through as what's the Agency going to do? I don't remember, I mean I know that the Commissioner was at the meeting where Gore summoned us at the end to let us go.

CC: See – this is what doesn't get caught in the paper record of events like this.

NB: Right. The other thing I remember about his staff, Gore's staff, is that they not only demanded documents but I think they interviewed me, at least once, maybe a couple of times. And this was not all that long after Watergate. Do you remember the question that they kept asking John Dean – did there come a time when?, in the Watergate Hearings, did there come a time when? you know whatever... And I remember thinking that the questions that those two staff people were asking were sort of well did there come a time when, and the answer was no, because it hadn't happened at all, but you know... I felt like I was in Watergate.

CC: Well, I'm thinking of "What did the President know and when did he know it?"

NB: Right, there you go.

CC: The question to Alexander Butterfield.

NB: Let me add to that. Because it will get it done. I thought that was bad enough with respect to Gore. But later in the year, later in my tenure, I worked with Bob Wetherell and the Bureau of Foods and Gore's staff on [House Committee on] Energy and Commerce on the infant formula legislation. Those infant formula events had happened before I got to FDA, but the resolution – the legislation – happened while I was there. One of the things that FDA really wanted in that legislation was the authority to require recalls of infant formula.

At the time, FDA still had no defined recall authority, unlike, for example, the Consumer Product Safety Commission, which had sweeping recall authority with which I was familiar from my work in that area. And there were lots of other parts of the legislation. It substituted informal rulemaking for the formal rulemaking that would have had to have been used before the infant formula legislation passed to define the content and so forth. But one of the things that FDA really wanted was recalls because that stuff. What's the name?

CC: Neo-Mull-Soy.

NB: Neo-Mull-soy and Cho-Free had been in widespread distribution, the problematic stuff, and they really were a problem. And I think it was Syntex, right?

CC: Yes. Syntex was the manufacturer of both formulas.

NB: I think Syntex had run a recall, but FDA had no recall authority and no way to compel them to do a recall. And so, in many ways it was like Elixir of Sulfanilamide, where the FDA field force had to go grocery to grocery to make sure it was gone. I don't know that it was as extensive as that. So we wanted recall authority. And it didn't seem to commend itself to Gore, particularly. There was this odd provision in the bill that said that if you were going to run a recall, you had to consult with FDA. But it didn't give FDA any authority to compel a recall under any circumstances, even for infant formula. And we kept pushing and pushing and pushing. Gore and his staff ... Gore's staff knew that that provision was not a recall provision because we had discussed it with him, because it was sort of a strange provision, as I said, if you're going to run a recall consult with the FDA.

CC: I think that's the way the Agency's regulations governing voluntary recalls are – or at least were – written at the time.

NB: That's true.

CC: But you're right – it's not a recall authority.

NB: But you know I think kids had been severely injured and I think even a few died in the infant formula thing. I'm not sure about the deaths, but the injuries were very real. And so then Congressman Gore gets up on the floor of the House and cheerfully says that this bill has recall

authority for FDA. And – you know – it could have been sort of an accident. We had a very strange kind of recall authority. But he was taking credit for the recall authority, which wasn't recall authority. And that wasn't as stark as the generic drug thing, the retaliation business. But it really bothered me, because I don't think, I don't think a serious person would have said that that statute had recall authority.

[DR-100-0032.wav at 1:20:16]

CC: Right.

NB: And I'll use the word "serious." And the thing that's so troublesome is, of course, that Gore is a smart guy and maybe his staff told him it was recall authority but maybe ... I don't know, I'll never know how it happened or why it happened, but it wasn't true. And it made me mad, and, as you can tell, I'm still mad. So that's the other reason I've never, I wouldn't vote for him for President. Now we can proceed. We're done with Mr. Gore. Maybe.

CC: Maybe, maybe not. I was going to ask you about the Rely tampons toxic shock syndrome issue. But do you have more to say on the infant formula matter?

NB: The only other thing, as I said, most of, almost all of, FDA's actions on infant formula happened before I got to the Agency – it was mostly done. But I do remember one hearing before a Senate committee, which included Richard Schweiker who later became Secretary of HHS, he was Mrs. Harris's successor in the Reagan Administration. One of the questions that everybody

kept wanting to ask FDA was how come FDA had never prescribed the ingredients in infant formula?

Just briefly what had happened in infant formula was that Syntex, in an effort to remove the sodium from the infant formula, which was thought to be a good thing at the time, had taken out the salt, i.e., the sodium chloride, and in the process, by taking out the sodium chloride, had removed an essential nutrient – the sodium wasn't an essential nutrient, but the chloride was. And that's what had caused the kids to get so sick – the lack of chloride.

So one of the questions that FDA was constantly being asked was why hadn't we prescribed the ingredients of infant formula? And I mean, there were kind of two answers. One was that there had never been anything like this before and so it never really occurred to anybody to do it. The other was that FDA did have the authority to issue standards of identity for foods but those standards required formal rulemaking, and for whatever reason, we hadn't begun that process yet. I think maybe because we were figuring that the new statute would pass and we could get going and do it informally under that statute. I don't remember why.

But I do remember explaining to Senator Schweiker, who had asked a question – I think he asked the Commissioner, but this was the kind of thing that got turfed to me, and properly so – why didn't we just go ahead and issue a rule? And I said because we, as an institution, didn't have authority to just go ahead and issue a rule. You had to go through rulemaking, and in this case, it would have been formal rulemaking. Schweiker said “well, why didn't you just do it?” And finally I said well, because we don't have authority to do it the way you would like to do it. But if you'd like to, if the Senate wants to give us that authority, that would be good.

But it was such a struggle. I mean it's so hard to make people ... actually, his question was a perfectly reasonable question and I'm not sure why we hadn't at least started the process. But it's so hard to get people to understand some things you just don't have the authority to do.

CC: And they just don't happen overnight.

NB: Well, right. But as I'm sitting here talking about it I'm wondering why we didn't start. I don't know.

CC: What ended up happening – just to bring that particular issue about requiring the formulation full circle – is that the formulation for infant formula made part of the statute, which was a very easy way to make the standard instantly required, with the authority for the Agency to modify it if necessary.

NB: And it's with 553 [5 U.S.C. 553] rulemaking, right? It's not formal rulemaking.

CC: Right, it's not formal rulemaking.

NB: But as a general matter you don't really want things prescribed in statutes like that. It was necessary then but as a general rule ...

CC: I agree. But it was okay because FDA had the ability to change it. The statutory formulation has never been modified – I don't recall any reason that people thought the formulation needed to be modified.

Let's go to the big one, Rely tampons. I can summarize or maybe you can summarize the issue and how it got presented to FDA.

NB: The issue with Rely tampons was there had been an outbreak of toxic shock, which was a version of septic shock, and I think it had killed some women and made some others very sick.

CC: Yeah, I don't know about that.

NB: The Centers for Disease Control, their Epidemiology Intelligence Service, had done some work and had done a study and found that women who had used Rely tampons were more likely than other women to have suffered from toxic shock. This was a case control study with all the pluses and minuses of such a study, but there it was. And I think there was a preliminary study and then I think a later one and it caused an uproar within HHS. (The Centers for Disease Control, of course, was another component agency of HEW at the time.) But it turned out that tampons are also a medical device so the question was what to do about these Rely tampons and what to do about toxic shock.

I don't remember the details of how it arrived at FDA, but it arrived at FDA and because it was both CDC and FDA, and it was such a big issue, that it arrived also at the Secretary's level. And I got involved very quickly in trying to figure out what to do about all this. One of the first things that had to happen was that the two physicians who worked on it at CDC, Kathy

Shands and Bruce Dan, and I had been talking on the phone already. FDA reacted fairly quickly but wasn't necessarily getting too much cooperation from CDC, which you know published this study in the *Morbidity and Mortality Weekly Report*. But they didn't have any regulatory authority at all and they were not used to working with FDA.

One of the things that FDA never fully appreciated about Secretary Harris and to some extent, about my role with Jodie Bernstein and [Mrs. Harris] was that I could and I did get her involved very quickly and [got her to] tell CDC "Look you've got to work with FDA here, you have no regulatory authority, they do, this is going to have to be their thing." And that worked several times with her on several different issues. We can talk about some of them later. But it was very useful to FDA to have the ability to, I mean, I guess the Commissioner could have done the same thing, maybe he did, but you know she did do that.

CC: I think in his second oral history interview, Paul Hile talks about sort of the chronic problems between CDC and FDA.

NB: Yeah. They were very arrogant.

CC: And they didn't want to share their data because they wanted to publish it and we wanted to act on it – we, FDA.

NB: Right, we had the same problem. FDA had the same problems with NIH [the National Institutes of Health]. I remember some death at the Sleep Center over at NIH or some place at NIH where FDA had regulatory authority over the drug company, so we had to get the Secretary

to tell NIH “Work with FDA here. They have a legitimate role.” But anyway back to toxic shock.

CC: One of the things Paul Hile specifically recalls is that you got on the phone and had a fairly direct conversation with someone at CDC. And I think he spoke with some gratitude ... I mean, he realized that that was a problem – a chronic problem – working with CDC, and that through this conversation, you were able to at least get some forward movement.

NB: I don’t remember the sequence of events – I may have talked to the lawyer who was the Assistant General Counsel of HHS for CDC – but I’m sure that Mrs. Harris, possibly at the request of Jere Goyan but certainly with my involvement as well – talked to Bill [William] Foege, who was the head of CDC at the time and asked them – told them – to cooperate with FDA, that we had to take the lead because we had the only authority.

I’ll just mention in passing that I wasn’t sure then and I’m not sure now that tampons and sanitary napkins are medical devices. But FDA had asserted authority over them in the classification process and it [was never challenged.] Proctor and Gamble, which manufactured Rely, chose, I think wisely, not to argue about whether it was a medical device or not. If it hadn’t been, they would have had to go deal with the CPSC, which would not have been as smooth and productive for them as dealing with FDA turned out to be, given the situation.

CC: Well, it’s interesting you should mention the status of tampons and menstrual pads because I was going to ask you had they been classified and you’re saying they had been classified as part of the classification process under the Medical Device Amendments of 1976.

NB: At least preliminarily they had been classified.

NB: One of the things that I learned in private practice is that all sorts of things were classified that made no sense to be medical devices and that if the companies had had any sense, they would have objected to the classification. For example, I actually worked on the classification document for a few things like treadmills when I was here, and we sorted it out so that only the treadmills that were intended to prevent, treat, or mitigate the disease or diagnose disease were medical devices and that other treadmills were not. But I never understood why industry allowed some of these things to be classified as medical devices, not just tampons and sanitary napkins.

In any case they had been classified, they were, and, for whatever reason, P&G nor any of the other companies ever chose to contest that in the context of toxic shock, and once that was done, it was done, they were medical devices. So the first thing that I remember at least – I know from some of these other oral histories that there were things going on that I don't know that I knew about at the time, but in any case, if I did I don't remember them – a bunch of FDA people went down to CDC to talk, I guess, to Bruce Dan and Kathy Shands about what they had found, what their data showed. The people who went, as I remember it, were from the Bureau of Medical Devices, and maybe – I don't know maybe – Bev Chernaik went with them, I don't remember. When they got back to the airport and they stopped at a drug store and bought a whole bunch of tampons, different brands, Rely and a lot of other brands and they brought them back to this conference room at HHS – it must have been Jodie's conference room – to have a meeting. And one of the things that I remember is that a lot of the men looked like they'd never touched one before and they're handling them like they were grenades, you know. And women

know which end you open, you know, so that the thing doesn't fall apart, but they didn't seem to know that, so there was quite a lot of this – it is irrelevant to the legal story, but ...

CC: No, it's not irrelevant. This is the part of the story that's not captured. We want to hear and record this.

NB: It was just funny. At that meeting, there was a great deal of speculation about what might have caused the problem, whether it was the applicator causing abrasions in the vagina, something like that, whether it was ... speculation like that. And, of course, not all the tampons were the same and – I don't remember – different brands had different kinds of applicators, so there was some discussion about that. But basically that preliminary meeting was to try to start to try to figure out what to do.

At some point – I don't think it was at that meeting – at a later meeting with Secretary Harris she said “Well why don't we just ban tampons?” And I said “No, we don't want to do that.” And she said “Well, there are alternatives,” meaning sanitary napkins, and I said “No, not really.” And I don't know how many years older than I she was, but I was quite sure that there were no alternatives, and I have always said, and I'll say it for this oral history, that I've always thought that women should have access to every job there is. But that was almost, it's the only time I can remember in my career where FDA's Chief Counsel's being a woman and being me really mattered, because without that who knows, we might have banned tampons. Okay, so anyway, we didn't do that.

CC: Let the record reflect that I'm grateful. (Laughter)

NB: So together with various lawyers on my staff, we started looking into what the alternatives were for legal action.

CC: Do you want to say who those lawyers were?

NB: I know Arthur Levine was involved. And I keep thinking Bev Chernaik.

CC: She was doing device work then and I think Mike Landa might have been involved. He remembers working with you on TSS.

NB: And as I mentioned earlier, the Medical Device Amendments were relatively new, but they had two provisions that were really important. They had an imminent hazard provision, which allowed us to get an injunction against further distribution, and they had a repair-replacement- recall provision, which was pretty much like the CPSA provision that had been passed, the Consumer Product Safety Act provision, that had been passed just a few years earlier.

And at the same time the medical device people were doing this, I have this recollection that Mark Novitch and probably Stuart Nightingale – I'm not sure – who was the Associate Commissioner for Health Affairs, were also talking to CDC about their data, their study, their case control study, and how solid it was and so forth. The other thing that happened is that we held a meeting. Paul Hile and I ...

CC: Who was the ACRA at the time?

NB: Yes, he was the Associate Commissioner for Regulatory Affairs at the time. And, by the way, one of the great civil servants of American history. He had come out of the field and he had this wonderful balance of knowing what the field did well, what headquarters did well, and how to meld them and he knew a whole lot about a lot of stuff at FDA and how to make everything work. And he was just sensible and wise and smart.

[DR-100-0032.wav at 1:40:06]

And so Paul was a very good person to live in a foxhole with, as I did with him and Gerry Meyer on the Marvin Seife business. And he was also doing a lot of the coordination of the various pieces of FDA – Bureau of Medical Devices, Chief Counsel – on toxic shock. And I remember a meeting that we had with FDA and CDC and P&G. I don't remember that there were other medical device, other tampon people there, there may have been, but I don't remember, and trying to figure out how to proceed here, what we were going to do.

And both FDA and CDC wanted to inspect the factory and they were going to go separately and P&G said “Well can't you come at the same time, so we can have one inspection and get it done quickly?” And at first the FDA people and the CDC people who had never been anywhere together and I don't think they'd ever even dated. (Laughter) They were saying no and I was sitting next to Paul and I turned to Paul and I said “The FDA people have to agree to this, right?” I don't know if there's anybody from CDC there to make them agree, but I knew I could deal with that later. And Paul agreed. So we said to P&G “We'll work it out, FDA and CDC will come at the same time.” But that was a perfect example. And that wasn't so much

rivalry as just bureaucratic norms. They'd never inspected with FDA before, they all thought they would be looking at different things and it didn't occur to them that they should all be looking at the same things. And as it turned out there was nothing to see. It wasn't a contaminant in the manufacturing process which in a way would have made this all a lot easier and less complicated. So that happened.

So we – the Chief Counsel's Office – decided that the data that CDC had was enough to satisfy our burden of proof under Rule 11 [Federal Rules of Civil Procedure] that requires you to think about whether you really had a decent case – you don't have to know you're going to win but you've got to know you've got a decent case. By that time I was conducting the discussions with P&G, which were with Tom Laco, who was an Executive Vice President, he was a very high ranking guy on the consumer product side of the business, and Powell McHenry, who was their general counsel.

CC: What's his name?

NB: Powell McHenry. M-c-H-e-n-r-y. And so I said to them "Look, you need to recall these tampons." In the early stages of this, P&G had put up a little bit of an effort to contest the CDC findings and argue that it wasn't really happening. But at the same time that they were doing that, they very quickly started talking to us, and I was the one who was talking to them. And I said to them, "Look, you've got to recall these things because I'm prepared, I'm satisfied that we have enough here for me to go into court in Cincinnati and bring an imminent hazard case and we're working on the papers. And they said "No, no, don't do that." And I think wisely so. I think we had a very good chance to win such a case, but even if we hadn't, Congress would have

either acted to give us the power quickly or the public reaction would have been terrible. I mean we were careful about it. I really was. We poured over that statute.

CC: It occurs to me that – I'm sorry to interrupt, but my recollection is that Beverly Chernaik handled the recall- replace-refund – the triple R – regulation. So she might have been involved for that reason.

NB: I know Arthur Levine was at some of the meetings because he didn't entirely like what I was agreeing to. In any case, so we started negotiating this recall. And as I mentioned, I had done a lot of CPSC recalls and the famous recall under the Radiation Control for Health and Safety Act, whose provisions were, I think, generally similar if I remember correctly. Or maybe we just did it voluntarily and used the CPSA as a model. So we started negotiating this recall, and I also knew a lot about advertising from my FTC days.

So we started making lists of things that they [P&G] would have to do and how they were going to do this recall. And one of the things that was really important about it was that we insisted and they agreed that they would send out the notices to the wholesalers and the wholesalers would send out notices to the retailers and P&G would have to pay for everybody to do all this stuff so that the notices would actually get to the retailers.

And that was novel in the FDA world. I mean, the intricacies of the relationships between the manufacturer, the wholesaler, and the retailer, which I knew a fair amount about from my CPSC efforts in private practice and then how to, I think, this recall had advertising in it as well, if I remember correctly, we made them recall, and stop advertising, and a lot of stuff like that. So this recall was all encompassing.

I mean it was, all the things that maybe hadn't, certainly hadn't been done right with, couldn't be done right, with Elixir of Sulfanilamide, and all the things that maybe had or hadn't been done with the infant formula, this was a very comprehensive recall. And a lot of things were specified in very minute detail. When I look at it now, I think "Hmm, maybe it was a little bit overreaching actually." But it's okay.

And they negotiated very quickly. They knew they had to, you know – once they decided to do it, I don't think those negotiations over the terms of the consent agreement took more than, I think less than a week, and maybe less than that. I don't know. They basically stayed here [in D.C.] until we got it done. I don't remember if I talked to the Secretary or to one of her people but they basically wanted to know that we had covered everything. I said "Yes, we've covered everything."

Paul [Hile] and I were downtown, after I did that, we were down at FB-8, which is the Federal building where FDA hang out, across from HEW's headquarters. It's where the Bureau of Foods was, too, at the time. But the Commissioner had a suite there. And Paul Hile and I are the ones who signed the agreement, and Tom Laco and Powell McHenry signed for P&G. I remember Laco saying to me "Do you have the authority to sign this?" And it was a perfectly reasonable question. I said "Yeah, do you?" And he laughed, he said yes. So we all signed it and that was that.

The one thing, one of my staff members was very unhappy that I allowed P&G to not admit liability – in fact, allowed them to deny liability and just say that they were doing it to settle. He really wanted an admission, and I didn't think it was necessary. I didn't see any reason that FDA had a role in protecting them or condemning them. Either way the product is a liability.

And so I didn't do that and I know he wasn't happy about it. But I do remember, as I mentioned earlier, that when I got to the next policy board meeting of the Commissioner and his senior staff, John Villforth, who had been the one with whom I'd negotiated the TV recall, did say, "Well, now you hold the record of the two biggest recalls in FDA's history."

CC: That's interesting.

NB: One on each side. But I think FDA really showed its ability in that case to move quickly. I recognize, and I've been thinking about everything in retrospect, the data on which we acted were not the kind of data that would get a PMA [Premarket Approval Application] approved for a device or an NDA [New Drug Application] approved. On the other hand, when you have people dying, you have to think about how good the evidence needs to be, and we were satisfied that it was good enough, that CDC didn't go into it with any bias. They were just trying to figure out what was going on. And so it was at least unbiased.

After we finished with P&G, people started thinking about the other tampons and wondering whether – they still didn't know what it was that had caused the problem – and the counsel for one of the other companies called me and said "Listen we all need to talk to each other about what this problem might be and it's going to be harder for us to do that without the agreement of the Antitrust Division at the Department of Justice for all these companies to talk to each other. Will you come with us and explain to them that FDA wants this to be done?" So I did. And it was another one of these funny meetings that all of those outside counsel for the other tampon companies were male and the Assistant Attorney General for the Antitrust Division, Sandy Litvack, was male. We go to this meeting and we're talking about all these tampons and

by that time, the company counsel were getting pretty used to it, but Sandy Litvack had that look on his face like “I can’t believe this is happening to me. I’m discussing essentially an antitrust – it wasn’t a waiver – an antitrust blessing for tampon companies to talk to one another.”

(Laughter) It was just funny.

CC: Do you remember, was it during your tenure that the other companies’ products were scrutinized? I think the ultimate conclusion from what data were assembled was that other tampons contributed to TSS but not at the rate that Rely did, so that led to the tampon labeling.

NB: Yeah. This all happened in September/October of my tenure and I was gone by January 20th, so I don’t think we had made much progress on anything definitive about the causes of the problem. And most of the rest of it happened later.

CC: Right.

NB: I just want to go back for a minute. I’m just glancing at the summary of the consent agreement. It does require a consumer notification program, so that’s where my advertising experience came in handy. And I remember that the full agreement, for example, required that they use the same media and it was something like the same frequency that they had advertised Rely in the first place, so what we were doing was relying on their own research and behavior with respect to the promotion of Rely to define the audience that ought to see the materials – the ads – for the recall, which is pretty elementary. That all came from my advertising background at the FTC.

CC: It's interesting that three or four different facets of your background at all come together when you dealt with this problem.

NB: Right. And partly for that reason, I mean obviously it wasn't good that P&G made Rely tampons that caused all these problems or probably caused all these problems, but once they decided they had to deal with it, they dealt with it and it proceeded smoothly and quickly. I don't complain, I never have complained, about P&G's behavior once they realized what they were doing.

CC: I've seen, through my involvement with a couple of foods matters, that companies realize – smart companies realize – they need to protect their brand and whether the evidence is clear cut or equivocal or whatever, they are going to take action.

NB: I think that's often true. But it also raises questions about – speaking now as somebody who also spent a long time in private practice, much longer than I did at FDA – there are a lot of things that companies acquiesce in in their dealings with FDA and, for that matter with other agencies, that they may think – or maybe do – protect the brand in some sense but they give the agency far more license and far more power than it really ought to have, because the agency's wrong. And companies can live to regret that, because especially if one company's always caving in, even though they don't really need to and FDA doesn't have the authority or is factually wrong, then everybody else looks worse.

CC: Right.

NB: So, yes, you're right, a lot of companies will act very quickly to protect their brand, and should, but FDA's not always right, so I'm not so sure.

CC: Well, I guess I don't mean to say that whenever FDA raises the flag that companies should go directly and promptly without thinking or evaluating the evidence to protect their brand, but I think that's an incentive.

NB: I think FDA thinks they should. I think FDA much more so than the FTC from beginning to end, concluding yesterday and probably it's happening today, except we don't know about it, FDA is much more inclined, institutionally, to think that companies should just do what FDA tells them, period, the end.

CC: And I'm not in a position to dispute that with you.

NB: And I think that leads to bad habits on the part of FDA and on the part of companies. But that's a different question for a different day.

CC: And why is that?

NB: Part of the reason is that FTC is run by lawyers and lawyers are institutionally used to there being another side and to both sides probably having something to say and for somebody

else to resolve it. FDA isn't run by lawyers, and 98 percent of the people who work at FDA aren't lawyers, and they're much more into the exercise of power, expecting not to be challenged. I don't think that's good for FDA and I don't think it's good for the companies. But anyway it's another issue for another day.

CC: I don't know that it's for another day – my silence is because I'm the interviewer not because I disagree.

NB: That's fine. Most people do disagree.

CC: I think it's interesting to think about the different mind sets. That is, if you are a scientist, you believe that you have – this is an over generalization – you have data and the data are empirical and therefore, you're right. And I would completely agree with you that, as a general rule, lawyers know there's more than one side to an issue.

NB: Right, even in many scientific issues there's more than one side. I mean, among other things, since FDA's operating under statutes and regulations, the question of how much of what kind of evidence you need to make what kinds of decisions is both a scientific question and a legal question. I wasn't kidding when I was talking about toxic shock that we not only looked at the statute but thought hard about whether the data we had were an appropriate basis to bring a case. I think all lawyers are required to do that by Rule 11 [of the Federal Rules of Civil Procedure]. But you can take this more seriously or less seriously. Most of the decisions to

proceed at FDA, they're not made by lawyers. They're not made in the litigation context, they're in some other context.

I don't deserve any special credit, I don't think, for thinking about the role of Rule 11 in the first imminent hazard case. I mean, there were reasons not to bring the first imminent hazard case under the Medical Device Amendments and go down in flames. That would not have been good for the institutional authority of the Agency to bring the next imminent hazard case, even if it were a better case, let's say.

I don't know that the government should be thinking in terms of winning every case it brings, but the first case you bring under a new statute you really should think about it. I mean, if you have a reasonable basis to bring it, you may decide to bring it even though you're afraid you might lose but you know there are various questions like that. I think FDA scientists overstate both – not always – I mean there are lots of people at FDA who continue to think about what the other side might look like. But I think institutionally, there's a tendency to not want to think about the legitimacy of the other side, even in the scientific context, nor to think about the legal standards and whether they have to be as high as they're being set and the policy implications of setting them higher than the statute requires. Those are important questions that I'm not sure are thought about enough at FDA institutionally today. But let's leave it at that.

CC: I want to ask one more question about toxic shock – about the agreement. What was the enforcement mechanism for that agreement? What if P&G had said we know we signed this, but, what if P&G had violated it? Or P&G hadn't done what the committed to do. How were we going to enforce it? I'm asking because the agreement wasn't done in the context of a judicial proceeding.

NB: No, but it was done under ... it had an enforcement mechanism built into it so that if they had violated it we could have gone to court and seized the products or ... So it was enforceable.

CC: Well, I don't want to quibble, but maybe not. By that I mean that the terms might not have been enforceable, but you could have, you weren't precluded from taking an enforcement action under the FD&C Act.

NB: Yeah, but both were true. Is it section 518, the recall, repair, replacement provision? I don't have it in front of me, but it has some self-enforcement, as I recall, it has some self-enforcement provisions.

CC: It's almost noon, so why don't we take a break.

[DR-100-0033.wav]

CC: Following a break, we're resuming the interview of Nancy L. Buc, former FDA Chief Counsel.

Nancy I'd like to turn to another substantive project that you were involved in while Chief Counsel, Alpha Fetal Protein Test Kits, AFP, and maybe you can talk about where that issue stood when you came to FDA, what your involvement was, and any other recollections you have about AFP.

NB: This issue involved test kits that would diagnose alpha fetal protein [AFP] levels in pregnant women using blood samples. AFP was a marker for a possible neural tube defect and in its worst form, spinal bifida, in the fetus. And until these test kits came along, and of course diagnostics and medical devices, the only way you could get at AFP levels was, or through a marker for spinal bifida and neural tube defects was through amniocentesis, which could only be done relatively late in the pregnancy. But AFP tests could be done relatively earlier in the pregnancy and, as it happens, and also relevant, at a stage where abortion was much more feasible and doable if that's what the woman decided on.

By the time I got to FDA, FDA had put out, I don't remember if it was a notice of proposed rulemaking, or an advance notice of a proposed rulemaking, to decide how to go about regulating these test kits. The reason that they were thought to be a very special regulation was that in the first place, you couldn't do the test just once; rather, in order to be certain, you had to do a confirmatory test. And the two tests had to be separated by – I don't remember – a month or so, or two weeks or so. So you needed to do two of them and the data were hard to interpret because this was a genetic problem.

FDA had proposed that, and they were hard to read and they were a tricky business and the information wasn't 100 percent clear cut – there were false positives and false negatives and all kinds of stuff floating around. So FDA had essentially proposed, if I remember correctly, that these tests could only be used or sold to university kinds of clinics where they had, not only an obstetrician, OBGYNs, but also genetic counselors. There was a requirement for genetic counseling information for patients, and all kinds of heavy duty regulatory stuff. Part of the reason for all this was because the information wasn't clear cut, and FDA was very unhappy at the idea that a woman would make a decision on the basis of imperfect information – for

example, if she decided to have an abortion after the first test, before she got confirmation or even after the second one, without genetic counseling, without all this stuff.

And the comments were in and FDA was working on a new, I guess they thought they were going to be working on a final rule, and I looked at all this stuff and I was really very unhappy with a lot of the pieces of the puzzle. It seemed to me that what it betrayed was an over-medicalization and over-regulation of a test kit which was what it was, it wasn't perfect certainly, but it provided very useful information. And it was mostly in the context of trying to prevent a woman from doing something that the FDA people and a lot of the commenters thought was stupid – particularly that a pregnant woman shouldn't be thinking about having an abortion on the basis of all this imperfect information when it could be made better with the help of all this regulation. In a way, it was a classic of a combination of, it didn't literally say this, but women are idiots and can't be trusted to make decisions unless they have all the information that the men around them want them to have. In fact, I think one of the comments or one of the criticisms of what we later did was that a woman shouldn't be allowed to decide to have an abortion without the agreement of her partner or husband or male partner. And mind you, this was after the Supreme Court had already decided that that was an unconstitutional burden on the right to abortion. There was also a very heavy overlay of “women shouldn't be running around having an abortion just for spinal bifida, that she shouldn't be allowed to do that for this condition.”

CC: I'm sorry for the interruption. Isn't spinal bifida a fairly significant birth defect?

NB: Yes, it could be. And some of the kids were born anencephalic, i.e., with no brain. This was not trivial. And even if they had a brain, it wasn't necessarily a very functioning brain. And even if the spine, even if there was a full brain, the spinal bifida could be profoundly crippling. And in any case, by that time, the law was that women could have an abortion for any reason or no reason. And so for FDA to load this thing up regulatorally, for those kinds of reasons, seemed to me to be inappropriate.

CC: Let me just ask you. Who were the proponents or what was your impression of who the proponents of this approach were, whether an institutional or individual?

NB: I don't remember. The only person I remembered at all was Don Beers, who was the lawyer working on this regulation. And I don't know why he was working on it since he didn't do devices as I remember. But in any case, I don't remember that I ever met with the Bureau of Medical Devices people. Maybe I did – I just don't remember. But the other thing that really bothered me about it was that it's certainly the case that genetic counseling has proved to be difficult and, to this day, you see articles in *The New York Times*, *Consumer Reports*, *Science* magazine, *JAMA* [the Journal of the American Medical Association], and the *New England Journal [of Medicine]* about how difficult it is for most clinicians to deal with the odds that this is going to happen and what the genetic background is and all that kind of stuff. So I don't minimize it. And on the other hand, when I read this stuff about how you did the genetic counseling for AFP, I remember saying to Don "you know we've just come through the Vietnam War period, I mean this isn't any more difficult than draft counseling, and that was done

routinely by amateurs.” And that was one of those things I was probably justly famous for. Maybe I shouldn’t have said that but it was also true.

CC: Well, they are both decisions in an ethical context.

NB: And I was also concerned that limiting it so intensely to university medical centers was going to deprive most of the world of access. It would be nice if you lived in New York or Boston or San Francisco but if you lived in most of the country, you’d have no access to any of this, and especially since you had to go back for a second test. And then there was the counseling requirement. So I wasn’t too happy with the whole thing.

The other thing was that everybody said well you could just have amniocentesis. But as I’ve mentioned, the amniocentesis couldn’t be done until later in the pregnancy. It didn’t work until later. And it was invasive and if you weren’t going to have amniocentesis for any other reason, which you might not – not every pregnant woman had amniocentesis – there was no reason for it. And it had its own problems – some percentage of interfering with the pregnancy. And if it happened too late to have an easy abortion – not that any abortion is ever easy, but a medically easy abortion.

CC: Right – during the first trimester.

NB: First or even early second, I think. I forget when amniocentesis was done. So I tried to figure out what we were going to do about this. What we decided to do was to issue a new proposal which raised all the questions that I wanted to raise and have another go around. I think

we started to do this when we still thought we probably were going to win the election. I'll come back to that later, because this was the fall of 1980. And so FDA put out a new *Federal Register* notice before the end of the year, sometime in 1980.

CC: November 7, 1980.

NB: So it must have been right around Election Day.

CC: Right.

NB: In which we raised all the questions that I wanted to raise about it: is it really a good idea to do it only at university centers, because that would cut off access or is it okay to do it at places that can just provide all the necessary services one way or another? I don't know that I thought of genetic counseling by phone – there was no Skype – but, for example, is the genetic counseling really necessary at all or does it have to be done by somebody who's certified and certified by whom? And just asking one question after another about both the benefits and the risks or costs of doing it the way that FDA had originally proposed to do it.

And I figured that what would happen (which is what did happen) was either we would collect all the comments, but at least they'd now make some sense, because we had asked questions that invited people to really think about this stuff instead of just sort of mindlessly calling it over-regulation or insisting on all of it. I was hoping that we could get a better set of comments and, in any event, then we could think through what to do about it. As it turned out, we would leave it for the Reagan Administration.

And it was the case that of course they won the election and we left it for them. And it did somewhat amuse me that it left them with their choice of what was obviously over-regulation or worrying about abortion, and I believe in the end, they chose to go the route of cutting back on the regulatory regime so that it became somewhat sensible. The other thing that we did was that we drafted consumer information to go with the kits so that the woman – I don't remember if that had been proposed in the first place – but we did draft a consumer, a patient information piece. This was after we'd already issued the patient package insert regulations, which we'll come back to, I know, which I think I did the draft of. Do you have the *Federal Register* notice?

CC: I do. Do you want to look at it?

NB: Is there a draft patient information?

CC: Yes, there is.

NB: I worked really hard on that. It is hard to boil everything down to fifth grade or sixth grade or whatever and still provide really good information. I know it's not easy and I'm sure what we drafted wasn't perfect – I don't know how close it came to what was ultimately adopted - but we tried really hard so that the woman herself would have an opportunity to make decisions for herself with whatever information she chose to get and what advice she chose to heed. But it was her decision. It wasn't anybody else's decision. And the consumer information – the patient information – was intended to facilitate that. It was a useful lesson in how hard it can be to do it, but it didn't change my mind at all about how important it is to try to do it. That was an example

of simply, I mean maybe it's the second case after toxic shock where it mattered that the Chief Counsel or somebody involved in the process was a woman and had had occasion to think about abortion in a way that maybe not everybody else had had a chance to think about it.

But in any case, I know it was a byproduct of just trying to bring some common sense to the whole thing and not trying to substitute other people's judgments for the judgment of the patient, the woman, who was going to have to make all the decisions, whether to have the procedure at all, what to do with the information, and what to do with the pregnancy and not let the system overload that with what they wanted her to do.

So I was and I am proud of that effort, just as a way to try to make the regulation, I mean I think we did need to have regulation, I don't think they should be put on the market with nothing, but I tried to make the regulation sort of responsive to the common sense of the whole thing from the perspective of the woman, rather than from the perspective of the medical system. I mean people talk a lot today about over-medicalization of some diseases and maybe that was an example of regulation – over-medicalized and over PhD'd – regulation. It was just too much.

CC: Was there any involvement from the Secretary on this?

NB: I don't remember. I know that ... it may well be that the Commissioner and I talked to her about it, at one of our regular meetings with her. I don't remember.

CC: Anything else on AFP? It is interesting that there was such a concrete view about how this information would be delivered, processed, and, as you said, it seemed to be very restrictive and not honoring the person who was the one that ultimately would have to make the decision.

NB: I don't think you should be so surprised. I mean if you think about all sorts of issues of the Bureau of Biologics, the Bureau of Medical Devices, and the Bureau of Drugs – or the Centers as they now are called – have had to deal with and how they feel about home use of medical devices, home use of diagnostics, and even OTC therapies, most of them – in medical devices there are more engineers – but most of the people who are thinking about these things are physicians.

And this was in an era – which still persists but it was much more intense and endemic then – that the doctors were making the decisions, not the patients. They didn't think in terms of saying to a patient “Here's what we know, here's what we don't know, here are the benefits, here are the risks, you decide.” They told them what to do. I mean that was in an era where patients weren't always told they had cancer. I mean we weren't done with that yet. This was just a particular example of it in a context which also involved abortion, which seemed to make people crazy in a way that I think it probably still does. But the idea that it was, I mean, it only been a year or two since the Supreme Court had decided. I think it was the Pennsylvania case where the question came up about whether the woman had to get her partner's or it was assumed to be her husband's consent and because it was the husband he was thought to have a bigger stake in the decision, more than just some random partner of a single woman. And I don't remember the name of the case was. I think it was in that six to three case out of Pennsylvania with Justices Souter and O'Connor, basically voting to preserve the right to abortion. I didn't reread all that stuff but I bet if reread the AFP stuff, it just reeks from the paper. As I recall, Sid Wolfe was critical of a lot of it because it left the woman too free to do abortion and he is, after all, an MD.

CC: So this was a product of who was playing and the era of the culture in which they were playing.

NB: It was also a product of a kind of thinking which we've talked about before – if you can over-regulate it, you might as well, why not? People at FDA then, and to some extent now, weren't thinking in terms of “If you limit it to universities then big time docs get to play, but you've cut off access to at least half, if not more, of the population.” And they just didn't think in those terms. And the same with the genetic counseling, I mean, genetic counseling was sort of new – it was like a new toy and everybody thought “Oh, that's good we'll have a [counseling requirement.]” If I remember correctly, they wanted the genetic counselors to have a particular kind of certification. FDA was always big on licenses and certifications and stuff like that, whether or not they were any guarantee of quality and the performance of the services. We're going to come to this when we talk about the DES and the cattle. With that issue, FDA and USDA wanted the DES tags to be removed from the cow's ear only by a licensed veterinarian or somebody who had a particular licensing – perhaps a USDA- licensed veterinarian. It's a simple little procedure – it was analogous to this genetic counseling thing. I had come from FTC where we had done a lot of work on state over-regulation, of licensing – of TV repair people, cosmeticians – and whether the licensing made any difference in the quality of the service. So I had that kind of logic in mind when I was thinking about whether the genetic counselors had to have some particular certification. Hence the joke about the draft counseling.

You've put your finger on several of the issues, but partly, it was just that they didn't even think in terms of over-regulation and enough regulation, they didn't think in terms of the patient's autonomy rather than the whole system telling her what to do, and they didn't think in terms of access, to make it available for patients. I mean, maybe some people did, but it sure didn't show up in any of the drafts I saw.

CC: I think that one of the chronic limitations of FDA – and this is also one of the strengths – is that a lot of the employees have been here a long time. I know in my own work on juice HACCP, our initial proposal would have been much narrower if we had had anybody who had been in the industry and dealt with shelf stable juice. But I think you're right that there's this mentality "If we can do it, if we think we can sustain it, we're going to do it."

NB: That raises a much broader issue. We joked about whether I had any conflicts when I came in or I joked about it. And I didn't.

CC: And I laughed.

NB: But as lawyers, we know a fair amount about how to screen for conflicts in terms of particular matters and particular issues and so forth. But even more so now than was the case then, there's this notion that nobody at FDA should almost ever have worked in the private industry in any capacity, and various people have taken a lot of criticism because they worked in industry.

CC: Some people get their names in *The New York Times* editorials.

NB: Right. And some people have been completely disqualified, for example, as Commissioners simply because they had worked in a pharmaceutical company or been lawyers who represented the pharmaceutical companies. I understand that there's potentials for certain kinds of bias and certain kinds of conflicts, but the result is that – as you say – there's hardly anybody at FDA that has much other experience, not hardly anybody, but there are too few people at FDA who have any other experience, even at another Federal agency.

This means it's difficult to do two things. One is to realize that there's more than one way to think about things, whether you know the facts or not, and the other is to actually have some real world experience doing something. I would argue that, for example, my experience in industry made what I was able to do with the toxic shock recall far more effective, because of that experience. I know a whole lot about recalls. That's a good thing, not a bad thing. It's less true more recently but many of the Chief Counsels did have private sector experience of one kind or another, teaching, private practice. I think it helps FDA to have that kind of breadth.

CC: Well, I don't know about Billy Goodrich, that's before my time. But I think actually every Chief Counsel, with the exception of Margaret Porter, had some private sector experience. And the current Chief Counsel, Liz Dickenson, does not.

NB: As Liz always tells us, the summer before she went to law school – before she came to FDA – she was working in a canning factory in Alaska.

CC: Right. So that's her private sector experience?

NB: Right. And again this is not in any way a criticism of any particular person who hasn't had that experience, because what can substitute for it is the realization that you don't know everything there is to know and either read all the comments or meet with the company and listen to them and think about the possibility that they might know something that's useful or even that they might be right.

CC: For me, one of the important things you've pointed out – and you don't have to have worked in private industry to think about – is the idea of patient access.

NB: No, you don't. But part of how you think about ... again part of it was the experience at the FTC where you think about competition and competition policy and some of it may have come from that and some of it probably comes from the FTC's emphasis on consumer information. The FTC was much more focused on providing the consumer with the information that they needed to make their own decisions.

CC: As opposed to providing information to the medical professionals?

NB: As opposed to somebody making the decision for them, whether it was the company or professionals.

CC: Do you think that this problem, this limitation, has evolved at FDA?

NB: It's gotten worse. It's gotten much worse. It's much worse.

CC: And why do you think it's much worse?

NB: It's much worse because there's more hostility to industry – not just disagreement, but hostility. There are a lot of people at FDA who think that industry's just plain evil.

CC: And that's a generalization across the board regardless of the product area?

NB: Yeah. I want to be careful about this – it's not true of everybody. But it's true of many. And one of the places that you can really see it is with advisory committees. In some ways, it's a reflection of the journals. I mean, the *Journal of the American Medical Association* and the *New England Journal of Medicine* require all sorts of disclosures about what your commercial ties are. And that's true for FDA advisory committee members as well. But nobody ever worries about the academic who is so hostile to industry and is so deeply dug in that they're just as biased in one direction as any industry person could possibly be in the other.

CC: Is there a way to root that out with the academician? I know this really isn't history but this is fascinating.

NB: Well, I don't know. The question is ... To me, the question is does the process find ways to ask the people during the process itself, "Are you really dug in? Are you dug in and why or are you capable of listening?" It's sort of like jury qualifications.

CC: I was thinking of *voir dire*.

NB: Yeah, *voir dire* for juries. I don't know how to do it for FDA or for advisory committees. But I have no doubt that because the standards for ... I mean, transparency is important and I'm not saying that all of these conflicts should remain, or all of these interests, commercial interests should remain undisclosed. That's not my argument – it never was. They should be disclosed. The question is should FDA really not hire, should the Commissioner really not ever have been in industry? Should this one, that one, the other one never have been in industry? Is that really good for governance? It's not. And I think FDA's management could do a much better job than it does of talking to the staff about the importance of listening to the other side. It's okay to disagree and ultimately, of course, FDA has all the chips. Ultimately, they get to decide on anything that doesn't have to go to court where there's a judge.

CC: Right.

NB: They get to decide on NDAs [New Drug Applications] and PMAs [Pre-market Approval Applications] and BLAs [Biologic Licensing Applications], and things, food additives, whatever. They get to decide. They have all the chips. But before they get to exercising and making that decision, they should be asking themselves and should be forced to ask themselves "Have I

really thought about the other side?' Many of them do. This is not everybody I'm talking about here. There are a lot of people. And I'm not saying that FDA's people shouldn't have strong views about how things should be done. Of course they do. And they're in the best position of anybody to see that certain things that industry tries to do are always a bad thing.

That's not ... I know in private practice that I occasionally found myself saying to my clients "Listen, you know FDA's right about this. There are some things that you just shouldn't argue about. Of course FDA's right. There are 50 cases that say that."

CC: Right.

NB: Or "There are 20 PMAs where this has been decided and should be decided that way." I'm retired now, but I'm not alone in private practice in telling clients when FDA's right. I mean, for one thing, they shouldn't spend a whole lot of money fighting about silly stuff or stuff where they're going to lose and deserve to lose. But I'm not so sure that there are many people at FDA who tell their colleagues "You know, the industry's right" as there are private lawyers who tell their clients that FDA's right. Maybe there are, but I'm not so sure.

CC: One of the things that's different about being a lawyer at FDA is that you have what I used to characterize as a "professional client." And whether or not it's true, they purport to know more about the technical aspects than the lawyer does.

NB: Well, that's true, they may well. But that's not the end of the matter.

CC: No, I absolutely agree. I'm just saying that it becomes harder to say to somebody "You're wrong about this." I think the most I was ever able to do because I didn't have a technical background was to push people with questions. I'm not trying to justify what goes on.

NB: But a lot of what FDA has done, especially in the last 10, 20 years, has been to try to argue that all the decisions that they're making are purely scientific issues. And that's very clever of the scientists because what it does is it has the effect of keeping lawyers out of it, keeping the law out of it, keeping policy out of it, and importantly keeping Congress out of it. But as we've discussed before in this interview, the decisions are not purely scientific issues, they're scientific issues being decided under a statute or under regulations, most of them are. Some of them aren't even that. They're just decisions that they make. And to say that it's all science converts the whole thing into something where nobody else can have anything to say except them and they're both prosecutor, judge, and jury. And it may well be that they're often or even mostly right about the science, although I wouldn't concede that, it's certainly not true 100 percent and I hope they wouldn't even claim it's 100 percent, but many of the decisions that they want to talk about as science aren't science.

Let me give you an example not in drugs. All the debate about, much of the debate about nutrition labeling and particularly health claims and how much data and what kind of data you need for health claims for foods, qualified health claims, and also actually, and I know this is relevant for you, what is and isn't a dietary supplement, are not only science questions.

Although there is no question that there's science in there, they're science policy questions about how much should you want for health claims and how much should you, what should the disclosure or what should the health claim look like and what kind of information is

useful to consumers and do you really want for a product that is almost by definition safe, recognizing that nothing is absolutely safe, but has relatively little risk, how much data should you need to have and of what kind to make what kinds of claims?

Those are partly science questions, the quality of the data, and to some extent the importance of the claim, but mostly they're science policy questions. And FDA had often tried to act as if they're purely science questions. And the same is true in other areas of regulation – for drugs, medical devices, biologics, for example in the promotion area, lots of other areas where the judgments, even for an NDA.

We've talked about this, I mean, substantial evidence is defined in the statute, it has a lot of meaning. FDA has been able to work with it as it has traditionally been able to work with most statutory definitions. But it's not always easy or even possible to get the FDA scientists to think about the possibility that they can interpret those words in a different way for policy ends that are worth having and still be compliant with the law.

CC: We were just talking about AFP. Do you think that was an issue with AFP where you have a certain construct? And maybe it wasn't with AFP, but I'm trying to take this back to what you encountered when you came to the Agency – that there was a certain framework or construct but an inability to see that there was some give in that construct.

NB: No, I don't think so. I don't remember arguing with anybody about whether the AFP regs in any form would have been illegal. I guess the question was how to restrict them, they were restricted devices I guess if I remember, vaguely guessing in retrospect.

CC: That's probably not a good example.

NB: What the issue might have been. So, no, I don't remember that particularly. And I don't remember, most of the substantial evidence debates had been had, in various NDA cases, I don't remember having to deal with that. A lot of what I'm saying now isn't history – it's what I think now, and it's the product of course of having represented clients and some I won and some I lost and some were called on account of rain. And again I don't argue that every time my clients lost that FDA did the wrong thing or that it amounted to what I'm talking about.

[DR-100-0033.wav at 00:40:06]

CC: But I think what you're saying is important because you have had a history both of working in the Agency and working with certain people who continued to work in the Agency. You left in 1981, and I believe Mr. Hile retired in 1986. So somebody that you knew and you knew how he thought was still here. I mean this is all to me building on your history.

NB: And again there are lots of people here who I think are extremely good at what they do and take into account all the various pieces of the puzzle. This is not, and it's not meant to be, a blanket condemnation, but there is an institutional tilt I think in trying to make everything be science so that lots of people with other perspectives are excluded from the thinking process. And I don't think that's a very good idea. And I also think that there's a tendency to, there is a tendency to think that only FDA people are the appropriate arbiters of the science. And that's ... I mean, ironically it's sort of unscientific. I mean, the basic logic of science is you do a study,

somebody else does a study or tries to confirm it. Intellectually, in science, there should be another side. And it's not ideal when the FDA people are representing all sides and there's really only one side.

CC: And it's not ideal when there's not an openness or trust to, for example, have a collaborative discussion about what certain data mean.

NB: When I was Chief Counsel, I met with almost anybody who wanted to meet with me, whether the issue was strictly legal or whether, as had often been the case, the Chief Counsel was acting as kind of a safety valve for other parts of the Agency. And I remember some of the staff saying why do you meet with all these people? And I always had the same two answers. One of them was that meeting with people was a good idea because you might learn something. You listen to them, you hear what they have to say, you might learn something. And the other reason was that no matter what we ultimately decided the people who had had a chance to say what they thought directly to a decision maker, if it was my decision or at least to somebody who was somewhere around the decision making process, that if they had a chance to say what they thought and they'd taken a decent shot they would feel better about it. And you know we're not in the feelings business, but I meant feeling better in the legitimacy sense.

I believe that when I was Chief Counsel that when we were doing regulations, patient package inserts, I know, for example, with patient package inserts, we actually read people's comments. You read the comments and you thought about them. And the *Federal Register* notices tried to respond seriously to serious comments. And now, of course, often there are

many more comments, there are hundreds of comments on some big rulemakings, but sometimes or often agencies contract out the reading the comments process.

I've never been sure that that was legitimate under the APA, under the Administrative Procedure Act, but I'm sure it's not legitimate as a matter of how the government should function that nobody who's making the decision or seriously working on the decision has really come to grips with whatever anybody's had to say. You just get summaries of comments.

CC: Sometimes the comments are summarized but I'll just tell you how I've worked with it. First of all, I wasn't reading the comments to start with when I was in the Chief Counsel's Office, but reading what the client wrote up might prompt me to go back and read the actual comment. But I have to say on the last rule that I worked on, while I didn't read every comment, I read a lot of the comments where I felt I needed to understand clearly the specifics of the comment.

NB: You don't have to read them all. A lot of them are repetitive and some of them aren't worth reading. But it's pretty clear to me these days that the process of reviewing comments is contracted out at FDA as elsewhere sometimes and that's really not okay. FDA does relatively little rulemaking anymore and so this whole issue isn't particularly important, but Jodie Bernstein and I used to always say that, well I used to say that the Consumer Product Safety Commission used to do its responses to comments and rulemakings and other things by saying the commenter says x and then the CPSC says screw you and that that wasn't terribly likely to be very persuasive in court. FDA had a tradition, which it did have, and I hope still has but I'm not so sure, of taking comments seriously and explaining why FDA agreed or disagreed or had

modified the rule or hadn't modified the rule. That kind of careful preamble writing is very helpful in protecting the institution in court.

I think FDA was somewhat careless about that with some of the early dietary supplement stuff where the DC Circuit basically told them they did have to pay attention to the First Amendment and I think to some extent FDA invited that by being careless about it and I know FDA, we believe FDA was careless about it, and it wasn't a rulemaking, but in the Washington Legal Foundation case where they basically just told the court what they wanted to say and didn't take the other argument seriously at all and Judge Lambert's famous line about FDA mistakes its place in the world, and mistakes its place in the universe I think. That kind of stuff is not good lawyering. I don't think it was the lawyer's fault – I think that's what the Agency wanted to do. But I'm digressing here.

CC: No, it's very interesting, particularly your point about how do people in FDA look at the comments and the commenting process. I don't remember what the particular matter was but it involved the Office of Food Additive Safety. And I don't know why but my recommendation was we reopen the comment period on a narrow set of issues. It might have been on the Flavr Savr tomato – maybe part of that. I remember saying to a mid-level supervisor – you know, he's saying why are we doing this? I said, "Look, one of two things is going to happen: we're going to get the same comments and we already know what the response is or we're going to get something new and we need to know it now rather than later and pay attention to it, learn from it, and respond to it." I think there's a lot of dread about notice and comment rulemaking in FDA for people far removed from the end of the process.

NB: I'm talking in very over-generalized terms here and I'm sure I'm doing a disservice to a lot of individuals at FDA and maybe even big organizations at FDA. But I'm not doing a disservice to everybody because there's a lot of this kind of one sidedness built into almost any large institution.

CC: I know you want to, and I want to, move on, but let me ask you one last question on this, putting this in the context of where we are in the domestic political situation with all the polarization. Do you think that's part of it? I don't mean because of partisan politics and Parties – I just mean that everything seems to be so black and white now – You're either them or us.

NB: Yeah. I don't know. There's not much doubt that ... I think in some ways politics has always been like this. It's often been more savage and less sophisticated and subtle at the public level than some of us would like. But that was certainly true in the Jeffersonian era and ... I can't remember who it was, I think it was ... I may have the people wrong, James Blaine running against Grover Cleveland or somebody and the line about Cleveland, Blaine's people saying Cleveland was thought to have fathered an illegitimate child and the Blaine people had this kid who was saying "Ma, ma, where's my pa? Gone to the White House, ha, ha, ha."

You know that kind of stuff, the particular issue wouldn't seem like such a big deal today, but in context it's... I don't know. I mean, you certainly can't look at the ...

CC: We don't have to talk about that. I was just sort of curious.

NB: Maybe, I don't know. I'm not sure politics is the same as regulation, regulatory agencies.

CC: It may not be.

NB: Maybe it is.

CC: I said we'd move on, but let me ask you another question about politics and the current state of things. What do you see when you look back over 35 years of knowing FDA – 40 years or 50 years, whatever it is – what's your view of how politicized the Agency is or is not? Was I naïve in thinking that it wasn't politicized in 1978?

NB: When you came to FDA?

CC: Yes – when I came. You were a political appointee. Rich Cooper was a political appointee. And I'm not saying just in the Chief Counsel's Office

NB: I think that, yes. I was a political appointee, and I thought that was appropriate. I know that there were a lot of people in the Chief Counsel's Office and at FDA who would have preferred a career person. Margaret Porter wasn't FDA career, but she was a career government employee, and a lot of people like that. I think the Chief Counsel...

CC: But she was actually originally a political appointment. No, no, no. I take that back. Tom [Scarlett] was the last political appointee, and then Dan was.

NB: I think that it's appropriate that a Chief Counsel be a political appointment, which is not the same thing as saying that the Agency should be politicized. But as I've said, I think a lot of the issues that an agency has to deal with are policy issues, and it's appropriate that policy come from the President and through the President to the Secretary. And the Supreme Court's cotton dust and benzene cases say that there is nothing wrong with that. I mean, various procedures, litigation, rulemaking and so forth have constraints on them about what can be political and how the process has to be done.

And *MVMA v. State Farm* says that you can't just come in and turn something upside down for no reason, which is going to surprise perhaps some of these Republican candidates should they arrive at the White House and find out that they can't necessarily reverse an EPA final rule just by saying ... Somebody will give them a copy of *State Farm* and they'll figure out how to do it maybe. But I think FDA is much more politicized in part because the people who have succeeded Congressman Fountain in holding hearings and even Senator Kennedy have better media to utilize and to make it somewhat political. There have been some very notable decisions on Plan B and then again on Plan B that seemed to have been political. And a lot of that has to do with how you think what the role of the Secretary and the Commissioner should be in all of this. I'm not sure that saying that it's political or has been politicized is necessarily a bad thing. It depends on what you're politicizing them into.

CC: I guess I'm trying to distinguish – and this gets back to your question of whether it is a policy issue or is it a scientific issue?

NB: Or both.

CC: Or both?

NB: As is so often the case.

CC: Or is it a purely scientific issue versus a scientific question with policy aspects to it? I guess I'm thinking about the President on Plan B saying that he wouldn't want his daughters to have access to this drug. But that's not the legal standard. And that could have been more appropriately and better cast as a policy decision.

NB: Somebody should have asked Mrs. Obama what she thought about that issue rather than Mr. Obama. But in any case I think that's a good example of the intersection of a lot of the various issues we've talked about, if you think of safety and efficacy one way then it's purely a scientific issue. If you recognize that pediatric use or used by kids under a certain age but above another age is not purely science, but partly policy and that the question of, I mean that's a safety question essentially, is not just science.

And whether the President should have that view, whether he does have that view since I'm not exactly sure whether that was a *post hoc* statement or was factored into the process ... I don't know enough about, I don't think any of us knows enough about who said what to whom before those decisions were made.

But that's the question I'm asking is do you want to cast the question of – I don't know what it was – 12 to 18 year olds – as a science issue, is it only a science issue? I don't think so. I think it's a very science, policy, law, discretion, and importantly, who gets to decide? Putting

aside the law of it – whether the Secretary had the authority to do what she did – I think she did – but putting that aside, do you really want to say that that issue, that’s a perfect example is something that is only science? I don't think so.

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NB: Think about history and that question of how politics and policy figures into all these things. Think about patient package inserts, for example, which we haven’t talked about yet, in terms of exactly what happened. FDA had been working on patient package inserts and providing information to patients. They’d already done it with respect to, I think, oral contraceptives, and when I was there, the question was whether to broaden that out to all drugs or more drugs or something like that.

There was nothing in the statute then that required FDA to undertake that process and there was nothing in the statute that required FDA to do the Orange Book, the therapeutic equivalences. There’s all kinds of things that FDA does that it chooses to do by doing rulemaking or by litigation or by some other process where the decision whether to do it is a combination of an Administration or the agency’s or somebody’s thinking that this would be a useful thing to do, an important thing to do, a good thing to do, and whether it’s lawful and whether it’s scientifically justifiable, if that’s what the issue is, the science.

There are other issues like AFP where somebody files an application for a PMA [Premarket Approval] and FDA doesn’t want to do it unless it’s restricted and so it goes through the whole AFP process. There are some issues that are thrust upon FDA. There’s no question about that. Toxic shock, the DES and the cattle, although that had been preceded by rulemaking.

And there are other issues where the agency has to choose whether it's going to do something or not.

And that is a political issue in quotes, political in quotes, in the sense that it's up to every Administration to decide what it wants to do and how it wants to do what it wants to do. And some of these things are bipartisan; the generic drug stuff got done through Republican and Democratic Administrations, as I mentioned earlier, because the Republicans had, Casper Weinberger had, a set of imperatives that he needed to deal with and the Democrats didn't disagree. They were in favor of generic drugs, too. And it happened to save Medicaid money, fine.

So I don't shrink from saying that the Agency is politicized. I just ask the question what do you mean by politicized in particular cases or in general and whether there's actually an intrusion into a decision that does need to be scientific, do the data really show xyz? Or whether it's asking a set of questions that surround a scientific decision that are appropriate to be, let's call them policy if you want, or political.

And different Presidents and different Secretaries handle that in different ways. I remember one question where, I don't remember who it was, some movie star wanted to bring back to the United States some goof ball therapy for cancer. And Secretary Harris called me up and said she'd gotten an inquiry from the White House about whether this person could do that and her question to me was what would we ordinarily do? What would FDA ordinarily do? And I said FDA would allow it. It was an informal personal use exemption. It wasn't an exemption, but we just didn't bother with stuff like that where the stuff wasn't toxic and wasn't going to be used by anybody else and wasn't going to kill anybody. It wasn't going to work, but it wasn't

going to hurt anybody, except in the sense, of course, they would forego some other therapy. But I think if I remember correctly, the person was past that and ultimately died of whatever it was.

I mean, is that political intrusion? Yes. It went to the right person. It didn't come to FDA, it went to the political person from the White House and she asked me the right question, which is what would FDA ordinarily do? And my answer was FDA would ordinarily allow it. They just wouldn't bother. So she told the White House okay. And it happened. There's nothing wrong with that.

CC: Your comment about what do I mean by politicization is a fair one. Maybe I'm just using that as an easy shorthand for involvement of a broader spectrum of the political powers like the White House.

NB: Or Congress.

CC: Or Congress.

NB: I mean, most of the pain comes from Congress for most agencies. It doesn't come from the White House, it comes from Congress, and most of the time. And since Congress always has both parties and since who it is doesn't necessarily match the White House and therefore, the Secretary and the Commissioner and so forth, but you know under the Constitution that's Congress's legitimate function, just as much as it was the Supreme Court's decision ultimately to decide the tobacco case.

It can be painful. Not everybody in Congress does hearings that are fair or nice or intelligent. But many of the hearings are fair and nice and intelligent whether FDA is right or wrong.

CC: I think that most lawyers accept that there is this legal structure. There the Executive Branch, the Judiciary, the Legislative Branch. And we've all got roles to play. It's the intersection and the bouncing off of one another that creates the results, some of which are challenging. I think some non-lawyers may not accept that these are appropriate roles because it's not part of the structure that they have had to think about or work with.

NB: That's a fair point and since FDA has many, many more non-lawyers as we talked about before than it has lawyers... But I don't think that's the only thing that's going on. I think that FDA and particularly recent Commissioners have made a big deal out of FDA's being a scientific agency deliberately to try to exclude other players. And I don't think that's appropriate.

CC: Although this is fascinating to me, and I know it will be interesting to others, let's go back to some of the substantive things you worked on. Let's start by talking a little bit about other aspects of the generic drugs matter. I don't know whether you have much to say about the litigation, the paper NDA policy. When I say the litigation, by the time you came, Lannett had been decided with its dictum about the approval requirements for generic drugs, followed by Premo Pharmaceuticals and Pharmadyne. All this leads up, at least in my mind, to Waxman-

Hatch. I always called it Waxman-Hatch, but I guess it's now Hatch-Waxman, the '84 amendments.

NB: Yes.

CC: Of course, a piece of this that did happen during your tenure is the publication of the so-called Orange Book of approved drug products with therapeutic equivalence evaluations.

NB: Right. While I was Chief Counsel, FDA was continuing to litigate with Premo and Pharmadyne and continuing to work out various particular drugs under DESI [Drug Efficacy Study Implementation] to try to get DESI wrapped up. And one of the things Secretary Harris said to me right when I started was that it seemed to her that FDA took way too long to get things done and that she thought I should make sure in my tenure that FDA finished up DESI, the Cosmetic Ingredient Review, and something in foods, what was ...

CC: Colors?

NB: Oh, Colors. Color Additives.

CC: The Color Additives Review.

NB: DESI and the OTC Review. And I, of course, said I would take care of all of that.

CC: Yeah, how'd that work out?

NB: Little did I know. I did make a contribution to getting DESI done. I hired a lawyer, a woman who was going to work part-time, it was the first part-time lawyer I think in the Chief Counsel's Office, to work on DESI. And I pushed other people to work on DESI. So I tried to contribute but I didn't succeed, of course. Not to mention the Color Additive Review and the OTC Review. But I think, in 1992, my law firm, my then law firm, we celebrated the 500th anniversary of Columbus's voyage to America, the 30th anniversary of DESI, and the 20th anniversary of the OTC Review in a single party.

CC: Which firm was that?

NB: In 1992, that would have been Weil, Gotshal. It as a small part of the firm, the whole firm didn't participate.

CC: Good party.

NB: What were we talking about?

CC: So I'm asking you about the litigation, the generic drug litigation.

NB: I wasn't particularly much involved in the specific cases or in the particular DESI products or at least not that I can remember. I did probably what I was supposed to do, but I

don't remember any detail. The part I did work on was the publication of the Orange Book, which we did in – I don't know – November, October, November, December of 1980, and that was ...

CC: Published on Halloween 1980.

NB: It was on Halloween. So I was close. I think Forest Patterson was working on that in the Chief Counsel's Office and that was really important because what FDA and HHS and FTC had been working toward had happened in the states – that a lot of the states had substitution laws that allowed pharmacists to substitute for the brand name, a generic drug that they either were required to or permitted to substitute. There were many fewer states that prohibited substitution by that time.

But in order to make that work well they needed to have a source of information about which drugs actually were substitutable. And the purpose of the therapeutic equivalence list was to give the pharmaceutical industry writ large – the wholesalers and the retailers and the individual pharmacists – information about which drugs FDA thought were substitutable.

FDA had already been sued by the time I got there and I had nothing to do with the litigation. PMA challenged that whole concept as improper in all sorts of ways.

CC: PMA was the Pharmaceutical Manufacturing Association?

NB: Yeah. Now Pharma. But then they called themselves PMA, Pharmaceutical Manufacturers Association. Pharma had lost, PMA had lost, and FDA had won. But we had to

put out the Federal Register notice to accompany the first publication of the Orange Book. And we did – the 1979 revised proposal and the 1980 final document. Ironically, the 1980 document says at the end “effective date of regulation,” even though we insisted that it wasn’t a regulation, which it wasn’t. I noticed that last night, should have fixed that. But it’s too late.

CC: You think it’s too late to issue a notice of correction?

NB: Probably. But those two documents between them discuss a lot of the, both the policy and the scientific issues about which drugs FDA would consider to put on the list. It didn’t discuss the specific drugs on the list, it did discuss a couple of the specific drugs that weren’t on the list, that weren’t substitutable. It was an enormously important step to take because it put FDA in a position of saying that drugs were substitutable, one for another. What’s so interesting about it in retrospect is that FDA essentially assumed that drugs were bioequivalent unless there was a reason to think that they weren’t. And that’s a judgment that – you’re frowning? But look at it again...

CC: No, I’ll tell you why I’m frowning in a minute.

NB: I had forgotten that’s sort of the way it was constructed and that was something I think that gave the branding industry a lot of problems. And the ‘84 Hatch-Waxman, Waxman-Hatch, changed that so that in order to get an abbreviated new drug application, you had to prove the bioequivalence or do something else.

CC: The reason I'm frowning is I've been sitting here trying to recall the specifics of this issue. I handled a seizure case involving a veterinary drug – the case was the veterinary equivalent of the Premo problem. I'm just trying to remember if that was 1980. I tried the case in St. Louis, it went up to the Seventh or is that the Eighth Circuit? Anyway then it was appealed to the Supreme Court and cert. was denied. But it was one of my first trials and I know I presented somebody who talked about the fact that just because you had the same active ingredient didn't mean it was bioequivalent. So I'm not sure the left hand knew what the right hand was doing, I guess. And I don't know whether that was during your tenure or the year after. It was either 1980 or 81. I mean the case is reported, I could find it.

NB: I'm not entirely sure I read those two Federal Register notices last night correctly because I was surprised at that framework. In any case, FDA did put out this list and it did make, I hope, I know it made substitution easier for many drugs. But it was only a short period of time as these things go, because by 1984, there's no question that all the new abbreviated new drugs under Hatch-Waxman had to demonstrate bioequivalence. And FDA got locked into an intense, detailed, scientific – with policy overlaid – discussion of how close was close enough.

CC: Right.

NB: And that debate still goes on. FDA just recently downgraded a drug from AB to whatever it is if it's not bioequivalent – it can still be marketed but it can't be substituted from an FDA standpoint. It's rare, but it happens. But the therapeutic equivalence list was kind of a last

step in a HHS/FDA/FTC multi-state effort to make it easier to substitute generics for brand name drugs.

CC: As we talk about this 34 years later, 35 years later, almost 35 years later, and this is why part of your discussion is so fascinating because of all people I know both, because I litigated that case and because I was in the Chief Counsel's Office and knew about the Orange Book just generally, but now the idea that a generic drug can be substituted for a pioneer is just, well, of course you're going to do that – it's not an unusual thing. But I think it was a very big step.

NB: It was a huge step because as the two *Federal Register* notices say for a long time a lot of state laws prohibited substitution. I think the consumer movement broadly stated and the imperatives that Medicaid created – remember that Medicare didn't have any drug benefit yet – it was Medicaid.

CC: I see, right.

NB: That had a drug benefit. And the need to hold down drug costs but to do it only when it was fair to do it. It was only fair to do it if the drugs could be expected to be equally safe and effective.

CC: There was something I read, and I don't know if it was in either of these notices, but one of the policy considerations driving those in charge of Medicaid was that they needed to ensure

that the less expensive generic drugs, if they were going to be substituted, were not of lesser quality.

NB: Right, exactly. You couldn't have second class medicine for poor people.

CC: Right. Exactly.

NB: And on the other hand, they really did want to save money. I mean Medicaid was expensive – I mean, it's expensive now but it was expensive then – and being able to substitute generic drugs saved Medicaid a fortune. Much of Medicaid's reimbursement policy since then has been how to reimburse for brand names and when and how to reimburse for generic versions of those brand names. And a lot of that was taken up again in Hatch-Waxman.

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I mean one of the things that Hatch-Waxman did, in addition to the tradeoff between patent rights and various kinds of exclusivity rights on one hand and generic drugs on the other, was to resolve exactly that question in a way that guaranteed probably better than the Therapeutic Equivalence List did, the quality of the generics. I mean there are all kinds of things about that notice that are very interesting to read in retrospect – FDA relied heavily on compendial standards, which had become much less important, then relied heavily on dissolution rates, which I think are now understood to be only somewhat related to bioequivalence.

CC: Right.

NB: And FDA relied on good manufacturing practices. In effect what they said that they wouldn't put a drug on the therapeutic equivalence list as equivalent unless it was in compliance with GMPs, which immediately made me sit up and take notice as a recent private practitioner of wondering whether during that entire period from 1980 to Hatch-Waxman overtook it whether you could interpose FDA's putting you on the Therapeutic Equivalence List as a standard that would put you in compliance with GMPs. But anyway.

CC: That's an interesting question. As I remember my tutorials on bioequivalence, I think the one manufacturing issue that could make, arguably could make a generic drug less bioavailable was if it was a tablet and it was compacted differently ...

NB: Well, there are lots of ways that they could handle it. That's one of them.

CC: Right. But my point is that there were issues in manufacturing related to bioequivalence. I think the whole science has come a long way. So in terms of the Orange Book do you remember who you worked with?

NB: Yeah, my recollection was that it was Forest Patterson.

CC: But did you have any contact with people in the Center or were there policy issues?

NB: No, the Orange Book was something that I think everybody agreed we needed to have and I'm sure that the Bureau of Drugs wanted to do this. I mean they had done yeoman work on the quality of having generics and the quality of generics with the paper NDA policy and it's clear that they had, the chemists in the Bureau of Drugs, must have worked on this. I mean, you could tell from the topics that are discussed. I don't remember that I talked to them. What was really important since FDA had already been sued was how to state essentially the administrative law logic that allowed FDA to do this. We went out of our way to say, listen, this is not a rule, this is not a regulation, this is not anything, it's not an order, it's not anything that compels anybody to do anything, it merely tells you what FDA thinks as a matter of its informed scientific judgment about certain drugs.

And, as I said, the litigation had already been won by the time the 1980 *Federal Register* notice came out. But there was a lot of administrative law logic to play with and we did. That's the Chief Counsel's Office putting its administrative law and Food, Drug, and Cosmetic Act and Public Health Service Act knowledge at the service of what the Department and the Bureau wanted to do anyway. And we did. We were happy to do it. It was clearly, I mean, it was fun and it was clearly right. It was never undone.

CC: Right. But that's an example of where, to the extent that the scientists don't really want the lawyers to play and however they manipulate that or arrange that...

NB: Well, they needed us to play there.

CC: That's exactly it.

NB: And we did, because there was no disagreement there on the policy. I mean, this wasn't something that we did grudgingly. We had a good time with it.

CC: You mentioned paper NDAs and I just wanted to go back to that. That policy sort of became public in the late 1970s and there was a paper that was subsequently published and it may have been because of a court order. But Marion Finkel authored this policy paper. Did you work with her at all?

NB: I don't remember working on it. I mean ...

CC: Do you remember working with her on any other matter? She was one of the few high ranking women in FDA – she was the Director of the Office of New Drug Evaluation, I think.

NB: I don't know. She had a variety of different jobs and Dick Crout, who was the Bureau Director, I think used her to think about specific topics. I've since read NDA reviews that she did when she was a reviewer. But I don't remember working with her. I mean I worked with her. I certainly knew her.

CC: Right.

NB: And I worked with Dick. And I worked with Bob Temple, who Dick also used on special topics.

CC: Yes.

NB: He was then ... Bob's only a year or two older than I am. He was relatively new to FDA when I was there and Dick used him on special projects because I remember sitting with Bob for hours helping to prepare Dick Crout's and Jere Goyan's testimony on something or other. I don't remember what it was. But he and I were happily getting ...

CC: Good foxhole partner.

NB: Absolutely. And Dick often used him on situations where the other people in the Bureau were sort of either under attack or dug in and they either needed protection from somebody new like Bob or we needed somebody to explain or to put, to help write testimony for Dick or for Jere to say "Well maybe we shouldn't have done it that way, but we'll do it this way the next time."

CC: Okay. Anything else that you recall or want to say either about generic drugs or the Orange Book?

NB: No. We should talk about patient package inserts though.

CC: That's a good follow on. Okay, let's talk about patient package inserts.

NB: That was another one where FDA had been working on it for quite a long time before I got there and what its policy was going to be had been pretty well worked out and had made the PMA people pretty mad. FDA had already required – I don't remember what they called them – but patient package inserts for oral contraceptives to give women information about the benefits and the risks. And I think PMA had sued FDA and lost, if I remember correctly.

CC: I think that's right.

NB: Then FDA moved on to think about doing patient package inserts across the board for all drugs. I don't think they were talking about biologics, but I think that's partly because there weren't too many biologic drugs then that were regulated under Section 505 of the Food, Drug and Cosmetic Act, so we're talking about drugs. And I think the proposal that had been made in 1978 or 1979 applied to all drugs. And when we took it up and started as I said reading the comments, I remember Arthur Levine and Michael Peskoe were working on this, if I remember correctly.

CC: I'm pretty sure that Michael worked on it, I don't know about Arthur. Maybe just to have a litigator's eye?

NB: And I didn't have much to contribute to the idea of shouldn't we do it, the Administration, this was when the Administration was very interested in it, it was the kind of consumer oriented stuff that Secretary Harris cared about and Jodie Bernstein, of course, cared about. She and I had in common the FTC background where consumer information was thought

to be a good thing. Let's not forget that I started out in truth in lending, which was a form of consumer information, and worked on other things where there was consumer information at stake.

So I didn't have much doubt about, I didn't have any doubt about the basic logic of it. The one thing though that I was able to help with were a couple of aspects of how it was all going to work. Again I had and the Commissioner I think had some ... he had been a pharmacist, although he was the kind of PhD pharmacist that hadn't done much retail pharmacy, but he had done some and he certainly knew a lot about the basic logic of it all. And so one of the questions was who was going to make these things available and how it was all going to work. I was also able to help with that because I think by that time I'd probably worked in private practice on the FTC's, the Magnuson-Moss Warranty Act, about how warranties were going to be made available. I think that preceded my time at FDA. Maybe should have looked that up before I made that statement, but I believe ...

CC: I think Magnus and Moss was early 70s, so it would be likely.

NB: Yeah. So I worked on that while I was at Weil, Gotshal. I know I did, because I worked on it while I was at Weil, Gotshal in New York. And then the other thing that I was able to help with was, and again this came out of some of my FTC background, is the FTC had always had a preference for what they called performance standards over design standards; that is, if you were working on standards for houses, let's say for the housing code, it was good if the pipes had to be able to withstand this much pressure, but you shouldn't say how the pipes should be built or what materials you should use, you shouldn't constrain the design in that way.

You just had a performance standard that said how they should perform and leave it to the pipe people and house builders to figure out how to do it. And I think that as it had come to us in 1980, FDA had been planning to write the patient package inserts and what we did was to give everybody a choice between using the language we wrote, we drafted, I think we drafted the ten ... As it turned out, we decided to do an experiment, we decided not to go from oral contraceptives to everything and we picked ten fairly popular drugs where we thought that consumer information – patient information – would be really helpful in their making the choices about the their drugs.

And the final reg gave people a choice between writing their own that had to comply with certain performance standards or using ours. So nobody could complain that they didn't want to be at sea and at risk of evil FDA enforcement so they could use ours if they wanted to or they could write their own if they preferred. And I think we also allowed collaboration sort of the way REMS have turned out, so that all the manufacturers of a particular drug could get together on doing it or the wholesalers could do it or the retailers could do it, however they wanted to do it. It just had to comply with the performance requirements and get handed out.

So that was another area where I think some of my background was probably helpful in allowing for some choices, which both made the whole project cheaper because people had choices and allayed a little bit, not much, but a little bit of the industry ... well, the industry was very unhappy about it. I never quite understood why the PMA people were so unhappy about it, because I always thought that if they gave patients a patient package insert that disclosed the risks that they would be better off from a product liability standpoint than if they hadn't, but that never seemed to appeal to them anyway. They were so at odds with FDA and so at odds ...

CC: I wonder whether it was just “there’s got to be more to this” or the nose in the tent fear. I know with the food industry that always seemed to be an issue.

NB: I don't know why they were so upset about it. But they were. But that was one where Secretary Harris, through Jodie Bernstein, kept a very close eye on our getting it done. They wanted it done. I don't know I guess it's because they wanted it done before the election.

I think it came out in September of 1980?

CC: I thought I had it here. Or maybe it's in my notes. The final rule was in 1980. So it was before the election I think.

NB: It was before the election. I know we got it out before the election, because ... I don't know that they had much ... I mean again it's the kind of thing where the Commissioner and I would have briefed the Secretary and probably on this one the HHS General Counsel in broad outline about its substance. But there wasn't much doubt about its substance. They paid close attention to our progress in getting it to them but they didn't much mess with what we were doing.

CC: I think now if FDA were to prepare, probably regardless of the organizational component, consumer information, people would be asking for consumer studies to show that the method of communication to consumers was effective. In other words, was the information presented in a way that consumers could understand it? Was that an issue 35 years ago?

NB: No, it was a question of whether they could understand it was something we thought about and talked about and tried to write to all the time. But the idea of consumer studies wasn't as common then as it has become.

CC: I think FDA has long thought – and I am over-simplifying it – that as long as the information provided to consumers was truthful and accurate that it would be useful...

NB: It didn't matter whether they could understand it.

CC: You have to wonder about how many physicians read drug information ... whether physicians read it, whether patients read it?

NB: There's a lot of different questions embedded in that, but there's no question that not all patients read anything and not all physicians read anything. But that doesn't mean it's a bad thing to have those things. And I think that both prescribing practices and patient practices have changed over time and the availability of this kind of information has been very useful to physicians and patients alike. I think that the prescribing information, the official labeling which FDA for some reason always refers to as the label, which it's not...

CC: You're right, not under the statute. Unless it's glued to that bottle.

NB: Yeah. But in any case, the official, the full prescribing information is not easy to read although it's been improved in the last I don't know when they changed the regulations, but it's

easier to read now than it used to be. I've always thought that one of the useful aspects of patient package inserts is that they're available of course not only to physicians but to nurses and other health care practitioners and although they would never admit it, they're a useful shorthand for the official, the full prescribing information.

That's one of the reasons I also have been an advocate of direct to consumer advertising of prescription drugs. I think a lot of those ads are seen by physicians and other health care professionals as well of course as by consumers and contain both the basic efficacy information and the basic safety information. No physician ... well, not every physician is willing to admit that. But that's how they learn about the risks of drugs or that drugs are available, but I'm sure they do.

CC: They're consumers of a different sort, but they're consumers, too.

NB: They're consumers too. I know that with patient package inserts and with the AFP proposal, we tried really hard to write them simply and carefully and I'm sure that we succeeded to some extent and failed perhaps even to some extent or maybe even a larger extent.

[DR-100-0033.wav at 00:40:04]

Most people say lawyers are terrible at writing clear stuff and we tried. And I haven't looked back at them to see how much I now think we failed, but we tried. Today, you're right, there's no question they would be studied. And the tradeoff between clarity and richness, if you will, might be made differently from the way it was made then. But all I can say is we tried.

And, of course, the other thing is that not everybody has to read them for them to be a useful public health thing. We were doing some costs then. The Carter Administration was big on cost benefit, and some of the early efforts to do cost benefit and economic analyses and stuff began then. They weren't statutorily or legally required, but the Administration wanted to have them.

CC: Who was in charge of OMB at that time? Do you remember?

NB: I don't know. My later law partner Kate Beardsley was working at the Regulatory Council in those days. I know she worked on some of this stuff. I don't know remember who the OMB ...

CC: I just wonder sort of where that emphasis came from?

NB: Well, it came from, it definitely came from OMB but I don't know remember who led the charge.

CC: This is a bit of a digression, but there was an initiative in FDA certainly after you left, although I think there have been multiple initiatives, Operation Shakespeare, which I think maybe Larry Bachorik, Cindy's and my supervisor, worked on. And then there was the Plain Language Initiative – you would have been on the outside for that one. But one of the problems for me with “plain language” was always – “well we're writing a regulation about a technical matter, so some of it needs to be technical.” Do you have any view from the outside about that?

NB: I'm like most lawyers. In reading some of this stuff that's in "plain" English, I find it just appalling, because it just seems over simplified and sort of silly and on the other hand I suspect it does help people who are not lawyers and who don't necessarily have hours and hours and hours to devote to it to get a better sense of what the *Federal Register* notices are about. So I can't imagine a lawyer who doesn't sort of cringe when they read some of that stuff.

CC: I'll give you a list off the record.

NB: But on the other hand the purpose of trying to make government accessible is a desirable purpose.

CC: Right.

[DR-100-0037.wav]

CC: We are back after a short break. This is the continuation of the oral history interview with former Chief Counsel Nancy L. Buc. We were discussing patient package inserts for human drugs. I have one last question I'd like to ask about this initiative. There was a final rule published before the end of the Carter Administration and then in 1982, the then-Commissioner Arthur Hull Hayes, Jr., withdrew the final rule on the basis that a voluntary patient information program for human drugs would be sufficient to meet patient needs. I wanted to ask you was your opinion about that withdrawal – whether you have views about it? We've talked about

over-regulation and whether, in the end, this outcome is okay because, by and large, patient package inserts are provided with prescription drugs.

NB: I know that when they came in, the Reagan Administration put all regulations on hold. One ironic consequence for FDA of which was that as you know the animal drug NADAs were done by regulation, which meant that it had the effect of putting all the animal, there were a couple of animal drug NADAs pending. They then had to say never mind, that's not what we meant.

CC: Right. Somebody hadn't done his homework.

NB: Right. But anyway. And, yeah, I do remember that Commissioner Hayes, I don't think the patient package insert regulation maybe ever went into effect.

CC: There were a number of stays and then it was ultimately withdrawn.

NB: But isn't there some ... is there no longer any requirement that it be done? I thought something had substituted for it somewhere along the way. I don't remember.

CC: You could be correct.

NB: Maybe it's also voluntary? I don't think so.

CC: You know that's a good question and let's just ...

NB: Someone can do some research.

CC: I plead ignorance and you can plead informed ... I don't know.

NB: I certainly don't know.

CC: Let's go on to the last substantive matter that I wanted to ask you about and that is the DES and cattle. Like several of the things that you have discussed, you sort of came into the middle of an ongoing FDA regulatory effort.

NB: FDA had previously issued a final regulation banning the use of DES, it's a growth promotant in cattle. And while I was there – I'm thinking maybe roughly the summer of 1980, I don't remember exactly when this was – FDA and USDA learned that a large number of cattle ranchers were using a DES tag in the ear, that's how they administered the DES in their cattle. It was a huge uproar because it was clearly in violation of the regulation and therefore the law. And the reason USDA was involved was because of course they regulated the cattle on the hoof, we had issued the regulation. But they basically had to enforce it.

It was clearly illegal and kind of poking, the cattle industry poking a stick in the eye of both FDA and USDA. And what I remember was a meeting at, the first meeting that was held at FDA, Carol Tucker Foreman, who was the Assistant Secretary of Agriculture for whatever that oversaw the Food Safety Inspection Service.

CC: FSIS.

NB: FSIS at USDA. And her band came to this meeting and I was there with I guess the BVM, Bureau of Foods people, and I don't remember who else from the Chief Counsel's Office worked on this, I don't know, maybe Mike Taylor was still there. I don't remember.

CC: Bob Spiller had done the administrative withdrawal hearing.

NB: I know Bob Spiller worked later on the cases.

CC: Bob had done the hearing and maybe at that time ... well, I don't know. I'll think about it.

NB: But in any case... And this was at a time when the price of meat was going up. It was a real problem for the Administration, although nobody in the Administration told me that, I mean, I just knew that the price of meat was going up as did Carol. And the way I remember this meeting is that initially both the FDA and USDA staff people basically thought that we should just shoot all these cattle and be done with it – they're clearly in violation of the law. And I looked at Carol and Carol looked at me and we had this sort of image of bureaucrats shooting, I think there were like 500,000 head of cattle, which was enough to matter, you know, watching government bureaucrats shoot cattle that most people would have thought were fine on the six o'clock news. And that didn't seem metaphorically speaking, that didn't seem ideal.

So we inquired further as to whether it was possible to remove the DES and make the cattle, restore the cattle to a safe level so that there wouldn't be any DES in the bloodstream or in the meat. And it turned out that you could, that you could take these tags out of their ears and then I forget what the washout period was, 30 days or 60 days or something like that. And this wasn't all that complicated, we settled on instructing the ranchers if they wanted to sell the stuff to remove the tags and have a washout period. And that would avoid the problem of, we postponed the arrival of the cattle to market by 30 or 60 days or whatever it was, but it would avoid the more draconian thing.

And some of our staff were not happy about that. I mean they were clearly in violation of the law and not much doubt about that. But then the question came up which we talked about earlier about who was going to take these tags out of their ears and the USDA people thought it was really important that the vets who were doing it be USDA certified or licensed, I forget what they call them, vets. And my FTC anti-trust competition policy background kicked again and I was like well, and I think we agreed that anybody could do it after a dutiful inquiry in how complicated the procedure was and whether Carol or I could do it if properly instructed and that we didn't actually, we may have thought that but we didn't say that.

CC: Get matching overalls?

NB: Yeah, right. And that's what happened. And then most of them complied or destroyed their cattle. It wasn't an issue. But there were a few who didn't either and I remember Bob Spiller going out to, I think it was Kansas, to bring, I don't know if it was a seizure or an injunction.

CC: It was a seizure action filed.

NB: Because the cattle were in violation of the Food, Drug and Cosmetic Act. And I think the judge wasn't too happy about it if I remember, although I think he ultimately prevailed.

CC: No.

NB: Did we lose?

CC: Actually I looked at this and I remember, so this must have been, the seizure was filed on May 14th, 1980.

NB: So this happened earlier in in the year.

CC: And that involved bone beef. So it had already been processed and it was frozen.

NB: Well, why was that FDA's?

CC: Because we took the position that meat on the hoof was food under the Act, and processed meat. I'm not sure why.

NB: I know he worked on some of these cases.

CC: Actually I think it was a Federal Meat Inspection Act violation. But Bob Spiller and a colleague from the Consumer Litigation section, a fellow named Bob Donlan who is no longer alive, who was sort of a mentor to me and was a good friend of Bob's, and had been a Justice, a career Justice Department lawyer, they tried this case along with Larry McDade, who was also from the Consumer Litigation section. And I remember they had a newspaper clip about "the Federal big guns" coming to try this case. That was the headline.

And Judge Kelly who was the District Court Judge concluded that the residues in the meat were not sufficient to adulterate the meat. That decision was affirmed by the 10th Circuit. The appeal was taken not by the government; rather, there was a request for EAJA – Equal Access to Justice Act – fees, which were denied by Judge Kelly because the government's position was substantially justified or whatever the legal standard is. That was the part that was affirmed. FDA lost on the adulteration issue, which was under the Federal Meat Inspection Act.

NB: I have in my notes that *Food Chemical News* reported in May of that year that Congressman Foley had said that it was a good thing we didn't order destruction of the animals so I guess Carol and I were upheld at least by Congressman Foley. I mean most of it, once we figured out that we weren't going to allow them to be shot on the six o'clock news, you know, it all was very straightforward. I mean, most of them complied, one way or another, either by destroying their own animals or by removing the tags and having washout periods. So it wasn't a big deal. But there were a couple and I had forgotten that we lost that case. That's sort of awkward. And that may have ...

CC: That was after you left, because the opinion didn't issue until May 1981.

NB: Secretary Harris was furious about this. I mean, she just viewed it as just a violation of law that was clear. I mean, they weren't supposed to do that. And she threatened prosecutions, although I don't think there ever were any.

CC: I think there may have been a grand jury investigation.

NB: But if we ultimately lost the civil case you can see why there wouldn't have been any prosecutions.

CC: And I'm not sure ... you know if it had been brought under the FD&C Act, I would have to think about it a little more ... there was the Delaney clause and the DES proviso. It was clearly illegal. But I didn't read the case close enough to know that.

NB: It's memorable mostly because one segment of industry obviously felt quite free just to ignore the Feds. That's sort of western ranching sentiment and that was pretty interesting.

CC: Wild West cowboys?

NB: But the other thing that was interesting ... I mean, I think that's the first time I ever met Carol Tucker Foreman. We later became friends and did various things together in the private

sector later, but it was just such an interesting experience to see how it played out. But anyway...

CC: You mentioned, though, that Secretary Harris found this appalling since it was a blatant violation of the law. Was she okay with the resolution that you and Carol Tucker Foreman came up with?

NB: Yeah. Because it wasn't actually ... I don't remember what kinds of questions she asked. I mean, the first question was whether you could actually withdraw it and be safe from the risks that the DES imposed in the first place. And once we knew the answer to that it was fine to do that. But that didn't mean that she wasn't still mad at the people who had done it in the first place.

CC: Well, because it was as you said, a clear violation of the law.

NB: There's one other story I want to tell which isn't related to ... I think it might be related to ...

CC: It doesn't have to be related to anything.

NB: One other story that's definitely part of my history at FDA is that at some point when ... I can't remember who the manufacturer was of cyclamate, was that Abbott, I think?

CC: Abbott.

NB: Abbott Labs sued FDA and HHS on the cyclamate decision, which had preceded my arrival, but I was still there for the litigation. And the lawyer for Abbott, who I think was George Burditt. They had sued us in Chicago and he had subpoenaed or filed a document request or whatever for documents in the possession of the Secretary and FDA on the basis for the decision, which was fine. And Secretary Harris, there were I don't know about five or ten specific documents that had her notes on them or my notes to her, something like that, that we withheld from production as privileged. And this was not Freedom of Information Act privilege, this was litigation challenging the decision privileged. And she had gone over them personally. I mean, she didn't let me decide what was privileged or not. I gave her the documents and she herself reviewed them and decided she wanted to claim privilege, which only the Secretary could do. And so we withheld and they got dozens if not hundreds of other documents, but not these five or ten, I forget how many there were. Not very many.

So George tells the judge that HHS or the Secretary was lying about whether these documents were privileged which was not very nice of him.

CC: I would say not.

NB: Or maybe he didn't use that word. And so I had occasion to ask the staff lawyer how an agency claimed privilege in a case like that, if we were going to insist on it, which we were. The lawyer that I had asked the question of was Ed Basile. And a day or so later Ed appears in the door to my office but with a large group of people, staff lawyers behind him. And I said come in. And he said ...

CC: You need to know Ed Basile is about six five, six six.

NB: Right. But there were a lot of people there. For all I know you were there.

CC: No, I wasn't there.

NB: And he said I'm here to report to you, I've done the research and I'm here to tell you how you assert privilege in a case like this. I said okay. And he said the way you do it is General Counsel appears in court and then goes to jail until the decision can be sorted out. You got to have a ... And he handed me the transcript of a hearing, I think it was the SEC General Counsel had been escorted out of the courtroom on his way to jail when the person was claiming the documents relented and they found some other way to work it out. But I've never forgotten that and in the end, I didn't go to jail. That turned out to be right, that's how you claimed it. But what I always remember is Ed appearing with this huge retinue of other staff lawyers who thought, as I did too, you know that this was a pretty funny answer to the simple question of how you claim the privilege.

CC: Were they there just to see?

NB: Yes, to see my reaction. Yeah, yeah. I mean, he knew I was going to be sort of pretty interested in that answer. And you know he handed me the transcript of this SEC hearing and that seemed to be the way it was done. In the end we explained, somebody explained to George

that these really were privileged and to knock it off and he did. We didn't have to turn those documents over.

But I was just, I was really angry. I mean, if you didn't say that the Secretary was lying, he raised the question about whether she'd actually done it herself or whether we were doing it for her, and he was right, that the privilege had to be claimed personally. But Patricia Roberts Harris, she of the *George Washington Law Review* and years of practice as a lawyer and a person of enormous integrity and counseled by Jodie Bernstein and Nancy Buc, was not about to not do it herself. She did it herself. And his sort of casual assertion that she did not, did not make her or Jodie or me very happy, maybe he didn't accuse her of lying, he accused us of sliding over it.

[DR-100-0037.wav at 00:20:22]

But that, coupled with Ed's appearing in my office with all those people to see what my reaction was to how you claim privilege, was one of the highlights of my career.

CC: I don't think I could have been there because I think ...

NB: You would have remembered it.

CC: No, I think I was too afraid of you to go to be amongst a group of people. Come on, I hadn't practiced law more than a year, 15 months.

NB: None of those people were afraid of me.

CC: He was taller and more experienced than I was.

NB: There must have been 15 people there. It was really funny.

CC: So you mentioned George Burditt. Did you have any other encounters with George Burditt when you were Chief Counsel that you can talk about?

NB: I think I argued with him sometimes at FDLI and stuff like that. I didn't take this personally necessarily. I don't know why he thought Mrs. Harris hadn't done it herself and I don't remember how he asserted that or exactly what happened, and I don't remember any follow up problems. I mean, as I say, in the end he didn't get those documents. So we must have worked it out. So I don't have any ...

CC: And I was just going to segue into briefly, before we talk about your FDA colleagues, as long as you mentioned George Burditt if there were other people in the private bar that you dealt with when you were Chief Counsel that there was a notable or noteworthy experience?

NB: A lot of different people came to see me and I mention I had pretty much of an open door policy. I remember Alan Kaplan coming into tell us that we shouldn't drive papaverine off the market.

CC: What was papaverine?

NB: Some drug.

CC: The name is not familiar to me.

NB: I don't know that we ever got around to it, I doubt it. But most of these people I had never met before, because I knew the anti-trust bar, some of them, and I knew the consumer protection bar, the CPSC bar wasn't exactly very big. So this was the first time I'd ever met a lot of these people. George Burditt, Alan Kaplan. I remember, what was the name of the guy that worked with Clark Clifford? Bob? Represented the OTC drug people?

CC: Oh, Bob ... starts with a P.

NB: Yeah.

CC: Not Peskoe.

NB: No. It will come to me.

CC: He had his own firm for a while with Ed Allerra.

NB: No, no, no.

CC: Not that one?

NB: Not that guy. The guy that was Clark Clifford's partner. Different guy.

CC: Oh, different guy. Okay.

NB: It will come to me.

CC: The one that married Linda Carter?

NB: Yeah.

CC: I don't know his last name. Clark Clifford married ...

NB: No, no. The partner married... The OTC drug Category III litigation that Bill Schultz brought was in progress when I was there. And that guy came in and he was one of the few who was sort of insulting, although I think he would have insulted any Chief Counsel. He was just sure that he was a bigger deal than you were. In contrast to ...

CC: Well, he did marry Linda Carter, who was Superwoman.

NB: Yeah, well, fine. So I do remember him. I remember Jim Phelps who came in. One of the ones I remember is Dick Kingham ...

CC: He was at Covington, right?

NB: He was at Covington and he was about a third year associate, and as was typical of Covington, they cheerfully sent third year associates off to see the FDA Chief Counsel. They were always very good at delegating to anybody who could do things and do them fine, they let them do no matter how junior they were. So here comes Dick Kingham – he was really good. I mean, I'm not sure I knew that he was a third year associate. By that time I wasn't that much older than he was, but a little bit.

CC: Robert Altman was Clark Clifford's partner.

NB: Yeah. Bob Altman. That's right.

CC: Like the movie director.

NB: Yeah. And I remember Dick Kingham came in to see me about something. He was very impressive, three years out of law school or not. I'm sure I met most of the, or many of the practitioners. And in general, I was always happy to see them. I mean, a lot of them were really good at what they did. A lot of them were FDA alumni. I remember some comments that were filed by, was it Ray McMurray and Bill Pendergast?

CC: McMurray and Pendergast – yes.

NB: I remember reading their comments and I don't remember what they were on or whether we did what they wanted or not, but I remember being really impressed with how high quality they were. So it was fun meeting all these people in the private bar and I was always happy to ...

CC: I was thinking of Bob Pinco as opposed to Robert Altman.

NB: I know him, but I met him later. But Bob Altman was pretty sure that he knew everything about everything and that it was within the power of – it was called the Proprietary Association then – it was within the Proprietary Association's power to tell us what to do. And, of course, he was very unhappy about the fact that Bill Schultz was suing us. I met Bill Schultz too. He was doing a fine job hanging us out to dry in that litigation.

CC: Well, it's all part of the process.

NB: Yeah. And I met Milton Bass who was the long time lawyer for the generic industry and for some of the dietary supplement people. Milton was a terrific lawyer. He was really smart and personally ...

CC: Bass, Ullman, and Lustigman was his firm?

NB: Yeah. He was fun. He was really smart. I mean, he tied FDA up in knots for years on all sorts of cases. And people like that are fun.

CC: I think it's refreshing to me that, I don't remember your conveying then – not that I had a tremendous amount of contact with the front office as we used to call it – but you're certainly not conveying animosity now.

NB: No.

CC: Well, you know there were people, and I won't name names, who referred to what you and I would call the other side as "the enemy."

NB: I know that. I had started my career at the FTC where lawyers on the outside were not generally referred to as the enemy. There were some firms that maybe you liked better than others. And the Chairman I worked for, Miles Kirkpatrick, who himself had been in private practice for his whole career until he became the Chairman of the FTC and before he chaired the American Bar Association Committee on the FTC that had followed the Nader's Raiders report on the FTC, Miles always used to joke about the "minions of entrenched greed," which were all the people on the outside and his former clients. And you know, we always used to, I always used to joke about them too, because at some point I became a minion of entrenched greed.

But you know it was a joke. It was a little bit of an edge, but it was a joke. And there were people at FDA, I mean, the lawyer on my staff who objected fervently to the way we settled the Rely case without an admission of guilt thought I was still a minion of entrenched greed who was basically yielding to the outside minions of entrenched greed. But the custom at the FTC, because we were all lawyers, was that you knew the other side were lawyers, too.

And then when I was in the private sector between the FTC and the FDA, I dealt with lawyers and government agencies, FTC, CPSC. I didn't treat them as idiots or bureaucrats. You treat them respectfully until you find out that you can't for one reason or another and then you do what you have to do. Appeal, file papers, but there's no ...

I remember not long after I started, I remember Joel Hoffman, who was at Wald, Harkrader, and Ross, came to see me about something that he and a staff lawyer had been sparring about and I think the staff lawyer just basically refused to see him. And I'm not sure I'm remembering this correctly, but I mean there's no reason for that. As I said earlier I would see almost anybody. Didn't mean I was going to do what they wanted me to do, or that I would recommend to the agency that it do what they wanted, but I would see them. And as long as they treated us respectfully, it seemed to me that it would be appropriate to treat them respectfully. You knew Alan Kaplan?

CC: Yes.

NB: I mean, what are you going to do? Start a fight with Alan Kaplan? That's ridiculous. He had a position. His client had a position. Fine. It's okay.

CC: Actually, I was smiling when you mentioned Joel Hoffman because I did a DESI hearing and he represented the proprietary company. There were like five lawyers representing various companies, and Gene Lambert represented one of them. That's when I learned that Gene Lambert and his wife and David and I had been married by the same rabbi. And suddenly Joel was cut out of this little conversation ... you know it's just funny things that you remember.

NB: I mean, Joel is really smart. He's a really good lawyer. He was sort of gruff.

CC: Yes.

NB: But inside he wasn't gruff.

CC: No.

NB: He was a really nice guy as it turned out. I got to know him.

CC: He apparently had figured out during the hearing – when I didn't think it was clear – that I was pregnant. He later said to me “Are you feeling okay?” And I said why are you asking? And he said well you're ... I said how did you know? He said “I just could see it in your face.”

NB: And he was from that firm.

CC: Wald, Harkrader.

NB: Wald, Harkrader was the firm of Selma Levine, the first woman who was a major practitioner of the food and drug law. She died early in a car crash... She worked in the Chief Counsel's Office for Billy Goodrich.

CC: She was sort of a mentor to Joel, wasn't she?

NB: Yes. She was. She was Joel's mentor. And she and Bob Wald represented one of the companies in the Hynson litigation – I think they represented Bentex, if I remember correctly. And you know, those cases all went FDA's way. But it's a mark of some distinction that you were one of the counsel who got the Supreme Court cases for the industry people who made it to the Supreme Court.

And in fact that's part of what I'm talking about now. I mean, there are lawyers at the FTC but there are more of them at the FDA who really think that it's not, that you become a bad person when you're in private practice. And I don't think that's appropriate and I don't think it's true or right.

CC: I'm thinking about my own exposure and training. A lot of the members of the private food and drug bar were not people I'd worked with – because I was new – but I knew these people had been part of Chief Counsel's Office and that was sort of a sisterhood, well, brotherhood. And as far as I was concerned, all of these people sort of got a pass, they were entitled to respect until they showed otherwise. But that wasn't always the undercurrent, the training, in OGC – it depended on who was supervising you among other factors.

NB: In many respects, that's what I was talking about with the revolving door, I mean, the people who had been in private practice or other government work and come to FDA and the people who leave FDA to go to private practice or other government agencies – a lot of those people are among the biggest supporters of the Agency. You don't stop believing typically that

FDA has an important role to play just because you go into the private sector, but you're allowed to represent your clients. But most of us because we know ... I mean, I know how good a lot of those lawyers inside the Chief Counsel's Office are. I mean, when I was, there they worked for me. I know they're good lawyers. And you don't blame lawyers necessarily for their clients.

CC: Hopefully.

NB: Hopefully. But I think you're right, it depends both in the public sector and the private bar who trains you as to how you deal with your adversaries on the other side.

CC: And at least for me, as I developed as a lawyer and got to know different people and develop my own internal sense of what was appropriate and not appropriate, I was able to discern who deserves to have what type of treatment. In other words, I might tell you a few things that I might not tell somebody else.

NB: Miles Kirkpatrick always used to say also you can disagree without being disagreeable. And that was good advice.

CC: Yes. And I'm not always sure that in the later years that distinction was made clear – you know, it's a socialization process. I think it's the beginning of the black and white and who we meet with, and we don't meet with anybody.

Here's something that I hadn't thought about before and maybe you don't have any recollections, did you work much with Bob McConachie who was the chief of DOJ's Consumer Affairs Section? Or was Pat Glynn the chief by the time you got there?

NB: Yes, Pat was.

CC: Did you have much interaction with that section?

NB: Yes, I had some. I had some, but not a lot. My tenure was not characterized by some of the big litigation that happened before me and after me. Although I talked to Pat about some things, I don't particularly remember... One of the kinds of cases that I did preside over was a bunch of laetrile cases. I mean I remember being very frustrated as Chief Counsels generally have been by the unwillingness of Assistant U.S. Attorneys to bring our cases. Laetrile was a matter of high policy for FDA and at one point we actually tried to, Judge Bohanon was sitting on a bunch of these cases.

CC: Luther Bohanon, District Court of Oklahoma.

NB: And we went to the Court of Appeals to mandamus him to decide it, and Mike Landa wrote this footnote, it's one of the great footnotes of all time – he was working on this case, in this mandamus case – in which he said the remedy of mandamus is not unknown to whatever circuit that is in Oklahoma.

CC: Tenth Circuit? I think it's the Tenth.

NB: And then he had a string cite, A versus Bohanon, B versus Bohanon, C versus Bohanon ... (Laughter) He had found all the cases where somebody had successfully mandamus'd Judge Bohanon about anything. It was a great cite. It was a great cite. I think we lost the case, but I've never forgotten Mike Landa's footnote.

[DR-100-0037.wav at 00:40:06]

CC: Were you involved with Mike on the *Bivens* action that was brought against Leonard Farr? *Michaelis*?

NB: I don't think so.

CC: I think that was maybe after your tenure.

NB: I might have been. It might have been during my tenure, but I don't remember.

CC: Mike and I talked at length about Judge Bohanon and the *Bivens* case.

NB: Maybe he had already written that footnote in a different case. But anyway ...

CC: No. I think it was after your tenure.

NB: You just remember these little bits of craftsmanship.

CC: But that's what makes it – I don't know if “fun” is the right word – but interesting and they are fun recollections. I had a case with Don Burley – he was the attorney in the Consumer Affairs Section – and we had an argument about whether or not to put a certain footnote in the brief. And to this day, I'm sure if I ran into him, he would say “So how are you about that footnote 17?” I think ultimately – I was the advocate for putting it in the brief – I think ultimately Pat Glynn, who decided, decided to put it in. And it wasn't a clever footnote, it was just, it was substantively important as far as I was concerned.

So are there other Justice Department lawyers you remember? Or experiences or the relationships?

NB: No, I knew more of them later when I was in private practice than I did when I was there I think.

CC: Going back to the “we/they” issue, I think one of the things that I recall as a very new staff attorney doing litigation, being schooled by senior litigators and the deputy for litigation, was they didn't get along with the Justice Department. And it took a while for me to figure out that some of these lawyers were really good, had skills that complemented mine in the sense that they had skills I didn't have. I mentioned Bob Donlan – he had children that are about my age. So he was a very senior lawyer. He had gone with the Attorney General to put James Meredith into the University of Mississippi. I mean, he had some stories. And I learned a lot from him

about just instincts and trial practice. To be able to formulate your own sense of people and how you were going to deal with them as opposed to the institutional opinions of them – that was important.

NB: I certainly knew that those relationships had been variously easy and uneasy. But it just wasn't, it doesn't loom large in my own recollection of all this.

CC: We've been talking about relationships, and I'd like to move to the last part of this interview to ask you to reflect on some of the people in FDA that you worked with and what it was like and what you remember. Let's maybe start with Jere Goyan, the Commissioner who was appointed about three months before you were.

NB: He got there about three months before.

CC: He replaced Don Kennedy, who had resigned and returned to Stanford. So let's start with Jere Goyan. You didn't know him before your appointment?

NB: No, I didn't know him before. But I saw him basically every day except when one of us was out of town. I think he was somebody who, he had a lot of knowledge and experience about certain aspects of the drug industry. I think sometimes he couldn't quite believe that the Commissioner's job was what it was, which was to deal with a lot of these crises, many of which had legal policy ramifications that were completely outside his experience. I mean, all lawyers have experience in dealing with certain kinds of crises. If you think of, clients generally don't

come to see you when they don't have a problem, whether the problem is of a counseling nature or a litigation nature.

And I think Jere was sometimes somewhat surprised by the kinds of questions and issues that the Secretary had for him and I think I was able to help him think through what his views were on some of these kinds of things that were a little bit outside his experience.

CC: Was he a "talker through" kind of person?

NB: Yeah. He was always willing to talk. And he relied a lot on the people he was working with. He relied a lot on Paul Hile, which made excellent sense. I think he relied a lot on Gerry Meyer, who even though his title was administration, I mean he was another one of those people who just knew a lot about a lot. I mean, he had done a lot of different jobs at FDA over the years and at HHS as well.

CC: Who was Jere Goyan's Deputy?

NB: Mark Novitch was acting and then I think appointed during most of that period. He relied on Mark a lot. I think Mark, Mark was one of the MDs. Jere relied on him because he was an MD but I think Mark was a nice guy, but I think he was really kind of old school and was one of the people who was resistant to Secretary Harris's involvement and therefore, also my involvement, in a lot of things. Mark is very well liked in the food and drug community. He knows everybody. I'm not sure that all his advice to Jere about how to deal with the Secretary was always helpful to Jere.

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NB: I think and there's no question that Jere relied on Sandy Miller in Foods and Dick Crout in Drugs and Hank Myer in Biologics.

CC: These are all the Center Directors.

NB: The Center Directors. And I think he got good advice from all of them in their various fields. I mean, Biologics was I don't want to say was the back water because scientifically, it was really important, I think to some extent they were all still bleeding from polio.

CC: What do you mean "bleeding?"

NB: After the Salk vaccine was approved, there had been batches from Cutter Labs that hadn't been processed properly, an early lesson in GMPs really. And I can't remember if they caused polio or if they had some other adverse reaction. But a lot of the people who had been in the old Bureau of Biologics when it was at NIH and had worked on polio...

CC: Which included Hank Meyer and Paul Parkman.

NB: And Ruth Kirschstein, who by then had moved onto NIH but who was a good friend of all those people. They'd been sued, there'd been all sorts of things. And I think the Cutter Labs

experience turned what should have been a triumph because they had worked very hard to approve the Salk vaccine quickly. It was important. I mean, it was an early version of a priority review, and rightly so.

CC: This is like 1953 or 4?

NB: Later than that I think, because we didn't move to Pittsburgh until later, 1955. So mid to late 50s. And then there was this awful debacle that tainted the first, a lot of the first production from Cutter. And they were all, I don't want to say responsible but involved because what they had approved had gone south for reasons that had to do with what everybody later is what we now call GMPs. But that aside they regularly did the blood supply and some vaccines, but Hank, he and Paul had invented the German measles vaccine as I recall. So they were stars in that area.

To some extent, you know, the Center for Biologics thought they were superior to everybody else because they had come from NIH, which they didn't much want to do, they didn't want to leave NIH, to come to FDA to do regulatory work. They were scientists. And that attitude may still be there in Biologics.

CC: I think it's still there.

NB: But to the extent that he needed Biologics help, I don't remember any crises from Biologics. I'm trying to think who was ... I guess Les Crawford was running Veterinary Medicine.

CC: I believe so. Yes.

NB: So he was probably involved in DES stuff and other things. And Jere, I think, relied on me, because a lot of these issues had legal components or policy components and besides, I was there at the Secretary's instruction to help him through this stuff.

CC: He was the first pharmacist and he was a PhD, not just a bench pharmacist. Do you think he was miscast as Commissioner? I mean, he seemed to have a narrow background, but then...

NB: In some sense all Commissioners are miscast.

CC: Yes.

NB: FDA is very proud of the fact. First they were proud of the fact, for a long time they were proud of the fact that they were run by MDs, as if Harvey Wiley, was Harvey Wiley an MD?

CC: Yes. I think so.

NB: He wasn't exactly practicing medicine. But okay. They were very proud of the fact that it was MDs. And then turns up Don Kennedy, who was a Ph.D. And they liked Don Kennedy, so they amended it to allow for MDs and PhDs. And Jere had a Ph.D. And he'd been the Dean of the School of Pharmacy at UCSF and he was unquestionably an academic and a real Ph.D. So

that was fine. But in a way they're all miscast in the sense that, as I've said, I mean being the head, much of what they do isn't medicine or Ph.D.-ness. I mean, Sandy Miller was a Ph.D. also, in foods. But none of the Commissioners' PhDs or MDs had anything to do with food. They didn't have much to do with the kind of engineering that was important in the Bureau of Devices or Radiation, rad health people and many of the drugs and biologics and vet medicine and devices and foods issue were legal policy science issues for which, maybe all scientists are trained but maybe they're not.

And at one point, I remember being on a search committee or advising a search committee that was looking for, maybe it was a successor to Dick Crout or deputy to somebody, I don't remember. And I said well you could have a lawyer do this. And they all looked at me aghast. And I said, yeah, you could and put it out that the head of EPA had always been a lawyer and they said well that's not science. I said, well, yeah, it is. The safety questions that are posed by various kinds of toxins and water and air. That's all science and it's all law. And they said well, we're different. We're MDs, PhDs. So were they miscast?

Was he miscast? No more than any of the rest of them, except that it may be that some of the others had a better feel for some of the policy issues and the politics of it. I know, for example, that Jere and Mark both decided not to resign when the Carter Administration came to an end, because they thought that as scientists they would be carried over by the Reagan Administration. And that was just naïve. And also sort of wrong-headed. I mean, in the sense that I've been talking about. Those jobs are policy jobs, ultimately, science policy, but policy. And I resigned, both because I thought I should because I thought they were entitled to their own General Counsel and because I didn't necessarily want to work for them. But even if I had

wanted to work for them, I would have resigned, I think, because I think each Administration is entitled to its people.

And I think that's a view that a lot of FDA career staff don't much like and didn't much ... just aren't happy about. And as I said earlier I think that's a fundamental right. And I think Jere's and Mark's thinking that they could stave off being fired because they liked their jobs as I said was naïve and kind of illustrates some of the problems that they'd had earlier even with their own team in how to think about issues.

CC: Their own team meaning the Secretary?

NB: The Secretary who appointed Jere and ...

CC: And understanding that there was a process and those people had power and were entitled to exercise it.

NB: Yes. They weren't alone in that. I can remember a meeting, I don't remember what the issue was, but I remember Jere was there and Dick Crout and probably Mark and I don't know who else, and the Secretary and I'm sure some of her people were there, and she was asking questions about whatever it was, and they were basically just stiffing her – not being at all forthcoming with the answers. The questions were perfectly reasonable questions. And at one point, Dick Crout said that he just didn't know much about this issue, which was not an ideal thing to say to a Secretary who thought being prepared for meetings with her would be a fine

idea. And she said to him “Dr. Crout, I’ve read more about this in the newspapers than you’ve told me.” And they were sort of unembarrassed by that. The idea that this was her thing ...

CC: That she was entitled to ask.

NB: The statute gave her this ... The other one I remember was some issue where FDA I think had done the right thing legally in some question, the kinds of scheduled drugs that had quotas, but Secretary Harris had just been bombarded by Congress on the issue and she convened a meeting. This was another meeting with the Bureau of Drugs and the Commissioner was there. And again, I don’t remember what the issue was and I don’t remember what FDA was doing was right or wrong or sensible or not sensible or whether we really should have blamed DEA or what.

But, in any case, they were basically saying to her “well, what business is it of yours how we do this?” I mean, it wasn’t in so many words, but that’s what it boiled down to. And she just got really angry and said “I’m being bombarded by the Congress and I can’t defend you.” I mean, she didn’t put it this way, but she said I can’t either defend you or sell you down the river unless you tell me more about what’s going on here. I have to, she said I’m the insulation between you and the Congress and you and the White House and I can’t do that if you’re going to behave like this. And again I’m not quoting her.

CC: No. And I'm thinking about who was in a position to sort of socialize them about situations like this?

NB: Well, that was sort of my job. The Commissioner should have been doing that. I mean, he should have been standing between the Bureau and her, but I'm not sure anybody knew it was necessary. I don't say this ...

CC: And when I asked you if you thought Dr. Goyan had been miscast, it wasn't about his intellect or his scientific background. Rather, it was more what you characterize as – you know – to get “the small p political” part of the job and that he wasn't equipped. You can't model certain behavior if you don't understand it yourself. And to have people like, I think Dick Crout and to some degree probably Sandy Miller, they weren't used to having people probe that way with them.

NB: But Dick and Sandy were both much more politically skilled, notwithstanding what I've just described, I think, than the Commissioner. I don't remember any meetings with Sandy and Secretary Harris, but he was a different ...

CC: And I'm not saying they weren't politically skilled. I'm saying that to say, in some respects their ability to run interference, be whatever they were—obstructionist – with the Secretary, is a political skill, it just wasn't appropriate in those circumstances.

NB: I mean, it's one thing to stand up for your views and it's another thing to essentially resist her authority, and I don't remember a situation where somebody who stood up for his or her, in my case, views, I mean, she may have decided a different way, but I don't remember any

problems with that. But she was very sensitive to resisting her authority and that's what happened in those two situations with the Bureau of Drugs.

CC: Let me ask you about two things about Secretary Harris. One, what was her background, where had she worked before she came to HHS? Do you know?

NB: Well, she'd been the Secretary of Housing and Urban Development in the Carter Administration.

CC: So she'd been a Cabinet official.

NB: In the Carter Administration she'd already been the Secretary of something. She had been Ambassador to Luxemburg at some point. She'd been the Dean briefly of the Howard Law School. I believe she had been in private practice before she went to HUD. I want to say she'd been at Fried Frank. And in an earlier, I'm trying to think how this would have worked...

CC: Was she involved in the D.C. government?

NB: She ran for Mayor after she left HHS.

CC: But before that, wasn't she like maybe Corporation Counsel or something like that?

NB: No, I don't think so. I don't think so. Her running for Mayor against, she ran in a primary against Marion Barry.

CC: A lot of people can say that.

NB: Yeah. I supported her.

CC: No kidding.

NB: I'm trying to think, I want to say...

CC: So she'd been the head of a big organization – H.U.D.

NB: Right. And she'd brought some of those people with her.

CC: So the second question I was going to ask was do you think the way she was treated by some of the senior FDA officials was replicated or repeated by officials at NIH, speaking of physicians, at CDC, and whatever the predecessor organization of CMS was.

NB: I don't know. I do know that she ... I don't know. I don't know that most of what they did had the same kinds of public consequences for HEW as FDA's adventures. But I just don't know.

CC: Okay.

NB: I know that some of the people at NIH ... I mean, I'm guessing that both NIH and CDC thought that she should stay out of their business, too. But I don't know. That would be consistent with their general behavior. I mean, NIH didn't even necessarily like their own directors. They gave Bernadine Healy a terrible time.

CC: Let's go to some other FDA people. You talked about Mr. Hile, who, during your tenure, before you came, after you left, was Associate Commissioner for Regulatory Affairs. I would say your description of him could be summarized in my own experience – maybe more importantly, in my own words – he was the consummate gentleman and treated people ...

NB: I don't care about that ... calling somebody a gentleman is sexist. He was ...

CC: Okay. So. I got the reaction I wanted. But he was polite, he was respectful, no matter to whom he was talking.

NB: Well, that's fine. But he was also, he could be very tough and, as I said earlier, he was really smart, he was wise, he had a lot of experience but he wasn't the kind of person, as my father used to say, had 20 years' experience – one year's experience 20 times. He had lots of different experiences at FDA and in his various jobs at FDA, and he integrated it all into a really useful and effective approach to everything I ever dealt with him on.

CC: How often did you deal with him?

NB: A lot. A lot.

CC: In his second oral history – he was interviewed twice – he said that you played a greater role in the program affairs at the FDA than even Peter Hutt and certainly greater than Merrill, Cooper, or Scarlet.

NB: It may be true.

CC: And I think he meant it as an observation.

NB: No, I think that may be true. I mean, I think that the Commissioner with whom I worked and the Secretary for whom I worked wanted me to do that, and needed me to do that. Wanted me to do that or needed me to do that.

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CC: He mentions that, after the election and then the installation of the Reagan Administration including Secretary Schweiker, there was not only the 60 day moratorium on regulations for the entire government but soon after that Secretary Schweiker withdrew some of the FDA delegations of authority. In his interview, Paul said that you told him that Secretary Harris was

thinking about doing the same thing and that was one of the things she advised Secretary Schweiker to do.

NB: I don't remember that. What I do remember is that after we lost the election, Secretary Harris called in all the people who, I mean I don't know what she did with NIH and those people, but for FDA, she called in the people like me that were going to be meeting with the transition team and she said "Listen – I want you to give them every help you possibly can, hold nothing back, this is not political, this is basically the government of the United States." And she said that when she became HUD Secretary, Carla Hills, who had been her predecessor at HUD, had told her people to behave and to do the transition openly and not try to hide stuff and not try to fool around with it, that it's important that the government run properly and that we should behave with Schweiker's people the way Carla Hills had behaved with her and go forth and do right. And it was really interesting because we were not happy, of course, in having lost...

CC: Do you remember how soon after the election that was?

NB: No. But you know it was before the transition started.

CC: Right. And I guess that happens pretty quickly.

NB: Yeah, and she told us to ... well, I mean, I think she knew that it was going to be Schweiker so it couldn't have been immediately. But I do remember that. And I don't know, I mean, Paul might be right that that's what I said. I don't know that she would have necessarily

needed to withdraw the delegations if she had people there that she could trust to make it work.
So I don't know, maybe I did say that.

CC: That's just interesting.

NB: It is interesting.

CC: I think his observation was that some of the things that happened after the Reagan Administration came in about more involvement from the Department in FDA affairs, which has continued to this day, might have happened in a second Carter Administration.

NB: I do remember one other thing, which is that the Schweiker people, I think I have this right, the Schweicker people wanted everything, this may have been after she left and we were just kicking this around, but they wanted everything in particular form and only so many pages and only so many bullets, something like that.

CC: That wouldn't surprise me.

NB: And I remember talking to her and Jodie one day, I guess at lunch, I mean, she didn't think your memos to her needed to be any longer than necessary. But she didn't insist on that kind of goofy formatting, she would read whatever you gave her, as long as it was well done and it could be as long as it needed to be. I think that was an interesting, a small but interesting, indicator of how willing she was to be informed.

CC: That's interesting, because as a staff lawyer and in CFSAN, at times it seemed like it was form over substance. And, you know, how many, what the margins had to be, what the type had to be, seemed to be more important than getting, communicating the substance.

So we talked a little, or you talked a little, about Mark Novitch who was the Deputy Commissioner during your tenure or most of your tenure. Any other thoughts about Mark Novitch or particular things you worked with him on or role that he played?

NB: Mark was very much a part of the Old Boys' Network.

CC: And who else was in the network?

NB: I don't know. But Mark's the one I think of in connection with these advisory committees. When Secretary Harris would send back and reject an all-white male list for an advisory committee, I mean, Mark was often the one who had put together that list since they were typically MDs or he put it together with help from other people. And it wasn't that he was hostile, as far as I could see, to working with women or certainly not hostile to working with minorities, I don't think that was the issue. It was just that his world hadn't changed as fast as Secretary Harris's and mine. And as Jimmy Carter said, there were a lot of women General Counsels at the Cabinet level in the Carter Administration. The joke was that if you asked a little girl during the Carter Administration what she wanted to be when she grew up, she would say a wife, a mother, and a General Counsel. And I wasn't even at the Cabinet level, but in addition to Jodie, there were Sarah Weddington at Agriculture and I think Linda Kane was at NHTSA.

Susan King was I think the chair of the CPSC then, I'm not sure. There were other women floating around.

CC: And there started to be federal judicial appointments.

NB: Pat Wald was an Assistant Attorney General, and later a judge.

CC: She was the one I was thinking of. So you mentioned all the Bureau Directors and how they served Commissioner Goyan, but how much did you interact with, let's start with Dick Crout. Was he the Director the entire time of the Bureau of Drugs?

NB: Yeah.

CC: So did you work with him, for example, on the PPIs or generic drugs?

NB: I worked with him and his people, Bob Temple and Marion Finkel and various other people, Jerry Halperin.

CC: His Deputy.

NB: All the time on all sorts of things. And I don't particularly ... the Chief Counsel used to attend the ... the Commissioner met once a week or every two weeks or something like that with each of the Bureaus and I always went to those meetings. And they were at 8:30 in the morning

which was fine. And they would invariably put up slides because they were scientists and sometimes I, to tell the truth I would fall asleep because it was dark and they had these slides. But most of the time I stayed awake.

So you know I worked with all those people at those staff meetings all the time. If you ask me specifically what did we do at those meetings, I don't know. They told Jere what was going on and he would ask them questions and sometimes when something in particular was going to be on the Secretary's agenda, because he met with the Secretary I think every two weeks if I remember correctly, something like that. I don't think it was once a week. There would be some preparation for whatever that was, if there was a legislative thing, he'd invite some other people to those meetings. So, yeah, I worked with all of them. I don't remember anything much in particular, but I thought Dick was doing a good job and he didn't much want, I don't know that he was particularly happy to have lawyers involved in anything he was doing, but he needed us because there was so much litigation.

CC: Do you think he understood that?

NB: What, that he needed us? Oh, yeah. I mean, he knew he needed us for the litigation. But I think if you asked him then or you asked him now, he would probably say, yeah, but that's all, go to court and leave me alone. And I don't remember what the issue was, but one of my favorite stories about the Bureau of Drugs is Marcia Gardner was one of the Drugs' counselors and she came one day and asked me if they could do something or other and I said no, tell him that's stupid. And she came back the next day and she said they want a legal reason. And I said

fine, tell him it's really stupid. And you know that doesn't necessarily say much for my judgment, but it was okay. It's one of the other good stories that needs to be on this record.

CC: I think my own experience, and maybe this is what you're saying, is sometimes what lawyers can do is – characterize it how you want, do the “front of the Washington Post above the fold” test, or the how will this sound before a three judge panel, or how will it play – add common sense? And I think that I particularly found it difficult to get people to buy in to the fact that I had a good sense or good judgment about things that maybe were scientifically accurate but weren't persuasive on a gut level.

NB: There are a lot of different pieces to that puzzle, but it all comes back to what we were talking about before. The question is what should the Agency be doing? And some decisions about what the Agency should be doing are almost entirely scientific and there's not much role for lawyers in that, although as I've said even on things that sometimes seem very scientific there is a role for lawyers because the scientific decisions are being made under the statute or under a regulation.

But beyond that I don't think that lawyers at either corporations or government agencies necessarily have to be giving legal advice, although that may affect whether the documents are privileged or withhold-able under the Freedom of Information Act, they're as entitled as anybody else if they're in the senior leadership of the Agency to help frame up the question of are we doing the right thing? And that includes both the substance of are we doing the right thing, should we be doing something else, should we be doing this, should we be doing nothing?

And also framing it in terms of how it will sound. Not just to a court, but, as you said, on the front page of the Washington Post. And that's a function of senior leadership. And I came from a tradition both in the government and in watching my clients of watching senior lawyers and in some cases even junior lawyers, but I was a senior lawyer by then, in quotes, and certainly at FDA, insisting on a role in the leadership of the Agency.

And I think that was appropriate, not only because I was instructed by the Secretary to do that, and not necessarily enthusiastically, but by the Commissioner also to do that. And as time went on, because I had proved time and again that I had some ability to help the Agency through thinking through crises of various kinds but also simply because with Secretary Harris and Jodie Bernstein and I all thinking that lawyers should serve that role. We did it. And some of them liked it more than others. Sandy Miller was much more receptive to that ...

CC: Let's talk about Sandy Miller. In what respect?

NB: Again I don't have specifics in mind, but he was much more willing to let anybody who had something useful to say to help think about whatever problems he was confronting.

CC: If you were at the table you had a voice?

NB: If you were at the table and he respected you – and happily he respected me – you were allowed to talk and participate. And I think he was, I mean, he must have been involved in the DES and cattle stuff, I mean, he was happy to have me. But just in general I mean part because he's not an MD. I mean, some of this is just MD-ness. I mean, I remember one ...

CC: Maybe some of it's generational, too?

NB: Well, yeah, but as between MDs and lawyers and PhDs and lawyers in general it's MDs versus the world. I mean, there's an arrogance that goes with that white coat that transcends who you are if you're not an MD.

CC: Now that's interesting, because my experience with David Kessler was different. He was an MD and a lawyer, but maybe that's part of the answer. The reason I said if you were at the table you had a voice is because, in large part, that's the way he ran his meetings. Maybe those meetings weren't particularly efficient, but if you were somebody even fairly new to the issue or whatever and you had an idea, it was the idea that got discussed and got on the table, not your status.

NB: Well, as many people pointed out, David Kessler had an MD degree and a JD, which didn't exactly make him either a doctor or a lawyer.

CC: That may be true, because he was not a clinician and he was always an administrator.

NB: But, in any case, I mean, I think generally at FDA it was easier to ... I mean, I never had a problem when I was at FDA with John Villforth because he and I have known each other for years because of the allegedly radiating TVs, which I say again weren't actually radiating, it was just a ...

CC: But you worked on that problem together and you developed mutual respect.

NB: Right. We knew each other, yes. And so I never had a problem with him. And there wasn't much to do. I don't remember much happened at Rad Health while I was there. But that was never a problem. The medical device people lived in their own world all together.

CC: Did you work much directly with David Link?

NB: No, David Link left early in my tenure and I don't even think ... I know Vic Zafra was acting for a while. I don't remember much about ... I wasn't much involved in their stuff expect for toxic shock where whatever they were doing I'm not even sure I even knew about because I was busy negotiating this consent agreement. And that was that. But in terms of the Bureaus, I mean, it was much harder to deal with the MDs. And that continued in private practice. I mean, MDs are MDs.

CC: Do you know that's something about medical school or...

NB: I think it's medical school and ...

CC: The Hippocratic Oath?

NB: I think it has to do with great responsibilities rest on your shoulders. And that's true, it does. They're dealing with, many of them and much of the time, with life and death and all that even though many of them are ...

CC: Dermatologists.

NB: Dermatologists. But there's something that comes with the MD that makes them special in their eyes in a way that excludes everybody else. And lawyers are, it's harder to exclude PhDs from the world if you're an MD than it is to exclude lawyers and if the lawyer's also a woman, you know... I remember one guy in the neurology division, whatever they called it in the Bureau of Drugs used to refer to their meetings as rounds. He said they were going to discuss such and such an issue at their rounds next week. I'm like right. But he wouldn't let me call it a meeting.

CC: It's just interesting. Using language and "in-group language" is a way to exclude people.

NB: I don't know whether it was just that Sandy had a different kind of brain and a different kind of personality but as I say he was just willing to include people who might be able to help.

CC: And I think in order to want help, you have to understand that you have a problem that needs a solution and maybe part of that ...

NB: Not every problem ... I think you're being too specific about it. I think it's just a question of who you're willing to let be on your team and it was easier to be on the team, on Sandy Miller's Bureau of Foods, than it was to be on the team of Dick Crout's Bureau of Drugs even though much of the time I was, in both places.

CC: What about Gerry Meyer who was an Associate Commissioner?

NB: Gerry Meyer is another of those people that because of that Marvin Seife thing and ... I mean, he's another person that you were happy to have in your foxhole.

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He was another one who'd been, I'm not sure if he spent much or any time in the field, but he'd been around HHS because he started at HHS and then came to FDA, if I remember correctly. And he'd done a bunch of different jobs at a bunch of different levels at FDA and at HHS and he was another one who was just smart and experienced and knew probably where even more bodies were buried than Paul Hile did and just knew how to work through a problem and how to operate and how to get things done or decide not to do something, which was also very important. So I like Gerry Meyer a lot. I loved working with Gerry Meyer. I always did.

CC: He had a good sense of humor too as I recall.

NB: That's right. Paul would laugh at jokes and it's not that he was in any way resistant to humor, but humor's important to me and Gerry Meyer had a better sense of humor than Paul that's the only thing I'll say about...

CC: I do remember one of those Commissioner meeting when I was doing device work and we must have been talking about the OBGYN device classification and they were passing around, I think it was a diaphragm, and there were maybe a couple other women in the room but I remember Gerry saying turning and saying to me "Well I have a very musical family." I didn't get the joke. I said what do you mean? And he had to explain to me.

NB: He was a great civil servant.

CC: Yes. And career.

NB: Yes.

CC: What about Bob Wetherell?

NB: I really liked Bob Wetherell.

CC: He was the Associate Commissioner for Legislation.

NB: Yes. He had to deal a lot with downtown, as they always called it, at HHS, because the HHS, the guy, Bill, I can't remember his name, Bill something who ran Legislation for Mrs. Harris was one of her most trusted people. And so Bob had to deal with that guy a lot. But he'd not only been around for a long time, and he knew just everybody on the Congressional staff and he had a really good sense of what we could do and how we could do it to fend them off or keep them calm or keep them happy you know without having to give up anything important. And he was a wonderful coach in advance of hearings. I mean, he was really good at finding out what questions they were going to ask you so that we could prepare and at figuring out, you know we'd hold these long meetings before certain kinds of hearings, at figuring out how you could answer the question and sort of stick up for yourself without giving away things that you didn't want to give away, substance and information. There were some hearings, Congressman Whitten, Jamie Whitten...

CC: From Mississippi, right?

NB: From Mississippi, yeah, who I think was himself a farmer, but he had this thing about the Delany clause and absolute zero and all that kind of stuff. And so there were certain kinds of things that were just kind of punch lines about things that you would be asked and you just had to know what the answer was and give it, and Bob was wonderful at knowing both what the question was going to be, because I mean in that case Congressman Whitten had been asking the question for I don't know 20 years or something, and what the answer was going to be and Congressman Whitten knew that that's what the answer was going to be and it was sort of I know that you know that I know that you know that I know. But Bob was really good at that. So

I never felt unprepared for those kinds of things and he was usually a very good predictor of what was going to happen with these hearings.

CC: Was that because he just could anticipate or did he have connections? Or both?

NB: Both. I mean, he had excellent relationships with even the people who gave FDA a hard time. I believe he had a good relationship with Walter Sheridan, who was Kennedy's main investigator and who had you know originally worked for I think for Robert Kennedy tracking down Jimmy Hoffa. I mean he was a very tough, good investigator and in some respects, FDA was beneath him. Whatever else we were, we weren't Jimmy Hoffa. And I believe Bob had a good relationship with him. I know he had a good relationship with Gore's people, notwithstanding my particular misery.

I mean, he'd been around for a long time and he was understood to be an honest broker. I don't think he ever sold FDA out and he didn't sell the Congressional people out. He was an honest broker. And most agencies with any luck have somebody like Bob who knows all those people and has tutored them. I mean he helped a lot of them on FDA issues.

CC: Do you know if he ever worked on the Hill?

NB: I don't. I don't know.

CC: It's interesting that you describe Bob as an honest broker because he was one of the two people that, when the Reagan Administration people started moving the pieces on the chess

board, both he and Wayne Pines were moved from their positions. And I think he was missed tremendously after that, both because the people who filled the job after him didn't fill the job the way he did, didn't cultivate the relationships and the knowledge. And also because he was just effective and a decent person.

What about Bob Temple? You must have worked a lot with Bob.

NB: I did, although I don't remember the specifics of it. But I mean I knew from the beginning that he was really smart and he was really good at thinking, you know, figuring out what the Bureau was actually doing. I mean, there's a certain amount of ... there was always some whistle blowing and some stuff where Congress had figured out that what we were doing was sort of silly or wrong or something. And Dick would invariably, Dick Crout would invariably, enlist Bob Temple to come tell me and Bob Wetherell and the Commissioner if need be, but this was usually in preparation for getting the Commissioner ready. We were the sherpas in that context. Bob would tell you, Bob would figure it out. He was Bob Temple from the beginning except that he was younger and I was younger, too.

CC: And an amazing intellect and articulate. And talk about a good sense of humor.

NB: Absolutely. He had been at NIH, Bob was. I learned much later that he had been doing a fellowship in endocrinology of something like that, which is ironic because his later career was very focused in cardio renal. But he'd been an endocrinologist and he'd worked with a guy that I later ran into in something that I did in private practice, but wherever Dick found him. Dick

made a lot of important contributions to FDA, Dick Crout, there's no question about that. But one of his greatest contributions was finding Bob Temple.

CC: Do you know what year Bob came to the FDA, because he was, I believe he was here when I came in 1978.

NB: Yeah. Not that much before we got there.

CC: Because I don't think he's retired.

NB: No.

CC: He talks about it.

NB: He's been talking about it for 20 years.

CC: Yeah, I know. But he's really one of those individuals that has had a tremendous impact for a long time – on a lot of people and on a lot of policies – a lot of water under the bridge.

In the context of Bob Wetherhall and you've talked about Gore. Anything else you can remember or say about your interaction with the Hill?

NB: No, I mean, I went with Jere as Chief Counsels do to a lot of hearings. Most of the people who presided over those hearings are just names now. I mean, it was before ... I mean,

Henry Waxman had been elected to Congress but he wasn't yet Henry Waxman. And some of the people that we appeared before were defeated in probably in the 1980 elections because the Republicans took over the Senate that year as well, I think.

CC: I think that's right.

NB: I mean, I remember a hearing where I wasn't appearing but ... remember DMSO?

CC: I do. I handled a DMSO search warrant when you were ...

NB: DMSO made Congress crazy. I remember I think it was Senator, must have been before Senator Kennedy and Senator Hatch had produced Daryle Lamonica, who was NFL quarterback who had used DSMO to heal his thumb or so he thought. Everybody was mad at FDA for withholding the wonderful DSMO from not only NFL quarterbacks but everybody else.

CC: The American public.

NB: And, of course, the stuff as you recall was all over the place because it was an industrial solvent. It was in every hardware store in America. And so FDA's position was essentially impossible, because it wasn't intended, in the hardware store it wasn't intended for use in prevention treatment mitigation or cure of a disease, although it was bought for that purpose. So it was a mess.

CC: Anybody else before I move to maybe a couple final questions that come to mind of colleagues. Do you want to say anything more about June Stephenson?

NB: No, I've already said she's the best secretary in the world and one of the nicest people. What else could I possibly say?

CC: I don't know. I just thought I'd invite you to add more... we're talking about people. That wasn't a secret question.

Someone told me, one of my colleagues, one of my staff member colleagues, that in your farewell to the office after Carter was not reelected, you warmly encouraged the staff not to lose heart or be despondent at the impending new Administration and observed that parties and Presidents come and go but the important work still needs to be done and we should keep pushing the ball whatever party had control of the White House. And the person, and I honestly don't remember who it was, although I have a pretty good idea, admired you for that. Do you remember that farewell or thinking about what you were going to say to us?

NB: I hope I thought about what I was going to say to you.

CC: I'm sure you thought about it, but I mean...

NB: But that was consistent with what Pat Harris told us about the transition. I mean, I knew that some of their policies were going to be different, and so did all of you. I also knew that there were, as did all of you that there were, large chunks of things that FDA did, did and does,

that any Administration is going to do. I mean, it was after all the Republicans who had to deal with the cranberries, remember? And I think Bon Vivant.

CC: I believe so.

NB: And probably would have had to do something about toxic shock and a lot of other things that happened. Not every issue was, despite my strong assertion that a lot of issues are not just science, but policy and law, I mean, in a way that sort of assumes that you guys might miss me, which might have been an inappropriate assumption. But maybe not. And I think you know probably what that meant was that ... I mean, I had the luxury of going back to private practice. I never, by the time I gave that speech I probably already knew I was going back to Weil, Gotshal. And so I didn't have to stay and put up with whatever was to come. But the Chief Counsel's Office has been a great office in Administrations, Democratic and Republican, for a very long time. And really that's never changed.

CC: There is an affinity among all of the former staff members. Well, I don't know what it's like today. But I certainly feel an affinity for anybody who's worked there, whether or not I've practiced there with them.

NB: Right.

CC: As I pointed out when we honored Gary Yingling, long before there was a British TV show or the American knockoff, we called it "the Office."

NB: Right.

CC: I have two more questions. Somebody told me that Rick Blumberg made a t-shirt for you when he left. Do you remember that?

NB: I don't. What did this t-shirt say?

CC: I don't know. I was just told to ask you about it.

NB: I don't remember. I think I have every t-shirt I ever collected. But I'll have to look for it.

CC: I'll have to run down who asked me that. Last question and this really wasn't going to be my last question, but realize I didn't ask you, you went back to Weil, Gotshal after Carter was not reelected or Reagan was elected and your tenure at FDA ended, and sometime after that you opened your own firm. What prompted you to do that?

NB: Well, it was quite a while. I went back to Weil, Gotshal in 1981. And I started, Kate Beardsley and Geoff Levitt and I started our own firm in 1994. So it was quite a long period of time.

CC: Had Geoff Levitt been at Justice? Or is that a different Levitt?

NB: No, he'd been at State before he came to Weil, Gotshal. And after we formed, it was original Buc, Levitt and Beardsley, he left relatively soon, after a year or two, so it was Buc and Beardsley until it ended. From the time I joined Weil, Gotshal in 1972 to the time I left in 1994 with that year roughly in the middle, to be at FDA, it had changed a lot. It had gotten a lot bigger. After I went back to Weil, Gotshal, most of my practice, not all of it, I still did a lot of FTC stuff. Kate Beardsley did most of the CPSC stuff when she came. But I did do some of that. But then of course I started to do a lot of FDA stuff. And you know some people accused me of having gone to FDA for the sole reason of punching my ticket and developing this practice.

CC: Some people in the inside? On the outside?

NB: Both. But I'd gone to FDA because it seemed like, although I was initially reluctant, once I was talked into it, I mean, it was, I had gotten a little bit bored in private practice and it turned out to be absolutely fascinating. I loved it. And it was inevitable that I would do it in private practice.

CC: Interesting. I don't know that anyone's ever said that about Rich Cooper.

NB: Well, right. Or anybody else.

CC: Right. But as far as I know, Rich wasn't a food and drug lawyer before he became FDA Chief Counsel.

NB: No, he wasn't. And he wasn't as much of one afterwards. He still did all kinds of litigation but he was certainly a food and drug lawyer. And a very good one.

CC: Yes.

NB: But Weil, Gotshal had gotten bigger and bigger and bigger. When I started there in 1972, I think I was the 120th lawyer or something like that that had ever been at the firm. And by the time I left we were much, much, much larger than that and the food and drug practice was a much smaller practice than most of the practices. Weil, Gotshal had one of the earliest really big bankruptcy practices, corporate tax, all that kind of stuff. And they all had much more leverage. They used lots and lots and lots of people. So it just wasn't as much fun for the smaller, for this niche practice, and it would have been very difficult to make sure that Geoff and Kate got to be partners at Weil, Gotshal.

[DR-100-0033.wav at 01:00:19]

CC: Were they with you at Weil, Gotshal?

NB: Yes. And some other people as well. But the more I thought about it – that was the year I turned 50 – I decided, we decided that we didn't need all that. I didn't really need a tax practice and a bankruptcy practice and all the other things. And also Weil, Gotshal imposed some conflict problems, because the corporate people, I mean I always used to joke that the corporate

people thought that it was a conflict for us to represent anybody that any of their clients might later want to acquire. But it was just time for a new adventure. And so we did.

CC: And how was it?

NB: It was great. I never regretted it and never looked back. It was nice not to have to you know argue with people if you wanted to cut a bill or ...

CC: Because you were the boss.

NB: Yeah. Kate and Geoff ... as I said Geoff left relatively early ... and if Kate wanted to cut a bill or if I wanted to cut a bill, we cut a bill and that was that. Partner meetings were held at lunch. It was fine. It was great.

CC: It sounds like it. It sounds like it suited you and it suited you at the time in particular. Before I turn off the tape recorder, anything else? I think I've wrung you dry.

NB: I think we've covered all the ground I expected to cover and a lot that I didn't and I hope readers will find it interesting.

CC: I think it's fascinating and I think the ground that you didn't anticipate covering is equally interesting.

NB: Good. Thanks.

CC: Thank you.

[END OF INTERVIEW]



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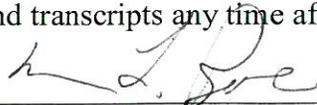
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