



**FDA**

**U.S. FOOD & DRUG  
ADMINISTRATION**

OFFICE OF REGULATORY AFFAIRS

**Oral History Interview with  
Lawrence Bachorik  
Director  
Office of Communications  
1978-2015**

**FDA Oral History Program  
Final Edited Transcript  
July 18, 2016**

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*Lawrence Bachorik, c. 2013*

## **Oral History Abstract**

Lawrence Bachorik came to FDA in the fall of 1978, as a speechwriter in the Office of the Commissioner. Over the next three and half decades he played an instrumental role in developing and administering FDA communications and media relations, writing speeches for Commissioners Donald Kennedy, David Kessler, and Jane Henney, and starting FDA's Office of Public Affairs (now the Office of External Affairs).

## **Keywords**

public affairs; media; public information; speechwriting; communications; stakeholders

## **Citation Instructions**

This interview should be cited as follows:

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## **Interviewer Biography**

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

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

## **FDA Oral History Program Mission Statement**

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

## **Statement on Editing Practices**

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

[BEGINNING OF DR-100\_68.wav]

CC: This is another in a series of oral history interviews for the Food and Drug Administration. Today is July 18, 2016, and we are interviewing Larry Bachorik at FDA's White Oak Campus. Larry served in FDA, on and then off and then on again, for 35 years or more in various positions. This is Catherine Copp, and Suzanne Junod and I are conducting the interview.

Larry, we are very excited to have the chance to talk to you today. Let's start by having you tell us a little bit about your background and early history.

LB: I was born in Battle Creek, Michigan – also a Midwesterner. I lived there for 18 years – lived in the same house for 18 years. I went to college at Cornell University in upstate New York. That's where I met my wife. It was a turbulent era – in the late '60s and early '70s. I wanted to become an English professor. I went to graduate school at McGill University in Montreal, Quebec, Canada.

CC: And what year was that?

LB: I started in 1971. I lived in Montreal for five years. I had a full scholarship but I had to teach for four years to get the support. The fifth year, I made good progress on my dissertation. It actually took me six years to finish the Ph.D. We were married after my fifth year, and I completed my dissertation and taught part-time at the University of Vermont for that sixth year. At that time, my wife was beginning her fourth year of medical school at the University of

Vermont. So my career plan was to become an English professor, possibly at a small college somewhere. What my wife and I thought would happen was that I would be a tweedy English professor and she would be a physician at the student clinic. We thought that was a likely scenario.

CC: We know that you didn't become long-term an English professor. My recollection is that there was a period where there weren't a lot of academic jobs available, and many people who had planned on an academic career didn't have one. So what happened with you?

LB: Well, that's right. And I think the period has been for about the last fifty years. The situation in humanities and, I think, in the sciences as well, is that many people who have trained, even at the best universities, and got Ph.Ds., are finding what used to be known as "alternative" careers. Even in the sciences, many scientists don't have academic careers anymore as bench scientists – they will go with industry or be involved in science policy. Some of them teach in high schools and junior colleges.

CC: Let me interrupt you there – I'm sorry. Tell us what your field was.

LB: Oddly enough, for the time – the turbulent late '60s – I was keenly interested in Restoration and 18<sup>th</sup> Century British literature, which is known as the Neo-Classical Period. So everything was very formal, and the English writers at the time, the poets especially, tried to emulate the great classical poets of Greece and especially Rome, because England thought itself to be the heir to the Roman tradition, and the classics were very, very important. It was an odd

kind of juxtaposition with all the unrest on campuses and my studying this kind of very formal period of English literature.

My real passion was Restoration drama, which is roughly the period between 1660 and 1700 in England, after King Charles, the Stuart line, was restored to the English throne in 1660 after Oliver Cromwell and the Commonwealth. That's why it's called The Restoration. The king then was King Charles II, and there were two theaters in London. My dissertation was about the adaptations of William Shakespeare in the 1660s. I could go for hours on that but I won't. But essentially, I studied and wrote about how one playwright in 1660s London rewrote and re-envisioned Shakespeare for the new, modern audience in the Restoration stage of England.

[DR-100\_69.wav]

CC: So how did you end up in the D.C. area and, ultimately, at FDA?

LB: Sure. I had good advice from one of the people on my thesis project, and he suggested that Washington, D.C., would be a good place to locate to once I finished my degree, because of the presence of the Federal government. At the time, the government was hiring people with a humanities background – people who could write clearly and organize arguments. And the idea is if you're a scholar, you can communicate well, so that's why we ended up in Washington. My wife was doing – wanted to do – her internship and residency in what was then a new field, primary care internal medicine, and as it turns out, George Washington University had a new program in that area with a very vital and charismatic department chairman. GW wasn't

necessarily her first choice, but we worked together and found an option that was good for both of us.

So, as luck would have it, over the summer when we moved to D.C., which was in 1977, I finished up my dissertation. I submitted it and was going to defend it in November. And as soon as I finished – I submitted the manuscript in July that year – I updated my resume and went personally to all the English departments at universities and junior colleges in the Washington, D.C., area. And when I got to Georgetown, I walked into the office and nobody knew me, but immediately I recognized a woman who had been a grad student while I was at Cornell and lived in the same residence where I had lived. And she remembered me and I remembered her, so I had a little bit of a connection there. So I left the resume, we had a nice chat, and the summer went on and I was getting ready for my thesis defense.

On the Saturday morning of Labor Day weekend, I get a call from the chairman of the English department at Georgetown University saying that their resident expert in Restoration and 18<sup>th</sup> Century British literature, my field, had resigned abruptly to go work for the General Accounting Office. Apparently, this individual had been denied tenure that previous year, so I think this was his way of getting back at them to resign at the last minute. So it was a sheer good luck. The chairman asked me if I'd be willing to teach the departed faculty member's class on modern satire, which the syllabus was all ready for, and, of course, I said yes. I'd be there. So within an hour-and-a-half, I was at the English Department at Georgetown University at a faculty meeting.

That fall, I taught the one course in modern satire. It was mostly novels from the 20<sup>th</sup> century. And then, another bit of chance, one of the Elizabethan scholars had taken ill – had surgery or something – and after about six weeks into the semester, she was no longer able to

teach her course on Edmund Spencer's epic poem, *The Faerie Queene*. I had read *The Faerie Queene* in part as an undergraduate, and it was not my favorite piece of poetry or literature. But I was a good soldier and I – they asked me if I could teach that because Shakespeare is Renaissance, and so I straddled those two periods. I took up the burden of finishing this upper level class – both of these classes were upper level classes at Georgetown – the class on *The Faerie Queene*.

At the same time, I'd also gotten an appointment at George Washington University to teach one section of freshman English. This was a common practice back then, and it's even, I think, more common now, where qualified people, experts, are hired to teach on a per-course basis at universities and junior colleges – certain amount of money for teaching the whole semester. My recollection was I was paid \$700 to teach per class at both Georgetown and George Washington. No benefits, no nothing. That was the fixed rate and I was glad to do it, because it was an academic job

CC: And at this time Gail – I'm not sure you've used her name yet – but your wife Gail was in her residency or internship?

LB: Yes. The terminology is that the first year is your internship year and the second and third years are termed residency; second-year resident, third-year resident. This was her first year post-MD, post-graduate. She was having the crazy hours of being in the hospital and on duty 36 hours straight every third night, so it was a brutal schedule. It's different now because the rules have changed, but basically, I would see her one night out of three. The first night she'd be in the hospital and work 36 straight hours. Second night, she's come home at 6:00 in the

evening and pretty much go right to sleep. And then the third night, she would have gotten a full night's sleep and she'd come home at whatever time she came home and I'd get to see her. It worked out well because I was teaching part time and really being kind of a househusband, which I was totally comfortable with.

CC: So that accounts for 1977. Then what happened?

LB: In the spring of '78, I had taught a class at Georgetown. I then taught in the summer school at Georgetown, the summer of '78, a survey course of English fiction. In the fall, I actually picked up a class at George Mason University, a once a week freshman English class that met Monday evenings from 7 to 10. So once a week, I had to drive out to Fairfax from close-in Virginia where we were living. But it was interesting, because the students there were typically older adults, at least people in their 20s and even into their 30s perhaps. They weren't 17 or 18-year-old young people who had just finished high school. Many of them were people who were nurses who were getting their bachelor of science in nursing. They hadn't gotten it yet. Or going onto a mid-level career and they needed some, you know, they needed some basic credits. So that was very rewarding and I enjoyed it a lot, because they were interested and they were dedicated and they knew why they were in class.

Anyway, it was in the fall of 1978 that I connected with a friend of mine from undergraduate school, from Cornell, Tom Grumbly, who was actually Don Kennedy's executive assistant at the FDA. Don was Commissioner of the FDA at the time. Tom and I knew each other from 1967, from when we were freshmen, and he was back in town and he had reconnected with Don Kennedy, whom he'd met at OMB, I believe. So Tom just casually told me that there

was a writer/editor position in the Commissioner's office at the Food and Drug Administration, and asked if I would be interested in applying. So I thought about it. The academic life was good and I was happy with it, but I was teaching a class here, a class there, and it wasn't really a career path toward anything.

CC: Georgetown wasn't offering a tenure track?

LB: No. In fact, about the same time that I heard about this job at FDA, Georgetown had wanted me in the fall of 1978 to teach two sections of a class but one would be Monday, Wednesday, Friday, and the other would be Tuesday, Thursday or something like that. I asked the chairman if I could please have both of my sessions, both of my classes, with the same day schedule so that there would be at least two days a week where I could stay home and do scholarship, you know, and work – because I had to – in order to advance, I'd have to do research and publish. And the chairman said no. He wouldn't do that. So I'd been a good Boy Scout – I had picked up all these classes for people that were ill and I taught summer school – I was there when they needed me. So that was a pretty clear signal that the folks at Georgetown weren't going to be interested in me long term for a tenure track position.

So I applied for the FDA job and was interviewed and, lo and behold, they hired me. I was hired under an unusual authority, an IPA, an interagency personnel agreement. I was able to be hired noncompetitively for the term of a year, because I had from Georgetown, also from George Mason, a letter of appointment. I think at Georgetown, I was a lecturer in English. And so with that piece of paper, once FDA decided they wanted to hire me, I could be hired for up to a year without going through the normal competitive process.

CC: And then did you eventually convert to a permanent position instead of under an IPA?

LB: Yes, I did. Yes, I did. I was – it was kind of an experiment, and I was still teaching part time. I think, I can't remember for sure, I know I had one class at George Mason University, the evening class on Monday evenings. And I think I was carrying one more class at Georgetown at the time. When I started in November of 1978, I was part time and I worked two or three days roughly a week until January at least. And I was a writer/editor in FDA's Office of Policy Coordination. After the holiday season, I was only teaching one class and that was the evening class at George Mason. Sometime in January '79, I started working a full 40-hour week at FDA, and was teaching at night. So, you know, my Mondays were busy, but I'd go right from FDA out to Fairfax and teach for three hours and get home at 11:00 at night. Strangely enough, I think, I really enjoyed the work at FDA and I liked the culture.

CC: Why do you say strangely enough? I'm just curious.

LB: Well, it's in the late '70s that Presidential candidates started to run against the bureaucrats in Washington. Jimmy Carter even did.

CC: Yes, he turned off the hot water in Federal buildings.

LB: Yes – he turned off the hot water. I had read, as a grad student – in the fall of 1976 – I had read a book called *The Chemical Feast* by a fellow named James Turner, and I didn't know



who James Turner was. And it was all about how the FDA was allowing these harmful ingredients and food additives and substances into our food supply, and it was really bad for us.

I didn't do much pleasure reading, because I was working on my dissertation, but I do remember being taken by that book and wondering why the government didn't do a better job of protecting us. And so I had a little bit of – that's about what I knew about the FDA. But I didn't realize until much later that James Turner was a Nader-ite and he definitely had a point-of-view – it was his job to do an exposé. And then the culture generally was, there were lots of assumptions about civil servants and bureaucrats, you know, maybe not being as smart or as able as people in the private sector.

So I came in with an open mind, and I was just enormously impressed by FDA employees and their dedication to the mission of the agency, as I came to understand it. And they were not at all like the stereotype that sometimes used to be trotted out and maybe still is today. They were interesting people; opera buffs and athletes and people with a passion for their work, of course, but also they were interesting people in their own right. So I was very impressed by the caliber of people at the FDA. I found that I was well-suited to the culture, and I really enjoyed the work that I did. And the office where I was in FDA seemed to think I was doing a good job and liked my work, so after three or four months, certainly by February of 1979, the administrative person in the Office of Policy Coordination and I started talking about how we could get me into a permanent slot in the FDA.

CC: Who was the head of the Office of Policy Coordination at that time? Do you remember?

LB: It was a new office that Don Kennedy created. The director was Ellen Williams. She had come to the FDA from the pharmaceutical industry. The notion when creating the Office of Policy Coordination, as I understand it, was to have one central place in the Commissioner's Office, in the agency, where regulations could be strategically thought through, where a need for regulation could be surfaced and some strategic thinking and planning could be done about how the rule would actually be shaped and fit in with everything else that FDA does.

I can't speak to this directly, but I gather that the perceived need was that regulations would bubble up from the various, at that time, FDA bureaus – the Bureau of Foods, Bureau of Drugs – and they would hit the Commissioner's Office and they might not necessarily be in sync with overall agency policy. I'm just speculating here. So anyway, the idea was to have an office that could, as the name suggests, be more strategic and coordinated in issuing regulations.

CC: Also, at this point, in 1979, Richard Cooper is the Chief Counsel, and the previous chief counsels, primarily Peter Hutt and Richard Merrill, were major policy forces in the Agency, particularly Peter Hutt. As I understand it, Peter was legendary for trying to run the agency – my words, not anybody else's. I think that, in some ways, maybe left a policy vacuum, as it were, which, was appropriately – again, in my judgment – moved to the Office of the Commissioner and the office that Ellen Williams filled.

SJ: You may not be in a position to know this, but was the FDA Policy Board still operating? That was the chief policy making group in FDA for a very long time.

LB: I think it was. I think it was.

CC: I think the Policy Board continued to operate – certainly into the '80s

LB: I mean that was basically the Commissioner, the one deputy Commissioner, and then all the associate Commissioners, right? That was the Policy Board?

CC: And I think the Center directors, or what were then called the Bureau directors. But when you look at the evolution of the agency over the decade of the '70s, when Peter Hutt becomes Chief Council – Suzanne has, I think, said the same thing – that's when regulation starts to really take off, with the regulations, writing regulations. So anyway, I think your idea about why this office, the Office of Policy Coordination, was established is probably fairly accurate.

So let's get away from big questions and talk about exactly what you did that you enjoyed so much? Because you said you enjoyed it.

LB: Well, the immediate issue was that the Commissioner, Donald Kennedy, was spending an inordinate amount of time editing his own correspondence. Letters would be drafted in the Centers or in the Office of Regulatory Affairs and would make it through that, you know, whatever Bureau it was. I said Centers a minute ago. They were Bureaus at the time. And then it would come up to the Commissioner's Office. Part of the Office of Policy Coordination was the Executive Secretariat. OPC at the time had three components and that's – the executive secretariat managed the Commissioner's meetings and correspondence.

CC: Who was head of exec sec then? Do you remember?

LB: A woman named Carla Mouré whose husband, Mickey Mouré, was a major force at HHS in management and operations.<sup>1</sup> I'm not sure what – I think he was an assistant secretary. I'm not sure what his title was. So I think the main reason that the Office of Policy Coordination wanted to hire a writer/editor was to have someone clean up the correspondence before it went to the Commissioner so that he wouldn't have to spend his valuable time making it less bureaucratic, less formal, more a good classic English style.

[00:20:13]

SJ: Boilerplate was traditional.

LB: Boilerplate or somewhat – what's the right word?

CC: Stiff?

LB: Stiff. Obfuscating. A little pompous sometimes.

SJ: Often citing the chapter and verse without really telling you what they meant or how they even used it in the past. Is that accurate?

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<sup>1</sup> The U.S. Department of Health, Education, and Welfare became the Department of Health and Human Services in 1979.

LB: That's part of it, and then just some of the stilted language. Like, letters would start, "We are in receipt of your letter of such and such." It sounded like something out of the Victorian age.

CC: Was Commissioner Kennedy, Dr. Kennedy, looking for someone who could make these letters more his voice?

LB: I think that's part of it, yes. He was – Don Kennedy was an inspiring figure and we may touch on that more later, but he cared deeply about the voice of his own correspondence and he had his own – I mean he wanted the letters to reflect his own personal style, and not some, you know, nameless bureaucrat.

CC: Right. I started at FDA's Chief Council's office in September '78, so we're basically starting at the same time. And I remember Don Kennedy used to eat lunch with a group of people from the Chief Council's office.

LB: Mostly the lawyers. I mean he'd sit down there and the lawyers would --

CC: Yes – at that one table down in the Parklawn cafeteria. And I didn't eat there all the time, and maybe this isn't where I heard it, but when he came to FDA, the style in Federal Register notices was to say, "The Commissioner" as the subject of the sentence, such as "The Commissioner has decided that," and he eliminated that, because I think he thought it sounded sort of regal. In fact, it was the agency, not the Commissioner personally, who was making

decisions and so on. I think that dovetails with his desire to have his correspondence reflect his voice. It's interesting to me that that practice goes back eight or nine Commissioners, to where Don Kennedy is actively managing his voice as the Commissioner, I guess.

LB: I'd like to make a more general point about a personal voice versus good, clear communications. One of the things I did run into when I was rewriting the Commissioner's correspondence was the passive voice. I mean I edited it quite heavily and I took passive voice, which is the staple of bureaucratic writing, and I made, to the extent possible, I would make those sentences into the active voice, and action verbs and not "is" and "was" and "were". And I did some major surgery on a lot of the correspondence, and sometimes people would – well, they would often be defensive about it if they were the author, but they would fall into the notion of, "Well, you know, I just – it's the Commissioner's style that I can't do, and you can do it."

But it's more than that. It's good, clear, basic English prose. And it's not the – I mean Don Kennedy cared mostly, I think, you know, as much about having his writing be straightforward and clear and logical as any particular voice that he had.

CC: And where do you think that came from with Dr. Kennedy? I mean he was a scientist. He was an academician, but he was a scientist.

LB: Academicians even in, especially maybe in English or in communications, are notoriously convoluted writers. I mean academic papers are often, and I think this translates into other of the humanities and even economics and so on. But sometimes there's this jargon and

jargon and jargon and more jargon. It's not very clear. So being in English doesn't necessarily mean you're going to be a clear writer.

But I think Don – Don was just a – he was an intellectual – he was very, an intellectually alive and creative person. And I think he was – I don't know if he was well-read or not, but he was incredibly articulate.

CC: Well, just to finish the circle on Don Kennedy, he went on to be the president of Stanford University, after he was the Commissioner of Food and Drugs. So he was a very, very capable individual. That reflects – but anyway.

LB: So my inference is that he had a well-rounded education. I don't know where his undergraduate degree was from or whatever, but he clearly could speak and write very eloquently, and that was important to him. So that's why, you know, he spent so much time editing his correspondence, and that was partly what I was brought in, mostly what I was brought in to do, at the time.

CC: So you mentioned to me, when we were discussing the possibility of this interview, how this editing, at least temporarily, culminated in "Operation SHAKESPEARE." I remember it vaguely, but of course, as a lawyer, I thought it didn't apply to me.

LB: It did, by the way.

CC: I'm being facetious. When you were describing use of active voice and action verbs, I recalled some of my supervisory work in the Chief Counsel's Office. I did a lot of supervising of lawyer writing and those were some of my principles, so it must have rubbed off.

Two things. One, I'd like you to talk about that project. And two, I just thought it was interesting that when I searched for "Operation SHAKESPEARE" on the internal FDA website, I discovered that, in fact, it is still referred to 35 years later, which I think is a very interesting legacy.

LB: Well, I'll have to find out where you found that.

CC: Well, I have the page so I'll give it to you.

LB: It's in one of the oral histories, I know.

CC: No. This is not from the oral history. If you were still an employee and went to the Inside FDA website, you would find a reference to it. So what was Operation SHAKESPEARE?

LB: What happened was, we know that Don Kennedy cared deeply about clear communication. There was another writer/editor who was already in the Office of Policy Coordination when I arrived as a part time employee, and she was working on a style guide for the FDA.

CC: And who was that?



LB: I don't know her name. I'm not sure I even met her. She, to me, you know, as someone who was in his late 20s at the time, seemed like an old person. Probably younger than I am now. And she had an office where she could go close the door, as most of the full time employees in the Office of Policy Coordination had.

When I came into the office, I worked in a common area at just a table where the secretaries were. This was pre-computers and personal computers, and I did my work with a lot of number two pencils that were well-sharpened and I just did the editing by hand on drafts. Anyway, for whatever reason, that project, the style guide, wasn't going well. So I don't know what happened to this person, but lo and behold, not too long after I arrived, she was gone. And between Don Kennedy and Ellen Williams, they wanted me to run a good writing program for the FDA. Ellen was a very creative person and she and I would sit down and brainstorm. The actual title, Operation SHAKESPEARE, I came up with, and it's a long acronym. There's one letter that doesn't quite work, but Operation SHAKESPEARE, the Shakespeare in it stands for "Some Humor Art and Knowledge, Easily Studied and Practiced, Enhances Any wRiter's English." And the cheating is on "writer" because it's a W, not an R, like the – next to the last letter in Shakespeare's name.

So we made, you know, I wrote up this proposal, Ellen approved it, and I wrote I think it was a memo to the Center directors, the Associate Commissioners – the Policy Board probably at the time – launching Operation SHAKESPEARE. And I don't have the memo anymore, but I remember Don signed off on it – but he underlined "Operation SHAKESPEARE" and his handwritten note said something like, "Okay, but don't make it too cute."

And so for this program, we actually had a little pre-campaign. I went to the FDA art graphics shop. A guy named Dom Summa ran it, I believe, at the time. S-U-M-M-A. I explained what it was all about, and he created a poster and a flyer. The flyer we duplicated by copy machine – it just said "Operation SHAKESPEARE" and Shakespeare was in big, bold letters. "Food and Drug Administration." That's all it said. And I hand distributed these and tacked them to bulletin boards all around the Parklawn Building, a couple of weeks before we launched it, before the memo went out to the Policy Board.

And then we created a poster and Dom and I talked, and I've still got a couple copies of it, but he illustrated a Shakespeare-looking man with a quill pen in his hand, a big feather pen, with a dog, sort of floppy-eared dog, looking up sheepishly. And the caption was, "Operation SHAKESPEARE. Has your writing gone to the dogs?" And we put this poster up all around the agency as well. So it was fun.

CC: Was this program confined to FDA headquarters or was there an effort to involve the field offices?

LB: It mostly was – it involved headquarters, although there were, you know, people – the need for clear communication was evident throughout the agency. And the other thing we did is we created, or Dom created, a graphic for a three-ring binder. The idea was that the binder – that there would be seven or eight or nine chapters in this manual and they were being rolled out over time.

I wrote an introduction that Don Kennedy signed, and then there was a first chapter and a second chapter and a third chapter, and they were going to be supplemented and released over

time. Unfortunately, the binder never got filled because in June of 1979, Don Kennedy was called back to Stanford to become the president. I did do a chapter or two over that summer, but then the momentum went out of the project, of the actual style guide part of the project, and then we had a new Commissioner, Jere Goyan, for about a year, and I was pulled off to do other things.

But the other part of Operation SHAKESPEARE, which was actually giving seminars and sessions on good writing, that continued for a couple of years. And I actually was, around the time that Don Kennedy left, I was able to hire – the office hired another writer/editor who did some of that editing of the correspondence, but also helped me design and teach – they weren't really classes so much as one-off seminars around the agency on how to be a better writer.

CC: Are there other projects that you remember from the period you were in the Office of Policy Coordination? And at some point, I think Ellen Williams leaves. She wasn't here all that long either.

LB: That's right. In fact, she became a special assistant to the Commissioner. I think that was probably after Don Kennedy left. I think she worked with Jere Goyan in that capacity, and I think by – certainly by the early '80s, maybe 1981, she had left. She had left the agency.

My work in those early years was a lot of editing of not only correspondence, but also, you know, memos, things going to the Commissioner. Since the Executive Secretariat controlled the Commissioner's correspondence and that included memos up to the Department, I would often be involved in revising those memos to make them clearer. So my duties were writing and editing, and, for a year or two, I would hold good writing classes.

I remember once – what I did when we launched Operation SHAKESPEARE, I went personally and met – I think Ellen was with me for some of these meetings – with each of the Bureau directors at the time. And, you know, basically this was coming down from the Commissioner and the Commissioner wanted a good writing program at the FDA, whether it was called Operation SHAKESPEARE or whatever, you know, the Commissioner would get that. And so it got some serious traction. I remember the center – the Bureau director in the Bureau of Drugs. Jerry Halperin was the deputy.

CC: Right.

LB: And was it Dick Crout?

CC: Yes, Dick Crout. J. Richard.

LB: J. Richard Crout, and they took it very seriously. I remember – it's kind of amazing in retrospect – we booked one of the big conference rooms down on the third floor of the Parklawn building, and I must have – I had a two-hour session with, it must have been 250 or 300 people from the Bureau of Drugs. I had old-fashioned transparency slides and I went up and I had gone through Exec Secs files and correspondence, warning letters or correspondence with companies, and I had pulled out –

SJ: What not to do?

LB: Examples of particularly – of things not to do, right. Right, Suzanne. I guess it was a bit audacious at the time, but I was trying to make some general points, you know? Avoid the passive voice. Use the active voice. Be simple and direct. Don't use a fancy word, necessarily, or a Latinate word, when a good, plain Anglo-Saxon English word will do.

One of the things we did with the Operation SHAKESPEARE notebooks is – we probably produced 300 of them or so – I don't know – we bought an equal number of copies of Strunk and White's *The Elements of Style*. And that was put in the pouch in each of those binders. In fact, in Don Kennedy's introduction to the style guide, which I wrote but he revised and signed off on, we referred to Strunk and White – it's called “the little book.” You know, “get the little book.” And that's a lot of principles there.

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There was a lot of concern about so-called overregulation, and that the government's, you know, stifling innovation. And I think part of that was the complex and sometimes not easily understood regulations themselves. So we may talk about deregulation more later in the next decade, but I think that the push for clear writing and good writing and clearly understood regulations was part of the environment at the time.

You asked about any specific projects that I recall from the late '70s. I was very involved in editing food draft food labeling regulations. The FDA had held hearings on the food label. I don't remember the exact dates. In the late '70s sometime – maybe '77 and '78 – there were big public meetings around the country, and the FDA was going to revise the food label. And jointly with USDA there was a proposed, a set of proposed rules on the food label, both for the FDA-regulated products and the USDA-regulated products, meat and poultry. I remember spending

several weeks in the fall of 1979 editing all of the proposed rules that FDA eventually issued on those. And it was an effort that we coordinated with USDA.

CC: Now did that regulation ever become finalized? Because, you know, when we jump ahead a decade or more, we have NLEA and a new food label.

LB: I honestly don't know. I don't remember what the outcome was. I think it probably didn't bear fruit.

CC: Right. Because I'm thinking this was very close to the change in administrations.

LB: I think the proposals probably were published.

CC: Right.

LB: And we could easily verify that.

CC: Right.

LB: But I'm not sure what happened. I don't think there was any change in the food label. What I do remember is, after spending a week or two, probably full time, doing pencil edits on the draft regulation and somebody else would actually, the secretary I guess at the time, would actually make the changes. I remember when I went down to the Bureau of Foods to talk to

Sandy Miller and some of the senior people there about Operation SHAKESPEARE, one of the senior people there said, "Yeah, well, I don't know. I think our writing is fine. The Commissioner hired some fancy writer/editor to revise all the food label proposed rule and it didn't make any difference." So this was – I mean that was the mentality that that one confronted often – "Our regulations are fine. The way we write and communicate is fine." And that isn't necessarily the case.

I was also involved in revising some regulations for Victor Zafra, who was the Bureau of Medical Devices' deputy director. I did a lot of work on some of the early medical device regulations – they might have been the classification regs – and revising them, putting them into more straightforward English. I think the outcome of that was – I don't think – I think most of my recommendations were not accepted.

CC: I had the privilege of – and that's in quotation marks – working on two different device classification packages as a new lawyer in the Chief Council's Office. And I do remember that a lot of those regulations were standardized language and that at some point, we received new standardized language. So maybe you had some influence.

LB: Oh, good. That's nice to know.

CC: I want to close out this phase of your career by asking if there are other people you remember, either managers – not necessarily in the Office of Policy Coordination – or peers. You mentioned Sandy Miller. You mentioned Vic Zafra. Any other people? Did you ever go to the Commissioner's management meetings – the ones for which there was always a "goldenrod"?

I think the Commissioner met weekly with each of the Centers – Bureaus – and the Bureau director. Were you ever in any of those meetings?

LB: Typically not. Don Kennedy did meet every week for at least a half-an-hour with the whole – with much of the staff of the Office of Policy Coordination, including Ellen Williams and her deputy. I mentioned there were three staffs in the Office of Policy Coordination. Another staff was a policy analysis staff, and they were sort of – that was the new wrinkle, I think, in OPC. And they were already in place when I arrived, but there were three or four, four or five maybe, mid-level employees whose job it was to think about policy. And they had kind of a “beat” system. You know, one would be assigned mostly to drugs issues for example, another one to foods. And they were kind of the Commissioner's eyes and ears in the policy world for regulations, emerging issues, developing trends. And Don would meet – we'd actually go to the Commissioner's conference room – I think it was Tuesday mornings for a half-an-hour, 45 minutes, which is a big chunk of the Commissioner's time. We would actually get face time with him, and I was involved in that, which was enormously, you know, enormously helpful just to be able to observe him and how he spoke and how he managed things.

A kind of interesting sidelight. One of the policy analysts at that time, his name came up again in 1986 at the time of the Challenger disaster. And he was the engineer who had expressed concerns about the O-rings that failed because they froze in the cold temperature. That was an FDA alumnus – I don't know if he was working for a contractor at the time. Morton Thiokol is my recollection of the name of the contractor, or whether he worked for NASA, but his name came up in the coverage. So these were bright, thoughtful people who actually did spend time



analyzing FDA's policies and whether they were regulations that were needed or when the regulations were coming through, what things needed to be changed about them, and so on.

You asked about other people. John Villforth at the Bureau of Radiological Health and his deputy Jim Benson – I remember them. They were very enthusiastic about Operation SHAKESPEARE. I don't remember doing a lot of training there, but they embraced the notion.

And one of the senior people at that center at the time, a guy named Bob Sauer, to this day, still calls me "Shakespeare," just because that was my nickname back then because of Operation SHAKESPEARE.

CC: Bob Sauer works down the hall now with his brother in the same office.

LB: I know they're still involved.

CC: That's sort of classic FDA.

Oh, there is one other thing I wanted to ask you. You have a degree in English from Cornell. You have a PhD in Restoration drama from McGill. How did you handle being in an agency that handles so much scientific material? Was that a transition for you or, just this other body of knowledge that you absorbed?

LB: I've always been interested in science and math. I started college, undergrad, as a chemistry major and decided that I didn't want to be in a lab. I probably had some half-baked notions of what chemists actually do, but I wanted something where I was dealing more with people on a daily basis and what I viewed as being more isolated in the lab.

I've fancied myself a pretty quick study and fortunately, especially in any FDA area that touches on human medicine, with my wife as an internist, I had easy access to lots of background information. So there would be times back in the day when I would actually call my wife at work and say "What do you know about this drug?" or "Here's a procedure that's being talked about," or whatever. So I had sort of a built-in support. It was definitely an adjustment, but I don't remember it being that difficult. A lot of what I've done in my career is – and we'll probably talk about this more later – I view as kind of translation – taking sometimes fairly complex concepts, whether they're scientific or medical, and trying to understand them myself, interviewing people about them, and then expressing them in language that is intelligible to an ordinary layperson.

CC: Not that this interview's about me but that's my experience as well other than I never studied any science. When I'd work with people from the Center for Foods, I'd explain my background and say "Look, the last science class I had was winter of 1972. It was Ann Arbor. And it was an 8:00 class. How many do you think I got to?" I would learn from the scientists themselves, but again, the translation function is common except I was translating stuff to create arguments to support a certain legal theory.

I wanted to let you say anything you might recall about working with Dr. Goyan, because there was a short period when he was Commissioner for about 14 months or something like that. In the last year or so of the Carter administration – and there was also a change in the Chief Council during that period. Did you do work, similar work, for Jere Goyan?

LB: My recollection is that Don Kennedy left in June of '79, and I remember one of the projects I worked on over that summer was a briefing book for the new Commissioner, although we didn't know who the new Commissioner would be at that time. But I remember spending July and August, and it was the Office of Policy Coordination's job to prepare the briefing book for the Commissioner. And Dr. Goyan – you say 14 months. He was around 14 months. That means he must have come in September or October of '79.

CC: He came in October of '79.

LB: Okay.

CC: According to a cheat sheet that I created a while ago.

LB: Okay. So we spent a lot of the summer actually writing up summaries of the executives, of the Policy Board members, people in FDA. And describing some of the program areas and there was a section, I'm sure, on the tough issues of the day, the things that the Commissioner would need to know.

And so, as a writer/editor in that office, I saw all the Commissioner's correspondence that went through Exec Sec – all the letters that the Commissioners would sign came through me. And that's something actually I forgot to mention with Don Kennedy. There's this whole system. I don't know if they still use it. There were orange folders, and those were the Commissioner's correspondence, and that's what I would spend a lot of my time on during those first few years. They'd just come in and I would revise the letters and then a secretary would make the changes

on a word processor and they would go into the Commissioner for signature. So I did that same function for Dr. Goyan, as well.

CC: Are we talking IBM mag card era?

LB: My recollection was, when I got to the Office of Policy Coordination, they had just bought one or two Wang units, word processing units.

CC: I guess those weren't very widespread. Actually the first couple weeks in September '78, we got words processors in GC. We didn't have Wangs in GC. We had Lanier word processors. So that would have been the beginning of word processing which, of course, facilitates editing in a way that typewriters don't.

Let's move on to your next position, which was as a speechwriter. How did that come about? That's a little bit different. It's still the English language, but –

LB: Well, the roots of that – that started really even to some extent in Don Kennedy's time because Don had a marvelous speechwriter, a man named Timothy Larkin. And Tim had been a speechwriter, I think, at the US Postal Service. And I don't know how he came to FDA, but when I arrived in '78, he was Don Kennedy's speechwriter. And he was a master speechwriter. The speeches that he wrote for Don Kennedy were, as you might expect, very well-crafted and they were also very often thematic speeches – they were kind of classical in the sense that they would say, "Here's what I want to talk to you about." And they would have a theme that was reintroduced maybe with an anecdote or a story, and that theme would continue through the

speech and they were all of a piece. I don't think the Commissioner had a speech a week or anything like that. I remember seeing Tim Larkin's speeches and they were really almost little mini works of art.

I don't know how this process worked, but you know, clearly Don, as an articulate man, cared a lot about his speeches. I was interested in that early on, and I would go have lunch with Tim and talk to him about speechwriting. I think as early as probably sometime in '79 or not much later than that, I expressed an interest to Tim in learning more about the craft. He shared some drafts with me of things he was working on, and I think he actually offered to have me draft a speech or two for one of the Associate Commissioners. So it was a little bit of an apprenticeship that I did under him. Tim was also a poet, and he published independent volumes of poetry. Lived on the Eastern shore, drove in. He definitely wrote for Jere Goyan, I know. I don't remember exactly when Tim left but I think it was maybe when the change of administration happened in '81.

I will say that one of the best lines that he ever wrote was a line that Jere Goyan delivered at his farewell brunch. And he started out the speech by saying – this is Dr. Goyan – saying, "I'm leaving the FDA the same way that I joined it 14 months ago. Fired with enthusiasm." So that's a line that I'll always remember. Tim Larkin wrote that line.

So that gives you a taste of what Tim could do with a turn of phrase. In the early '80s, I don't think any particular speechwriter was hired for the new Commissioner. Arthur Hull Hayes was the Commissioner under – the first Commissioner under President Reagan. And I frankly don't remember when he started at FDA. He was certainly there by '82 and maybe '81.

CC: April '81 is what my records show.

LB: Okay. So the speechwriting function was moved to the Office of Public Affairs, which at the time, the Associate Commissioner was Wayne Pines. Wayne was writing the Commissioner's speeches then, so he wrote speeches for Dr. Hayes.

In the meanwhile, I had become – I had been a training specialist for a while. That was how I got to be a permanent employee, and I was in that series for a year and then I got a promotion back to the writer/editor series. So that's what I was doing in the '80s.

But I still was very interested in becoming the Commissioner's speechwriter, so I went to Wayne Pines, the Associate Commissioner for Public Affairs, and basically volunteered my services.

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I said, "Hey, you know, I'd like to get more involved in speechwriting. I know you're writing the Commissioner's speeches. Give me some assignments." So that's actually how I got started in doing speechwriting for the Commissioner. I think probably from Wayne's perspective, he was running FDA's media shop and Office of Communications, which put out publications in the FDA magazine, *FDA Consumer* magazine. He was dealing with media all the time, so I'm sure he was delighted to have an extra pair of hands to help with the Commissioner's speeches.

CC: Was this before Dr. Hayes came? I ask because my recollection is Wayne Pines, and I think it was Bob Wetherell who was head of the Office of Legislative Affairs, got transferred out of their positions.

LB: That's right. That's right.

CC: They didn't get the boot. They just got moved around early in the Reagan administration. My memory could be faulty on that. But I'm trying to track things date-wise as to when you might have gone and raised your hand with Wayne.

LB: I think the first speech that I actually wrote for Dr. Hayes was probably in summer or fall of 1982. I had a whole stack of speeches that I kept the hard copies of and when I retired six months ago, I just, you know, I gave them to the History Office. I'm sure they've got copies of them all. So I know that by late '82, I was writing speeches for the Commissioner. And I believe Dr. Hayes left the agency in the summer of '83, is my recollection.

CC: Yes – September '83.

LB: He was Commissioner for a couple of years – two years and change. Two-and-a-half years.

CC: Yes. Two years five months, so two-and-a-half years.

LB: Somewhere in that period around 1982 or so, I was still in the Office of Policy Coordination. Ellen Williams was gone, and I think maybe the Policy Coordination Office was eventually dissolved. I worked with the head of Exec Sec – the person I was working for in '82,

'83 period was a man named Dan Brand. B-R-A-N-D. He had come up through the field and had been someone I'd worked with from the start. He supported my being the Commissioner's speechwriter, and he and I worked a deal where we got the speechwriting function transferred from public affairs to the Executive Secretariat.

CC: Was he the head of Exec Sec? That's sort of my recollection.

LB: He was the head of whatever that office was called. I can't remember if it was still the Office of Policy Coordination. It may well have been.

CC: So, talk to me about speechwriting. It seems like a very – I don't know if the right word is intimate, you're putting words in somebody's mouth. So it seems to me you have to know what that person thinks, how that person talks. I'm sort of curious about the process of speechwriting.

LB: It does require getting into the head of the speaker or the principal --and how they think and how they articulate thoughts, how they put sentences together. One of the essential things about being a speechwriter is to have a good ear and to be able to listen and to – mime isn't exactly the right word, but as I said earlier, get inside the person's head and actually say things the way you think they would say them. So fundamental to that is the ability to have face time with the principal, with the speaker. And it doesn't have to be one-on-one time. But to be successful, a speechwriter has to be in the same room with the Commissioner or the Secretary or whomever, and observe that person in action to hear how she expresses thoughts, how she



handles ideas – the articulation, the putting together – I mean literally, how phrases are joined. So you need face time with the person. Whenever I've either been a speechwriter, I've insisted on having access to the speaker. Or when I've supervised speechwriters, I've insisted that they actually get to go spend time with the Commissioner or the Secretary.

CC: Would you go to some random meeting on the Commissioner's calendar – let's say was meeting on an AIDS protocol? Or were there specific times when you could sit down one-on-one or one-on-two with somebody else?

LB: In general, the way the process would work – and it varies, of course, from Commissioner to Commissioner, depending on their individual style – but the best way, the ideal way, is not only to have the general access to the Commissioner – and that doesn't mean being in all the Commissioner's meetings, but being able regularly to be in the same room with the Commissioner. But it also requires one-on-one time to talk about specific speaking occasions.

CC: And what ideas will go in a speech?

LB: Right. And sometimes the meetings can be formal. It really depends on the Commissioner's style. When I was writing for a particular Commissioner, I would always send an agenda in advance. You know, here are the topics we have. Here are the speeches we're going to cover. You know, maybe a few nuggets on each one; what they want to hear, what their interests are. Other times, a Commissioner might be less formal, and we just go in and say, "Well, what do we have? Let's talk about this, that, or the other."

But being able to sit down with the principal and actually say, "Okay, we've got this trade association on December 15<sup>th</sup>." I might say, you know, "What are your thoughts?" Or the Commissioner might say, "Well, what do you think we ought to be talking about?" That would – that has to happen pretty early on, ideally. I would always do research on the group and the occasion – I would always talk to the outside group or the organization, whatever it was, and find out what their agenda was and why they wanted the Commissioner and what issues they wanted her to talk about. I would bring that to the meeting. Usually the Commissioner, I mean ideally in the best meetings, the Commissioner also has a vision or an idea or a set of priorities, of points that we want to make sure that group gets from the Commissioner.

CC: So it sounds like – at least the way it worked with some of the Commissioners – maybe all of them – you were both a writer and a substantive advisor. I mean you did research, you talked to the groups, so you could give guidance and say, "Well, this group is interested in hearing about this particular topic." It wasn't just going in with a steno pad and taking notes and then creating a speech.

LB: No, that's right.

CC: It was interactive.

LB: That's right. That's right. That was one of the most interesting aspects of the job, to actually be able and help – you know, to go in and help shape an agenda. And it's a responsibility, but it's also very invigorating to be able to do that. FDA has had periods that were

easier, in terms of its public health mission, and some more difficult periods. But throughout, if you're involved in the first draft of anything, you're helping to shape the agenda. And that's an important fact to remember.

CC: You recalled writing a speech for Dr. Hayes in 1982. Do you remember – was that the first speech you wrote? I mean what was the first speech you remember writing?

LB: Well, the first speech I remember writing was back in 1979 for a person who was the deputy to Ellen Williams in the Office of Policy Coordination. This was somebody who had come over from the Bureau of Medical Devices. He was a radiation physicist, I think, a guy named Marv Rosenstein. I just remembered this because it was early in my career.

He was a kind of wry guy, but he had to give a speech on food labeling, because, as we talked about earlier, food labeling was in the air. We'd had hearings on it. And so Ellen asked me to write a speech for him. I had read Tim Larkin's speeches for Don Kennedy. And the title was something like "Reading Between the Lines: The New Food Label." And the metaphor that I used was the universal price code or the universal product code, the UPC, which was brand new at the time. And, you know, not many stores or places had those laser scanners at that time. So I had this notion, and I think it worked for the speech, of having this funny little pattern of black and white lines, parallel lines, and then above it a long series of Arabic numerals. And that was new, and so the notion of reading between the lines, like, "We're going to tell you what you really need to know about the food label." But it also fit, like, between the lines of the black and white was this new technology. So that's the first speech I remember writing.

CC: Do you remember how it went over?

LB: I didn't go to it. That's another thing that's very important for a speechwriter, especially early on, is to be able to go to the speeches themselves. To actually see the speech being delivered, see how the client, you know, what works, what doesn't work. Are there lines that they stumble on? So those should be, you know, particular combinations of words to be avoided in the future. That's not always possible, obviously. But, you know, whenever I was a speechwriter for a Commissioner and the venue was nearby in Washington – I would make every effort to be there, to see him or her in action. So those are a couple of early speeches.

I wrote some speeches for myself. I gave a few talks early on, but the first speech that I remember getting a lot of attention and having an impact was a speech that Dr. Hayes gave where he announced that the FDA was imposing a voluntary moratorium on direct-to-consumer advertising.

CC: And that was direct-to-consumer advertising on drugs?

LB: Yes. Prescription drugs. It was a speech in New York. I think the group was the Pharmaceutical Advertising Council. It was a trade group. I think it must have been, I think it was in February. I'm pretty sure it was February, so it must have been 1983, because Dr. Hayes was gone by – later that year.

CC: Yeah.

LB: And that was one that I remember I was drafting it fairly at the last minute, and I remember being a little surprised and almost astounded to see, in the next week's *Pink Sheet*, that the speech was featured very prominently, that the lines I had just written a week or two, a week ago or so previously, were – that was FDA policy out there and it was an important and high visibility issue.

CC: I'm thinking of the interview we did with former chief of council, Nancy Buc, who talked about the effort in the latter part of the Carter administration, to develop direct-to-consumer advertising for prescription drugs. So the next step in the process is with Dr. Hayes and, of course, the change in the White House.

Do you remember any other hot button issues during that period? This is 1982. You were a speechwriter from 1982 to 1985, which was up to and then through Dr. Hayes' tenure. Who was the acting Commissioner after Dr. Hayes left?

LB: I think it was probably Mark Novitch.

CC: Yes, Mark Novitch. Did you write speeches for Mark Novitch? Do you remember?

LB: Mark had a writer that had been with him for a long time, a fellow named Ken Flieger. I did write speeches for Mark Novitch. I remember doing one sometime in that early '80s period, but I did that on a few occasions probably, but Ken was his go-to speechwriter.

A huge issue for the FDA in the early '80s, and this was before I was the speechwriter in 1982, but deregulation was just a kind of an overarching issue. I think President Reagan's

campaign, in 1980, had a pretty distinct theme of the US economy is overregulated. One of the first things that President Reagan did was establish a President's Council on Regulatory Relief. It was headed by a fellow named C. Boyden Gray. I remember this because I spent the summer of 1981 on this issue. One of the things that the Council did was put out a call to industry across the US that were, in any way, affected by regulations to write to the agencies that regulate them and make suggestions for regulatory relief. I don't remember whether it was done on an agency by agency basis, but I think everything was funneled into C. Boyden Gray's group and then it was parceled out to the EPA and the Consumer Product Safety Commission and the FDA and NIOSH and all the other regulatory agencies.

I spent the summer of 1981 composing and editing and finalizing letters to these citizens, to these companies that had written into the President's Council on Regulatory Relief, responding to their suggestions. That was a huge – that was a long term effort. It was a huge – I think it was a big priority of the Reagan administration. The way it translated into FDA in the early 1980s was probably the best crystalized in the phrase “voluntary compliance.” And a case in point was the effort to reduce added sodium in the food supply. Dr. Hayes was a well-known cardiologist, and so that was certainly one of the themes of his speeches, was the importance of reducing sodium in the diet, but reducing it through a voluntary program, not a mandatory regulatory program.

CC: Now, do you think that the voluntary aspect was something Dr. Hayes believed in? Or was that part of the more overarching themes of the Reagan administration, anti-regulatory?

LB: I can't say whether that was – I mean, he certainly espoused it, whether it would have come from him or not, but it was one of his major themes, as Commissioner, to do that.

Interestingly, we just talked about direct-to-consumer advertising of pharmaceuticals. Again, that was voluntary, but it was complied with, for sure, and it lasted for a long time, until David Kessler, actually. In the pharmaceutical advertising area, it was a voluntary initiative but it was moving in the direction of asserting more control over a part of FDA's responsibilities.

CC: Okay. So I was going to ask you, if you weren't writing speeches for Mark Novitch, what were you doing if you were a speechwriter?

LB: I wasn't a full time speechwriter.

CC: Oh, okay.

LB: I'd have to look at my personnel record, but I was a writer/editor the second time. I mentioned I was a writer/editor and then I was a training specialist. Then I was a writer/editor again – around 1980. And then at some point, I think '82, I became a policy analyst. And that's when I was writing speeches. My job title wasn't speechwriter.

CC: I see.

LB: That was my informal job title. I'd call people up and say, "I'm the speechwriter for Dr. Hayes. I need to talk to you about sodium in the food supply." But my formal job title was

policy analyst. So there was a lot of other stuff that I did. I was a staff director on one of the sub staffs in the Executive Secretariat, so I had three or four employees reporting to me, and I was responsible, I think, for foods and vet medicine, monitoring issues, going to meetings with the Commissioner on particular issues.

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So I was involved in policy and substance, and I wrote speeches as a part of my job, but it wasn't a full-time job.

CC: I think we've seen an increase over the past three or four decades in how frequently the Commissioner and other upper level management, senior staff, are speaking publicly.

LB: It'd be interesting to look at that, because I think probably in Don Kennedy's day, I would guess he might have given one, you know, one major speech a month or something. We should go back and look in the Drugs library or the FDA library where they have all these speeches. It would be interesting to know how that changed. It certainly varies with Commissioner to Commissioner, because some Commissioners enjoy the speechmaking process and others don't. So to some extent, it's personal preference.

CC: I think implicit in the conversation we've had so far is that the speeches you were writing were sort of public speeches to particular constituencies, like the pharmaceutical manufacturers



or whatever. Were you ever involved in these early stages in developing Congressional testimony?

LB: Testimony? I was – yes. But it wasn't until David Kessler's time that I got really involved in Congressional testimony, but I do remember drafting testimony for Don Kennedy way back in 1979. So I had a hand in it from time to time, but it wasn't until I was head of the speechwriting staff and worked with David Kessler that I actually had a substantial role in testimony.

CC: Hopefully we'll remember to go back to that because I'm interested in understanding both how your work might have been different and how the speech itself would have been different. Early on, when you were writing speeches, was there internal clearance? Like if there was a speech about food labeling – you talked about writing one for Marv Rosenstein – would that have been run through somewhere in the Bureau of Foods?

LB: This is close to 40 years ago now. That particular speech, I'd be surprised if it went through anybody except the Office of Policy Coordination. Because I think maybe that office was – and I know it was very involved in food labeling. I don't think it touched on legal issues. I'm pretty sure it didn't go to the Office of the Chief Counsel, but I'm not sure.

CC: It's not like today where there's a lot of internal review, above and below.

LB: Yes. That's definitely true. When the Commissioner gives a speech, there's always a formal or fairly formal clearance process. And in my experience, that always involved the Chief Counsel's office. Nothing the Commissioner says on the record in a speech or in testimony goes out without at least the lawyers looking at it because, you know, what she said moves markets, establishes policy. But for someone at a lower level, not necessarily, at least back then.

CC: I personally remember seeing – if I was involved, if I was the counsel for any particular legislative hearing, I always saw the testimony. I can't imagine that I saw all the Commissioner's speeches that would have touched on things non-legislative things for which I was the legal advisor. Again, this is an example of how practice and procedure and clearance have evolved as communication has become more widely available. I mean, Commissioners' statements may always have moved markets, but I think now people see these statements much more clearly as doing things like that.

Anything else you have to say these early years, before you left FDA? I have two additional items I'd like to ask you about, in no particular order.

First, the agency's efforts to label aspirin because of the risk of Reye's syndrome. And second, the FDA effort to rewrite the NDA and IND regulations, the new drug regulations and the investigational new drug regulations. Were you involved in either of those?

LB: I was involved in both of those issues. To start with, the IND/NDA rewrite. When Dr. Hayes would talk about them as important initiatives, kind of reform initiatives at the FDA early in the Reagan years, he would summarize what they were designed to do and how they would improve the regulatory process and the new drug review process. But I don't have a lot more

substantive to add on that, but I would like briefly, since we're in the drugs area, to talk about the issue of providing information to patients about prescription drugs, which you may remember was a high priority of Don Kennedy when he was Commissioner.

There was a move to provide so-called patient package inserts, information in lay language that patients would receive when they got prescriptions filled or refilled a prescription. My recollection is that this went through the rulemaking process and final rules were, I think, in place or about to be in place at the end of the Carter administration. So in late 1980.

I'm not, as I say, clear on whether those rules had been finalized, but if they weren't, they were about to be finalized. One of the things that happened early in 1981, when President Reagan was inaugurated, was that there was a moratorium put in place on all regulations in the Federal sector. And so what this meant for the patient package insert initiative was that that was stopped. When the moratorium was ended, the way the process worked at the FDA, if I recall it correctly, was that we reevaluated whether there was a need to have mandatory information provided to patients when they filled their prescriptions. I believe there was a series of public meetings – I don't know if they were formal public hearings. Anyway, the question was reopened and public meetings were held and I also know that there were legislative hearings on the Hill on the issue of providing information to patients about prescription drugs.

The upshot of this initiative is that it did not come to pass and that, I think, in the spirit of the times, what happened was a private coalition was formed – it was called NCPIE, the National Council for Patient Information and Education. And I believe FDA was a partner with NCPIE, and the notion was that this organization would work to make sure that patients got information at the time of prescription and that NCPIE would supply the information and educate patients about the risks and benefits of prescription products.

So that was an example of how, I guess, the climate changed, from the '70s into the '80s, and how something that had been envisioned as being a mandatory Federal requirement moved more into the private sector and became a voluntary initiative.

CC: Are there other similar events from that period?

LB: Well, there's one other – I'd like to follow up on the other issue that you mentioned, which was Reye's syndrome. Again, I'm not a scientist or physician, but there was growing evidence that there was an association between something called Reye's syndrome and the use of aspirin in infants and children, and that, essentially, giving a child up to the age of about 13 aspirin when they have a fever should not be done. And even though the evidence was pretty clear, there was a lot of pushback from the regulated industry about the FDA's intention to change the labeling of these aspirin products to point out that they should not be used in someone 13 or younger with a fever.

What I recollect about that is being in a meeting on this topic with some colleagues at FDA, and also a representative of our parent Department of Health and Human Services. This was a day of not only news releases, when news releases were used – they still are – but video news releases were kind of a new communications technology. FDA's been pretty much at the forefront of these communications practices over the years, and the agency had recently sent out a video news release highlighting the importance of not giving aspirin to children with a fever. These video news releases had been sent out to – I don't know – something like 500 or 600 television stations around the United States. In this meeting, there was some concern expressed from people, not at FDA, that these releases were out there. And the question was raised of

whether they could be recalled. In the end, I believe, that was not done. The video news releases stayed out there, but I just raise this as an example of how there was pushback when the FDA, in carrying out its public health mission, was engaged in proactive communications.

CC: Were the video news releases issued during the Reagan Administration? I mean during – were they post-'81?

LB: I'm sure they were. They came out of the Office of Public Affairs, and I think this occurred – the instance I'm talking about probably occurred in 1983 – and the video news releases were current, so I'm sure they came out during the Reagan years.

SJ: And what was the objection? I'm not clear on that.

LB: Well, I don't remember the specifics, but the notion that FDA would be warning – there was concern from manufacturers that FDA would be warning patients and parents not to give or take aspirin to their children.

CC: I think at that time period, FDA's public communications were not subject to review and control by the Department. That that was something that was evolving. I'm trying to figure out how these releases got on the street, and then somebody says, "Well, can we pull them back?" And the somebody that wants to pull them back wasn't involved in their initially getting out there, I think.

LB: I think you can fairly infer that. I have no direct knowledge of that. I didn't join the Office of Public Affairs until I returned to the FDA in 1989. But clearly, there was great concern when it came out in this meeting that the video news releases were already out. And the issue was whether FDA was expected to, you know, somehow call them back which, of course, was not done. But there was great surprise in the room when it was discovered that these things had already gotten out.

CC: So does that sort of come full circle on your first tour of duty at FDA? Have we covered everything up until the time you return in 1989?

LB: Dr. Hayes leaves in the fall of 1983. Dr. Young came within a few months – he came in July – Hayes left in September '83 and Young comes in July of '84.

CC: And I assume that Novitch is, again, acting Commissioner during that period.

LB: I think that's right. The good thing about FDA is that the professionals know how to do their jobs and they do their jobs, whether there's a confirmed Commissioner at the helm or not. I mean life goes on and things happen, and the public health mission is still carried out. In terms of communication, it's sometimes a challenge because reporters and media think that when there's nobody in the top leadership spot, that there's some kind of loss of momentum or whatever. But things basically go on. All things being equal, it's better to have a confirmed Commissioner or a fully appointed Commissioner at the helm. Dr. Young arrives in 1984, and I was still the Commissioner's speechwriter, I still had the title of or the role of being the speechwriter for the

Commissioner, and that's something that I was able to continue doing when Dr. Young arrived, and I did that until I left FDA in late March of 1985.

CC: I think the use of degrees after one's name has become much more prevalent in FDA, you know? I don't know that I ever saw you use PhD after your name.

[1:00:00]

LB: Well, it did come in handy for me, personally, to have a PhD that I could put after my name if I wanted to. Because FDA's a very academic place – I think it's something like at least 20 percent of FDA employees have PhDs, and, you know, we're very highly educated.

And so it helped me. When I would call somebody cold, perhaps within the agency to interview them about a speech topic, it was always helpful to be able to say, you know, "I'm the Commissioner's speechwriter. Could I talk to you about such and such?" That opened lots of doors and I didn't do this very often, but I could sometimes say, "This is Dr. Bachorik." So it gave me a little credit, I think.

[01:39:58]

CC: So you leave in 1985. How come?

LB: I'd say it's three things perhaps in about equal measure. One is, I think probably the most important is, that the first half of the 1980s were not an easy time to be in a regulatory agency.

We've talked some about the political campaigns in the '70s, and the environment in the early 1980s. And with an effort on voluntary compliance and letting industry and setting it free so it's not shackled by burdensome – so-called burdensome regulation – it complicated, sometimes, our public health mission and goals. So that was part of it.

SJ: That was the first time in recent memory that the Federal employees were ever denied a raise completely, during the Reagan administration.

CC: I was also thinking about that there were a lot of rumors about RIFs, reductions in force. There was insecurity, lack of funds, and what you're saying, it's just harder to do your job. What were the other two reasons?

LB: Well, just to pick up on that, I do remember in the summer of 1981 in the Parklawn building, there were some pretty glum times because there were RIFs going on. I think it was at the old Health Care Financing Administration. And I believe FDA actually had to prepare for RIFs, so we had – what do they call it? Retention registers or something, where people had to be – employees had to be ranked based on their grade and the length of their service.

CC: You had three reasons you said?

LB: So it was not the best time to be at a regulatory agency, even one as good and prestigious and dedicated as the FDA is.



And secondly, I've talked a little bit about the importance of the relationship between a speechwriter and the client, the subject, the person giving the speeches. Dr. Young and I had a perfectly fine relationship and it was cordial and professional. And partly it was about me, that I didn't find working with him as personally rewarding as I had with other people I had written speeches for. But I wouldn't overemphasize that. I mean it's still a great gig to be the Commissioner's speechwriter, and to be able to interact with him or her and be involved in all of the really important issues that a Commissioner has to address. But at that time, I was in my mid-30s, and so I think the other factor is I was just looking for a change – doing communications work but in a different environment, and also leaving the public sector and being in the private sector for a while.

And in the end, I think it was a good thing that I did take that hiatus for almost five years, and I think it made me much better prepared to come back and do what I subsequently did at the FDA and public affairs and international programs and communications.

CC: So what exactly did you do at INOVA? What was it you got from that – you just said, it made you better prepared?

LB: I was hired as the director of public relations at Fairfax Hospital Association, which is how the organization was known at the time. It's now called INOVA Health System, and in fact, I was very involved in the corporate identity change, which the old Fairfax Hospital Association underwent in 1987 when we changed everything to INOVA Health System.

I was director of corporate PR. There were four hospitals in the system at the time. There were two nursing homes. There were urgent care facilities. That health care organization

is a not-for-profit group. It was a time of tremendous growth in Fairfax County, which is primarily the region that that hospital association serves. It had a visionary young CEO named Knox Singleton. He was at the helm of the old Fairfax Hospital Association and then INOVA for 30 plus years. Anyway, and with the growth of the defense industry and contracting in Northern Virginia in particular, and the tech industry in the '80s into the '90s, the population was skyrocketing and INOVA was, as it came to be known, was just on a real growth spurt.

So I wasn't involved in day-to-day media relations from the individual hospitals in terms of the classic PR for hospital. I was at the corporate level – I did do corporate media relations for Fairfax Hospital Association/INOVA Health System. So when there was a system wide issue, I would be the spokesperson or I would arrange for another senior executive to do that.

One of the reasons I was brought in there was to start a pretty ambitious publications program. The person that hired me was the vice president for marketing at the corporate level, and they wanted to, at Fairfax, increase their visibility and be more professional about their communications. So we created a four-color magazine that was quarterly for the medical staff in the hospitals. We created an employee newsletter, so we were involved very much in internal communications. And we also supported the fundraising operation. We had publications that were designed – they were periodicals for the not-for-profit side – the fundraising to support the local community hospital system.

One of the main things that I did and learned was I wrote the annual report every year for five years at Fairfax Hospital Association/INOVA. That was a big learning experience for me, not only just to conceive – it was a little bit like speechwriting, in the sense of constructing a coherent package that conveys information. Something that I really enjoyed in the process was working with the publications designers and the creative aspect of it. For example, what visuals

are we going to show? What images? What technology? What pictures of patients do we show to convey those kinds of messages? Each year, we had a different theme, and so that was really pretty exciting. And that all served me well when I had the opportunity to come back to FDA.

CC: Why don't we stop here and reconvene?

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CC: We're resuming the oral history interview of Larry Bachorik on July 18<sup>th</sup>, 2016 at the White Oak campus of FDA.

Larry, when we took a break for lunch, we had just wrapped up your four or five years in the private sector. You returned to FDA in 1989. Can you talk about the circumstances that brought you back, who hired you, and what your position was?

LB: I had been away from FDA for four-and-a-half years, and one day I got a call from Bill Hubbard – a call at my office in Northern Virginia – saying that after my departure, they still hadn't found anyone who could write speeches consistently for Dr. Young, who was there when I left. I had arranged for a former colleague to be the speechwriter for Dr. Young. Actually, it was someone I taught part time with at Georgetown, way back before I started at the FDA, and he had a similar background to mine, even to the same period of English literature.

He worked for a year at FDA as Dr. Young's speechwriter, and then I gather there were others, but nobody really took or stuck. And it turns out that Dr. Young was giving increasingly more speeches, and so the plan was to establish a speechwriting staff in the Office of Public Affairs. So Bill Hubbard called me out of the blue to ask if I might be interested in applying.

CC: Do you recall what position Bill had at that time?

LB: I think Bill was working in the Executive Secretariat. I think Exec Sec had been reestablished as a kind of operation, and Joe Levitt was the head of it, I think, and Bill was working for Joe Levitt in that position.

CC: That sounds like the right structure. Joe was my colleague in GC, and my recollection is he was offered a job in the Office of the Commissioner when Dr. Hayes was still the Commissioner. But then, after Dr. Hayes left, he went upstairs to the Commissioner's staff.

LB: Yeah. Joe was very involved in this too, because I remember after I talked to Bill Hubbard, Joe Levitt actually sent me a formal letter saying, that he hoped I would be interested in applying for the job and describing what it was all about. I found that letter when I was going through some old files around the time of my retirement. And, frankly, I thought my Federal career was really over. I didn't – I really hadn't contemplated coming back to the FDA or anywhere else in the government. I thought my future really lay in the private sector probably at a not-for-profit, like the hospital association.

So I thought long and hard about it. I was living in suburban Maryland and my job was 16 miles away, across the river on the Beltway. And the traffic then seemed bad, but it's a lot worse now. Anyway, I weighed that and the hospital environment – even though it was not-for-profit, it was a very competitive one. The job that I had at INOVA ... it was a business operation and it was, I won't say cutthroat, but they were hardnosed business people with a community

mission. I weighed the mission and I thought about how much I had been invested in what the FDA does and what it is. Then there were the personal factors – my children were like five and one or something, and I thought there might be a better work/life balance at FDA. So after thinking about it a long time, I submitted my application on the last day the job was open, and so I came in and was interviewed by Jeff Nesbit, who was the Associate Commissioner for Public Affairs at the time. This was probably like July 1989. June or July. I think Joe wrote to me in April. Apparently I passed muster there, so then I was brought back to interview again with Dr. Young. Not again, but, you know, I had known him before. And that went well, so they offered me the position.

There's a funny story about that. I gave my notice at Fairfax/INOVA Health System, and told them I was about to leave, and I got a call from Don Sauer saying, "Well, we haven't really made the offer yet. You know, it's not really a formal offer." So that was interesting for a few hours, but that was fixed.

CC: At that time, Don Sauer was Associate Commissioner, Deputy Associate Commissioner, Deputy Commissioner, for Management and Operations?

LB: The position that Gerry Meyer had had for a long time. Don was high up in the administrative world. So that got straightened out, and I left INOVA and came back to work at the FDA in the Office of Public Affairs, director of the speechwriting staff. The staff was going to have two speechwriters reporting to me plus secretarial help because Dr. Young was giving a lot of speeches and they figured they needed the horsepower to do that.

CC: Did you hire the two other speechwriters?

LB: Yes. I was hired as the director and I was able to, you know, to create the staff myself.

CC: And who were the first two?

LB: I hired – I had some help from a woman named Linda Quinones, who was kind of helping me with the admin stuff, the startup. She might have been involved in FOI. I'm not sure, but she was very helpful. We put out the job advertisements and I interviewed people. I hired two people, one from the inside-- a woman named Beverly Corey, who was a veterinarian and was working as a reviewer in the Center for Veterinary Medicine. By then, the Bureaus had become Centers. I had a senior and a more junior position. And then I hired in the more junior position, someone who was way senior [in age] to me, a man named Mike Kubic, Milan Kubic, who had been *Newsweek's* senior foreign correspondent when he was given a golden parachute in about 1988, I'd say. He'd been away from *Newsweek* for about a year, and he was a crack writer, a really terrific journalist, writer. And so I had this brand new staff, and we set about creating speeches for the Commissioner. As it turned out, Dr. Young accepted a position at HHS about three months after I arrived back at the FDA – something to do with emergency preparedness disaster relief.

He joined the Commissioned Corps and so he was a PHS officer by then. So anyway, he was no longer at FDA. Jim Benson had been, I guess, his deputy. Anyway, Jim Benson was made the acting Commissioner. I'm pretty sure he had the formal title. And Joe Levitt, who had been the Chief of Staff, was the Acting Deputy Commissioner at the time. And that arrangement

held for a year, I think, even a little more than a year, perhaps. From late 1989 until November or December of 1990.

CC: Frank Young left in December of '89 and David Kessler arrived in November of 1990, so 11 months. And my recollection is Jim Benson was the acting Commissioner. So what was that one year of the acting like? Did you write speeches for Jim Benson?

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LB: It was – it's an interesting comparison. I did write a few speeches for Dr. Young during the brief time that we overlapped again. And I was the lead speechwriter, so I would do – you know, I would, especially when I was still forming my staff, but even later on, I would do many of the speeches for the Commissioner myself. When Jim Benson became Commissioner, he had a very different style. Most people I'd written speeches for, up to that point, wanted a prepared text. And that's appropriate, especially for the Commissioner, because it's a formal record of FDA's policies and decisions and rationale for doing things. Jim Benson was a talking points kind of person. He didn't want full texts. He wanted, you know, headings. More than an outline, but less than a full text, so we would have section headings and we would do bulleted points under each particular area. And so this, of course, made it more difficult to establish a permanent record. In many cases, when he gave speeches, there probably is no formal text on the record.

Jim's tenure was more than a placeholder kind of situation. You know, he kept things moving along. I wouldn't say that there were new initiatives at the time. I remember when I was

being recruited in the summer of '89, and in the aftermath was the time when the generic drug scandal was breaking. And that was a big deal. FDA had a very high profile then, and not the kind of high profile that an agency wants to have.

At INOVA Health System, I had worked with Malcolm Gladwell who, at the time, was a Metro Section reporter for the *Washington Post*, and his beat was regional and local health care. So I had lunch with him on occasion, because he was trying to find stories for the Metro Section for his beat. By 1989 when the generic drug scandal was breaking, Gladwell had, you know, moved on and was still at the *Post*, I think, but he was covering that scandal. And I remember at the time I was being interviewed by FDA, he was on NPR, on All Things Considered or something. I told Jeff Nesbit when I interviewed with him that I had a relationship with Malcolm Gladwell and that would be helpful, perhaps, to the FDA and the ongoing – anyway. Of course, Jeff Nesbit knew – you know, he talked to Malcolm Gladwell, too. Anyway, so –

CC: This is Malcolm Gladwell who wrote *The Tipping Point*?

LB: Yes. *Tipping Point* and *Blink* and all that. Now he's a big deal reporter, author, for the *New Yorker*. He's been at the *New Yorker* since the mid-'90s, I think. About 20 years. Yeah, but it's the same – so I can say that I knew Malcolm Gladwell back when. So we spent a lot of time and energy on the generic drug issue.

CC: With generic drugs, there were true improprieties. When did the generic drug issues come to a head? Was that during Frank Young's tenure and then Jim Benson sort of rode through them? Do you remember the chronology?



LB: I think that's right. I think that's right. Because the big public disclosure that there were improprieties was happening, I think, in the summer of 1989 which is why I would have been hearing about it on NPR just before and around the time when I returned to the FDA.

CC: I guess what I'm trying to do is sort of connect the dots. You came to FDA knowing that there was some sort of problem with the generic drug program?

LB: That's right. Which was really a surprise, because the FDA I knew was very rules-oriented and totally by the book. It turns out that there were no products that were allowed to be on the market that were unsafe or ineffective. The issue was moving certain product applications, you know, abbreviated new drug applications up in the queue in exchange for services, whatever. There were at least two people involved in that, and then one of the supervisors, I think, also served jail time.

So it was a difficult time, and I remember a couple of outcomes. One of the first things I did when I got back to the FDA was to basically construct the chronology – almost a narrative – of what had happened with the generic drug issue and how it unfolded and what we had done about it. One of the upshots of the whole scandal, of course, was the creation of the Office of Ombudsman at FDA. And that happened during Jim Benson's time as acting Commissioner. Probably didn't happen until 1990, I would guess. I don't remember exactly the timing of that.

I think you'd be interested in knowing about what things seemed different on the way, you know, in the five years or four-and-a-half years that I was away. One of the things that was different for me personally is another senior executive got me included in the Monday morning

senior staff meeting, which happened every morning, every Monday at 8:30, I think. And so I was able, as the Commissioner's speechwriter, to go there and hear the exchanges and what was going to come up the next week and what the important issues of the day were.

CC: Who was that?

LB: The person who suggested it was an MD named – and he might be an MD PhD – Henry Miller, who was head of FDA's Office of Biotechnology at the time. And biotechnology was a hugely important issue for Dr. Frank Young, and I think under Dr. Young's tenure, I know he talked about biotechnology a lot, because I wrote some of those speeches. But also, I think Dr. Young created the Office of Biotechnology, which Henry Miller headed up and Eric Flamm was the deputy in that office. Maybe that wasn't until later.

So in the year that Jim Benson was acting Commissioner, we dealt with generic drugs. The Ombudsman's Office came into being. I remember writing some op-eds for HHS, for Secretary Louis Sullivan. Food labeling was gaining increasing prominence, and of course, it was in play on Capitol Hill, because the Nutrition Labeling and Education Act of 1990 was passed that year.

I think the first speech I wrote for an HHS Secretary was for Dr. Sullivan, and it was the famous "Tower of Babel" speech, that really did focus a lot of attention on the food labeling issue. There were amazingly outrageous claims being made on food labels, very misleading ones, and it became an important public policy issue and there was a lot of attention focused on it.

CC: So anything else about Jim Benson or the people that Jim had on his staff? I wanted to wrap up that period because the next thing that happens is David Kessler is appointed Commissioner. And that's the story for the next six years.

LB: Some of the players were the same in 1989 as had been in place in 1985 when I left. Some key positions were new. You mentioned Hugh Cannon was the Associate Commissioner for Legislative Affairs – he had come to FDA while I was away, probably replaced Bob Wetherell.

[DR-100\_71.wav at 02:03:00]

A note on that. Bob, at a time in the early, maybe '83, '84 period, the Offices of Public Affairs and Legislative Affairs had been combined. So what I was saying that in the '83, '84 period, Robert Wetherell, who had been the Legislative Affairs Associate Commissioner, also had assumed responsibility for the Office of Public Affairs. That might have been in the wake of Wayne Pines' departure. Wayne Pines was an SES [Senior Executive Service] member, and was reassigned to St. Elizabeth's Hospital around 1982 or '83. But anyway, the point is that there was a combination of legislative affairs and public affairs in the Commissioner's office in that '83, '84 period. Subsequently, and this I think happened while I was away, Mr. Wetherell was assigned to an FDA facility in Rhode Island.

LB: When I came back in '89, Hugh Cannon was a political appointee and ran the legislative affairs office. And the public affairs fellow, for a while, had been – and I don't remember his last name. Jack. I can figure it out.

CC: Jack Martin.

LB: Jack Martin. Yes. Jack Martin. I think they were close colleagues and maybe good friends, but by the time I came back, Jeff Nesbit was the head of Public Affairs.

But I'm reminding myself of something that happened that was quite important in the '80s. In certain key positions, political appointees had replaced career officials, and I'm thinking primarily of the Office of Public Affairs and the Office of Legislative Affairs. And this will be important later on, but Wayne Pines was a career civil servant and he was reassigned to St. Elizabeth's as a press officer. I don't know what the story is there, but he was moved to a different SES position. And at some point, Mr. Wetherell, who was also a career employee, was replaced by someone who was, I believe, his immediate replacement was political. But certainly by the late '80s, both the legislative affairs and public affairs jobs were political appointments. It's important to note because of the nature of the activity of those offices, and its importance in communications and relations with external stakeholders and the public health.

CC: Let's move on to David Kessler. What do you remember about David Kessler's arrival? I guess I was under the impression that you had been hired back to FDA by David Kessler, that somehow you had some preexisting connection with him, but that's obviously wrong. So you were already here when he shows up?

LB: Actually, I began working with him even before he showed up at FDA. Let me step back a little bit. I think this was an outgrowth of the generic drugs scandal, but there was a commission created to study the FDA and to make recommendation about its future. I think it was called the Edwards Commission?

CC: Yes. The Edwards Committee, I think.

LB: Committee. I think that's right. Committee. That sounds right. And everyone knows, in the FDA world, that Charlie Edwards was an FDA Commissioner sometime around 1970 and then moved up to the old Department of Health, Education, and Welfare. So Charlie Edwards was an important figure in public health and in HEW/HHS and FDA history. My first encounter wasn't really an encounter. My first awareness of Dr. David Kessler came at one of the meetings of this committee, probably in June or July of 1990. The committee met somewhere locally in the D.C. area, probably in suburban Maryland somewhere. I just saw him as one of the panel members, committee members, who spoke. I didn't have a direct communication with him, but I formed a bit of an impression.

In the fall of 1990 – this is still before Dr. Kessler had arrived – I spent a week in the Chicago district. As a speechwriter, I thought it was really important for me to get out in the field and see what the historical heart and soul of FDA was really all about. There was a woman in the Office of Public Affairs who had been a consumer affairs specialist in one of the districts, who we'd brought into the Office of Public Affairs to serve as our liaison between the press officers and the media people in FDA, and their field counterparts. She had arranged for me to

go visit the Chicago District, which was a vibrant and illustrative place. So I spent a week there, going on inspections with investigators. I mean I was in the back of a tractor trailer, opening boxes of medical gloves; I was in a wine shop where the investigator was taking samples of wine to remove the lead foil around the cork because we were concerned, at that time, about lead in wine, leaching into the wine. I went on a device inspection with a young woman investigator of a contact lens facility in the area. I had to get credentials, in order to be allowed into the facility. Almost to a person, even though I was a newbie and probably didn't look like I knew much about what I was doing, most of the officials at the firm turned to me and assumed that I was the main person because I was a guy. This was a bright, competent, capable young woman. She was a very good investigator from what I could tell. So I had spent a week in the field, and that gave me a really good sense of what the FDA does on the ground.

The reason I bring this up in this context is that, it was at that time that rumors were starting to float around that this Dr. David Kessler from New York City might – well, in fact, was the leading candidate to become Commissioner. So those were the kind of two pre-looks that I had or impressions I had of David Kessler.

It was early November 1990. I got a call that Dr. Kessler wanted to meet with me downtown because he was starting to prepare his most important speech that an FDA Commissioner gives, which is the Food and Drug Law Institute annual conference speech. And historically, that speech, at the time, was kind of a state of the union of the FDA. The FDLI meeting back then was held in December, middle of December, and that was when I first met Dr. Kessler at HHS offices downtown, and we probably talked for about an hour-and-a-half or two hours.

CC: Had he been appointed by that point because my records show that he was appointed the 8<sup>th</sup> of November, sworn in on the 8<sup>th</sup> of November, 1990?

LB: He had – I think he was probably already officially the FDA Commissioner, but he didn't come to the FDA until December, is my recollection. I mean in terms of showing up at the office every day and being a presence. There was some gap in that, I know.

CC: What he told us was that, whether it was Dr. Sullivan who offered him the job, whatever, he got offered the job and they basically wanted him to report practically on Monday. And at the time, he was running a hospital in the Bronx.

LB: Montefiore, I think.

[DR-100\_71.wav at 02:19:51]

CC: Yes, Montefiore Medical Center. And he has two young kids, so he's got to move his family. This is all very sudden. He also told us that he wanted to come and just sort of be in the agency without being the Commissioner for a couple of weeks. So there was a period when he'd been sworn in, but Jim Benson was still there as Acting Commissioner for this one-month period.

LB: Sort of a transition?

CC: Yes. As I said, he talks about this in his oral history interview. And my story that I promised you I wouldn't tell, but I'll relate enough to sort of put context on his arrival. I was working on the World Trade Agreement negotiations, and they were not going in a direction either EPA or FDA was particularly pleased with. And so collectively, we decided, at the FDA level, we were going to go brief the Secretary and try to get a letter from the Secretary or the Deputy Secretary to the U.S. Trade Representative, Carla Hills. And we're all in the Commissioner's conference room on the 14<sup>th</sup> floor of the Parklawn building – Jim Benson, Linda Horton, some other folks – and David Kessler walks in. And then Kay Hamric, who was, of course, the Commissioner's Executive Assistant, came in and said, "They want you downtown." So five of us piled into the Commissioner's car, including David Kessler, to head downtown. Thus my first encounter with David Kessler is on the drive downtown to brief Connie Horner, the Undersecretary, and I'm in the backseat of a Ford Taurus with Jim Benson on my left, David Kessler on my right, trying to explain to Kessler what the issues are. This is then made more comical because the phone rings – at that time, car phones were mounted on the hump of the car, which was where my legs were. But anyway, Kessler was there. I think he was also in the briefing. Ultimately, there was a letter to Carla Hills signed by somebody in the department – perhaps Secretary Sullivan – but that was one of Kessler's first days.

LB: He certainly kept the low profile in the Parklawn Building for a matter of three or four weeks, I think, and that may be why I was asked to go downtown to meet with him the first time.

CC: I know he also had an office in the Humphrey Building or in one of those other HHS buildings – whether it was in FOB-8 or the Switzer building – because of his membership on the



Edwards Committee. He had a space. I remember when we were going to go try to draft this letter after Connie Horner's chief of staff, who was a trade lawyer, dispatched us to draft a letter. And Kessler said, "We can go to my office." Well, we ended up going to FOB-8 where there were computers and stuff we could use. But let's get back to your story.

LB: In early November, I sat down with Dr. Kessler and we actually had a conversation. I brought a tape recorder or he did, I can't remember, but we had a conversation. And he and I discussed, probably mostly him, some of the substantive points that he wanted the FDLI speech to include and also the tone and, to some extent, the urgency. This was something that he'd clearly given a lot of thought to, and we spent a long time, 90 minutes or two hours perhaps. At the end of the conversation, we agreed that I would take the tape recorder and the tape and go off and draft his speech.

And so the first thing I did was I went back and transcribed the conversation, and even that was helpful as a speechwriter, just to physically type the words and began to get a sense of his rhythms and his speech patterns.

But I have to say that that was a typical and enlightening experience for me, typical of working with Dr. Kessler. We had about probably five or six weeks before the speech, and I believe the speech that I gave him the night before, the final copy of the speech the night before the event, I think it was draft seven. It was a real collaboration – I would send him a draft and then we would meet on it and we would talk about it and we would polish it. So this was a very labor-intensive process. It was a rewarding process, because the fact that he was willing to spend that much time on it meant that he valued the whole process and what we were doing together.

This FDLI speech was really his coming out in Washington publicly. And I went to the hotel where the speech was, – I think we huddled beforehand and he had practiced it, and he delivered it very well. And I was exhausted. I was emotionally exhausted and physically exhausted because Dr. Kessler does a lot of his best work at night, or at the time he did. So we would have many evening phone calls to talk about this speech. You can imagine.

I come home that evening and I'm sleep deprived and the kids are small and they're hungry, and so about 7:00 the phone rings, and lo and behold, it's Dr. Kessler on the other line. You know, "Hi, it's David Kessler." And I thought "Oh, my. Now what?" And he said, "I just wanted to say thank you." He said, "The speech has been getting rave reviews around town. Couldn't have been better. Thank you." So that was a good start, and I think the experience became emblematic of the working relationship that we had.

And it was also important in the sense of focusing a lot of energy and attention on important communications. But also a sense of being gracious – in other words, I mean many people might have said, "It's a great speech. Thank you." but not gone the extra step and made a phone call. So it was the beginning of a very rewarding professional time, certainly for me personally.

CC: When you worked with him on a speech, did he take a draft and put margin notes or line through stuff? I'm trying to think if I ever saw him write anything but his name.

LB: Typically, the way the process would often work is we'd have a speech to give. He'd have a speech to give. I'd be working on it with him, and I'd do the background research, as I

suggested earlier. Find out what agenda the group had, what we wanted – what I thought we wanted to say about it after talking to some people in FDA.

But often, we would – he liked to do things in person or on the telephone, not as a group process necessarily, but to get a lot of people together and listen to them and have them talk about what was important or what they thought the issues were. For a big foods speech that he gave, I remember driving down to FOB-8, the old building for the Foods center. I think Fred Shank was the director of the Center at the time. And we just got Fred Shank and the Commissioner and his [Fred Shank's] deputies in a room, and I had an old clunky laptop computer, which weighed probably 15 pounds or something. But I sat there and listened and took notes and watched, and he just, he would draw people out. He would say, "Well, what are the important issues facing the Center for Food Safety and Applied Nutrition?" You know, "What would you like to be doing that you're not doing right now or not able to do?" It was really a conversation and discussion, and I think he was a good listener. And it certainly was very helpful to me, as a speechwriter, to be part of that process and to understand the thinking behind why our experts thought something was important or not, or what the public health priorities would be.

So he was really a person who knew the importance of clear, forceful, dynamic public communications.

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He valued that. And it didn't necessarily come naturally to him, and so he worked hard at it. So it was, all in all, a very rewarding experience for someone like myself, who's a professional

speechwriter, but also more broadly someone interested in, and as we have to be at the FDA, in clear, effective communications.

CC: One of the things that –

LB: Can I just interrupt you? I didn't really quite answer your question. I started talking about the group process. Often what we would do as we were getting close to the end of finishing a speech, sometimes the night before, we would go through the speech line by line. I'd have it up on a computer screen or I'd have a hard copy in front of me, and this could go on from 9:30 at night until midnight, and we would painstakingly go through line by line. I would be changing words as he dictated, or we talked about what the right point was to make or how to make the point. And so that was really in my wheelhouse. I mean, I'm a word guy, and when you've got the head of an important agency, a public health agency like the FDA who cares about getting the exact word, the right word, that conveys the meaning and the impression and the tone, that's golden. That's wonderful.

CC: One of the things that a couple of us observed about working with David Kessler was that if you were in the room, it wasn't who you were that mattered. It was whether your ideas had substance. Anybody could talk if you had something pertinent or useful to say or to advance the discussion. And I guess the idea that he would collaborate, as opposed either to write his own speeches or dictate them, is another reflection of that. For me, at least, that was one of the fun parts about working for him. To be taken seriously. To be seen as value added. So I don't know

if that suggests to you any other general aspects about generally working with David Kessler. If not, we're going to go to some specifics.

LB: That's right. I think back then, we weren't talking about flattened organizations, but I agree with your assessment that if you had something of substance to say, he welcomed that. And for people more accustomed to the classic command and control, bureaucratic chain of command model, this was unsettling. I can remember several occasions when I was in his office talking to him about a speech. And let's say it had to do with an HIV drug. Dr. Kessler knew who the expert was on that particular antiretroviral pharmaceutical product, and he wouldn't call the division director or he wouldn't call the head of the Office of New Drugs, or whatever its equivalent was in the Center for Drug Evaluation Research. He would call the person that was the expert or that was responsible for that NDA – the new drug application. And not to put pressure on them or try to influence what they were saying. Just to find out. It's like, you know, he would put them on a speaker phone. He'd say something like "I'm here with my speechwriter and we're talking about this product and what are the side effects?" And that was pretty unorthodox, at the time.

CC: That's the kind of thing that I saw happen, and it was disconcerting to some people. I think at the time I was working for Margaret Porter. We'd be in meetings together and he was looking at me for answers. Not to her to know, because I told her 10 minutes before in a briefing what the answers were. He really wanted to talk to the people with the information. In his interview, he said that there was a tampering case. It might have been Pepsi, but it was something on the West Coast, and I think this idea of talking to the person with the information,

as opposed to going through the hierarchy, was most disconcerting to people in the field, which is probably the most hierarchical part of FDA. He told us a story about wanting to talk to the field investigator. And it took a while for people to understand, to call them, to get them on the phone, that kind of thing. If you're one of the people on the ground, it's exciting because you get to participate and be part of sort of the energy of the project.

You've mentioned Jeff Nesbit, and he was a political appointee in the latter part of the Bush 41 administration.

LB: That's right.

CC: It's my understanding, from talking to Dr. Kessler, that Jeff Nesbit was really the person who pushed Kessler to become a more active communicator in the public arena. And ultimately, he became the face of FDA. He certainly was the first Commissioner to be on the news a lot, where people knew who he was. How did that affect your job or do you disagree with that? Maybe I should start there. Do you agree or disagree with this developing public face and being out in the media, as a bureaucratic agency, from one perspective?

LB: I think it's clear that David Kessler fairly rapidly after becoming Commissioner developed a high public profile.

Don Kennedy in the late '70s was pretty visible around Washington. He was relatively young and bright and very articulate, and testified effectively on Capitol Hill. I remember, it was early in my days in Washington, but I remember there being a *Washington Post* Style section piece on Donald Kennedy. It's not unusual for a senior official to make it into the Style section, I

think, but it's pretty unusual for an FDA Commissioner to do that. So it's not unprecedented that FDA Commissioners have a fair amount of public visibility.

Despite the nature of our work, people care about what FDA does, and so there's just a lot of attention that comes with that. But in terms of developing a high recognition factor among the American population generally, and being seen as someone who's really out to protect the public and serve as the cop on the beat when it's necessary, enforce the laws fairly and judiciously, David Kessler had a very high profile.

CC: And, of course, he was coming to an agency that didn't have a great public profile when he came, because of the generic drug scandal.

LB: Well, it was more than that, I believe. The whole, however you would characterize the Federal government's engagement in the HIV epidemic, HIV/AIDS – the FDA was shut down in 1988 for at least a day. I wasn't here then, but protesters outside the Parklawn Building closed the agency. And so it wasn't just in the generic drugs area that the FDA was perceived to be found wanting.

CC: No, I think there were a lot of reasons. I think much of the FDA field, where they were supposed to be an enforcement arm – and enforcement really fell off in the early years of the Reagan administration and that was demoralizing to the field. So I think he had many tasks when he came.

[DR-100\_71.wav at 02:39:51]

Some tasks were public relations. Some were getting the AIDS drugs, figuring out expedited approval, for example, along with the people in the Center for Drugs. And, I think, inspiring the field force was also one of the critical things that he did early on.

LB: Let me tell you a story about that.

CC: Okay, good.

LB: There was a meeting of FDA senior officials, and I don't recall specifically whether it was a Monday morning meeting, the so-called general staff meeting – that happened weekly with the Center directors and the Associate Commissioners --or whether it was some other session to talk about the field operation. But what I remember very vividly, and I think this was quite telling, it was one of the first times that Dr. Kessler was meeting formally inside FDA with the Associate Commissioner for Regulatory Affairs, the head of the FDA field operations. And that was Ron Chesemore at the time. And whatever this meeting was, it was senior officials around the table, with Dr. Kessler and Ron Chesemore at the head of the table. And Ron Chesemore, as the FDA's leading or most responsible enforcement official, was using this occasion to present an enlarged plaque of the FDA badge that the field officers have with the number one on it. That's typically the badge that the Associate Commissioner for Regulatory Affairs has in his or her office. This was the formal occasion where that top enforcement official was presenting the symbolic number one badge to David Kessler. And without missing a beat, what David Kessler did was he turned around and presented the badge right back to FDA's head enforcement man



and said, "You're the one that should have this badge. You're the one with the staff out there that's doing that important fieldwork." And symbolically, – you talk about a loss of morale in the field – I'm sure that was a huge shot in the arm for that whole organization.

CC: Well, it was empowerment.

LB: One-third of the agency that actually goes out and does the gumshoe work to inspect facilities and track down bad products and so on and so on.

CC: Do you think that was prearranged? The dual exchange? I have no reason to think that it was.

LB: I never even thought of that until just now when I was recounting it to you, and I thought to myself – at the time, I certainly thought it was totally spontaneous. And I'd be surprised if it weren't.

CC: I was going to say it's perfectly consistent with the individuals involved that it would not be prearranged.

LB: Yes. And we know them – all three of us know both of them.

I want to make this point right now so that it at least gets made. That is, a trend that I saw over my 37 years, almost continuous service at FDA, is a changing role, or at least perception of the role, of the field operation at FDA. I mentioned this in my going away event in December,

but certainly my sense when I joined the FDA in 1978 was that the field was in large measure the backbone of the FDA, and it was really an important and very visible part of this agency. And it was pretty commonly thought that the Associate Commissioner for Regulatory Affairs, although the equal of all the other Associate Commissioners, was in some way kind of the *de facto* Deputy Commissioner. There was a real deputy Commissioner, but in the early years, my early years, the real deputy Commissioner was more, you know, just keeping things moving and operational and that sort of thing, rather than the day-to-day enforcement work of the field force. And that's the sense that, over time, has diminished – there's just been a greater emphasis on the part of the FDA that reviews product applications and approves products.

CC: Do you think that's due to user fees?

LB: It has a lot to do with user fees, I think, but for whatever reasons, the field part of FDA is not so visible. Its profile is somewhat lower, and yet it's really, really important.

This may also be related to another trend of less independence for the FDA within the Executive Branch of the Federal government. The FDA has never, in my lifetime, been autonomous, but it's become increasingly less autonomous as time goes on during the 35 or 37 years that I've been associated with it. So those two things may be somewhat related because, the closer you are to the throne, whether it's the Commissioner in the Office of the Commissioner, or if you're in Washington, D.C., as opposed to Seattle. There's kind of a centralization or consolidation of things.

So this is all a way of saying that, I think one of Dr. Kessler's goals was to empower the field as embodied by that exchange of the number one badge. And he also spoke about the field.

He valued the field's work – he talked to individual investigators and he actually wanted to speak to the people who were in the facility and had seen what the problem was, or were on the ground there and they'd gone into a site of suspected tampering or whatever it was.

CC: I think another contributing factor is that layers in headquarters have been added, like the Directorates, which are relatively new – the Office of Food and Veterinary Medicine, the Office of Medical Products, the Office of Global Regulatory Operations and Policy. It seems that the more weight near the top, the less visibility there is for the FDA field. I don't know the physics of it, but I've sensed the same thing.

And, the odd thing is, at the end of the day, you don't get a drug approval unless your facility can pass a GMP inspection. And guess who does the GMP inspections? The people out in the field. In his interview, Mike Landa sort of hinted at this – that a lot of the jobs that seem to be the powerful ones – and this is my characterization of what he said – they're actually, without the less powerful components, whether it's the operating centers or the people in the field, there's no need for those “powerful” jobs. And yet that seems to get lost.

LB: There would still be an FDA without the upper layers.

And in the context of the field, I don't know what the structure is in terms of the pay, pay grades, GS levels for field personnel. But I know that when I was in Chicago in 1990, the district director in Chicago, just like all the districts, was a GS-15.

CC: I think that's still true.

LB: That's an enormous responsibility, and back in the day, there was a laboratory branch, there was an enforcement branch, and there was an investigations branch, and those were all, you know, those were tough jobs. It was a lot of responsibility. And you walk around headquarters and the GS-15s are pretty common.

And that just – that's always struck me as, I wish there were more resources allocated to the field operation that way, given the great responsibility they have.

CC: Did you ever write a speech or talk to David Kessler about the field and his thoughts about the field? I mean, we're sort of projecting on him some views based on how he treated the field.

[DR-100\_71.wav at 1:00:00]

LB: Well, I remember – I think it might have been the second annual state of the FDA speech at the Food and Drug Law Institute that I wrote for him – it was either the second or third, so it would have been 1991 or 1992. In the early part of the speech, he talks about the number of enforcement actions, that warning letters have gone up by this much. And I don't remember the details anymore. We could look them up. So he emphasized the importance of judicious and fair enforcement.

CC: Right. And I'm now remembering, and maybe you heard him say this – he told us in his oral history interview, and I heard this previously, that he was not confirmed by the Senate in terms of having a formal hearing – there was a vote, because he had to be confirmed, but he

didn't appear before the Senate Committee prior to the vote. And he said when he met the Secretary, Louis Sullivan, Dr. Sullivan asked him what he planned to do, and Kessler said, "Well, enforce the law." And a year-and-a-half later when, in fact, he had enforced the law, some people – like, I think, Orrin Hatch – were surprised by how this statement was manifest and by Kessler's use of the field and of the law, to make people comply with the law.

LB: Perhaps the most dramatic speech that I worked on, certainly in the early years of David Kessler, was the speech where he announced the seizure of orange juice because of misbranding.

SJ: Yes. "Fresh." They used the term fresh.

LB: I mean, that went right down to the wire.

CC: What do you mean?

LB: Well, the discussions with the company were going on about whether the label, you know, was accurate and could it, you know, would it be changed? And my understanding is that, for whatever reason, the company didn't make any changes to its label, and so FDA took the legal action that we took. And we inserted a new paragraph in the speech at 9:45 at night, before it was given the next morning, describing what had happened.

CC: Kessler talks about this in the part of the oral history interview that we've done, and yes – the discussions broke down. Margaret Porter tells him, "Well, I told them we were going to

seize the product if they didn't agree." And Kessler said, "So seize the product." You know, like, "What do you mean what do you want to do? You told them what we were going to do. Go do it."

LB: So that confirms my sense of what transpired. It was in April of 1991, if I recall. In terms of communication, we knew this would be a big deal. It would get everyone's attention. I mean to hear Dr. Kessler talk about it after the fact, he was going along with the speech and it was a normal speech and the audience was attending more or less to it. And then when he got to those paragraphs about the seizure of products in Minnesota, I think it was like a lightning bolt went through the room. People really stood up and paid notice.

And what we had done from a communication standpoint, because we knew this would be newsworthy and important, we had a film crew there. So this speech was probably videotaped. I don't know – I don't think they were using digital, and this was a long time ago. We had satellite time, and we had those images up, and we were able to get them to the media that wanted to report on the story. So there were the soundbites of Dr. Kessler announcing this enforcement action.

CC: As I said, Dr. Kessler talked about that and I couldn't quite visualize what happened that day. Your story helps put together better what, in my own mind at least, what happened that day.

At the time, and even looking back, that was a pretty significant enforcement event. It was important for the morale of the field. It was important for the principle that labels mean something and a company can't just slap on some descriptor that they think is valuable from a sales standpoint. And it was important, I think, from a public communications standpoint, and

how we began to stage a little bit more and utilize communication to help the agency achieve one of its missions, which is educating the public, while at the same time, keeping the regulated industry on the right side of the law.

I find it interesting, particularly your description of that day, which leads me to a couple questions about how this all was planned or not. My first question is whether you are aware that after David Kessler arrived, there was any detailed strategy about how the communications piece was going to work? How it would be used? Or is this something that just evolved? Whether Jeff Nesbit has an idea, whether there was an office idea, whether David Kessler had an idea? I'm interested in how the communications "strategy" unfolded and whether it was planned, which is a simpler question, I think.

LB: A couple of observations sort of preliminarily. I was, first and foremost, until 1993, the first part of the Clinton Administration, I was a speechwriter. And so I wasn't directly involved in the broader communications with the media. Certainly, when we would work on a speech, we would think about how a particular phrase would be effective in conveying the FDA's position or communicating an important fact to the public. But I wasn't part of any communications planning that might have gone on. Secondly, Jeff Nesbit, who was the Associate Commissioner then, we've talked about him earlier, may well have had that. He had come to FDA after being Dan Quayle's press secretary, and had been very effective in his work there in the Senate.

So with those two things being prefaced, I can talk more specifically about media relations and communications once I stopped being the chief speechwriter and head of that staff and became more involved in the day to day media operation. But, essentially, when you take away all of the strategy and the delivery channels, if you're doing the right thing, you can

communicate about it effectively. So David Kessler, I think, set out to make sure the FDA was fulfilling its public health mission and that was pretty consistent across many fields of operation.

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One of those things was enforcing the law, and that's why that orange juice case and there was labeling of other products, such as spaghetti sauce, was important. So I think, in a way, the communications flowed from the actions. I think we get the cart before the horse often these days, because we focus on what are our talking points? Or how are we going to message this? If you do what you're supposed to be doing that's in the public interest, or whatever fulfills your organization's mission, then good communications can flow pretty naturally from that.

CC: That's very interesting. That's how you can have effective communication – just do the right thing. So when you were talking about a phrase that might get picked up by the press, that to me is a mini strategy but that's effective speechwriting for a public figure.

LB: Right. But when I was writing this speech, I'm thinking of the whole of the speech and how the major sections of the speech fit together and whether that's a logical argument. And within each of those sections, do the paragraphs flow, and in each of the paragraphs – how does it work? I didn't think I'm going to sit down and write a soundbite for the Commissioner. But what came out of, if the speeches was well-done or most effectively done – and this didn't happen all the time – certain phrases would pop out at you when you looked at the entire speech.



And that's what I found that Dr. Kessler would do occasionally. I'd give him a draft and he'd say, "Wow, there's some great soundbites in that." I felt good that he felt there was some good stuff in it, but it wasn't that I had set out to create good soundbites. I was more interested in the whole – I mean soundbites are important and it's great to have something memorable – but it had to be of a whole or entirely of a piece.

CC: During my time in FDA, I think I've seen an evolution in the quality and importance of communication from the agency. And I wonder whether that was purposeful or whether it was just “natural” evolution. I think David Kessler would be the first to say he was not naturally comfortable speaking in a public forum. We heard a couple interesting stories about his first time being on TV – by his own account, it wasn't particularly successful. And after that appearance, apparently Jeff Nesbit said, "No, you've got to keep doing this." And partly that Jeff Nesbit, because maybe that was his beat, so to speak, he thought it was important. I'm just trying to figure out sort of how this happened. Did people try something and it worked? Or did somebody sit back and spend three months saying, "This is going to be our global communication strategy."? Sort of like you might do if you were doing a corporate rollout.

LB: I think that's probably right. I'm not aware of anybody that, when Dr. Kessler arrived, sat back and said, "Well, you know, here's our communication strategy for the first three, six, and nine months."

SJ: Well at what point did he create the office headed by Sharon Kuperman, that handled his video communications?

LB: Well, let's make sure that's clarified. What Dr. Kessler did, eventually, was to create a separate part of the Office of Public Affairs. It was called the Broadcast Media Staff and it handled electronic media, radio and TV and then increasingly, you know, it wasn't much Internet stuff. So what evolved by probably '93 or '94 was one staff for handling print requests, the traditional media, newspapers, magazines and then a separate staff for broadcast or electronic media. That was something that he wanted to do.

There's a case to be made for that because the media are so different – there are different techniques that you use when you're on camera from when you're not and so on. That's an unusual arrangement for a media affairs office to have. And eventually, when I was Associate Commissioner for Public Affairs, I decided that we had to merge – remerge – those operations because we didn't have the bandwidth and staffing to have the luxury of separate staffs for broadcast and for print media.

I think to do television as effectively, news interviews as effectively, as David Kessler did takes a lot of work and a lot of practice. And I think having a separate – small separate staff – for that served him very well.

I mean, his interviews with *60 Minutes*, which is traditionally the toughest interview you can have for a lot of reasons, especially the last one, the second one. There may have been more than two, but I remember a couple were textbook illustrations on how to handle a challenging situation. But that sort of leads me back to my first point, which is if you've got good material to talk about, it's a lot easier.

CC: Yes.

LB: If you're not on the defensive. If most days you're doing what impresses many people as being the right thing then you've got better stuff to work with.

CC: Help me out here.

As you know, Kessler used to use that phrase when he disagreed with you. He'd say, "Help me out. I'm confused." and then you knew he disagreed with what you just said and you had to engage with him.

But my question is not that kind of thing. I'm interested in understanding when we get the 24-hour news cycle? Because I think that has an impact – I mean, this is no great insight – but I think it's had a tremendous impact on the delivery of news, what is considered news. And that may have been one of the reasons that he had to have, felt he needed to have, a separate broadcast media office. When does CNN become very prominent?

LB: I think CNN's coming out was kind of the first Iraq operation – in 1991 when we took back Kuwait but did not invade Iraq.

CC: Oh, right. During Bush 41.

LB: And Fox didn't come on the scene, I think, until a bit later.

CC: But this idea that there's always news going on, and so there's just much more “news” now with cable. I mean when I grew up, we had four TV stations because we could get the CBC as well as the four U.S. networks. But now there are hundreds of television stations.

LB: That's not my sense. My sense was that broadcast interviews require, on the part of the person being interviewed, specific skills. And so to have a person or two who are really good at coaching the subject of the interview was important. But at least back then, 20 years ago, there was a different way of handling producers of electronic media. There's a lot of upfront prep work with the electronic media, in terms of scoping out what the interview's going to cover, getting ground rules established, providing background information. At least back then, that wasn't necessarily the case with print reporters. So I think it was more Dr. Kessler's level of comfort with having a separate staff to do those specific things.

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And also, the person that was the director of the staff had done a very good job of managing Kessler on television and prepping him and so on, and he felt very comfortable with that model.

CC: My thought about the rise of cable and 24-hour news is that it just multiplies the opportunities to be interviewed. Instead of just three major news outlets, you've now got – I don't know how many. And that that it was one of the drivers.

LB: I think it's true, but not related that much.

CC: Okay. That's fair.

LB: If you look at the FDA, I mean how often is the FDA Commissioner interviewed, you know, on a cable news network? David Kessler did it pretty often.

SJ: My sense was always that it was the events driving the interview, not the cable news trying to come to us, looking for filler.

LB: Many an interview request by the cable channels or the networks are just, are simply turned down. And I don't know if that's more or less than it used to be.

CC: It's just – I grew up watching NBC News. Not that I remember every broadcast, but we watched it as a family every weeknight. Who was Commissioner? Maybe Charlie Edwards? But I wouldn't have known Charlie Edwards.

LB: Right. Right.

CC: The reason I am pressing this is that there's a rise in the prominence of the agency, of the Commissioner of Food and Drugs, and of David Kessler as the face of the Agency. I'm trying to identify the dynamics leading to that, and what did he choose and the agency choose to take advantage of? I think it's a fairly complicated mix.

LB: Yes, but certainly I would never say that the rise of cable television helped FDA establish a higher profile. What I would say is that David Kessler, I think, consciously, maybe not from the start, but at a certain point, he determined that it was in the FDA's best interest to have a higher profile and for the public more generally to understand what the FDA is doing on its behalf and just to generate a greater awareness of how essential FDA is to the health and safety of Americans. And so a prominent, well-covered enforcement action raises that profile. A fast approval of an important therapeutic biologic helps that. Any time something like that is done, it's an opportunity to talk about public health and FDA's ability to work on behalf of the public health.

I think David Kessler was very effective at doing that, and as more outlets became available, he was able certainly to use them. He would go on CNN, I think. He was on CSPAN. CSPAN goes back to the mid-'80s at least. Maybe the early '80s and he would do stuff with CSPAN even though its viewership wasn't that great. It was definitely a sea change, I think, when Dr. Kessler came, in terms of the FDA's profile awareness.

Throughout the '80s, FDA had, on the Roper polls of Federal agencies, and Suzanne, you probably know about this, but there was a question or two about FDA always. We stopped investing in that at some point, and I don't know when. But the FDA typically ranked first, second or third among Federal agencies, right up there with the National Park Service, I think. So we had the stuff the public knew about us, and we were pretty favorably viewed, I think. But in the '90s, the profile was way higher and Dr. Kessler really was the face of the agency.

A couple of just examples of that. At the time, my wife was on the faculty of the medical school at George Washington University and she was very involved in the curriculum and was teaching as well as doing clinical work. And medical students – during when Kessler became

Commissioner and subsequently, they had a much better understanding of the FDA and its role and they knew what FDA was doing, and they expressed interest in possible careers at the FDA. That's an example of how effective communications and a higher profile for the FDA can really pay benefits. There was a second point I was going to make, but it's escaped me. So maybe it'll come back to me. How about that?

CC: I think what you just said is sort of what I was thinking. It sounds like there was, as far as you're aware, no major institutional strategy about using the media in its various forms. But that certainly David Kessler saw it – he had a personal strategy to utilize, particularly, the broadcast media, in a way that it hadn't been used before because it helped him achieve what he saw as FDA's mission. I mean, it wasn't just that people thought, oh, he's a pretty face. Let's put him on TV. He made himself available and he was articulate and well-behaved. I don't know what makes somebody attractive as an interview subject but I think a lot of it, as Suzanne said, was the issues of that period.

LB: One of the things that emerged, I think, in the '90s in particular, is that reporters didn't want to talk to a spokesperson, either on camera or for print media, and they didn't want to talk to an office director. They wanted to talk to the head of the agency the person that was really in charge. And David Kessler made himself available.

SJ: And he was very good.

LB: And he was very good. He was very disciplined. He would talk the issue through and say, "Here's the background and these are the three important points." We'd agree on those, and he would go off and he would do – he can do six or seven interviews in a row with the major print outlets, and they would all be individual interviews, often five-minute interviews on a particular announcement we were making that day. But the message would be there, and when you looked at the coverage, reporters got it. And so if there were two or three important public health points, say, about the safety of the blood supply and it's important to get a transfusion because the slight risk of something bad happening on the basis of that transfusion is way, way less than the risk of not getting the transfusion that you actually need. I didn't say it in the right way, but that's the basic message, you know? That is, the risk of not getting a blood transfusion is way greater than the slight risk of getting a transfusion. But those were the important public health messages to get out, and when you've got the head of the agency focused and engaged and giving that consistently, that's effective communication and it's good for the public health.

CC: So that's a good summary. And we're talking mostly about the media, but there was other communication going on, and I don't know if you can make any general statements like, there's communication with the consumers, there's communication with the medical professionals, the Hill, the regulated industry. Do you have any observations about how that was sort of evolving within the agency during this period? That is, did we see a shift in other areas of communication when Kessler comes?

LB: I'm going to do the bureaucratic thing here and talk about organization for a minute because, especially in the area of communication with consumers and communication with



health professionals, the existing structure, traditional structure at FDA was Commissioner, Deputy, and several Associate Commissioners – Legislative Affairs, Consumer Affairs, Public Affairs, Health Affairs, which was the health professionals. When David Kessler came in, he established a different structure where he had five deputy Commissioners and then below those five were Associate Commissioners. And just right off the bat then, that you could see that certain Associate Commissioners are moved down a layer.

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And my perception, although I wasn't a Deputy Commissioner then. I wasn't even an associate Commissioner when Dr. Kessler came. I was director of the speechwriting staff.

One of the deputy Commissioners was external affairs, and for many intents and purposes, that means public affairs and legislative affairs. And health affairs and consumer affairs seemed to be less prominent at that time. I don't know exactly what inferences to draw from that, but what I would say is that, my sense is that Dr. Kessler reached – was attempting to reach – consumers more directly. I don't know.

CC: Now, a lot of the communication with consumers is through the web, if not almost exclusively, between the consumer updates and the general information that's on FDA's website for consumers.

LB: And probably most of that is through social media now, I mean people don't come to the FDA website. And to look for stuff, most people will do some kind of search on a web browser and that'll take them to an FDA page.

SJ: Have we talked about the *FDA Consumer* magazine? We need to probably move into that. Let's talk about the staff after you were head of speechwriting and how you came to be heading a much larger organization – how that happened and what you found when you took over.

LB: Well, it happened in stages. I didn't become head of the FDA's Public Affairs operation until 1999 on an acting basis. So from 1993 until 1997 or 8, I was a deputy in the Public Affairs Office. So –

SJ: Under who?

LB: I think we're talking about the transition from the Bush 1 Administration to the Bill Clinton Administration. David Kessler was the Commissioner during that transition, which was unusual in that he had served in a Republican Administration and then made the transition to be the FDA Commissioner in the new Administration, under Bill Clinton. He actually asked me to head up the Public Affairs office at that time, and I didn't feel that it was the right time for me to do it. Instead, I asked if I could be a deputy, so I was one of two deputies in the Public Affairs Office. My responsibilities in that position included the broadcast media staff, so the electronic media. And then the other deputy had the traditional press office. The –

SJ: Was that Brad Stone?

LB: No, it was Don McLearn at the time.

SJ: Don McLearn. That's right. That's right.

LB: Don and I had different beats. I was responsible for Center for Biologics, Evaluation and Research, and the Center – I believe the Center for Food Safety and Applied Nutrition, and Don had Drugs and Biologics. And I think I probably had CVM, as well, Center for Vet Medicine. But there was a period in early 1993 until April or so, there was no Associate Commissioner, and I think it was April of '93, Jim O'Hara joined FDA as the Associate Commissioner for Public Affairs. So that was my portfolio, really, for much of the 1990s, as a Deputy in public affairs.

I no longer was very involved in speechwriting because we hired a different speechwriter. We still had one of the other original speechwriters that I had hired, and I would get called in occasionally to work on a speech or actually to draft a speech if the circumstances demanded it, but mostly my focus during that period was on media relations. And I also had responsibility for the Freedom of Information Staff, which was part of public affairs.

The other deputy, I believe, was responsible for the fourth component of OPA, Office of Public Affairs, which was the Communication Staff, and that's the staff that handled publications, including the *FDA Consumer* magazine, which was a major publication and had something like 15,000 subscribers, and was an important part of FDA's outreach to consumers.

SJ: Please talk a little about Jim O'Hara. I remember him, but he was a character. What were his priorities?

LB: Jim O'Hara was a political appointee in the Clinton Administration. He actually had been a journalist. I believe his political connections were through the Vice President. At least I'm inferring that.

Jim had been an editorial writer for *The Tennessean* in Tennessee so I expect that he probably got to know the Gore family in his work there. Right before he joined the FDA, I believe he was in Washington working for one of the communications firms, one of the big firms that handles public relations, media relations, communications. He arrived at the FDA and was a very quick study and developed a very close relationship with Dr. Kessler on media strategy, and was, you know, was in frequent communication with Dr. Kessler. I learned a lot about media relations in the press and the media generally from Jim. He was very strategic, very effective in his relationship with reporters and correspondents in the electronic media. Although he was a political appointee, one would not have known that based on the day-to-day interactions with me and with the other deputy and with all of our staff members.

Whatever agendas might have been coming from the other parts of the Executive Branch for Jim or for the FDA, that was something that we didn't know anything about – we were simply a media and communications operation, and I think a very good one, at that.

Jim was very effective at grasping an issue, a public health issue, a public policy issue, in FDA's terms, and summarizing it in a couple, two or three, sentences. Jim was also effective at advising FDA spokespeople and the Commissioner, in particular, on the most important public communications – you know, what we wanted the media and the public to know about that

particular issue. And so he was able, especially in media relations, to manage and implement an effective media presence for the FDA. Once in a while, I would see his interactions with the parent Department of Health and Human Services, or even with the White House.

I know that when there was an FDA issue in the news – reproductive rights were always very big in the early to mid to late '90s – an issue of great significance like that, the White House would be interested, and as a political appointee, he would often be the point of contact. But he would, as I say, be very effective in capturing the issue in two or three sentences and then, you know, sending a very brief note to colleagues in the Executive Branch saying, "Here's the issue. Here's what we're saying about it. End of story." I think he freed up some space for us to communicate effectively with the public.

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SJ: Excellent. What were some of your biggest challenges dealing with Freedom of Information? My impression during this period is it hadn't been that many years since the Freedom of Information Act was put into place, and yet the agency was still getting more requests than any other agency, pretty much, in the Federal Government, and that we really hadn't gotten a handle on how to even begin to stay on top of it. But maybe by the time you came along that had been settled more than I remember.

LB: My recollection, I have some numbers in my head. We could always go back and check. I think the FOI laws date from the early '70s?

SJ: '76, I believe.

LB: '76, okay. So we're talking now '93, '94, '95. What surprised me when I assumed responsibility for FOI was the sheer number of FOI requests. That, coupled with how few of them actually came from the public. So, again, I haven't looked at these numbers in probably 15 or 20 years, but my recollection is that, at that time, FDA was receiving, I think, more than 100 or 110 or even 200,000 FOI requests a year. And a very small number of them – a small fraction were from the public. The great majority were from industry, and they wanted to find out, apparently, what the competition was doing. So it was really a question of resources available to devote to the task of identifying the documents and getting them out.

I think by the time I was involved, I know Gerry Deighton was the head of that office, and I think he'd made some good progress cleaning things up. The advantage of having the FOI Office in the Office of Public Affairs was that we could help reporters get information that they needed quickly because they often were on deadline and needed it right away.

But this is all old history, Suzanne. It's 20 years ago. In the late '90s, when I was running the Public Affairs Office, Linda Suydam, who was the Principal Deputy Commissioner at the time – this was in Jane Henney's tenure – Linda and I decided that, if we moved the FOI FOI operation more to the IT, the information technology part of FDA, that there would be a greater chance that they could get the resources to automate the process more and use new technology. And that's, in fact, when we made that transfer.

Some media observers, trade press folks, have thought that that was a mistake, because somehow they believe that we no longer had the responsibility to fulfill the requests in a timely way. That really wasn't the case. I do know that there has been litigation about FOI requests,

and I believe the current practice is first in, first out, that the actual order of filling requests has to be strictly maintained, and I think that's the result of litigation, but I'm not sure about that.

It's an important public function, of course, but again, what was surprising to me was how little of it was actually going to the public sector, whether through the media or to individual citizens, and how much of it was really generated by industry.

Fortunately, with new requirements that came online I think about 15 or 18 years ago, much of the information that's publicly available is simply posted on our website. So the number of requests even 15 years ago was going down quite dramatically. And the last I checked, I think it was something like in the mid-30 thousands or so. And it's probably lower today, because so much is available online.

SJ: Most of the hits online are still – especially most of the desktop hits – are still regulatory related and that kind of thing.

Okay, well obviously Kessler's career took off, even while you were working as deputy. But I know you were part of some of the hearings.

I'm a little fuzzy on that period before you took over, so if you have anything else we want to get on record for that, that's good. And then we want to get you taking over as head of Public Affairs.

LB: Okay. In the early part of Dr. Kessler's tenure, even in the first Bush Administration, since I was the speechwriter – and Catherine asked about this earlier – I would often be involved in testimony, but not in the formal submitted testimony. And, you know, most people probably know, if they follow Washington things closely, there's a process where the agency or the

organization submits usually lengthy and certainly formal written testimony in response to a request for a hearing, and all of that testimony goes through whatever department the agency's located in, and ultimately, it goes through the Office of Management and Budget. And there were strict deadlines for that testimony to be submitted to the Hill and so on. So I was not involved in that, typically. Sometimes on the budget testimony, I guess, but that often is a different process.

But what I was involved in was helping Dr. Kessler, and other Commissioners, with their oral statement at the outset of a hearing. So that whenever there was – especially in Dr. Kessler's early years, say from 1991 through '93 or '94 – when there was an opportunity for Dr. Kessler to testify in the House or the Senate, I would get pulled in after the formal testimony to be submitted to Congress, when that was pretty much in its final form. And then I'd work with Dr. Kessler on a brief three to five-minute opening statement. And that, with all due respect to the process of crafting and clearing and publishing formal testimony, that, from a communication standpoint, was quite important because that's the beginning of the hearing after the members have had their say and then the head of the FDA or whatever agency is testifying gets to say their piece and provide their perspective on whatever the issue the hearing is meant to be covering. So that's very important and it helps frame the issue from the agency's perspective. It sets the tone for the Commissioner and it's what's quoted from, typically, in the early coverage of Congressional hearings.

SJ: So did you find that to be some of the more interesting parts of your work? What were the things that captivated you?



LB: I think it was fair to say I was captivated both by the formal speechwriting process and by something less formal, or less involved, like the opening statements. What captivated me in formal speeches was partly the reporting of information and talking to the experts and getting all the information assembled. But what I enjoyed particularly was figuring out how the pieces fit together. So if I knew that our agenda was to make points A, B, and C about a particular issue, I'd have to generate all the information by doing research or talking to experts. But I would then have to sift through and find the most compelling facts that supported the various points we were trying to make, and then figure out what was a compelling way to arrange those facts into something that was close to a logical argument.

And there was an art to that. The thing that I found the most rewarding when it worked was to think of a central metaphor for the whole communication – for the whole speaking occasion – or to find an apt story that could open the discussion, the speech, that would help people understand, if not directly then by analogy, what it is we're really talking about. Sometimes I would spend three or four hours going through books of quotes or just sitting in my desk trying to blue sky about what, you know, how can this be meaningful to the audience?

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It was really the most creative part, I think, of speechwriting. So if I could find a metaphor or find an anecdote that kind of crystalized what the essence of this topic is, and then get it into a kind of logical sequence, then that was exciting and rewarding. The writing after that was kind of mechanical. I would always make an outline, though, and then – because I couldn't just – this is idiosyncratic – but I couldn't try to figure out what I was saying – in other words, the content –

and say it skillfully at the same time. I had to figure out what the ideas were going to be and then I would go back and go through them and articulate them the best way I could. Some people can just write, but I can't do that.

CC: So you said “when it worked.” Were there any speeches that bombed that you remember?

LB: I want to answer that question. No, I do want to answer that question, but the other thing, just to follow up on the end of Suzanne's other question. The other part that I found kind of engaging or creative was, in doing oral statements for testimony for a Commissioner, there I did try sometimes to think of soundbites. So in that case, in the case of a Congressional hearing with an opening statement, I would think in terms of soundbites, because we knew the cameras would be rolling, we knew the reporters would be there. And so if there was a clever turn of phrase, then I might spend some time in actually doing that.

CC: Well, and it could be because the audience – I didn't mean to suggest it was your responsibility, but you know, some were more successful than other, I assume. Maybe that's the way to ask it. And is any one speech that sticks out in your mind?

LB: Well, Dr. Kessler's first Food and Drug Law Institute speech I felt really good about, even though I was exhausted. But that speech was a six- or seven-draft one, and staying up late and doing last minute revisions and all that. But it's gratifying to see a major public official delivering the words that you had – that oneself had a role in crafting and creating.

Dr. Hayes, Arthur Hull Hayes, was an eloquent speaker. He didn't seem to have to work hard at it. His father was a well-known CBS radio personality, I think, during the '30s and '40s – certainly during the war years. I remember reading this in the early '80s. And I would talk to him once or maybe twice about his speech and then deliver the draft, the final cleared draft, to him but I didn't talk to him about how to give it or anything. He was just an eloquent performer. He might have had a thespian background, I'm not sure, but he would get up there and read the speech, and he'd do it dramatically and he'd do it with inflection. And the jokes – humor's a risky thing to use in speeches and I didn't use it very much.

CC: Because you have no sense of humor?

LB: I'm a very funny guy, but in a formal speaking situation, humor can backfire very easily, and more than that, many people who are even reasonably effective public speakers are not comedians and they don't deliver the material, perhaps, in a way that's funny. But Dr. Hayes would, he would nail it just about every time. I remember a FDLI speech where I had – I'd found a really good anecdote and he delivered it perfectly and it got a great laugh.

A few years later, I had written another FDLI speech for another Commissioner and that was probably my most embarrassing moment, because this Commissioner wanted the speech to cover too many topics, and it turned out to be not at all a thematic speech, but a laundry list speech – "We did this and then we did this and then we did that and these are the other important things." That's unfortunately how many speeches are so-called structured. But this was a Food and Drug Law Institute speech, the big speech of the year, and I had been at the agency for a while, and many of the people in the audience who were not with the FDA had been, and they

knew who was the Commissioner's speechwriter and so on. And the speech was, I think, 45 or 50 minutes long, which is way too long, and even with the FDA Commissioner, after about 15 or maybe 20 minutes, people just started leaving in droves. And that was kind of my worst moment as a speechwriter probably.

CC: So we know about that the least comfortable time was. What about successful speeches?

LB: I mentioned the one of Dr. Hayes when he spoke very eloquently and delivered the joke well. I think a couple of other successful occasions involved David Kessler. He was unusual, at least at the time, in actually addressing FDA advisory committee meetings and advisory panel meetings. And so I remember very early on, and I wrote those opening statements for him. One of them was on drugs for Alzheimer's disease. I was at the meeting, and I could tell that the audience in this case was very impressed that the Commissioner took the time to actually address this advisory committee meeting. He had substantive things to say about the development of potential therapies for Alzheimer's.

Similarly, with a meeting on HIV, the Antiretroviral Drugs Advisory Committee, he stepped up and addressed those issues directly. This was something that I think was new for the FDA, not just speaking before an Advisory Committee, but talking about the tough issues. David Kessler did this with some regularity, and I think the '80s are known for the relative reluctance of public officials in the public health arena to step up and discuss some of the really thorny and difficult and very obvious and apparent issues in public health, HIV/AIDS being the most traumatic one. But David Kessler confronted these things. Breast implants were a huge issue relatively early in his tenure. I can't remember the time – '92, '93 maybe.

SJ: Yes.

LB: We had public meetings on the safety of silicone gel filled breast implants. Huge, huge issue of interest to the public, and he spoke there and we spent a lot of time on these particular public statements. So those are examples, I think, of some pretty successful speeches.

I don't remember that we ever scheduled Dr. Kessler for the National Press Club, but certainly later Commissioners, such as Dr. McClellan and Dr. Henney and Dr. von Eschenbach, we definitely scheduled the so-called newsmaker luncheons at the National Press Club. These were regularly scheduled lunches arranged by the Press Club, and they were broadcast live on many NPR stations.

CC: You initiated having them be a speaker at one of those Press Club luncheons?

LB: Yes.

CC: So that was an outreach kind of thing?

LB: Yes. I mean, the Press Club has an agenda. They have, I don't know, 40 luncheons a year and there's a committee that arranges it. But if FDA feels that it has an important public health issue or initiative to talk about, then we can reach out to them and say, "Hey, we'd like the FDA Commissioner to schedule for a newsmaker luncheon. We want to talk about A, B, and C." We did the same thing for Dr. Hamburg, as well, a couple of times, I think, more recently.

CC: Let's turn to some of the significant regulatory issues and activities of the Kessler years and your involvement in those, starting with HIV/AIDS and AIDS therapies.

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AIDS was an issue, but not really being broadly addressed, when Frank Young was Commissioner. And I think when Kessler came on board, it finally got some significant attention in the Commissioner's office. So what do you remember about AIDS as a public health issue? What was your involvement in that issue?

LB: I think we sort of got accustomed to the relative silence about HIV/AIDS in much of the '80s, and I remember being surprised a bit, and pleasantly surprised, when Dr. Kessler would publicly talk about HIV/AIDS and really the crisis we were facing, and the importance of acting and acting quickly and putting a lot of resources into that fight. That was a big change, I think, in tone, and certainly I can't speak to all the operational issues, but clearly in David Kessler's first years, HIV/AIDS was a high priority.

I mentioned earlier about the advisory committee meetings and my involvement in drafting some of the Commissioner's statements and working with him on those. It was a big deal that David Kessler went to the Antivirals Advisory Committee meeting and addressed some of these issues head on. I think if one looks at the first one or two of Dr. Kessler's Food and Drug Law Institute speeches in December of '90 and '91, he talks about the situation that he inherited. This might be the second year when he came into the FDA, and he talks about cholera

coming up the coast of South America and he talks about HIV/AIDS and food safety issues. He goes through a whole litany. I just remember being impressed that he was bringing these issues to the floor and acknowledging them publicly in a way that hadn't been the standard practice previously.

AIDS was an important part of many of his speeches in that time, and I can recall being in his office working on statements or speeches, and he'd just pick up the phone and call someone or some two or three people in the antiviral drugs division in the Center for Drug Evaluation and Research, and he'd get them on the phone or he'd have them come into the office.

I think David Feigl was in that area at one point in the early '90s. I remember working on a speech on this, and Sandy Kweder was one of the people that I'd talked to, and she's become a leader, a senior person, in the Center for Drug Evaluation and Research. I think she's still there. This speaks to the commitment of Dr. Kessler to tackle these issues head on and bring attention to them, but also his way of reaching into an organization and getting people involved at all levels, to move the ball forward.

CC: And sort of rolling up his sleeves to move things along, too. I think one of the things he talked to us about in his interview was getting involved at sort of an operational level with AIDS and AIDS protocols and expedited approval and really being at the table, not just saying we need a program

LB: Well, I imagine he did this deliberately, but the organizational structure that he set up when he became Commissioner, where he had the five deputies. In many respects, the agency

could run itself without him, because he had a Deputy Commissioner for Operations, Dr. Jane Henney. The center directors, I think, reported to her at that time

SJ: But they didn't realize they were reporting to her, apparently, to hear her tell it.

LB: I haven't seen that oral history. I guess it's not done yet. But the point is that structure freed up David Kessler to know that the agency was in good hands, whether it was policy with Mike Taylor or external affairs with Carol Scheman, or operations with Jane Henney, or there was management. Mary Jo Veverka was the first person. That really allowed him to focus on what he thought would be the biggest bang for the buck or what piqued his interest or what was in the best interest of the public health. That allowed him to roll up his sleeves, to use your phrase, Catherine, and delve into those antiviral things. And that wasn't the only issue that he was deeply involved in, so maybe we take a look at some of the other ones like dietary supplements.

CC: Okay.

LB: That was a huge issue, I remember, especially over the summer of 1993. It was a big topic of interest on the Hill, among consumers, and the FDA was concerned. It hadn't been that many years before – the late '80s, I believe – where L-tryptophan had proven to be a dangerous substance, at least from one manufacturer. That happened at about the time I came back to FDA.

In 1993, if I recall correctly, Dr. Kessler wanted to focus on dietary supplements. There was a major effort. We sent investigators around the country to pick up samples of – I don't



know the number now – hundreds probably, of dietary supplements and vitamins. And then they were analyzed in FDA labs, and the idea was that we would issue a report on the purity, the potency of these products, just to do a survey of what was really out there. I was involved in some of the discussions of this, and my major role was to work on the introduction to that report. It came out sometime in the summer of 1993. There were some real issues in terms of whether these products had in them what they claimed to have in them, and at what concentrations, and whether those have enough to be active pharmaceutically or chemically.

So this report was a concern of the FDA and it contributed to the debate that was ongoing. And my understanding is that in the 1993 and 1994 period, Congress received more correspondence and contact from constituents about dietary supplements than about any other issue. It's well-known that there was an effective and orchestrated campaign in favor of dietary supplements. But in the end, what this debate culminated in, obviously, was the Dietary Supplement Health and Education Act of 1994, which set new framework for the regulation of dietary supplements. And it's the framework that we have now. I think generally, the American public doesn't understand that the dietary supplements and vitamins on the market are not subject to preapproval by the FDA. So it's an interesting case of how the public debate, the policy debate, was carried out and what the upshot of that was.

I do remember, and I think this was probably in the summer of '93 and probably around the time when the report came out, the FDA's report, that Dr. Kessler testified and members asked him questions. And I have a clear recollection at the very end, Dr. Kessler volunteering the observation, something to the effect of, "Well, it's all well and good if we adopt a new regulatory framework for dietary supplements that presumes that they're going to be safe. But I'm the first person you're going to come to when there's a problem and ask me why we didn't do

something about it." And so that, I think, that was not atypical of Dr. Kessler to sort of state what the position was and what the potential consequences might be.

CC: Would that have been something, a soundbite, that somebody offered up to him in a briefing? Or do you think that's something that he probably came up with himself.

LB: I think he probably came up with that on the spot – that would be my guess. But it's not often that one hears that kind of statement of truth to power, of a clear statement of, "Okay, well if this is the direction we're going, here are the possible consequences." That's not often the case.

SJ: There were allegations, at the time, that Dr. Kessler was so involved in food labeling on the one hand, but also emerging tobacco, he just sort of took his eye off the ball when it came to dietary supplements. A couple of things you had said before now gave me the impression that might not have been the case. That there might have been pressure at other levels within HHS and elsewhere, that kept him from doing what he, under his natural inclination, would have been on top of.

LB: I don't have any direct knowledge, or I haven't observed anything specifically about how the outcome, how that outcome evolved. From my perspective, it was something that was a priority for the FDA to look at. I mean, whether these dietary supplements actually contained what they claimed to contain, and whether they did what they supposedly did. And we – the agency – did a report on it, and the Commissioner testified and we gave it our best shot from a public health perspective. And the legislative process played out, and the result was the 1994

law. So from where I sat in the FDA, I can't add anything more. Maybe other people in the FDA that were more involved with legislative affairs might have another perspective.

SJ: Well, certainly Gary Dykstra's report on dietary supplements was important, and you said you helped with crafting that?

LB: My recollection was that there was an introduction – maybe 10, 12 pages, maybe 15 – I don't know – in typed script – an introduction by Dr. Kessler sort of summarizing it. There's probably an executive summary – again, I haven't seen my copy in about 15 years – I worked on that with Dr. Kessler. So it was an issue that I was personally involved in and I thought was very important and it's just the outcome wasn't what one might have predicted or expected.

SJ: What everybody had hoped?

LB: Yes.

SJ: Catherine Price has written a book called *Vitamania* that documents some of the – some of what she was able to put together and some of the politics around it.

CC: In some respects, that may have been an example where, despite all his other successes and being able to move the agency forward on other issues, on this one, David Kessler didn't get what he wanted or what he thought was best for public health. I've never thought of it that way, until listening to you talk and sort of what he said about consequences.

LB: We talked earlier about raising the profile of the FDA and having David Kessler be recognized as the face of the FDA and the spokesperson. But I mean not just a mouthpiece, but someone who actually embodies the mission and the values. That can be very helpful when you need to reach people directly. In having a higher profile for the FDA and to some extent, for himself personally, I think Dr. Kessler, in other circumstances, increased the odds of success, because there was what I perceived as a growing constituency or section of the public that actually was more engaged in FDA, more aware, and had a better understanding of “Oh, that's what they do.”

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CC: You started to talk, Larry, about NLEA and used that as an example of – to use the phrase I coined – Dr. Kessler rolling up his sleeves. Can you sort of expand on that?

LB: Right. This was, I think, a very important, teachable public health moment where we had a new modern up-to-date usable food label, the new Nutrition Facts panel that was mandated by the law. My understanding is that the final regulations were issued at the very end of the first Bush administration. Dr. Louis Sullivan was very involved in those. FDA had to go through the process of informing industry about the new requirements, about making sure that consumers became aware of the new food label, and understood how to use it. I think the new food label was required by 1994.

CC: That would make sense, yes.

LB: It had to be. Dr. Kessler mentioned it frequently in his speeches, and one of the points we frequently made was that the format was established and what had to be in the new label was well-known and well-publicized. So many food manufacturers were actually adopting the new label ahead of the deadline, and that built up some momentum.

But the point I wanted to make about rolling up one's sleeves is I can remember several lengthy sessions, I think some of them over the weekend at Dr. Kessler's private residence, where there would be a group of 15 or 20 people, and we'd get together and we'd brainstorm and discuss and come to some kind of agreement about what the best way of communicating this really revolutionary new food label to the public. What are the best channels for getting this message out? How do we describe its new features? How does one use it?

Dr. Kessler did a lot of interviews on this subject, and I remember him focusing, because at that time that's what nutrition science told us, focusing on the importance of fat. Not to worry about the grams, but if it's less than, I can't remember now, five grams or maybe he used a percentage. But if it's less than this percentage a day, that's low-fat. We had a regulation for what low-fat meant, but he was trying to help consumers put that into context. So this was a public health advocate, doing the work that was important and needed to be done, and really involving a large group of FDA people strategizing on the best way to make that happen.

I think the only kind of footnote I'd add, we talked about exercises or initiatives that were successful or less than successful, and one of Dr. Kessler's strongest characteristics is the ability to think outside the box and be really creative. And I can remember in the 1991 period, maybe 1992, as a pediatrician, he hit on the idea of starting young with a new food label, and food and

nutrition consciousness, and the notion of creating a kid's food label that would kind of accompany or be adjunct to the new Nutrition Facts panel. And we actually, we were – we made plans to move ahead with this initiative, or at least we were in the exploratory stages of it, and the idea was that if you could get youngsters to start thinking about the nutritional values, or at least be aware of them and what they were eating, they read something on the box, that that would be a habit that could carry on into later life.

I spent a day in New York City with Dr. Kessler, and we spent the morning at the Children's Television Workshop, and we talked to the people that produced, at that time, Sesame Street, about possibilities for promoting nutrition or a nutrition food label for kids. Then we spent the afternoon at Nickelodeon, a cable network for kids, and had a similar discussion with them.

So this is just the kind of creative approach and “we can do it mentality” that Dr. Kessler brought to his position. And that infused the agency and its leadership, I think, with lots of energy. And it also was, for me personally, kind of empowering to say, “Well, here's – what problem are you trying to work on here? What's a gap or what is a need that should be addressed and then how do we go about doing it?”

The kid's food label never materialized, but I just raise it as an example of the kind of thinking that was going on at the FDA during that time.

SJ: But we did have Curious George under contract.

LB: Yes, we did. As we were sketching out what this food label might look like and how we would apply it, we hit on the idea of having the fictional kids' book character Curious George be

kind of the spokesperson, I think, or symbol of it. So we actually, I guess, went as far as having the rights to use Curious George in some of our communications materials for a set period of time, which I think just expired, right?

SJ: It expired in 2014, and we have the models they used in the exhibit case. Sharon Natanblut gave us the puppets and things they had put together to promote it. And I think they might have actually used it, just not for a children's label, just for the overall nutrition facts label.

LB: I think that's probably right. I think the Center for Foods probably did use it.

CC: Interesting. Somehow the kids' food label passed me by. What about some of the more public health crises that we had – the agency had to react to. One is BSE. Another one is blood safety. Were you involved in any of those issues and if so, how?

LB: I was very involved in both of those issues and, in part because later on, they were part of my media beat when I was a deputy in the public affairs office, one being a biologics product and one being in the veterinary medicine area. Let's talk about them in chronological order.

The blood supply safety comes first, and I started to be involved in it – I don't remember if it was 1991 or 1992. I'm sure it was one of those years, when there was a lot of interest on Capitol Hill in blood safety. Of course, much of it had to do with the transmission of – the potential transmission of – HIV, the HIV virus from HIV-infected donors. This, of course, hit the hemophiliac community particularly hard, because of the Factor VIII or IX clotting products that they would have to take. Representative John Dingell held a series of hearings on blood

safety, and I don't know when they started, but when I became aware of them was the early '90s. And they were, you know, they were tough sessions for the FDA.

A very well-known and respected investigative reporter, named Gilbert Gaul, G-A-U-L, focused the light on the blood industry, I think in the late '80s, maybe '88, '89, when he was at the *Philadelphia Inquirer* and he did some hard hitting pieces on the safety of the US blood supply. Anyway, Representative Dingell was very involved in this issue and it's squarely in the FDA's regulatory responsibility. So there was a lot of attention internally focused on blood safety. Dr. Kessler was quite involved in it, and I first became involved, I think, in helping draft some Congressional testimony on the safety of the blood supply.

I remember very clearly being called to his office one day, and I met two of FDA's national blood experts, one of whom is Ellen Morrison, and the other one was an investigator from, came from the Buffalo District, and I'm not remembering her.

CC: Her first name was Mary. Don't you think?

LB: Yes, I believe her first name was Mary.

CC: And I can't remember her last name – Mary Cardin maybe? Something like that.

LB: Something like that. Dr. Kessler wanted me to talk to them to enhance my understanding of how the blood supply is regulated, about the safety measures in place to ensure that blood and blood products are safe. That became the first of many sessions where I learned more and more about the blood supply, and then later on, I was dealing with reporters to discuss issues



surrounding blood safety. So it was a major preoccupation of my career. The point I want to raise immediately is an example of how FDA, when it does things right and communicates effectively, is able to communicate about a public health issue to make sure that it's in the limelight and the public knows about it. But to have it be covered in such a way – to help it be covered in such a way that it doesn't cause undue alarm.

The specific instance here was when the FDA initiated an unprecedented regulatory action and then entered into a consent decree of permanent injunction between the FDA and the Red Cross. This happened in May of 1993. It was soon after Jim O'Hara joined the agency, and it was unprecedented at the time and a very important announcement. The Red Cross at that time supplied about one-half of the blood supply in the United States, and basically, what we were announcing was that we had gone to a court and the court had blessed an agreement between the FDA and the American Red Cross, in which the Red Cross would agree to do certain things to improve the safety of the blood supply.

Well, this is a very potentially frightening issue for people to hear about, and the last thing that FDA wanted to do is shake the public's confidence in the safety of the blood supply because blood is a necessary product and it's vital and it's needed in surgical procedures and other emergencies. So we wanted to make sure that there wasn't a great scare. But on the other hand, we needed there to be a public understanding that FDA was taking this important enforcement action to increase the safety of the blood supply. So we had a very carefully titrated strategy, and we knew what we wanted to say, and because we enjoyed a good working relationship with the reporters that covered the FDA – this is something that had been built up over the two-and-a-half years that David had already been Commissioner. We prepared the field and this happened on a Friday afternoon. These things often do. And the upshot was that the

story in the *Washington Post* was not on the front page, but it was not – this is going to sound old-fashioned – it was not buried in the B-section of the paper. That it was in the A-section, the national news section, but, if I remember right, on page A-6.

So it got some prominence in the newspaper, but it wasn't on the front page, which would have telegraphed to readers at that time, that this was a pretty serious and important issue. That sort of thinking isn't so germane these days, when many people, if not most, read their newspapers online. But it was part of a carefully considered strategy of exactly what tone to take and how to phrase our news release and how to talk to the reporters about it so that they got the word out. Because we had to make sure that the public knew that we were taking steps to improve the safety of the blood supply, but we didn't want it to be a screaming front page headline. The last thing that anybody wanted to have happen was people refuse to take a blood transfusion or use a blood product that would preserve their life.

CC: Let me ask you about the specifics. I remember that the sort of internal conventional wisdom was that Saturday was a slow news day. So if you wanted – a lot of things happened on Friday, releases or whatever.

[04:19:53]

So you could sort of control when you release the news, but how do you control placement in a particular section? Maybe this isn't true.

LB: Well, the answer to that question is you can't control where the story is going to run, and the last thing a media affairs person would want to do would be to suggest to a news outlet where something should be or how it should be run.

But when there's a healthy and constructive relationship, when a media relations shop like the FDA's Public Affairs office, now it's called the Media Affairs Office, when they have a healthy relationship or a trusting relationship with media outlets where, you know, media outlets can call FDA and say, "How important is this?" Or to be there for them at 9:00 at night when they need a quote. It works both ways. If FDA has an important food recall and wants to get it on the AP wire, again, this is like 20 years now, 15 years ago, but it was important if you could reach the Associated Press news wire that went into all the news rooms of the country and all the TV stations. If something happened at 10:30 and you wanted it to be on the 11:00 news, you needed to get it on what was called the AP wire. It works both ways. You know, we're there for reporters when they need us, and they're there for us if we need to get something out. And that's based on trust. It's not a quid pro quo relationship. It's a relationship where there's mutual respect and trust.

So in the case of this consent decree between the FDA and the American Red Cross, we had the relationships with reporters who knew the agency and knew its issues and knew us, and knew that they could count on what we told them was the right story. Really competent reporters, when they trust someone, will sometimes say, "Really, how big a deal is this? Is this a big deal?" They ask because they want to be able to talk to their editors for advice. So this was an example, at least with the story that ran in the *Washington Post*, of how I think – I didn't deal directly with the reporter, Jim O'Hara did – we either conveyed or the *Washington Post*

understood or somehow in between, the story played out in what we thought was an appropriate way, and obviously the Post did, because that's where they put it.

CC: I guess the answer to my own question is you don't control it, but you influence it. If you don't write an inflammatory story – if you write a factual story – that suggests how important it is.

LB: Yes, as does the tone of our quote or our news release.

CC: Well, that's blood safety. What about BSE, so-called Mad Cow Disease? Always a great turn of phrase.

LB: Yes. BSE stands for bovine spongiform encephalopathy. My colleagues in the Center for Biologics Evaluation and Research hated it when reporters referred to it as Mad Cow Disease. And we learned in the media office and the press office not to ever say Mad Cow Disease, but they still sort of – and CBER held it against us when reporters would say “Mad Cow Disease.”

CC: In CBER or was it the Center for Veterinary Medicine?

LB: Well, it's CBER for the blood supply, I think, and more in CVM. You're right. I remember being on vacation in England in 1990, and, if I recall correctly, that's when BSE became an issue in the United Kingdom. Mad Cow – they called it Mad Cow Disease. I don't

need to go into all the details, but it was a very serious public health threat, and sometime around 1995, I think, there was concern that the US cattle population might be at risk of being infected with BSE.

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The disease causes symptoms and results in an outcome similar to Creutzfeldt-Jakob disease, which is a pretty devastating condition. And the only way it can be diagnosed is on autopsy, if you look at the subject's brain. I don't need to talk about all the causes and so on, but it was a serious public health issue. Meat products are implicated, and of course that's USDA.

The epidemic is thought to have occurred in the UK through the practice of feeding to cattle and other mammals animal feed that's derived from cattle and other mammals. This is done through the rendering process where the offal and neurological tissues and so on are processed and then added as a component of animal feed. The infectious agent is widely thought to be something called a prion, and that apparently survives the processing. So cows would be infected with it, and then when people would become infected if they either ate the infected meat or I guess were around infected cattle. Some young farmers developed these symptoms of Creutzfeldt-Jakob disease in the UK.

So anyway, there was a huge fear that this was going to happen in the United States, and the FDA's involvement is through animal feed, because we use similar rendering processes in the US. But also many other FDA-regulated products in the United States are, in one way or the other, derived from cattle parts, gelatin being an obvious example because it's made from bones.

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The many gel caps, medical medicines gel caps or the gel coating in capsules, in drug capsules are made of gel – the list went on and on and on. I think BSE touched nearly all FDA centers, that there was a potential human exposure in the US, to bovine spongiform encephalopathy, if this disease ever became established in the US.

We jumped on this right away. It was a huge effort, and just to cut to the chase, under Dr. Kessler, we went through a regulatory process where we did what's called an interim final rule, which means we, instead of going according to the, what is it, the Administrative Procedure Act where there's notice and comment rulemaking, and you propose a rule and you have a comment period and then the agency reviews the comments and then revises the rule and issues a final rule and explains why they accepted some comments and not some others. This was such an imminent issue that, in very short order, we issued an interim final rule designed to head off the risk of BSE coming into the United States. And if I recall, that rule took effect in early 1997. I remember talking to Dr. Kessler about it over the Christmas holidays, in 1996, and that was really shortly before he left. His last day was in March of '97.

Basically, these were regulations designed no longer to allow the addition of certain parts of animal carcasses – mostly the neurologic tissues like the spinal cord and brain, because this is a neurologically transmitted agent, it's thought – to keep them out of the animal food supply so that these so-called rendered products that come from animal carcasses would no longer be in the animal food supply and therefore would no longer be added to chicken feed or feed for swine or for cattle. That's probably longer than I meant to go on, and I'll stop there.

There's one media issue around this that I want to mention. So two things about this. One is – and this was probably in 1996 – we had an open public meeting and again, I don't remember – it's been so long – if it was a formal hearing. It was a session where anyone could come.

Reporters were there. We had experts and we were – the purpose of the meeting was to discuss ways of minimizing the risk that BSE. would come into the US, and what we needed to do, particularly for the animal food supply, animal feed, to keep it out of the US. The big reporters were there. Lawrence Altman, who's a physician. He was a good reporter. He was not only a doctor, but a good writer. Very careful and very powerful, and he was at the hearing and I'll tell a story about him in a second.

But I remember talking to someone – we had experts from Scotland who dealt with this epidemic in the UK and the people from the US, veterinarians, people from vet medical schools. And someone from the UK came up to me, and I must have been doing something in my official capacity at Public Affairs, and he said, "This is remarkable that you're having this open public hearing. This would never happen in the UK. We wouldn't be discussing these things openly like this." And, you know, that made me feel really good about the US. Because classically, and this is really a PR blunder, but at the height of the BSE outbreak in the UK, and this was probably around 1994, the minister of something like forestry, agriculture, and farms in the UK, was on camera eating a hamburger and I think feeding it to his daughter, as well, saying how confident he was about the British beef supply. Well, that's not the way you do it.

So fast forward to, I think this was probably right around the time, spring of '97. We had just issued the rules or the rules were starting to come out, and it's 5:30 and I'm due home to take over kid duty, and it's Larry Altman from the *New York Times*, and that's a call that you always take. And he basically said something like, "I've got evidence that if such and such doesn't happen, there's a high likelihood of BSE happening in the US." Or it was something – or if, you know, if this – if your new regulation doesn't also include such and such, I've got somebody who's an expert who's going to say that it's inadequate. So basically this story was going to be,

you know, we're still at risk. I said, "Look, how much time do I have? Okay, got a half-an-hour." But he said – you know, and this is not an uncommon thing, or it used to be "Here's my story. What do you have to say about it?" But I had a pretty good relationship with him. He trusted me and I trusted him, and I'd been there for him lots of times when he needed to talk to Bob Temple or somebody. So I called over to the Center for Vet Medicine, and I got the deputy director, who was – I don't remember his name now. I can dig it up, but he was competent, he was articulate.

CC: Was it Dick Teske?

LB: No. It was an African-American man, PHS Corps. I remember him wearing the white uniform. Really articulate, and he is someone that we had been confident putting in an interview situation before. And he said, "Oh, yeah. I've heard of that, whatever the concern was, and here's why it's not a concern." So I got him on the phone with Dr. Altman, the *New York Times* reporter, right away, and they spent 10 or 15 minutes. And Dr. Altman grilled him and he was credible and articulate and reassuring, and it changed the way that story came out. So instead of being, "Uh-oh, big trouble ahead." it was "Here's the new finding about BSE and here's how the FDA's regulation has it covered." I mean I don't have the details, but that was the gist of it. I'm telling that story not only because it illustrates how important it is to have good relationships with reporters and to be perceived as being credible, but also because, in those days, the FDA media operation had the freedom to grant interviews, set up conversations with reporters, without further clearance.



CC: Michael Blackwell was the Deputy Director of CVM.

LB: That's right. He was terrific.

CC: Let the record reflect I had to look that up in the FDA directory.

LB: That changed radically in the mid-2000s, and it still is the case, that FDA no longer has the authority to arrange interviews with any major media. Not the trade press, but with any one that you would recognize as media, without clearing them through the Public Affairs Office at the Department of Health and Human Services. That's a huge change.

CC: And to sort of tee off of that, have you been in situations, the Larry Altman situation, where you could have managed a story if you could have acted in 30 minutes without getting clearance? That's a change. Is there an impact from that change?

LB: I'm sure there's an impact because of that. I can't speak directly to it, because I left the Office of Public Affairs in 2005, and when I left, just as I was leaving, there were changes in the works to have the Department look more closely, monitor, and even clear media requests. So those changes were in the works as I was leaving. Maybe, they may have even started to take effect a few months before I left. It's a fact that it's more difficult to run a responsive media relations organization without being empowered to act quickly and get to the right person right away. Reporters need what they need when they need it, and if you can help them get the right expert quickly to help them get their story right, that can only work in your favor.

CC: Okay. Let's stop here for today. We'll set up some additional time to finish this interview.

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CC: This is another in a series of oral history interviews for the Food and Drug Administration. Today is August 15, 2016, and this is part two of our interview with Larry Bachorik. This is Catherine Copp, and Suzanne Junod and I are conducting the interview at FDA's White Oak Campus.

Larry, there were two topics that we did not discuss during part one of your interview. One is the Odwalla juice problem, microbiological contamination of an apple juice product. And you were also going to talk about some of the Congressional hearings near the end of David Kessler's tenure. Let's start with the Odwalla situation if that's okay with you.

LB: Actually, can we flip the two topics? I think Odwalla is a good transition to the broader issues we want to get to concerning Dr. Kessler's tenure.

CC: Alright. So let's start by putting on the record the status of the Congress. In 1994, during the first term of the Clinton Administration, the House changed hands during the midterm elections. That meant that a group of people, who hadn't been able to call hearings, et cetera, were now in power. And I think that is a significant shift. If I remember correctly, up until that time, the Democrats had been in control of both the Senate and the House during Kessler's tenure.

Let's talk about Joe Barton and who he was and what he did and how that affected FDA and your role, of course.

LB: I'm not expert on Representative Barton really, but to the extent that – which was a great extent – was I involved in hearing preparation and especially the oral statements that the Commissioner would give at a hearing, I can comment.

Of course, the Office of Legislative Affairs prepared the formal testimony. And that testimony was long and detailed and sometimes a little sleep-inducing. It was the whole record, and it would start off from day one of whatever the issue was and go through what the agency had done or was going to do. My involvement in Congressional hearings with Dr. Kessler was to draft the oral statement that the Commissioner would give – two or three minutes – at the outset of a hearing. That was kind of where the action was, I think. It was Dr. Kessler's take on the important issues to be raised at the hearing, the perspective of the agency, his perspective on those issues. Those were often high visibility occasions dealing with important and sensitive issues, and so getting the oral statement right was important.

Also as time went on, when Dr. Kessler would testify, it became a bit of a media occasion. He often said interesting things and was dealing with important issues, so there would be a lot of reporters in attendance. It was the oral testimony or the oral statement upfront that was often the words that would get into the coverage of whatever the issue was that day, so that's I think in part why I was involved in the oral statements.

CC: Let me interrupt you just one second. When you say the media were involved, are we talking about print media, broadcast media? By then you have daily C-SPAN broadcasts from the Hill. Maybe that's not an important distinction, but you can address that too.

LB: There would always be a lot of print journalists in the hearing room and there would be a long table set aside for journalists. Typically, it would be print media, but often producers from the networks would be there. It was less frequent that cameras from the networks or the cable news networks would actually be in the room. CNN was around in the early '90s. I think Fox didn't start until about 20 years ago. But there were times when there were cameras in the room as well.

Even back 25 years ago, it was important to get the first news cycle and to get it right. If Kessler were going to say something relatively memorable, he wanted to make sure he had it upfront in his oral statement. He might say something in response to questions that would also be of interest to policy makers or to the media or to the public, to the Members. It was all the media, but it was more print media than not.

One of the things about these hearings and one of my roles, especially later on in the late '90s when I was running the press operation, was we always – if it were an issue that was contentious that was the subject of a hearing, we'd also have to think about in advance how to get the Commissioner out of a hearing room. Sometimes that meant going back through the Members' exit out the back of the room. Other times, we would almost on the spot decide whether to do an impromptu standup interview in the hallway outside of the hearing room with the principal. That's a little more risky because it's not very controllable. Sometimes we would just go out the regular entrance but just keep walking and make sure that the Commissioner or

the senior official testifying just got out of there. We would schedule interviews by phone or on camera interviews at a later time that day. So it depended on what our strategy was.

In terms of Representative Barton, the reason I wanted to spend a little time on that is – I think the period was in '94, '95, maybe into '96 – there was a series of hearings on the subject of FDA's alleged retaliation against the regulated industry. Representative Barton of Texas took this issue on. He was very involved in it, his staff. And there was a series of hearings. I haven't gone back to look, but I'm sure there were probably at least three, maybe more, when Dr. Kessler was called before Representative Barton's committee to explain, to discuss specific products that were of great concern to Representative Barton and to the committee.

CC: Representative Barton was chairman of the House Committee on Government Oversight?

[Ed. Note: In the 104<sup>th</sup> Congress, Congressman Barton was chairman of the House Subcommittee on Oversight and Investigations, which was a subcommittee of the House Committee on Energy and Commerce.]

LB: I don't know. We'll just have to look it up for the record. I know it wasn't Representative Dingell's committee – it wasn't Energy and Commerce. I just remember that, as always, we would get the focus of the hearing in advance. There were specific issues that we needed to cover. And there was a lot of preparation and research that had to go on beforehand, preparation of Dr. Kessler's testimony, the formal submitted testimony or the oral statement.

I might add that formal testimony has a rigorous clearance process not only through the FDA centers and Chief Counsel's Office and Legislative Affairs Office – they draft it. But also through HHS and through the Executive Branch and the Office of Management and Budget.

Not so for the oral statements, at least back in Dr. Kessler's time. So that was another advantage of focusing some attention on the oral statements because they were typically done toward the day of the hearing and could reflect the latest developments and could be somewhat more colorful than the prepared testimony that went through the formal process.

There was a variety of products that Representative Barton's crew focused on. I don't remember all of them. There was, I think, an automatic defibrillator, a portable defibrillator, that allegedly FDA was keeping off the market that the Subcommittee thought could have saved lots of lives. Another was a medical device that could be used, I think, by patients to help detect breast tumors in women.

SJ: The mat?

LB: Yes. It was like a gel or a silicone or something that I think that women could do self-exams with that allegedly FDA was keeping off the market. Those are the two that I can remember. I haven't gone back. But I remember four or five such products, and FDA was being called on the carpet for standing in the way of innovation and helping patients get the products that they need.

CC: Well, not to quibble with what you are saying, but FDA often keeps products off the market. That's partly its job. I guess Barton's contention or that of other people on the Subcommittee was that FDA was inappropriately keeping products off the market.

LB: Right. In fact, he claimed that lives were being lost because of so-called bureaucratic delays or inefficiencies or unwillingness to let products on the market. I'm not really in the position to comment on the merits of the argument at this point.

But at the same time that this was going on, there was a very concerted public relations campaign that was, if I remember correctly, sponsored by, driven by, an organization called Citizens for a Sound Economy that took out half page ads, quarter page ads, I think sometimes full page ads, essentially attacking the FDA. One of the headlines I remember – and I have a file of these that I kept at the time, I hung onto them over the years – was superimposed on, I think, a graveyard, and the headline was something like, "When a drunk driver kills someone, they go to jail. When the FDA kills someone, they're just doing their job."

So it was very hard hitting and very important to the FDA. There was a time – I think it was in '95 – but in the Office of Public Affairs we would have a daily meeting, like, I think at maybe 4:00 in the afternoon where we would get together, the senior people in that office would get together, and talk about what had happened that day vis-à-vis this campaign. Basically it was a pretty full frontal attack on the FDA.

CC: Who was behind that? Did you know at the time? Do you know now? That takes a lot of money and some organizational heft.

LB: I don't. I'm pretty sure the organization called Citizens for a Sound Economy was what was driving it, but the question you're asking what was behind that. I do know that Phil Hilts, who was a well-regarded science journalist – he covered the FDA for the *Washington Post* probably in the '80s, I think, and then he moved on to the *New York Times* in the '90s – published

a book on the FDA. Suzanne, you probably remember when it came out – probably 2002, 2003. It was a book he worked on for about five years if I recall, and I think that book grew out of this campaign, general campaign, in a sense to discredit the FDA or to drive reform of the FDA claiming the FDA needed to be reformed.

I remember talking to Phil Hilts probably in 1998 when he was just starting the interviews for that book. I set him up with Dr. David Feigal, who at the time was head of the Center for Devices and Radiological Health. Hilts spent a long time on the book, but it was driven by – and I think he says in his introduction – that he wanted to write a comprehensive history of FDA and how it's responded to political pressures over the years. My recollection these many years later is that his effort and his interest was spurred by that campaign.

A couple of things I'll say about that book. One is that there's a chapter on Dr. Robert Temple, and it's a chapter on basically how Dr. Temple almost invented the science of clinical trials. I think that was a good thing for Hilts to have done – to really shine a light on how important one person, Dr. Temple, has been in the history of clinical trial design and actually having scientific evidence to back up FDA approval. So I was glad to see that.

The other thing is whenever there's been a new employee – not every new employee, but when I've hired someone at a senior position, say to be a speechwriter for the Commissioner and so on, one of the first things I do is tell him to look at Phil Hilts's book because I think it gives a good sense of the issues that FDA has confronted over the years.

CC: I wanted to go back to the group. What was the name of it?

LB: Citizens for a Sound Economy.



CC: They were putting ads in major newspapers?

LB: Certainly in the *Washington Post* I remember. I don't know other places. Probably the *New York Times*.

CC: But, in any event, before that and after that, was that unusual? Or were these types of advertisements or public relations efforts – were they common before that time in terms of attacking FDA? I'm just trying to get a context for this effort.

LB: As I was thinking about today's interview, I was looking at the book Suzanne was very involved in that was published in 2006 for the centenary of the FDA, centennial. Some of the illustrations and the posters and things that Suzanne found that are in that book, clearly the FDA had been attacked in the past for approving something or not approving something.

In my career from the late '70s through 2015, through last year, this was an unprecedented attack both in its breadth and its directness. To basically say “FDA is killing people” is pretty aggressive, so this was a very orchestrated effort. I can't speak to the motives because I don't know who was doing it, but certainly the FDA felt – in the communications area, we felt like we were under siege. That's why we had to have meetings every afternoon just to see what was going on and whether we needed to respond to the developments of that day.

You mentioned Congress turning over in the 1994 election. Representative Newt Gingrich was also one of the major critics of the FDA during this time. Certainly I remember on the issue of the portable defibrillators and I think also the breast self-exam pads, he was quite

outspoken and critical of the FDA for standing in the way of innovation or stifling business or endangering patients by not allowing important products (in his view) on the market.

SJ: Part of the issue too was that these critics didn't really understand FDA and the way the product approval processes work. They were lumping all this together. The breast pad simply didn't have the effectiveness evidence behind it, and as I recall, it wasn't even a success once it went on the market because it created a lot of false readings. As far as the defibrillator was concerned, I don't think they understood our concerns. The problem was in order to answer these approval denials, they had to have a certain level of knowledge that they didn't really have. They saw things through their own eyes. Of course, this is when Gingrich worked to shut down the government, which was something novel.

LB: That's right. The other thing I would say about the whole "retaliation," in quotes, issue is I believe for some of those hearings, FDA was also called upon to defend certain regulatory actions it had taken. I don't know the specifics anymore, but if we went back and looked, we'd see that in the formal testimony, the FDA was responding to charges that were sort of independent of whether or not these products that we've talked about were approved, that because a company had done something, FDA then allegedly retaliated against it through a regulatory action.

SJ: Was this around the time that the press blew up over our going in with allegedly paramilitary tactics against Burzynski? Am I misremembering?

LB: I was very involved with Dr. Burzynski's alleged cancer treatment. My recollection was – that issue went on for 15 or 20 years, but it really boiled up more later in the '90s, '98, '99, 2000 when FDA took some actions against Dr. Burzynski.

CC: We started this discussion with the focus on the Barton hearings. Is there anything in particular you remember? Any particular dialogue? Any particular hearing? Or were you just using that as an example of oral remarks and your role?

LB: I wanted to make the point about oral remarks, and that's how I was involved. But I think the more important and broader issue is that the FDA was under attack. It was a pretty well-orchestrated and focused effort to go after the FDA. I know in the early '90s – from '91, '92, '93, '94 – David Kessler reestablished FDA as a consumer protection agency that didn't hesitate to take enforcement actions when they were called for. It was in 1994 that he sent the letter to Chairman Waxman about FDA's beginning to look into tobacco. I don't think it's a coincidence that it was in the year or two after that this movement looked to, I gather, to rein in the FDA, to go after the FDA. I don't think it's a coincidence that that followed.

CC: Do you think the effort was aimed at FDA as an institution or as David Kessler as the Commissioner or both? Would a different Commissioner have been able to manage this? Obviously, if a Commissioner didn't take the actions David Kessler did, that would reduce the likelihood of this kind of retaliatory or poisonous – whatever – this public relations campaign.

But I'm just curious about how much of it might have been because Kessler was the face of FDA, and a prominent face?

LB: I think you've hit the nail on the head. Dr. Kessler was the face of the FDA. Ultimately, if I had to say, it was an attack on the FDA, not David Kessler, because Commissioners come and go. But if the FDA's credibility or authority or standing is diminished, then that's in the end not good for the country or for the public health. So it was a reaction certainly to Dr. Kessler's activism, and for someone like me that was at FDA for some 33 years, it's the institution that needs to continue to survive and to thrive to do its important public health work.

CC: You mentioned that you had these daily meetings in the Office of Public Affairs that this attack campaign was unprecedented, that it had an impact on the institution, and that you had these daily meetings. What else? Was there any other way of dealing with the attacks?

SJ: And a related question: how did the press handle this? Were you pleased with the press coverage? Were there certain reporters with whom you guys had a relationship to help set the record straight? There was a lot of material in those hearings required some corrections.

LB: I don't think I can substantively answer that. We could go back and look at the clips. And some of the clips I've kept copies of because back in those days we actually did the clips in paper. They were photocopied and sent around. Now everything is electronic. I do remember that a couple of opinion pieces in major national newspapers took this on and defended the FDA.

You ask if any particular reporters set the record straight. FDA's public affairs operation then and certainly under Dr. Kessler had very – I'm trying to think of the right adjective here. Our relationship with the reporters who covered us on a daily basis was one where they trusted FDA.

CC: Respectful?

LB: Respectful. Yes. I don't want to say it was productive because that implies that there's an agenda. But it was a good, open relationship. There was dialogue back and forth. Reporters knew that they could talk to Dr. Kessler or other senior people quickly to get their take on things. We would alert them when something important was breaking and so they knew that we would keep them informed of important things. And they knew they could call on us if they needed a quick reaction to something. So it was a very open relationship. We trusted each other.

Certainly during Dr. Kessler's time, and later as well, they were viewed as an important constituency with a legitimate role as the fourth estate to be a way to keep the public informed. So it – having a respectful relationship with the press – was a very important value for FDA. It had been traditionally, really. We might talk about that a little bit later, but we took very serious our role of keeping the public informed.

SJ: What was your relationship with Jim Dickinson? He was one of the people that employees looked to for specialized news coverage.

LB: Well, I think I should say Jim Dickinson was one of the leading trade press reporters who covered the FDA for decades. I mean, he was a fixture in the late '70s when I joined FDA. Everybody read Dickinson's FDA and it came out every week. Even when I was a young, relatively naïve employee in the old Office of Policy Coordination, I knew who Jim Dickinson was. He would roam the halls of the Parklawn Building.

SJ: You mean literally roam?

LB: Yes. And so would other trade press reporters. They would just go up and down the halls.

CC: I remember Lou Rothschild. He was around all the time.

LB: Yes. Lou Rothschild. *Food Chemical News*. Absolutely. With his pipe. And those trade press people knew the agency. In fact, in the late '70s, that's how I found out what was going on in the old Bureau of Foods – I read *Food Chemical News* every week. I knew more about what is now the Center from that trade sheet than anything else. Jim Dickinson soured on the FDA I think sometime in the '90s when reporters and especially trade press reporters were no longer allowed to roam freely throughout FDA's offices.

CC: Was that a function of – I'm trying to think – the Oklahoma bombing in '95?

Was that a function of overall physical security of the building or was that a policy?

LB: It was mostly physical security, I think.

SJ: That's when they created a single entrance into the Parklawn Building making it easier to control outsider access.

CC: But anyway I'm just curious. "He soured on the FDA?"

LB: Yes. Maybe later today when we talk about the environment in the early 2000s and FDA's decisions and communications about Plan B – I remember Jim Dickinson had a role then as well.

SJ: He was an important source of information for people within the agency before desktop computers simplified communications across the forty or more buildings that FDA occupied. He was influential in part because he literally left stacks of these newsletters in the hallways, and you could pick one up. The *Pink Sheet*, another trade publication, you had to subscribe to. Dickinson was easily available to employees.

LB: I'm glad you mention Dickinson leaving stacks of his publication around. That reminds me that it was around the time, I think, of the retaliation hearings and the Citizens for a Sound Economy. It certainly was in the late '90s, mid to late '90s. There was an upstart publication – I can't remember what it was called. *FDA Week*? It wasn't *FDA Today* because that was the FDA's internal newsletter.

SJ: I remember that. It competed with Dickinson's publication.

LB: That upstart just sort of popped up. My recollection is it tended to be not as balanced as some of the other trade sheets and was pretty critical of the FDA. So I always wondered whether there was some connection between that publication starting up – especially made available for free around the FDA – and this broader anti-FDA movement. So that's all. It was an important chapter in FDA's history. I might as well go ahead and make this point now because it's one I wanted to make before we move onto Odwalla.

Catherine, you asked about the extent to which this movement was a reaction to David Kessler personally or to the FDA more generally. Obviously Kessler was the face of the FDA. You can't distinguish him that much. But I will say that I think this campaign, the retaliation hearings and Citizens for a Sound Economy, in the mid-'90s, there was a growing movement to reform the FDA. In 1996, David Kessler testified at least once before the House on legislation to reform the FDA, to make it whatever, more responsive, less rigid, whatever. I don't want to put words in their mouths. And David Kessler was very skillful at answering questions at hearings and he would stand up to the members in a way that sometimes witnesses don't do.

And the reason I raise this is after Dr. Kessler left in March of '97, Mike Friedman became the Lead Deputy Commissioner. I think that was his formal title. He wasn't called the Commissioner. He wasn't confirmed. He was in charge of the agency for probably about a year and a half until Dr. Henney was confirmed in 1998. So in 1997, because no legislation had been passed to reform the FDA in '96, there was another series of hearings or at least one hearing on the same subject. Dr. Friedman, as the person in charge at the FDA at that time, testified.

I remember this very vividly even though it's almost 20 years ago, that when Dr. Friedman came back from those hearings, it was clear how much the atmosphere had changed. In



1997, the hearings on reforming the FDA were much less adversarial. There was more dialogue, I think. My feeling and the feeling in the Parklawn Building in the aftermath of that one hearing where Dr. Friedman testified was that it was much less acrimonious and that there was progress towards some kind of legislation that would be responsive to the concerns of Congress but also maintain the FDA's ability to protect the public health.

SJ: So we're talking the lead up to the FDA Modernization Act?

LB: That's right.

CC: The FDA Modernization Act was passed in November '97. The first cycle of the discussions was when David Kessler was still Commissioner in '96.

LB: In '96. That's right.

CC: But the other intervening thing is that Clinton gets reelected and gets a mandate. So even though control of the House doesn't change, you do have that part of the dynamic – '96 was an election year. –

I was very deeply involved in '96-97 with the FDA Modernization Act on the food issues. I think some the tension was the larger political context, but it's hard to know what all the factors were. I also think Mike Friedman – I don't remember him on the Hill as well. Friedman had a little more – Kessler was always very straight, very serious. Friedman had a little bit of humor to him publicly.

LB: And privately.

CC: Well, my point is Kessler had a very good sense of humor. You just didn't see it on the Hill whereas Mike Friedman. . . Well, let me just say that I gave Mike Friedman a pencil sharpener that was shaped like a nose because we were friendly and he went around and showed it to his whole staff. I would never have given that to Kessler. So maybe part of it was the change. The Republicans, if they wanted to do something, they needed to do something that Clinton was willing to sign. I do remember that there was more productive conversation in '97, but what all the factors were ...

LB: That's a good way to put it. The conversation was more productive in '97. I had a clear feeling that a good part of that was Mike Friedman. Mike Friedman was less of a lightning rod than David Kessler.

CC: And also the person who was running this legislative effort for FDA, it may have been the same person. But Bill Schultz, who had worked, of course, on the Hill for many years was by then Deputy Commissioner for Policy. He basically ran the internal discussions on the FDA Modernization Act.

SJ: In my encounters with his work on generic drugs, to cite another example, he comes across as brilliant.

LB: I don't remember when Bill Schultz became Deputy Commissioner for Policy, but he certainly was.

CC: One thing that I'm very confident of is my visual recollection – I can put myself in a meeting – some of them were uncomfortable, one in particular that I can remember in '97 with Bill on the legislation in the 14th floor of the Parklawn building. Anyway, I don't mean to quibble with you. It's just I'm trying to observe some of the broader dynamics –

SJ: One of the things that I remember during this period was that Gingrich and his group genuinely felt that there might not be a need for the FDA at all. In their imagined world without an FDA, they began to pursue their proposals to the logical extreme. At that point, it was fascinating,, as a historian, to see them literally reach the end of their argument and only to circle back and conclude “okay, well, I guess we do need an FDA to do some things.” In particular, they realized that industry itself was not willing to forego product approvals. And then they begin to focus on the specific changes they could make.

LB: Certainly in the pharmaceutical industry, for example, there's a strong case to be made for FDA's approval being based on sound scientific evidence so that people have confidence when they take a pill that it's going to be safe and it's going to do what it's claimed to do. And I think industry realizes that.

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CC: I think the other place, for example, in another product area, with foods, the industry's need is the whole preemption of labeling. That's critical in a global marketplace where you have foods being produced one place and distributed all over the country. I would agree with Suzanne's point on that.

LB: Well, speaking of foods, should we move on to Odwalla?

[Brief break]

CC: We're back in our discussion with Larry Bachorik. We're going to move to the discussion of the Odwalla apple juice outbreak. E. coli O157-H7 I believe was the microbe.

LB: O157-H7. Yes.

CC: Maybe you can tell us about your role in that outbreak.

LB: Sure. This is something that I wanted to make sure we covered for a number of reasons, partly because it illustrates the way Dr. Kessler often would work, partly because it illustrates the importance of communication in an outbreak of foodborne illness, and partially just because it shows the importance of a strong and independent FDA.

Basically there was a series of illnesses associated with an unpasteurized apple juice product. I don't recall specifically what the lead up was, but what I want to talk about is a

marathon conference call that we held with Dr. Kessler that went on for probably seven or eight hours.

My recollection is that it started sometime in the middle of an evening – and this was very typical of Dr. Kessler. We'd have evening phone calls about various issues. Sometimes it would just be the two of us, but other times, if there were a public health issue going on, it would be a cast of a dozen or several dozen sometimes. Anyway, there had been this outbreak. We thought it was traced to a particular product, apple juice by the Odwalla firm in California, unpasteurized apple juice. And the call probably started around 8:00 in the evening.

It started with just FDA people, Dr. Kessler, people from the Center for Foods, I'm sure, field personnel in the district where the inspection of the facility was. Call started. We were assembling the data. Dr. Kessler was very direct at asking questions as we talked about, I think, last time, pulling the field people in and talking to them.

CC: Talking directly to the field people.

LB: Right. To the investigator who had been in the facility, not to the district director or the head of the investigations branch in the district. Dr. Kessler always wanted to hear directly from the person who was on the ground or if it was a product related issue in a Center, the reviewer, the main reviewer, of a product. So after probably an hour or so, we added in colleagues from the Centers for Disease Control and Prevention to involve them, get their perspective, tell them what we were thinking, and so on. So building in our colleagues in the Federal Government.

And then it was probably, I don't know, two or two and a half hours into the call when we actually conferenced in the representatives of the company involved and the president of the

company. Probably there were a couple of other folks as well. What stands out is the president of the company – when Dr. Kessler introduced himself – didn't know who David Kessler was. So that stands out in my mind all these many years later. .

CC: Why does that stand out?

LB: Because you'd expect somebody who's manufacturing a food product to know who the head of the FDA is, especially somebody as visible as David Kessler. Certainly in the midst of an outbreak of illness that's been traced to your company's product. Anyway, that was just kind of a side observation. Then the conference call continued. We were talking with the company now at this point about options and what would go on. I think it was around 2:00 or 2:30 in the morning. Dr. Kessler asked me – we formulated a plan of action. We had talked about what we wanted to do and what we were going to say about it. He dismissed me from the call and said something like “Go off and draft a press release announcing the recall of this product.”

And so I did that. By this time, I was well acquainted with the working rhythms. I had FDA news release stationery at home where I was and I had an FDA mini office at home. I had an FDA computer and printer. So I drafted the release. I faxed it to Dr. Kessler. He approved it. So it was around 3:30 a.m. by then. I revised it, printed it out on FDA news release letterhead, then I called the AP, Associated Press, because that was the most important outlet to get something out right away. The Washington office. I think I might have woken up the guy that was covering. It was not somebody that I knew because I didn't usually call reporters at 4:00 in the morning. I said we've got an outbreak of illness. We're recalling a product. We need to get this on the news wire right away. Of course, the AP is so important because it goes into all the

news rooms in the country, all the radio stations, all the TV stations. And I think it was a four-year-old child had died as a result of drinking this product. .

The guy on the other end said, "Well, if you're calling me at 4:00 in the morning, it must be important." I faxed him the news release, and he got the story out on the wire. And I went to bed. I think I only slept a couple, three hours. I was in the office by 9:00 or 9:30, but the buzz around the Parklawn building was great, especially in the Office of Public Affairs. We'd had this marathon call. FDA was able to put out a news release in the wee hours and got the message out. That was one of my, I guess, favorite moments working at the FDA. Just being involved and doing a thorough investigation, doing the right thing after assembling all the players, and getting the word out as soon as possible so that no other little children or adults for that matter would drink that product and be sickened or even die from it.

It was a telling moment. It was typical. Fortunately, we didn't have a lot of situations like that, but it's not much of an exaggeration to say that it could be life or death. It was FDA, I think, at its best.

CC: Let me ask you a couple of questions related to David Kessler being, for lack of a better word, the leader in this Odwalla thing. First of all, I know in earlier parts of your interview you talked about his wish to talk to the boots on the ground people. What was your sense of how he talked to those people? I ask because that can be pretty intimidating if you're a GS-9 investigator out in some Resident Post. You're talking to the Commissioner. And historically, that wasn't normal. So how did that come down either in Odwalla or other instances where you saw that type of interaction? How did Dr. Kessler treat those people?

LB: Well, he treated them with respect. He made them feel that he valued their opinion and he really wanted to know what the facts were. Beyond that, he would ask them – he would often ask them what do you think we should do. Not only what's the situation but what's your advice about it.

You're right. That could be intimidating, especially for the field operation which has traditionally been very hierarchical and chain-of-command. To talk directly to the Commissioner, even if your district director is on the phone there, can be intimidating. The other thing I would say is that Dr. Kessler is nothing but intense. If he's nothing else, he's intense. That kind of intensity – sometimes people whither under that or are intimidated by it. It's not a bad intensity. It's just he's eager, he's focused. He's eager to get to the bottom of things.

CC: In your experience, how did the rest of the hierarchy deal with David Kessler going to the source? Did you ever see any resistance to it?

LB: No. No.

CC: We're talking about a behavior that is contrary to institutional culture. You just described it. The field's very hierarchical and had been historically. How did the people in the middle react if you remember?

LB: I don't remember any specifics. I can imagine that some middle managers or even more senior people might be threatened by that or might not like it, but it was the way things were. And I think most – especially if they were included-- it wasn't like they were cut out— if they



were on the same call or – it became part of the culture. So I don't think it was counterproductive.

SJ: The History Office and the historians were in ORA [Office of Regulatory Affairs] at the time and were included in some of these meetings. It certainly was empowering for us because people hadn't really asked us before about the background of some of the issues that Kessler was interested in learning about. "You've got five minutes. Give me the background on caffeine and Coca-Cola." How did we regulate that? When he found out that we had files to back up our words, Kessler would literally come to our office to consult and occasionally take our files. He had the combination to our office so he could come in on the weekends and go through files. I think he probably still has some at home.

LB: I think in a bureaucracy or any large organization, information is power. So I think to your point, Catherine, or yours, Suzanne, I think senior managers are people that weren't the experts on the ground that Kessler wanted to talk to. As long as they were kept informed, that was one thing. I think if individuals played hide the ball or weren't forthcoming about their interactions with the Commissioner, that probably would be a problem.

CC: What about this marathon session? I'm just focusing on Odwalla because you told the story, but there were many others I'm sure.

LB: Absolutely.

CC: I remember weekend calls myself on some projects. How did people react to that? From one perspective, at least, that could be seen as intrusive. It's the middle of the night, and I'm expected to be on this call. I think Mary Pendergast is the one who said her family started referring to Dr. Kessler as Dr. Death because he would call in the middle of the night. And how do you think Kessler managed that? I have my own views on this, but you were there. What was it like for you to be on the call? I'm sure it wasn't the only time. It may have been the only 2:30 a.m. call but what about other after hours calls?

LB: There was one time when I was working on a speech with him. We had drafted a speech. I think our call started at about 11:00 at night and the speech was the next morning. It was in Annapolis, Maryland. And this was a really long speech. I mean, it was way too long. It was probably going to be 50 minutes if he spoke quickly. It must have been 10,000 or 12,000 words, which is a long time. And we were going through the speech line by line.

At some point, I think, my wife came down. My office was in the basement. And she came down around 12:00 or 12:30 and said, "Are you coming to bed?" I basically said, no, I'm working with the Commissioner. Anyway, about 2:30 that morning or 3:00, I finally said to Dr. Kessler, "Look, I'm falling on my nose. Your speech is tomorrow morning. You've got to get some sleep too. We've got to stop." And we did. He took that.

So he was a very focused – and he worked best at night, I think. So that's just one example. When you're dealing with someone who's charismatic, like Dr. Kessler is, and he's got the gift that leaders often have – when he's talking to you, you're the only person in the world. At least that's the way I remember it. He's focused on you, and he's not attending to anybody else. Even if it lasts five seconds, it makes you feel very important. There was a lot of reflected

glory, I think. Being able to be on a call with the Commissioner and be engaged with something important, that could be very satisfying for folks. So there was often a sense of we're doing something really important and this is cool and we're making a difference. On the other hand, family life is important. Work-life balance is important. It's crucial to draw the line. I think some people were more successful at it than others. I remember times when I had to set limits, and it was difficult. I think some people set their limits at a place way before I set mine. It's a personal choice. I think you have to decide. Maybe there are people who decided they didn't want to do those marathon calls or they didn't want to be working into the middle of the night on things. So they were probably left behind.

CC: I remember working on olestra, I think. We had a weekend call – Bill Schultz, Dr. Kessler, Phil Derfler, maybe Fred Shank, me. I don't remember all the participants. And I set up the call. He was impressed that I could get five parties on a conference call – I said to him “I took telephone in law school, didn't you?” But his first question to me was, “Where are your kids?” This was a Saturday. He knew I had young children. I think it was a sincere question. I said, “Well, they do have another parent. I think they're at their swimming lessons.” He was able, I think, both to somehow get people engaged even when it was very demanding. You've hit on a couple of the examples.

LB: That reminds me of an episode. Talking about his asking about your kids. This was very early on. I think it was when we were still working on drafts of his first Food and Drug Law Institute speech, the one I mentioned last time. His maiden voyage in Washington. And I remember he asked to meet with me. Kay Hamric, his executive assistant, scheduled a meeting at

5:30 on a Tuesday afternoon to meet with him to talk about his speech. I think it was the Food and Drug Law Institute speech.

My wife was working full time. Our childcare expired at 5:00. I had made arrangements. I think she had agreed to be home early that night even though I was supposed to be covering. So I walked into his office, 5:30. And the first thing he said was, "I hope this time is okay for you." Being honest, I said, "Usually I need to be home on Tuesdays at 5:00, but I've made alternative arrangements." He said, "No. Go home." He sent me home.

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It wasn't like he was not mindful of family responsibilities. So that was good, but also he'd get involved and so focused that I think there were times when he'd lose track. Something about the group process, whether it was in somebody's living room or around a conference table or on a large conference call, that was a way that helped him think through issues and get all the facts together.

I remember early on in his tenure when we were talking. We were trying to figure out a strategy for communicating about the new food label, the Nutrition Facts panel. So this was probably 1992 or '93. It was a Sunday afternoon at his house, I think. We convened at noon, and there must have been 18 of us, 12. He brought in food. He had food brought in. We were there for several hours – four, five, six hours – talking about how do you communicate effectively about the power of this new food label.

CC: We're back on the record with Larry Bachorik after a short break. Larry, we're winding up the discussion of David Kessler. I wondered if you could give us your observations generally on his leadership style, some more global observations.

LB: Sure. I think he was a leader that inspired people to do their best, to go beyond what they thought they could do. He empowered people to think outside the box. I personally felt that way when I'd be working on a speech with him or thinking about how to communicate on a particular public health issue of importance. He encouraged us to think beyond – go a further step or think about an unorthodox approach to things. That was very empowering – I think that's the right word for it. He wasn't universally loved in the agency. He wasn't universally loved outside the agency. He was an agent of change. He made things happen in Washington. And when you do that, you can make enemies.

He certainly was not someone who was comfortable with the status quo. I'm sure he came in with an agenda of things that he wanted to do, he wanted to change. The leadership structure that he set up for the FDA allowed him to do that because the agency with several Deputy Commissioners, which was new, was able basically to run on its own. That allowed him to focus on what he saw as the most important public health issues.

CC: Let me just push you a little bit on the lack of “universal love” as you put it within FDA. Was this at the investigator level? The senior staff level? How did you see that play out?

LB: I think that the individuals who – whether they were a consumer safety officer in a district office or resident post or a reviewer of a product, a medical product, or someone in the

Center for Foods, I think they – when Dr. Kessler called upon them or they were in a meeting with him, I think they loved it.

What I witnessed was more in senior leadership. I know there were some senior leaders during Dr. Kessler's tenure who weren't enamored of his leadership style or the changes that he made in the FDA and its structure. Certain office's functions seemed not to be as valued under Dr. Kessler's leadership. The Office of Health Affairs and the Office of Consumer Affairs are two examples where, for whatever reason, attention wasn't paid to those offices as much in the past.

I think fundamentally and kind of to bottom line it, my perspective is that Dr. Kessler in a way had always had one foot partially outside the agency, that he wasn't captured the same way as other leaders might have been. By that, I mean he kept partially an outsider's perspective on the agency and what it was doing and how it would be perceived. So with him, it was never FDA, right or wrong. It was how is this going to look from various perspectives.

If you're a typical FDA employee – at least this was typical 25 years ago – there was an enormous amount of loyalty. FDA inspires that. That's one of the reasons we were able to do such a good job. But David Kessler didn't quite fit that mold. He always kept the outside perspective. He hired people from the outside as well.

CC: And that rubbed people the wrong way or was it, again, a challenge to the existing culture?

LB: I don't feel comfortable speaking to the motives of people who might have not been enamored of Dr. Kessler or his leadership style. He was certainly – he was the face of the

agency. He was very visible. He was not self-effacing, so perhaps that was not the traditional role of FDA Commissioners generally. One of his I think most brilliant characteristics was his thinking not only about what the right thing to do is based on the science but also how to convey whatever FDA was doing in a public way so that people could understand it and get behind it.

And he was I think brilliant either at doing that or knowing the importance of doing that and getting the right people in. So I've never – certainly in my career in the FDA, there's never been a period where FDA enjoyed greater public esteem and better coverage in the media than during those years when David Kessler was Commissioner, especially – yeah. Really almost from day one but certainly from '91, '92 until the time he retired.

SJ: He had regular access to the pages of *JAMA*, too, as I recall.

LB: He would publish editorial type pieces, opinion pieces, both in *JAMA* and in the New England Journal as well. I worked on doing some research for some of those pieces. There certainly was a regular FDA presence in *JAMA*. My recollection is that that was – we had one page, I think, a month in *JAMA* [*Journal of the American Medical Association*]. It was just “From the Food and Drug Administration.” My recollection is when I was involved in that, it was later in the '90s and it was typically the Associate Commissioner for Health Affairs, Stuart Nightingale, who would byline those. I don't remember that Kessler did that on a regular basis for *JAMA* when he was Commissioner, but he certainly would publish.

SJ: He was overseeing, though, what was going in the monthly *JAMA* piece.

LB: Okay.

CC: And does that continue, the *JAMA* thing? I guess since I worked primarily in the foods area, I wasn't aware of that.

LB: No. I think that might have ended around 2000. Dr. Henney – actually I know that in the '99, 2000, Dr. Henney actually bylined the pieces for *JAMA*. I don't think that continued. One of the things I worked on the last two or three years at FDA from about 2012 to 2014 was to reestablish some kind of presence, FDA presence, in the prestigious journals. We did work out an arrangement with *American Family Physician*, which is the widely circulated journal of the American Academy of Family Practice. I think that's the right title. It goes to all primary care docs in the U.S. We got a couple pieces placed in that publication. I know there have been discussions in the last year, year-and-a-half, with other major publications. I think *JAMA* was among them. I think Dr. Califf actually had been in conversations with them before I retired in December last year.

CC: Do you want to wind up on David Kessler? Suzanne, do you have anything else you want to ask?

SJ: I think we've covered that pretty well.

CC: Next up we had an interim Commissioner for close to a year. Actually close to two years. Sorry. The Lead Deputy Commissioner.



And then Jane Henney became Commissioner. Even though Dr. Friedman wasn't Senate confirmed and never held the title of Commissioner, he did run the agency for two years. Did you have any experiences with him or that transition? One thing that – well, I guess it didn't distinguish him. I was going to say he was a member of the Public Health Service. I don't know if that ever had an impact on his position. He came from NIH, NCI.

LB: I think even though we've left Dr. Kessler, I believe Dr. Kessler was instrumental in identifying Mike Friedman to assume whatever his formal title was but basically to be in charge of FDA when he, Dr. Kessler, left. And I remember Dr. Kessler telling some of the senior staff that he identified or that this person had been identified, Mike Friedman. I remember David Kessler saying, "You're going to love him. He's great." And he was.

His scientific and medical credentials aside, he was like a poppa bear is how I think I would describe him. He was very warm, very friendly. Affable and smart. It wasn't like he couldn't make the tough decisions or didn't engage. But he was, as we touched on earlier, he was less intense than Dr. Kessler. He had a more, I think, overt sense of humor.

I think he was more than a caretaker. Often people in a transition situation are just kind of there making sure the trains keep running on time. He left the strong impression that he was in charge. There was a steady hand on the helm. Primarily my interactions with him were around media inquiries, giving interviews to reporters. I remember he continued in Dr. Kessler's footsteps, valuing strong relationships with media outlets and understanding the importance of talking to reporters when they needed to hear from the Commissioner of the FDA about an important issue.

I guess my strongest memory of him – there are actually two, I guess. One I remember probably was in October of '97. Anyway, we had a *New York Times* interview. I don't remember the subject anymore, but it was Columbus Day, so it was a Federal holiday. I wanted to get him with this reporter who needed to hear from the Commissioner directly about the issue. I remember going to his house in Bethesda on a vacation day. He lived only like a mile from where I live. We spent about 45 minutes on the phone with a reporter. He was happy to do it. He was affable. He was well informed. He was articulate. He continued in the tradition of being available and accessible and willing to talk to reporters. And that made our life in the Office of Public Affairs easier and more rewarding.

CC: Were you then the Deputy in the Office of Public Affairs, Deputy Commissioner at that time? What was your title at that time?

LB: I was on and off – I was Acting Associate Commissioner for Public Affairs. The way it worked was David Kessler left in the last day of March in '97. Jim O'Hara had been his press guy, political appointee, from May of '93. And Jim stayed on at the FDA until late summer, early fall in '97, is my recollection. There was a hiatus between Jim and the next political appointee to be the Associate Commissioner for Public Affairs. And that lasted, I don't know, six to nine months. His successor came in, in I want to say April or May of '98.

So I was acting. There was a two-month period where I was acting. The other Deputy was acting for another period. And then the new political person, whose name was Lorrie McHugh-Wytkind, came in I think the spring of '98. She had come from the Clinton White House and joined the FDA just as the Monica Lewinsky scandal was breaking.

She knew all the players. She knew Mike McCurry, who was the press secretary at the time. On a personal level, I just felt sorry for her as all this scandal stuff was coming out. It was just difficult to watch. She knew all these people and knew the story behind it. Whatever you think about what happened and what went down, it was painful.

CC: How long did she stay? Because her name is not familiar to me – I could not have pulled that name out.

LB: She stayed for, I want to say, about a year. She left because the Department, HHS, wanted her to work in the office of the Assistant Secretary for Public Affairs. I think she left in April of '99 because that's when I became the Interim Associate Commissioner for Public Affairs. We had a very tearful good-bye. She really loved the FDA. She was happy. She and Jane Henney worked well together. She was very happy with the public affairs operation at FDA. My impression was she really did not want to leave, but she was a political appointee and they wanted her at the department.

CC: Okay. Moving from Mike Friedman – I guess I have one more question about Mike Friedman. Were you in a position to know whether he was considered for Commissioner and sort of what the machinations on that were?

LB: I didn't know any of the inside baseball at the time. I think there was a thought that he was in the running. I guess just looking back it seemed logical that he would be under consideration to be made the permanent Senate-confirmed Commissioner, but I don't really know

how that all occurred. That was something I wasn't privy to. He was always affable. He stepped up and did the job. But I don't know where or how the decision was made to nominate Jane Henney to be the Commissioner.

The other thing I want to get on the record about Mike Friedman was that he had interesting objects in his office. He never moved into the Commissioner's office, if I recall. He was always in the Deputy Commissioner's office. He had a signed photograph of The Who – the rock group The Who – on his bookshelf. Pete Townshend. It was signed to Mike Friedman from Pete Townshend. He was a pretty cool guy even though he was in a senior leadership position at the FDA, in a respected position and a medical person.

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CC: This isn't my interview, but I have to share this anyway. My favorite Mike Friedman – well, I have several Mike Friedman stories. But during olestra, we would have some of these late afternoon meetings. For some reason, people had a hard time – and by people, I mean some of the people in these meetings, including Bruce Burlington and Bob Temple. David Kessler called in people that really were smart people, very smart people, but weren't necessarily Foods people.

I remember Mike Friedman was there a lot. They couldn't keep track of the serving size for chips made with olestra, which was important because we were talking about snack foods. I think that this was when there was still a drug store in the Parklawn Building. I went down to the drug store and I bought about five different packages of snack foods in various sizes. I would bring them to these meetings and spread them out on the big table in the Commissioner's conference room. One day it got to be about 5:30. Mike Friedman grabbed this bag of potato

chips and took out his Swiss army knife and very neatly opened the bag. Then the chips were available. He was a character. I can't imagine any other Commissioner, Acting Commissioner doing that.

LB: The other thing I remember is at that time I was a runner. I would often run at lunch time. The locker room facilities for men and women at the Parklawn building were terrible. There were like three showers for men.

CC: One shower for the women.

LB: Well, that sounds about right given the way things used to work. But Mike Friedman would be down there in the men's locker room. He would have been lifting weights or doing some kind of workout. I'm not sure if he was a runner. He had a bandana that he'd wear around his head. He was – colorful is not the right word, but he was a bit of a type. He was his own man. He was very delightful to work with.

CC: Okay. Well, let's move on. Jane Henney is appointed, according to my records, in the middle of January 1999. So she's got basically two years left of the Clinton administration.

LB: She became Commissioner in '99, early '99?

CC: That's what my chart shows.

LB: I remember confirmation hearings in '98 sometime. Because Lorrie McHugh-Wytkind, being the political person in public affairs, managed, along with the legislative affairs person who was also political, the hearings. There was a lot of media interest in the Dr. Henney appointment and the Q's and A's.

SJ: She was the first to go through the full “advice and consent” approval process by the Senate.

LB: She was the first one.

SJ: So this was a new procedure for everyone.

CC: Yes. She was the first to have a formal Senate hearing.

LB: A formal hearing.

SJ: A formal hearing and a formal vote.

CC: And she was also the first woman to be considered for Commissioner, as far as I know. She was returning to FDA and she had been at the National Cancer Institute at NIH, so there a lot of reasons for people to be interested in her.

LB: She was Vince DeVita's Deputy, I think, at a very young age at NCI.

SJ: I would venture to say she had the best administrative experience of any Commissioner FDA has had. I think that may have been a significant consideration after the Kessler administration.

CC: So Dr. Henney becomes Commissioner. What was your interaction with her and what do you remember? For example, what were the differences in working with her versus Dr. Friedman and versus Dr. Kessler?

LB: Let me just preface all of this by saying that I had a warm spot in my heart for Dr. Henney because in her first tenure, when she was Deputy Commissioner for Operations, I remember it was late January. I think it was in '92. It was Super Bowl day, Super Bowl evening. Dr. Kessler had a speech or a testimony the next day. He called me, and he wanted major revisions to his text. So I said fine, I stopped watching the Super Bowl, and got to work and revised the speech. He gave it. It went well.

The Dr. Henney connection is that she actually called me the next day and thanked me and said, "I'm sorry you had to work during the Super Bowl, but it was important and I really appreciate it." Even though my recollection is it was Dr. Kessler's speech. That anecdote crystalizes what Dr. Henney was like. Just very thoughtful, warm. And as you said, she's a very terrific administrator, Suzanne. She was very attentive and very attuned to relationships, I think, and feelings. So Dr. Henney arrived in early '99 in her second stint. She was Commissioner. She was Senate confirmed. She was the first woman Commissioner. I at the time was a Deputy in a public affairs office. Then I became the Interim Associate Commissioner in April that year.

CC: Did she appoint you to that position?

LB: Yes. Yes. What happened was when Lorrie McHugh-Wytkind was called up to the HHS public affairs office, Dr. Henney named me as the interim. There was a job search, a job announcement. It was an SES position.

I should pause briefly here and make a bit of a detour. Since the early '80s, the public affairs and the legislative affairs positions at FDA had been political. That occurred under the Reagan administration, the first term of Reagan. [By 1999,] public affairs, legislative affairs for almost two decades had been political and not career appointees. Dr. Henney thought it was very important for those two positions to become once again career civil servant positions.

CC: Do you know why she thought that?

LB: No, but I can infer why. I think she thought that the FDA is such an essential agency to the American consumer and public health in the U.S. and the world, that political considerations in those sensitive areas should be secondary. This I know: She had to do battle with the Department of Health and Human Services to get these two positions reclassified as career SES. And she also then – having convinced the Department – she had to go to the White House. The White House Director of Personnel also had to be persuaded that these two visible, important positions in the Executive Branch should be occupied by career people and not political people. I'm sure there was a lot of heavy lifting involved in that.



Dr. Henney has a spine of steel. She's very principled. I think once she's set on a course of action, she's very determined and very persuasive and effective. Anyway, that's just by way of background. The opening was announced. People applied for it. This took a long time. I remember applying. I submitted my application in early November '99. The interviews were held probably within six weeks or so – that may be wrong. I wasn't appointed until April of 2000. I was selected for the job, but I didn't actually become fully fledged Associate Commissioner for Public Affairs until March or April of 2000.

CC: Did that same transition actually happen with legislative affairs? I'm trying to remember.

LB: Yes. It happened in legislative affairs before public affairs. Melinda Plaisier was the career lege person. Diane Thompson had been there.

CC: Right. But she was political.

LB: She was political. I don't know if there was an acting person between Diane and Mel or not.

CC: Well, Mel came from the Hill and was Diane's Deputy.

LB: She'd been at FDA for a few years.

CC: Couple of years.

LB: It's a big deal when the Commissioner comes to your office. I remember when my appointment came through. Dr. Henney and Linda Suydam, her Senior Associate Commissioner, walked up from the 14th floor up to the 15th floor and all the way down to the corner office on the 15th floor, where I was, to congratulate me on becoming the Associate Commissioner. That was really a big deal. I think for me personally but also for the institution to have those positions be career.

For Dr. Henney, the big issues in her tenure were biotech foods. We had public meetings in Washington, Chicago, and Oakland. She was very engaged on that issue. Rezulin was also a very visible public issue for the FDA at the time. There was a series of articles by the *Los Angeles Times*.

CC: What's Rezulin?

LB: Rezulin, R-E-Z-U-L-I-N. It's a diabetes drug. We may or may not talk more about that later. FDA got hammered on that. And then, of course, mifepristone, RU-486, a way to obtain an abortion medically as opposed to surgically. We can talk about those or not as time permits. What I wanted to focus on with Dr. Henney is in her two years, I would say the first year of her tenure as Commissioner was to some extent, maybe even a large extent, a reaction to David Kessler's tenure as Commissioner. I was able to see that firsthand being head of public affairs because she did almost no interviews with the media during her first year. This was very deliberate. I know she wanted to focus internally on the FDA. Internal communications. She didn't want to have a high profile outside of the agency.

I know she intended to visit every FDA district during that first year. I don't know whether she managed that or not. But she really was focusing on managing the agency and on the internal audiences. Now, one could infer from that that she was in part reacting to criticism of David Kessler's reign as Commissioner as being focused on external audiences, focused on attention in the media. I can't say that for a fact, but I believe that she wanted to – I know she wanted to – have a strong internal FDA presence and not be so visible to the external world.

CC: Let me just ask you just a factual question about that. When David Kessler came in, we talked about this, he had multiple deputies, which he talks about this in his interview. I think you said earlier today the agency could run itself. By the time Dr. Henney becomes a Commissioner, where is that structure? Do you remember? Is part of her need to run the agency a function of it can't run itself the way it did under David Kessler? She has a Deputy for Policy. I honestly don't remember who it was. I guess it could have been Bill Schultz.

LB: Bill Hubbard was the Deputy for Policy at some point there under Jane.

CC: That's probably by then.

LB: We should look up the structure. I think the deputy structure was still in place, but I'm not sure. I think it was. I directly reported to Linda Suydam, whose title at the time was Senior Associate Commissioner. Functionally, she was like a Deputy Commissioner. She was Jane Henney's right-hand woman and was very close to her. That's why the two of them came up – she was close organizationally. The two of them came to my office when I was appointed.

SJ: I don't know if the structure was still there, but she had a very small group of people in her media office that she relied on that worked very well together according to her.

CC: Ann Witt, Linda Suydam? But back to my larger point. Dr. Henney didn't have the deputy structure that Kessler had?

SJ: What I'm saying is that the structure may have remained on paper but that is not how she ran her office.

CC: That's my recollection as well.

LB: Maybe the deputies were gone. I think maybe they were all Associate Commissioners. My sense was Linda Suydam was above all the others.

SJ: Yes, she was.

CC: I think that's right.

LB: So maybe Bill Hubbard was Associate Commissioner for Policy at that time. I know he was at some time under Dr. Henney.

Just back to the overall point about the difference in how Dr. Henney approached things. The situation when Dr. Kessler was Commissioner was such that in our relationships with the

Hill, in our budget, there was legislative language in our budget and inquiries about the size of FDA's public affairs operation and how many people were in it and how much money it had. So public affairs and public visibility had become an issue by the time Dr. Kessler stepped down.

Dr. Henney's never told me this, but one of the first things she did was a fairly major reorganization. Maybe that's when the deputies went away. I'm not sure. But she downsized the Commissioner's office by ten percent. Now that I'm talking this through, this all seems to be coming together. That's probably when the deputies went away. She did away with the Office of Health Affairs, which had been a longstanding office. She did away with the Office of Consumer Affairs is my recollection. She decentralized programs like the MedWatch program that had been launched in 1993 by Dr. Kessler as an FDA-wide program then was devolved to CDER, the Center for Drug Evaluation and Research.

I always took that to mean the downsizing – sending out programs to the Centers – my sense was, and no one's ever told me this, but was that it was in response to concerns on the Hill about the centralization of power in the Commissioner's office, about the amount of resources in the Commissioner's office. I think this was a way to defuse those concerns and to maybe even empower the Centers and the Center directors more.

CC: One thing in terms of both the individuals leaving, the deputies, and the positions being structurally removed, I do know that many of the people David Kessler brought in had left. I think Dr. Henney may have been the first to leave, and then Mary Jo Veverka and Carol Scheman departed.

[DR-100\_80.wav at 01:40:20]

LB: Mike Taylor left pretty early on, too. Went to USDA.

CC: Mike Taylor left, but Mike Taylor's position was filled by Bill Schultz. That's a lot of heft there. I think the evolution is both in terms of are there people operating in those positions, people of significance and confirmed? And then do the positions continue to exist? I think the departures preceded the structural changes. This is all – it's actually consistent with what you're saying.

LB: But the point is to basically have an FDA Commissioner's office that's ten percent reduced in size, that's not so top heavy with deputies or doesn't have more than one deputy. That it's more decentralized. I think that was in part done with an eye to how that would play on Capitol Hill in reaction to what David Kessler was perceived to have done as Commissioner.

Mary Pendergast had left, and Stuart Nightingale's office was downsized but we were also starting to look at the challenges that were created internationally when we began to appreciate how much of our foods as well as food and drug ingredients were imported from overseas. So some of their energy and resources were moving in that direction.

CC: I think this is important because I think what you're talking about is globalization and its impact on the FDA structure.

SJ: The need to acknowledge that the world was changing and our mindset needed to change as well.

CC: Linda Horton left GC in the beginning of the Clinton administration because I had actually been the FDA person negotiating the WTO food agreements in the Bush 41 administration. Then Linda left and I think went to work for Mike Taylor because part of Mike Taylor's portfolio as Deputy for Policy was policy relating to international matters. At that time, there was still an Office of International Affairs.

LB: There were two international offices competing for a while.

SJ: One was in ORA and then we had Walter Batts in OHA.

CC: I just remember asking either Mike Taylor or David Kessler when they came to an OGC staff meeting how are you going to manage this because it's hard if you're working in an arena if there are two offices. So that's when a lot of this starts to happen, I think.

SJ: I'm just trying to make the point that some of the energy that had been in Consumer Affairs under –

LB: Alex Grant.

SJ: Thank you. Alex Grant, and under Health Affairs under Stuart Nightingale, was beginning to be funneled into addressing new changes internationally.

CC: I think the international affairs becomes more of a policy-making group as opposed to what it had been – managing FDA’s relations with the EU or whatever.

SJ: Mary Pendergast was reaching out to Russia. She was starting to try to educate people on what FDA did and how they did it. They were absolutely entranced with the idea of Frances Kelsey getting an award from the President for saying “no” to a company.

CC: So Dr. Henney’s tenure is a time of both purposeful change and I think some somewhat less purposeful change with people leaving and therefore positions – when you have a position and there's nobody in it and the clock keeps running, ticking, the machine keeps working, I think people say, well, maybe we don't need that position. I think there was some of that.

LB: That's possible. That's possible.

I don't know if I have it still, but I know that Dr. Henney sent a memo, a reorganization memo, in the spring of '99 explaining the changes and why she had done them and so on. She, as I said, the first year had almost no external profile. She did the budget hearings. She had been in New Mexico. I don't know if she was the dean of the medical school there.

CC: Chancellor for Medical Affairs or something like that, I think.

LB: And she had brought Linda Suydam with her from the FDA for a few years. I believe Dr. Henney was at New Mexico when she was recruited back to the FDA. The reason I mention it in the context of the budget hearings is that a Senator from New Mexico – I remember they had a



cordial relationship in the formal budget hearings. She would always say something about his home state. Domenici, I think. Pete Domenici.

She was effective on the Hill. She was very businesslike, very professional, very organized and articulate. It was a very different style from either from David Kessler's style on the Hill or Mike Friedman's even. Dr. Henney wasn't jocular in the way Mike Friedman would have been. I think to a point that you made earlier, Suzanne, she was an excellent, very strong administrator. You knew that things would be done in an orderly way. The FDA was, I think, superbly well run during that time.

The second year, 2000, was the crazy political season in Washington. Bush v. Gore election year. You don't expect lots of major policy initiatives to be moving forward in an election year. But she was a steady hand on the throttle. The main thing that I recollect from 2000 is the approval of mifepristone, the so-called abortion pill, RU-486, which happened, I believe, in late September 2000. Especially in a political year, it was a milestone. It generated a lot of public interest and publicity. From those constituents who disapproved of it, there was a lot of backlash even. So it was a courageous thing to do. It was the right thing to do based on the scientific evidence. I don't know whether it was a tough decision for Dr. Henney. Not that she made the decision, but it went forward.

CC: Who was the Center for Drugs Director at that time?

LB: Janet Woodcock had been CDER director, but Janet was in and out of the Commissioner's office as a Deputy. Mac Lumpkin was the Deputy [in the Center for Drug Evaluation Research], I know. I think Janet might have been CDER director, Janet Woodcock.

SJ: She worked with Janet Woodcock. I don't remember if we talked yet about RU-486.

CC: No, I think that's what it was. Going behind the scenes. On RU-486, were you aware of any involvement from either the Department or the White House on something of such a high level of interest and controversy?

LB: No. I'm not saying it didn't happen. They had to have been aware and briefed that this was going to be happening.

That product had a long history going back to David Kessler's time. Advisory committee meetings and applications and who the manufacturer was going to be and whether the manufacturer would even be identified and so on and so on and so on. But all of this came to fruition on Dr. Henney's watch. As the transition approached after the Supreme Court's decision in December of 2000, Bush versus Gore.

CC: The decision that decided the election.

LB: Yes. That George W. Bush would be President. It had enormous implications. For the incoming Administration, a Commissioner on whose watch the abortion pill had been approved would not be able to continue to be Commissioner. And I raise that because I think Dr. Henney would have been willing – knowing that she wouldn't permanently be the Commissioner under Bush II Administration, but I know she was totally willing. She would have served gladly during

a transition period to just smooth things along. The incoming Administration would have nothing of it.

CC: I talked to Nancy Buc about Commissioner Jere Goyan and his willingness to continue as Commissioner after there was a Presidential election and a change in parties. I think some of what Nancy said was that Jere Goyan was just a little naïve thinking that he could continue as Commissioner. He got the boot the last day of the Carter administration. What happened with Dr. Henney? How did that come down?

LB: I don't think Dr. Henney even got the boot on the last day of the administration. There was total radio silence. Nothing from the transition team. I'm pretty sure there was no communication whatsoever.

CC: How did she know what her status was? I don't mean to sound dumb.

LB: Well, that's something maybe she covered in her interview. I know she was in her office until the last day of the Clinton Administration. I know she would have been willing to stay on in a transition phase to smooth things along. I'm pretty sure that no one ever called her to tell her one way or the other. On that last day, she packed up her things and went home.

CC: Then the agency had, if I recall correctly, a rather, to my taste, odd smattering of people in charge for a while.

LB: Odd smattering is your phrase.

CC: Yes – it is my phrase.

LB: Emphasis on smattering, not odd.

CC: For the 25 years I'd been in the agency, there had been either a career Deputy Commissioner or there were people who had been at high levels of the agency that were running the agency when there was no Commissioner. And that wasn't what happened when Dr. Henney left as I recall. Maybe I have my transition periods confused. Who became acting Commissioner?

LB: The way it played out is Bernard Schwetz, DVM. He had been head of NCTR [National Center for Toxicological Research], I believe, in the late '90s. I believe Dr. Henney brought him to the Commissioner's office. I'm not sure what the title was. Chief Scientist? Anyway, there was no permanent Deputy Commissioner. And Dr. Henney had recruited for a Deputy, probably in summer of '99. I don't know when the announcement went out. My understanding was that there were no suitable applicants. I don't know. The effort to hire somebody to be permanent confirmed deputy of FDA in 1999 failed. I always assumed it was because a person at that senior level would be reluctant to uproot their family if they weren't from around here for basically a position that would be a year, year-and-a-half at the most. I believe this is right. When that didn't work out, she named Dr. Schwetz the Acting Deputy.

SJ: One of the things the Dr. Henney was extremely concerned about during her entire tenure had to do with recruiting talent, scientific talent. She was very concerned that we didn't have the talent we needed looking down the road to evaluate some of the new technology and the new products and the new science that was going to be landing at our doorstep. So that may be part of it.

LB: Anyway, on January 21st, 2001, I don't know if that was the exact date, but at some point Dr. Schwetz was named the Principal Deputy – whatever his title was. He was the person in charge. But he didn't have any official – he wasn't confirmed by the Senate. He hadn't been a leader at the Commissioner's office level in the FDA for very long.

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FDA knows how to run itself pretty much. But that said, it's always better to have a confirmed, bona fide, certified Commissioner in charge. Dr. Schwetz was very modest and reticent kind of person. I think it was easy for FDA to be overlooked at the Department or elsewhere during that time. My sense is that after September 11th, 2001, whatever the relationship between FDA and the Department was before that, 9/11 shifted everybody's priorities and the focus was on protecting the nation, on bioterrorism, on security, on getting clearances for everybody. And so I think that probably made having a permanent Senate-confirmed FDA Commissioner – probably moved it down on the priorities list.

So the bottom line was that Dr. Schwetz was in that position until, if I recall, April of 2002 when Les Crawford was named as Deputy Commissioner as a political appointee. He was

an old FDA hand. He'd been at the agency I think at least two separate occasions previously. And he was in charge until Mark McClellan became Commissioner I think in the fall of 2002.

CC: So that's a long time without a confirmed Commissioner.

LB: That's a long time. It was a hiatus of leadership.

The trade publications always will say when there's a hiatus like that – they would look at approvals or non-approvals of drug products, say, and say, well, the FDA is being more cautious now. It's not approving products because there's no Commissioner confirmed. That's always struck me as illogical if not almost absurd because the Commissioners are not involved in the review and approval of products. Drug reviewers and the Center people know what they need to do to review medical device or drug applications. I've always thought those kinds of arguments were bogus.

But that said, it's important for FDA to be visible and represented by someone in charge who's been confirmed, whether it's at the White House or on the Hill or in the public eye or at the Department. And so FDA was not well served by not having somebody permanently confirmed as Commissioner. That's one of the reasons that it was a shame that Jane Henney wasn't kept on at least for a few months to ease the transition. For obvious reasons that didn't happen.

The other thing that happened sometime during this time was the FDA got a new Chief Counsel and a new Legislative Affairs person probably sometime in I want to say 2002.

[DR-100\_81.wav]

LB: Did you want to say something?

CC: I was just going to suggest that we go back and wrap up about Dr. Henney if there's anything more you want to say.

SJ: We should note for the record that tobacco closed during that timeframe. Dr. Henney inherited the tail end of tobacco. So when Brown versus Williamson [*FDA v. Brown and Williamson Tobacco Co.*] was decided, some of that ten percent staffing increase that you talked about that had been devoted to tobacco could be reassigned.

LB: I don't know how big the tobacco office was. I know Mitch Zeller was head of it and Sharon Natanblut was the Deputy. For a while, I think they borrowed people, but I don't know how big it actually was.

CC: I thought they borrowed people.

LB: I don't think it was very big.

CC: They brought in Judy Wilkenfeld from the FTC but other than that, I thought the effort was staffed by current employees from elsewhere in the agency.

LB: Was the Supreme Court decision on tobacco in May of 2000?

SJ: Brown versus Williamson?

CC: *FDA v. Brown and Williamson Tobacco Co.* was decided in March 2000.

LB: My point is that the reorg was under way well before that decision. I don't think it's cause and effect.

CC: So it's decided before the election.

LB: And before the reorg. I think I've got the memo still. I cleaned out my FDA files a couple months ago. I think I might have saved that memo.

CC: Let's take a break for lunch.

LB: I'd like to wrap Jane Henney. I can do that after lunch.

[DR-100\_82.wav]

CC: This is a continuation of the oral history interview with Larry Bachorik. We've taken a break for lunch, and we're going to wind up Larry's recollections and thoughts on Dr. Jane Henney's tenure as Commissioner of Food and Drugs.



LB: Okay. Just to kind of conclude – Dr. Henney was the right person for the time. She was extremely well organized and a good manager. The FDA had a considerably, I would say, lower profile during her tenure overall. She did have some tough issues to deal with, and I've already alluded to a couple of them. I'll just mention Rezulin again. That was mostly because an investigative reporter from the *Los Angeles Times* did a series of stories over more than a year in which he basically was intent on proving the point that FDA was lax or not on the ball or even corrupt in approving this product and didn't listen to its experts. So that was a tough thing for us to deal with.

I'll just say that for most of my tenure in public affairs, I spent a lot of time explaining to our experts and senior executives why it was important, why it is important to talk to the media and to be on the record and to be part of a story because I really believe that. And it's important, but in this case, there was just no percentage for FDA because the reporter basically had the story and cherry-picked evidence despite our best efforts to answer all the questions. That was a tough time to go through.

The other thing I mentioned is biotech foods. I don't remember if Dr. Henney attended all of the hearings. I was at all three of them, and I know she was at Oakland.

CC: She was in Chicago, which was the first of the three public hearings.

LB: I was in Chicago, and that's fine. The reason I remember this is that I wrote a speech for her to give at Stanford University when Don Kennedy was president and I was there in the room. I remember. The only reason I bring it up is that Don Kennedy at this point had been away from the FDA for 21 years. He greeted Dr. Henney, of course, very cordially, but I was delighted that

he remembered me. It was a little bit like a mini West Coast reunion for Dr. Henney and me, for her giving the speech at Stanford.

The other thing I remember, at least at Stanford, it was such a politically fraught issue – biotech foods, genetically engineered foods – that the security people had a scanner, like an airport type scanner, brought into the entryway of the Federal building so that people's parcels would be checked through so there would be no risk of violence. That was pretty impressive back then for that to happen.

But Dr. Henney served the FDA and the nation well. I think FDA was a very well run organization at the time. In my time at the FDA, it was one of the best times really because she was a disciplined leader and someone that was great to work with.

CC: How would you characterize her? You used the word “charisma” or “charismatic” to talk about David Kessler. How do you think she motivated people? You characterized how Kessler did that. What about Dr. Henney?

LB: Looking back at her time, I don't associate that time with major FDA initiatives or announcements. To some extent, it feels in retrospect that we were more on the defensive for whatever reason. I think it was clear that Dr. Henney had very high expectations of employees, and so we strove to live up to those expectations. She was a good listener. I'd have one-on-one meetings with her twice a week typically. And I made sure that I was well prepared and not verbose. She'd want to know the answers succinctly. She'd listen. She'd listen very carefully, but she was “Let's hear the issue, let's make a decision, and let's move on.” So she was very businesslike. There was no wasted motion, I would say.

CC: Anything else on Dr. Henney or should we move on?

LB: I think we should move on.

CC: Larry, you've talked a little bit about the transition from the end of the Bill Clinton Administration to the beginning of Bush 43, the Administration of George W. Bush, and what was going on at FDA. Let's continue along that vein.

Dr. Henney left on the day of the inauguration. We had a series of different actors in the Office of the Commissioner. Then Dr. Crawford came. His position initially was Deputy Commissioner, but he was the Acting Commissioner. Then Mark McClellan came. So let's talk about that era.

First of all, just confirm. Were you still in that same position as Associate Commissioner for Public Affairs?

LB: Yes, that was, as we'd talked about earlier, a career SES position, Associate Commissioner for Public Affairs, that I was appointed to in the spring of 2000. So that was not subject to change, except under the ordinary SES rules, with a new person at the helm. I don't remember that Dr. Crawford was initially named Acting Commissioner. We should check this. I seem to remember that he was appointed Deputy Commissioner, period, and there was no Commissioner.

CC: Well, that could be.

LB: Just to clarify.

CC: But he was still running the agency, wasn't he?

LB: Yes.

CC: And as my recollection was, and you mentioned this before we broke for lunch, that there was a new Chief Counsel, Dan Troy, who is a political appointment. He's the Chief Counsel. Lester Crawford is the Deputy Commissioner. And Amit Sachdev – he came from the Hill and became the Associate Commissioner for Legislation, I believe.

LB: That's right.

CC: Those are the people in power. At least, my impression was they were the ones running FDA from the high level of the agency.

LB: That's right. That's right.

CC: So did you interact with any or all of those people in your capacity as Associate Commissioner?

LB: I interacted with them on a daily basis. Dr. Crawford had at the time an 8:30 meeting every morning with senior staff, and that included Dan Troy and Amit Sachdev. It was Dr. Crawford's meeting. He ran the meetings. We'd go around the table and everybody would talk about whatever was on their mind for that day, what we needed to prepare for or reiterate or watch out for, what we expected to happen during that day. In fact, at some point, the 8:30 became an 8:40 meeting because Amit could never be there at 8:30. I don't know if it was just he ran late or I think there may have been some HHS meeting or something at 8:00. Anyway, for whatever reason, he never could make it on time for the 8:30, so we started at 8:40 after a certain point. That was the reason why.

I remember going on a vacation in the spring of 2002. Dr. Crawford had not been back very long, but we'd known each other for a long time. I remember when I came back after ten days or two weeks out of the office, he told me how glad he was that I was back to manage public affairs. Things continued on.

I think there were two major differences in those years. One was internal to the FDA without a Commissioner in place. We can talk a little bit later maybe. But what I want to focus on right now is the FDA's relationship to HHS, to the Department.

It was very different starting in 2001. Remember, under the Clinton era, the Associate Commissioner for Public Affairs had been political, and for most of that time, it was Jim O'Hara. Then it was Lorrie McHugh-Wytkind later on. But they were able to run the public affairs shop. As I think I may have mentioned last time, Jim O'Hara was very good at dealing with the political stuff and not bringing it into our daily work at all. That was much less the case under the new regime.

You may remember that Secretary Tommy Thompson, who was I think Secretary for all of the first term of Bush II, he'd been governor of Wisconsin. He was new to the Federal scene, to Washington. And he had a notion of "one HHS." That was one of his major mantras. He as part of that wanted very much for there to be one email system for the whole Department. He claimed, at least, that email systems in various agencies wouldn't talk to each other. I'm not sure that was true.

But in any event, the most important thing and the reason I bring it up is Secretary Thompson centralized human resources in the Department. That had a big impact, and not a good one, on the FDA. Instead of FDA having its own human resources office that was well equipped to serve the needs of our agency, all of a sudden instead of having someone whom we knew and would understand what kind of person, what kind of skills we were looking for and how it was a priority, we were dealing with some decentralized office maybe in Atlanta or in downtown D.C. or something. That centralization of the HR function really hurt FDA. It's only been recently that we've started to get out of that, I think. The system was really broken, and it made it difficult for FDA to get the kind of talent that we need.

But the reason I mention this is primarily because of the impact it had on my ability to run the Office of Public Affairs – with that kind of centralized mindset – this seems incredible looking back on it now – but for me to hire a press officer with FDA – dollars appropriated through the Agriculture, FDA, and Related Agencies appropriations – I had to go to the Assistant Secretary for Public Affairs at HHS and get permission.

CC: You mean approval of a particular individual or approval for a spot?

LB: Approval to hire. Approval to hire, which was a big change. When this policy got out and the notion was that public affairs throughout HHS, Health and Human Services, was being centralized in a way that it never had before, there were actually at least a couple of stories in the *Post* about it. But it made it more difficult for me to do my job. It was kind of a systemic indicator of how the function had changed. In the late Clinton years, the Assistant Secretary for Public Affairs, even though the position that I applied for and was hired for was a career position, the Assistant Secretary urged me to apply because she knew me and she knew I would do a good job.

The relationship was different in the Bush years. There was almost a different approach to dealing with the media. That was cause for some friction.

CC: Who was ASPA, Assistant Secretary for Public Affairs, during Bush 43?

LB: That was a man named Kevin Keane, who I believe had worked with Secretary Thompson in Wisconsin. Like all things, in the immediate wake of September 11th, the Department pulled together and there was a good feeling of camaraderie between the public affairs office at the Department and the various agencies. We had conference calls about bioterrorism and preventing threats. Then, of course, as we mentioned earlier, the anthrax letters being mailed to the Hill and to certain media figures very soon after September 11th, within two or three weeks, I think, led to a whole other series of concerns. And we worked very closely in the Department among the agencies and public affairs, throughout HHS and the Department. That was a good thing and there was a lot of focus.

But part of that focus on terrorism helped FDA become even more invisible, I think, in terms of the Department. It was a big plus, I believe, when Dr. McClellan was nominated and confirmed as FDA Commissioner in the fall of 2002 because he was very qualified for the job. He had his Ph.D., economist, I believe, and an M.D. He worked in the White House under President Clinton. He was appointed under Bush II. Brilliant guy. He brought the kind of heft and stature and increased visibility to the agency that's important to have in communicating about the public health.

But I have to say that in the interim, those two years, two and a half years, when FDA didn't have somebody confirmed in the Commissioner's slot were tough years for the agency both in terms of not having someone to represent FDA in the higher circles of government, not having a visible and a confirmed leader. There were a lot of challenges. On top of that, the increased role, at least in the public affairs arena, of the Department in showing interest in what we were doing in public affairs at the FDA.

SJ: Go back and talk about Crawford's administration. He wasn't here for a while, but he also went out under a cloud. How was that affecting the work environment here?

LB: That's three years later. That's in 2005.

SJ: Oh, sorry. Okay.

CC: I'm curious. It's well known that Scott McClellan, Dr. Mark McClellan's brother, was the Press Secretary for George W. Bush for quite some time. And Tevi Troy, who was FDA Chief



Counsel Dan Troy's brother, was on the White House staff. I believed Tevi Troy was connected somehow to the Domestic Policy Council.

LB: And he became – he was a Deputy Secretary at HHS later in Bush II.

CC: I heard people talk about that there were two sides of the house in HHS. There were the Tommy Thompson people and there were the George Bush people. And then there were these unusual brotherly or fraternal connections to the White House from two highly placed FDA officials.

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Were you aware of these connections and did you ever see any manifestations of the connections?

LB: I'm much more aware of the connections and the styles of the McClellan family because I was in the public affairs realm. When Dan Troy was Chief Counsel, I'm not sure that I even knew that Tevi Troy was in the White House. I may have known it, but I didn't observe anything about any possible ties there. I can certainly say that in terms of FDA's public affairs work and our strategies for communicating with the media there was a profound impact.

The primary thing that happened was that FDA shifted into a mode in its press relations of being much more like the White House press operation. And here's what I mean by that. In most of my career, certainly from 1990 till 2000, the FDA Public Affairs office issued formal

press releases quite sparingly. We might do 30 or 35 a year. The upshot was – and in the McClellan years, that tripled or quadrupled. We probably put out – I haven't looked at the numbers in a while – but 150, 200, maybe even more than 200 news releases a year during the time that Dr. McClellan was Commissioner.

And in a way, it was good because we were communicating more and we were potentially making news more. As a practical matter, it meant that reporters couldn't rely on FDA anymore to tell them when we were actually making news because in the old days, FDA only put out a release when it was something truly newsworthy that reporters were going to write about. So they used that as a barometer. If the FDA's putting a news release out, we better get on the story.

CC: In fact that's what the guy at AP said to you on Odwalla. Oh, this must be pretty important if you're calling me at 2:00 a.m. and there's a press release.

LB: It was as much about 2:00 a.m. or 4:00 a.m., but yes.

In a way, I think the signal to noise ratio changed. What FDA had relied on extensively in the pre-2000 years were communiqués called Talk Papers, which I think were invented in the 1970s. They were already in effect when I joined FDA the first time in the late '70s. And those were meant initially for the public affairs specialists in the field or others who had to speak to FDA issues. They're kind of background papers that FDA issued. But they didn't have the weight of a news release and they didn't have any quotes in them, so that was the way we differentiated.

Before 2000, we might issue 150 of those Talk Papers in a year while only doing 30 or 35 formal news releases or press releases. That ratio just flipped on its head during Dr. McClellan's tenure. So every time we did something that was remotely newsworthy, we would put out a news release about it. And I think to some extent that probably reflected Dr. Mark McClellan's view of how communications and public affairs shops should work based on his observation and close ties to Scott McClellan in the White House press shop.

CC: Other than Mark McClellan's observing of Scott McClellan's and the White House's practice, what's the purpose of issuing all these press releases? I mean, did you ever either deduced it or were told this is why we're going to do it this way?

LB: I think the main explanation is it shows that we're active, we're on the job, we're visible. And I guess in an age when the Internet is increasingly important, we're just out there with more material online. And I have to say when Dr. McClellan was in interview situations – he's a brilliant guy. He remembers everything. But he was not shy about going on camera or talking to reporters. He learned stuff quickly. If we had agreed on the issue of how to limit the exposure of American consumers to potentially infected BSE, mad cow disease, agents, which was an issue during that time, if we wanted to make these following three points, we could put him on camera and he would do it just like that. He would do it in the next interview and the next interview.

The amazing thing is that six months later, if you said to him, we've got a reporter that wants to talk about restricting certain neurological materials from cattle, he would be able to go through those same three points. It's almost like turning on a tape recorder. So he was good for the agency in terms of visibility and credibility and facility in dealing with the media.

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CC: You mentioned BSE. What other issues were prominent during Dr. McClellan's tenure that you recall, the public affairs type issues?

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LB: One of the big items that I remember Dr. McClellan being instrumental in and involved in had to do with the preoccupation at the time, which was bioterrorism and the need to develop counterterrorism agents and to beef up the nation's capacity for defending ourselves. He was very active in that area. I remember an announcement where President Bush came to the NIH campus in the auditorium and Dr. McClellan was there, the Secretary was there. And I remember being invited to that. A big announcement was made on measures, how to develop better measures, a new initiative against bioterrorism.

My recollection is he was also very involved in fostering medical innovation and maybe even getting better data. He at one point wanted me to be his speechwriter. I did write some speeches for him. I think maybe even one for the National Press Club. He did give at least one speech at the Press Club. He very well understood how the media worked. He was a successful and effective spokesman for FDA. I think, given the times that we were living in then and given the two plus year delay in having an FDA Commissioner, FDA was very fortunate to have Dr. McClellan join us. It was, I think, unfortunate that his tenure was so short and he was called away, as he was, in 2004.

CC: This was after the Medicare prescription drug act. He went to CMS – the Center for Medicare and Medicaid Services.

LB: My understanding was that he was drafted to go to CMS to be the head of CMS, I think in the spring of 2004, and with the charge of implementing the new prescription drug benefits part D.

SJ: For Medicare part D.

LB: That was enacted by Congress in an all-night session, you may recall, and under, let's say, unusual circumstances.

CC: What was unusual about it? Just that it was all night? Congress has done stuff like that before.

LB: I'm not a student of legislation really, but I remember there being some unusual tactics used to make sure that the measure got through the way it did when it did.

SJ: It was also kind of counterintuitive for a Republican Administration to be backing an expansion of Medicare. There were lots of suspicions, I believe, as to who was really going to benefit from expanding this part of Medicare.

LB: There may have been some opposition to the plan because of the so-called “donut hole.” I’m not an expert. I’m just kind of remembering here. Maybe there was some resistance to passing part D. Anyway, it got through, but I don’t think it’s that often that people are held in session until 3:00 or 4:00 in the morning.

CC: Just to backtrack a little bit. You talked about the change in human resources when the Bush 43 people came in and Tommy Thompson and his one HHS, which leads me – sort of indirectly but still leads me – to ask you to talk about what it was like for you to be a supervisor in terms of having a number of people work under you. When you were the speechwriter, I think you had your own gig. Then as you moved up, you start to acquire both more responsibility but also more supervisory duties. Maybe you can talk a little bit about people that worked for you or how it was to have people work for you, which I don’t think we’ve really covered.

LB: Sure. Well, there’s a big difference between being a solo practitioner of speechwriting, which early in my career I was. When I came back to FDA, I had a small staff, two speechwriters. It was pretty easy to manage and there were not a lot of personnel issues to deal with. But then, when I became a deputy in the Office of Public Affairs, all of a sudden I’ve got ten people reporting to me and I’ve got the various management sorts of things to deal with, whether it would be budget or recruitment or dealing with issues of parking and space.

In other words, there are lots of other things that need to be done. I think it’s kind of a theme in management – it’s been an issue for the FDA over the years that in order to advance in one’s career and move up the ladder, it’s necessary to become further removed from the skills that

brought you there and to be spending much more of your day on things that maybe are not in your wheelhouse, that you're not as comfortable with, or not as experienced with.

I think that's a fact that FDA over the years in terms of having scientists and medical people in order to advance being moved up in the organization. I think FDA's dealing with that and has dealt with it. In my own case, I was lucky that when I became a deputy and then head of the Public Affairs office,, I always had people that I could rely on to deal with a lot of the administrative aspects. So when I was head of Public Affairs, I had Theresa Stone. Theresa Hoog Stone was my admin person for much of the time. She was invaluable for recruitment and hiring and dealing with intra-office issues.

I remember at one point we actually hired an outside consultant to come in and talk to us for a few hours just about the working environment and the esprit de corps, and we actually made some very constructive changes on the basis of those recommendations. That was helpful. Also, as I moved up and became responsible for all the media relations, I had to have a reliable director of the media affairs staff. As I said last time, initially there was a broadcast media staff under David Kessler that handled electronic journalism. I was in charge of that. There was another staff that did print.

When I became head of the whole office, I merged those staffs after a year or two, but I had a person, a guy named Brad Stone, who was the director of the media relations staff. He was someone whose judgment I trusted and was able to manage the day-in and day-out. I would still handle the major stories with the major news outlets typically, but when I was not available or there was too much going on, Brad or Brad's people could always fill in very nicely. So it's always a matter of getting to the next level and learning new skills and hiring good people and trusting them to do their jobs.

CC: Brad was somebody, if I remember correctly, started out as an FDA press officer.

Like way back in the day.

LB: Brad was hired in the throes of the early HIV/AIDS epidemic. This is kind of an interesting historical tidbit. At that time, the journeyman/journeywoman press officer job – the Public Affairs Specialist in the highest level – the job series went from GS-7 to 9 to 11 to 12 to 13 or maybe 11 to 13. The highest rank a press officer at the FDA could obtain was a GS-13. I'm pretty sure that Brad was brought in during the HIV crisis at a higher level, at the 14 level, because he had special expertise in blood issues. He came in at that level.

I wasn't in the office at the time [inaudible]. I was part of OPA, but not in the media part of OPA. I was on the speechwriting staff. But over time, and this was in part Brad's doing, Brad became the head of the satellite press office downtown at the old FOB-8, Federal Office Building 8. There were two or three press officers down there and a clerical person. That was the satellite office that handled foods issues. So Brad ran that office for many years. Then later on I brought him out to Parklawn to head up the staff – all of the press officers, including the foods ones.

But one of the things he did when he was head of that staff is that he managed to work with HR. to revise the job descriptions for the public affairs specialists – the spokespeople who handle press calls – and their job classifications were upgraded. Once revised, they qualified for GS-14 across the board. Again, this is an advantage of having FDA human resources in FDA, a human resources staff in the agency. Brad's effort was enormously helpful because it meant that we could promote our good talent from within and it made us more competitive when we went



on the market to hire because there was a higher career path for press officers. That was no small feat. It helped FDA's media relations program a lot. ,

CC: Any other people besides Brad Stone that were part of your staff that you remember or saw as having a particular impact or brought something to the agency that otherwise wouldn't have been presented?

LB: I can mention just a few people in passing. I know this is becoming a long interview. The fellow that launched the FDA's website, FDA.gov, is a former journalist named Bill Rados, who had headed up FDA's communications operation from I want to say the early '90s probably putting out the *FDA Consumer* magazine and FDA's fact sheets and brochures. We called them "easy readers." They were for lower levels of literacy to communicate in very plain language about FDA issues.

In 1995 or thereabouts, with the Internet catching on, Bill came to me with a proposal to split the communications staff in half and have one half focus on FDA's website and the other half continue with the more traditional activities like *FDA Consumer* magazine and fact sheets and that sort of thing. I blessed that, and it went forward. And Bill got that going back in the mid-'90s.

CFSAN had been the leader in FDA's web presence. I remember being down in FOB-8 in probably '91 or '92 and somebody down there took me to a computer, a CRT, one of those big fat monitors that we all used to have, and he showed me the FDA website. There was stuff on it that moved. Fish swimming or something on the CFSAN site. I thought that was pretty cool. So Bill Rados is the guy that got the FDA.gov site going.

LB: One of the problems that FDA had in the '90s and well into the 2000s is that each Center developed its own website with its own different look and feel. So there was no uniting look – you wouldn't know going from the Drugs Center website to the Biologics Center website that they were even part of the same organization. That didn't really get fixed until 2009, and I was involved in that as well when we actually adopted a standard platform and a content management system for FDA.

But I'm getting ahead of myself.

CC: But this is interesting – I don't know how much we've documented it elsewhere. So you're saying that the FDA Internet presence – as FDA.gov – began in the mid-'90s?

LB: Yes.

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CC: Do you know how that timeline compares to other agencies? Were we ahead of the curve, behind the curve on developing an Internet presence, which seems essential as we sit here today in 2016?

LB: I really don't know.

CC: Before we leave these early years of the Bush 43 Administration, let me just ask you about your experience with, your sense of, some of the more senior people that were certainly not only senior but also powerful. I have in mind people like Dan Troy, who was the Chief Counsel, Amit Sachdev. What was your experience working with them and their understanding of FDA and what they brought to the agency? Start with Dan.

LB: Dan Troy joined the agency 2001 to my recollection. He was there even before Dr. Crawford arrived as the Deputy Commissioner in early 2002. Bern Schwetz was still nominally running the agency. I'm not a lawyer. I don't know what particular judicial philosophy Dan might have brought to the agency. What I can say is that he was quite influential around the table in discussions. And having observed the interaction between FDA's Chief Counsel and FDA Commissioners since the late 1970s, for every Commissioner and every Chief Counsel, I was often struck by the different nature of the interactions between the Commissioner and the Commissioner's counsel.

Essentially throughout nearly all of my FDA career, the Commissioner would hear the arguments on an issue, ask questions, discuss with senior people, and then reach a conclusion. The Chief Counsel would then say, okay, boss, we'll do what it takes to make it happen or here's how I think we can go forward with it. And in the case of Mr. Troy, it was different. The response was often after the Commissioner had reflected and reached a decision and was leaning in a particular way, the response was often, well, I'm not sure we have the authority to do that, but we can look into it. So it just struck me as a non-lawyer as kind of a very different client-attorney relationship during those years.

SJ: Who was the “we,” the royal “we,” he was talking about? Was that part of the issue that people weren't sure?

LB: Well, I hadn't thought about it in those terms, Suzanne. But the “we” could be the Chief Counsel's office: “We as Chief Counsel and my staff attorneys.” Or I suppose could have been a broader “we.” It just struck me as off key somehow and not really the tenor of the relationship that I'd typically observed between a client and an attorney.

CC: What's interesting is that I've heard some people say that prior to Bush 43 the Chief Counsel's office had become – and these are my words, not what other people have specifically told me – sort of anything goes. They never said no to the Commissioner. One of the things the people point to are the continuing losses on First Amendment cases and that while you could come up with a legal theory, it wasn't necessarily the soundest theory. There wasn't the necessary level of rigor in the Chief Counsel's office in developing a legal theory.

Dan not only had his own philosophy but he also pulled the Chief Counsel's office back to where they would scrutinize the impact of the legal theory. That's in his defense.

LB: One of the notions that was current at the time was that Mr. Troy supposedly thought that FDA was losing too many cases for whatever reason – maybe for the reasons you suggested – and that we would be more circumspect in taking them on or we'd have our arguments be – I don't know what the right legal word is – more conservative or less trying to advance the law.

CC: Yes. I think Dan had his own philosophy, but I also think he wanted – there were certain things, at least initially – that made me think that he was a lawyer's lawyer. He was concerned about legal analysis and he had a particularly strong background in First Amendment law. He had successfully challenged the agency on some of the dietary supplement claims. That sort of eroded, but just it's another perspective on his saying something other than, okay, we'll do it because it's not always true that the agency has the legal authority. I would see the “we” in his statement as we don't have the legal authority meaning as a matter of statutory authority, but I wasn't at those meetings.

SJ: One of the problems with even discussing what that “we” means is that Dan had a way of grating on people. I'm not a lawyer either, so I'm not really sure, but people's perception of him was that he was difficult. Now it could have been because he was just a really good lawyer and that can come with the territory or there were always concerns that there was politics involved in the whole thing. We may not be in a position to know that.

LB: To your point – this is not really substantive, Suzanne, but your mention of politics reminds me that there would be times when he'd show up at meetings with a Republican National Committee coffee mug. That just struck me in a science-based public health agency where the goal is to be judicious and impartial – that seemed off tone a bit.

CC: Okay. I asked you about the other people that were political appointees, which was a little unusual in FDA. You mentioned Amit Sachdev and you've talked about Dan.

LB: I remember Amit as being an affable sort of fellow. Ran the legislation shop. What struck me most about him is that he seemed very concerned, more than other of his predecessors, about how certain FDA actions or proposed actions would play in the regulated industry and especially in the medical device area.

CC: Do you know why he had such an interest in the medical device area?

LB: I really don't. I really don't know. I had left the Office of Public Affairs, I believe, by the time he left FDA. I think he went to work for a company in the industry. I don't know what he's doing now, but it just struck me that he paid a lot of attention to that, and that seemed to me a bit unusual. Not that FDA isn't mindful of all of its constituencies, whether it's consumers or trade associations or health care professionals or any of the many multitudes of organizations, disease groups that we deal with. But that's the main recollection I have about that.

CC: What about Tevi Troy who was on the White House staff? Did you have any contact with him?

LB: Not when he was at the White House.

CC: Then he went on to the Department?

LB: He became the Deputy Secretary. I think it was before the governor of Utah became Secretary, Mike Leavitt. Anyway. The timing isn't so germane. My recollection is that I had a

meeting that involved Tevi Troy when I was still head of public affairs at FDA. So that was some time in 2004, maybe early 2005. The issue, if I recall it, was tissue transplantation and safety of human tissues, which FDA regulates.

The issue was disease transmission from donated human tissue – tendons, ligaments, corneas, that sort of thing. We were trying to decide whether to go on camera or maybe we had decided we were going to go on camera with *60 Minutes* on this issue, which was a huge – it's kind of the acid test. If you decide to go on camera with *60 Minutes*, you're really in the big leagues.

CC: Who was going to be on camera? Do you remember?

LB: I don't remember. I'll give it some thought.

CC: We took a short break off the record so Larry could reflect a little bit on this story. Larry, why don't you tell us – you were telling us a story about a meeting at HHS in preparation for a *60 Minutes* story. You told us that was with Tevi Troy, but I think you've recollected something different now. Why don't you clarify that?

LB: Right. As I was starting to tell the story, a couple of the details didn't ring true. So I'd like to start that over at least in part. It was a meeting at HHS. It was a meeting on the issue of the safety of human tissue for transplantation. But it did not involve Tevi Troy. What happened was that the Chief Counsel and I – Dan Troy – went down to the Department to talk about this potential interview, and I believe it was with the Deputy Secretary at the time, maybe early 2005.

As we talked about what FDA would say on camera, I began to wonder what this was all about. At the conclusion of our discussion, it wasn't clear to me whether we were going to have a message that would be focusing on how FDA is protecting the American people from potentially unsafe tissues or whether it was more about protecting the executive branch from criticism.

CC: Was that unusual? Or was there a shift in emphasis?

LB: Well, it was unusual, I think, on two accounts. The FDA, as we've talked about, earned a lot of public trust over the years, especially, I think, in the '90s when the agency was active in cases protecting American patients and consumers. So it was unusual for me to feel that our messages weren't as strong on protecting patients as I was accustomed to. But secondly, it was also unusual for FDA's message to consumers and to the public to be vetted at that level.

CC: Let's wrap up your work as the Associate Commissioner for Public Affairs. Anything else you want to say about that before we move on to your next position?

LB: Yes. I'd like to say a few things about that. So I had been in that job as a career civil servant, head of the public affairs office, since 1999. The public affairs office at FDA was, I think, well thought of and functioning at a high level. I would have put it up against any public affairs office elsewhere in the Executive Branch. But over the summer of 2004, there were a couple of glitches that happened. I found myself in a position of having the Assistant Secretary for Public Affairs be concerned about FDA's public affairs office.



Granted, it was an election year. It was 2004. But one of the things that the acting Commissioner at the time, Dr. Lester Crawford, had as his priority for that summer was to launch a new initiative that would portray FDA as innovative and showing the way and being a leader in public health issues. As we talked about that over the summer, we hit upon having him give a major address at the National Press Club. I think it was one of their series of newsmaker luncheons that occur weekly.

It didn't occur to me that that would be an issue, the Commissioner giving a speech at the National Press Club. But when I called the public affairs office at HHS a few days before the speech to inform them of it, they were quite concerned. I got the feeling that they were decidedly unhappy. The speech went on pretty unremarkably. I think there were no issues around the speech. But I had the feeling that the senior political people in the public affairs office at HHS, our parent department, were concerned.

So I found myself over the next few months in a more difficult position. Eventually the situation evolved to the point where Dr. Crawford began asking me what other duties I would like to assume at the FDA.

CC: Before we get to that, at least in my experience, speeches of high level agency officials, prepared remarks, went through a lot of clearance. Do you recall whether that speech was cleared at HHS or OMB?

LB: I would be very surprised if it had been. FDA speeches, in my experience over 30 some years, really would never be cleared by the Department or OMB. Now, that said, there probably are occasions, certainly with a major announcement, a policy initiative, a product approval that

might be contentious or controversial – where there's a formal FDA or HHS or White House rollout. Then the whole package of materials would be subject to approval by any interested parties in the Executive Branch. That happens routinely. It happens more and more now as rollouts have become just the standard way of doing business. For a speech of an FDA Commissioner, even the speech at the National Press Club, in my experience, no, it would probably not be cleared outside of FDA. And I've written speeches, Press Club speeches, for three or four Commissioners.

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CC: Do you recall was there a specific topic for that particular speech of Dr. Crawford? Was sort of a general kind of discussion of the agency?

LB: I think there were two things from my perspective. One was the Assistant Secretary for Public Affairs was surprised that I hadn't cleared the speech with him beforehand and I was telling him about it a few days before the speech. In fact, I was called in on the carpet about six weeks later and asked why I hadn't cleared it. And I told them frankly that I didn't realize that the Commissioner of Food and Drugs needed to clear his speeches with the Assistant Secretary for Public Affairs. So that was one thing.

The other thing is that one of the issues over that summer and had been for 2003, 2004, was the re-importation of prescription drugs. Big issue. Big consumer issue. Political issue. Any issue that's big in an election year is going to be sensitive. And I recall that Dr. Crawford had said some things on the record in an interview in the previous week or two about the re-

importation of prescription drugs. So I think those two things – that's how I interpreted the HHS public affairs concern.

SJ: So Crawford himself had taken it upon himself to comment on that issue. It's not something you had written?

LB: No. Well, the comments were in a wire story or a newspaper story. Yeah. Those are the two things that I can think of.

SJ: So your suspicion is that you were maybe the fall person? I can't imagine. First of all, I can't imagine Dr. Crawford not sticking up for you with the National Press Club. Did he not know he had to get something cleared? Was it really your job to know?

LB: I don't know whether Dr. Crawford thought about whether to clear his remarks with HHS, but what I can say is that in the wake of my meeting downtown with senior officials – probably this was in September now of 2004. I was in Dr. Crawford's office with him, and he took a call from public affairs at the Department. Clearly from what I could hear, the call was about me and their discomfort with me. After he hung up, I asked Dr. Crawford what that was about. He told me he was defending me, which was clearly not the case. So it was my mistake to assume that since every Commissioner I'd ever worked for up to that time, 25 years or so, would stand up for their employees – I was mistaken.

CC: Before we went on this side discussion, you said that there was a period or a point at which Dr. Crawford started asking you about what other duties you might want to have at FDA. What happened after that?

LB: Well, I gave it some thought and looked around the agency to see what other areas of work probably in the Commissioner's office that would be suitable for someone with my skillset and my experience. I had several ideas. Dr. Murray Lumpkin, Mac Lumpkin, at that time was Deputy Commissioner for International and Special Programs, I believe. He had been Deputy Director in the Center for Drugs as recently as 2000, and then he had left that position to become Deputy Commissioner for International and Special Programs I think that same year, 2000.

He knew of my situation and suggested that I take a detail in the Office of International Programs, which was part of his portfolio. That sounded like a good match for me. It was communications. The title I had there on detail was Senior Advisor for International Policy and Communications. That's what I did. I went on a detail, and then was made permanent in that office at the end of the detail. I was grateful to Dr. Lumpkin for finding a good spot for me to land. He had been the first FDA employee to actually spend time and live in London at the European Medicines Agency. At that time it was EMEA, the European Agency for the Evaluation of Medicinal Products [also known as the European Medicines Evaluation Agency].

And he'd spent, I think, a couple of months there. This was maybe in 2002 or so. He made a lot of contacts there. The head, basically the chief of staff for the EMEA at the time, was a man named Martin Harvey-Allchurch, and Mac arranged with Martin for me to go and do a summer, 11 weeks or so, 11 or 12 weeks, at the EMEA in London as a consultant. There had been new regulations, European Union regulations about transparency, openness, freedom of

information. I was sent over there to be a consultant and help them develop a communications plan for opening up the EMEA, now called the EMA, the European Medicines Agency. That was a career-changing experience. It was something really good that came out of all that.

CC: Before we go into what you actually did in the Office of International Programs, do you have anything else to say about being reassigned or that period?

LB: Well, personally, it was a difficult period for me, but it was really more than that. What I really care about is the FDA and its mission. And what I saw increasingly during the 2001 to 2005 period was the fourth estate, the media, being viewed more and more as another constituency to be manipulated or to be managed or to be addressed. That was contrary to the way I had always approached public affairs in the Federal government. It may be a bit naïve, but my approach had always been that the fourth estate – that a free press is crucial to democracy and that the fourth estate has a right to know about the work of a public agency, warts and all, good things, bad things. I defended that right and really tried to have as open a window onto the FDA to the public, including the media, as possible. That didn't work out in the end.

The other effect, I think, of that period is that under new leadership, the FDA's Office of Public Affairs suffered a steep decline. I'm not saying that because I was no longer there. My deputy Brad Stone moved to another office within the FDA. Many press officers with a long tradition and rich knowledge of FDA issues and how to work with the media left that office. So within a few months, certainly within a year, the office was a shadow of its former self. That was unfortunate.

I'm not talking really personally here but just in terms of FDA communicating with the public. Things have recovered. FDA's always going to have dedicated people. They'll get the word out. But there was a real sea change.

CC: When you say that the fourth estate, the press, the media, were – I think first you said manipulated, and then you said managed, actively. What's an example of the manipulation or the management that you saw that seemed new or different?

LB: I think manipulated might not be the best term. It's a little strong. I don't think it's really possible to manipulate the media. You give the facts to the media. You give them access to your experts. You give them information. They report what they see. That was probably the wrong word to use.

SJ: But access is the key. That's the way you control the story is you control who has access and who doesn't. Was there any effort to control who has access?

CC: Or to whom the press had access?

LB: Absolutely. Absolutely. In the fall of 2004, in September, in September of 2004, a new Associate Commissioner for External Affairs was appointed to the FDA. She was a political appointee, an attorney, a member of the Federalist Society. Her name was Sheila Walcoff. I don't think she had any media experience or public affairs experience. I think my first meeting with her was when I was called down to the Assistant Secretary for Public Affairs office. Within I'd

say a month of her arrival, a new process was instituted within the FDA public affairs office requiring all media requests for interviews to be cleared through the Department of Health and Human Services. That was brand new. That had never been the case in practice before.

So you're right, Suzanne. Access to the media is very important. A fundamental issue is that reporters have a right to access to agencies. That's fundamental, and that should be honored. It was no longer the case. That doesn't mean that agencies can't decide – agencies should always be able to decide whether to go on camera or not or whether to go on the record or not with a print reporter. But it doesn't allow agencies to withhold information that's releasable.

CC: Are you suggesting that this approval of interviews process that was new, a Departmental level of approval, was, at the end of the day, the impact was that publicly available information was not being made publicly available?

SJ: Well, it just – I'll answer in part that just the process was so slow.

CC: No, I know there's a process piece. My question is what was the ultimate impact of this besides delay?

LB: Well, I'm not comfortable saying the change in the interview process requiring HHS approval, I'm not saying that that kept information from reporters. I can't in all honesty say that. I would hope that that did not happen. But what it certainly did was decrease the effectiveness of FDA's public affairs and media relations operation for the reason that Suzanne mentioned. It just delays everything. So reporters have deadlines. And if you can't get an answer to them before

their deadline, they're going to file. If your point of view isn't in the story and you have something really important to add but they've already filed it –

CC: You might as well not have a point of view?

LB: The second day story isn't the same and a correction isn't the same thing either as a first story.

SJ: During that period is a concrete example. It was the anniversary of the pill. A colleague and I had written an important paper on the approval of the pill. Reporters got hold of it. It had already been published, but they literally had to have someone from the Department on – I was at a conference. They had to arrange a phone call that had FDA and HHS on the phone to clear this piece that was saying nothing other than what had already been published. If they did that with everyone, I can't even imagine. Wheels grinding to a halt.

LB: Well, there is a process in place now. I haven't been involved in it for a long time, but I was working fairly recently alongside people in the FDA media affairs office now. It does happen. It's just I don't know how long it takes on average for approval to come through. I'm sure there are understandings between HHS public affairs and FDA media affairs where it can be pretty expedited. I'm not in position to say how that is. Certainly in my experience, it made the public affairs operation way less nimble and way less responsive. That has had a deleterious effect on FDA's relationship with the media and ultimately with the way it's perceived in the nation.



CC: We're resuming the interview of Larry Bachorik, and we're basically going to wrap up.

Larry, you went to the Office of International Programs – you mentioned that Mac Lumpkin found a place for you in OIP. You were there for a couple of years. What were your duties there?

LB: After I came back from London that summer, the first summer I was in that office, my portfolio consisted primarily of international organizations, the OECD, the Organization for Economic Cooperation and Development, which is based in Paris. I was a couple of times part of the U.S. delegation to the part of OECD that deals with chemicals. The Environmental Protection Agency was the U.S. lead for that organization. I was there not in a speaking role but to consult with them in Paris – with the U.S. delegation – on issues involving FDA-regulated products that might have something to do with the ecology, the EPA issues. The main thing I remember there, a substantive issue, was nanotechnology, which was very big both for the EPA and for us. There was a special session on nanotech that I attended that first year.

The other organization that I had responsibility for was the World Health Organization, WHO. So I got involved in some interesting things, mostly, I think, having to do with the foods area, with *Codex Alimentarius*. I did get to take one trip to Geneva. It was over the winter of 2005-2006. It was February 2006, when there was a movement to have a treaty on counterfeit drugs, internationally binding treaty on counterfeit drugs.

[01:20:00]

The U.S. position under Bush 43 was that we didn't want to get involved in a – there's a term of art for it – a legally binding treaty of a certain sort. The U.S. position was that we would work on the issue, but we wouldn't commit ourselves to a more formal kind of arrangement. So that was our position in that meeting. I attended that meeting in Geneva with – I'll fill in her name later. Enforcement person from drugs. Pharmacist and JD. She was in drugs compliance.

SJ: Justina Malina?

LB: No, she was in Drugs compliance. She still is in Drugs compliance. She's a Deputy Director. Ilisa Bernstein. She was the good cop. I was the bad cop. But anyway, that was the extent.

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Then I was out of the office much of the summer of 2006 because I had an illness. In late 2006, early 2007, we were looking for duties that I could do that were more commensurate with an SES position. I talked to Mac Lumpkin again and I talked to Scott Gottlieb, who was a Deputy Commissioner at the time. There was some thought of how I could get reintegrated into FDA's broader communications function. In March of 2007, I began a detail as a speechwriter for the Commissioner at the time, Dr. von Eschenbach. He had been appointed Commissioner of FDA after the short-lived tenure of Dr. Lester Crawford, who in fact was appointed and confirmed – was nominated and confirmed as FDA Commissioner in the summer of 2005, I believe. His term was short. He left the office in, I want to say, September of 2005.

CC: He served about ten weeks officially.

LB: Dr. Crawford left under a cloud. His replacement, at least temporarily, was Dr. von Eschenbach, who at the time was the director of the National Cancer Institute. Very powerful position at NIH. He was appointed kind of suddenly. Dr. von Eschenbach's initial thought was to serve simultaneously as head of the National Cancer Institute and Commissioner of Food and Drugs, though I think there was some skepticism about that from the start. It wasn't long before it was clear that Dr. von Eschenbach needed to devote his full time and attention to the FDA.

I came on the scene in March of 2007, and the opportunity was offered to me to become a speechwriter again as I had many years before and to work for Dr. von Eschenbach. I thought about it. I've always enjoyed speechwriting, so I became his speechwriter. He was a prolific speaker. Spoke a lot. The main things I did for him were basically – usually they weren't formal speeches. They were outlines with mostly sentences, some sentence fragments, but they were more than talking points but less than a full text of a speech. That was just his preference for public speaking.

It was a bit tricky because of the formatting. Everything would have to be bulleted out. Ultimately, the product that we delivered him was a series of note cards – five by eight, I think, is the size, so bigger than a standard three by five recipe card. He'd have a little leather box, a speech box. For me, the formatting was always a challenge, but I figured out how to print out his speeches on these notecards. He was a very good speech giver, unlike some former speakers that I had written for, because I think he probably practiced but also he wasn't tied to the text. His head wasn't down in a lengthy manuscript. He saw the bulleted points in large type. He was a

very effective speaker. Very positive. Very optimistic. He was kind of a booster for the FDA, I would say.

I think my initial detail was 60 days. Then it was extended another 60 days. Things had gone so well. This was in the Office of the Chief of Staff at the time, who was Susan Winckler, a pharmacist [and an attorney] who'd joined FDA, I want to say, in 2005 maybe. She became Chief of Staff within a year, maybe less than a year. She took over for Patrick Ronan, Patrick Ronan, who was Chief of Staff.

Catherine, you had mentioned Dan Troy and Amit Sachdev and some of those people that were political appointees. I think Patrick was as well. He was Chief of Staff during that time. I'd known him before I left public affairs. I think he may have also had a role in having me come back to a broader FDA communications function in the Office of the Chief of Staff.

Anyway, at the end of the summer of 2007, Susan Winckler asked me if I'd be interested in being the Assistant Commissioner for External Relations. I said sure. Dr. von Eschenbach approved that, so in late September 2007, I was back in the ranks of the Assistant Commissioners at FDA. I had as my responsibility the external relations function of FDA, which is consumer affairs work, and some Native American, tribal, minority work.

But for that first year as the Assistant Commissioner, I was also still Dr. von Eschenbach's speechwriter. I stayed with him mostly until the end of the Bush II Administration, although toward the summer of 2008, a political appointee from HHS wrote a few speeches – this person was on a detail, I think, to FDA and wrote a few speeches at the end for Dr. von Eschenbach. I was happy to be doing that again. It was great to be back in a more ambassadorial relationship between FDA and the outside world dealing with consumer groups and others.

Then with the election of President Obama in 2008 and, of course, the Administration changed. Dr. von Eschenbach left in ... I want to say March of 2009, I think, was when Dr. Josh Sharfstein was nominated as the Principal Deputy Commissioner. Was that his title? I think it was.

CC: Or Deputy Commissioner.

LB: Maybe he was Acting Commissioner. He might have been Acting Commissioner for a while. Anyway, there were six weeks or two months before Dr. Hamburg was nominated and confirmed.

CC: Dr. Hamburg started in May. Dr. Sharfstein was certainly around and running the place early on.

LB: You mentioned Dr. Frank Torti earlier today. Dr. Torti was an academic physician from, I think, Wake Forest. Dr. von Eschenbach had brought him in in 2007 with the express role of creating an FDA fellowship program. Dr. Torti did that. It's a program that's been, I think, quite successful and is still in existence today.

I should also say, going back to Dr. von Eschenbach, one of the things I did for him when I was his speechwriter was he had a Friday afternoon email that he called "Andy's Take." His first name was Andrew. Every Friday afternoon, sometime between usually noon and 2:00, if we were lucky, we would send out an all-hands FDA email called "Andy's Take." It went to all FDA employees. Mostly I drafted them. One of his close aides would then push the button and send it

out to all the employees. That continued right through the end. In fact, what made me think of it is Dr. Torti also did a few all hands for him in the interregnum between when Dr. von Eschenbach left in January of 2009 and Dr. Josh Sharfstein. Dr. Josh Sharfstein started in March.

I should also say, as Assistant Commissioner for External Relations, I also had as part of my portfolio the *FDA Consumer Updates*, which are electronic articles that FDA posts on its website. They replaced the *FDA Consumer* magazine in 2006 when I was not part of that operation. We also did a number of other communications tasks.

With the transition of Dr. Hamburg arriving in May of 2009, Susan Winckler was still there as Chief of Staff. She stayed on until June or so for the transition. There was no Associate Commissioner for External Affairs for many months, really about a year, I think. So the various offices like the Office of Public Affairs, the Office of External Relations, my office, we reported directly to the Commissioner or to Dr. Sharfstein for a while until an Associate Commissioner was named. Again, another transition. A change in personnel. Lots of new appointments. Dr. Hamburg brought in people in various capacities.

The one thing I would comment on, which was a little surprising to me and somewhat disheartening, was that for a career senior civil servant like myself who had been in the executive branch for the last decade, it took us a while to win the trust of some of the new political appointees under the Obama administration. That was puzzling to me and it made things somewhat difficult. Throughout my career, there have been good times and there have been times that weren't so good. Certainly in the position I had during the 2000s as a spokesman for the agency and as representing the FDA, there were times when the message we had to give and to tell reporters and the public was a difficult one. But we stuck it out because of our

commitment to the agency. So it was hard to not be trusted fully at the outset. I'm not the only one who experienced that.

CC: I want to pursue that, but I also want to – I'm just curious. On these “Andy's Take” emails, where would the topics come from for those? Were those things that were suggested to Dr. von Eschenbach? Did he come up with them? The reason I ask is that the current Commissioner, Dr. Califf, has his Rob's Report. I guess alliteration is always useful. My sense of those is that he generates those topics and writes them himself. What happened with Dr. von Eschenbach?

LB: It was I think probably similar to the current Commissioner. Many of them would be the ideas that would come from Dr. von Eschenbach. I think the process was we had to have an approved topic by Monday afternoon or Tuesday morning, and then I would usually write it certainly I think by noon on Wednesday. Later on, I'd have other people write it sometimes. We were on a tight weekly schedule.

Sometimes we would meet with Dr. von Eschenbach briefly just to say what are we doing this week, but we always had to go into those meetings prepared with ideas of our own to suggest to him. But maybe like Dr. Califf, Dr. von Eschenbach often had something that was topical that he wanted to talk about. Sometimes it would be kind of on the fly. I remember one time he was visiting a port in the Southeast of the U.S. or a facility. He got inspired and he dictated something and then we worked on it. It was often quite topical. It was kind of fun.

CC: Do you recall whether prior to Dr. von Eschenbach and these weekly emails, other Commissioners had weekly communications? I don't remember them. Of course, the advent of email made it much easier, although there had been email for a while.

LB: There wasn't much of an FDA internal communications program. For many years, the old Office of Public Affairs, which is what I joined in 1989 as a speechwriter, director of the speechwriting staff, had the communications staff part of that office which put out *FDA Consumer* also put out a monthly newsletter, a print newsletter, called *FDA Today*. The History Office here right behind me has binders of that.

It was discontinued, I want to say, in '94, '95, for budgetary reasons. Then there was really no formal internal communications program. In fact, that's one of the main things I did in the Obama Administration. Early on, it was suggested, probably May, June 2009, that we ought to have an internal newsletter. We thought about the options over the summer and whether the Office of Public Affairs should do it, which had a new director, or whether the Office of External Relations should do it. Since I have the writing chops and I had a staff of three or four writers, I volunteered to take it on. I'll tell you, it was one of the most challenging projects I've ever had. I'll speak about it very briefly or somewhat briefly.

We didn't launch it until August of 2013 for multiple reasons. I had a prototype issue ready to go. It would have been an electronic newsletter. I had the copy all set. I had a design. It would have been an email newsletter, but it actually had some art and had formatting. That was ready to go, to be launched, in March 2010. That's when the new Associate Commissioner for External Affairs came onboard, a woman named Beth Martino. My first meeting with her, I said, "Well, I've got this newsletter. It's ready to go." She said, "Well, I hate to do this, but I'm going



to put a stop to it. I think we should do a reader survey. We should survey employees to see what they want."

So I took a deep breath and said okay. Then we actually designed a SurveyMonkey survey that we worked on with the Planning Office. Nancy Ostrove, who's a social scientist and some of her colleagues. It was actually a fun project. I wanted to get the newsletter out, but since the decision was to do a survey – but we didn't get it launched until I think November that year, 2011. This is typical of FDA employees. We had remarkable participation. We had I think something over 50 or 55 percent. It was huge. I won't say huge. It was a really big response, and that's typical of FDA employees. They're just dedicated to the place. Maybe it was only 40 percent. I've got it in my file somewhere.

So what I then proposed to do and I talked to Dr. Hamburg about it, I came up with a proposal. This was by now the summer of 2012. I proposed to create an internal blog for FDA so that we would have posts. What we really wanted to do was have an interactive feature so that employees could comment. We were hoping that it would create a social media community. There would be interactions. We might even have employees volunteer to post material or write material for this internal communications device.

That project came a cropper mostly I think on the issue of resources because rightfully so, there were issues of who was going to moderate the blog. I mean, we couldn't have a system where employees could respond to an internal blog post unfiltered. I wrote a comment policy. I had lawyers look at it and FOI people look at it. There couldn't be any personally identifiable information, so called PII.

SJ: It has to be 508 compliant.

LB: 508 compliance was an issue. This all just takes an enormous amount of time. But what finally tipped the balance into not moving forward with that project was the resources that it would take to moderate the blog. Our office, the External Relations office, was prepared to do that. But we anticipated that there would be human resources concerns potentially raised or EEO concerns. People wanted to comment on something. Let's say it's an article about a new branch in the Center for Drugs or something and someone has a gripe with the director of that. So we had to go to the Office of the Chief Counsel, and they were less than enthusiastic about the additional workload of having potentially to review a comment to the blog by an employee or our response to it or whatever. That was in the fall of 2011. So what ultimately happened, that's partly the reason we moved ahead with the *FDA Voice* external blog.

[DR-100\_86.wav at 01:00:20]

Virginia Cox was the Associate Commissioner at the time because Beth Martino had left after about a year in the spring of 2011. Virginia Cox came in right after Labor Day 2011. She had worked at FDA previously. Anyway, so Virginia was very keen on creating – she was originally keen on the internal blog but then decided the best use of resources would be to create the *FDA Voice* external blog, which was launched in December of 2011 and still is going strong to this date. That was part of my responsibility through the remainder of my career at FDA.

Finally, we worked with FDA's web and digital media shop, which is part of the Office of External Affairs, a sister office to my Office of Communications, which was renamed in 2013, a bit of a reorg there. We came up with a new design. We assigned one employee to creating the content. I'm quite proud of it. It started three years ago this week. First issue was in August 2013,

as I said, I think toward the end of the month maybe. So it's been going strong for three years, so FDA does have an internal communications vehicle. It's called *FDA Link*. Yeah. We've tweaked it. I say “we” – it used to be “we.” After a year or so, we made some changes where the employees can actually print out articles. It's a good online presence, and it's only available inside the FDA firewall. You can't get access to it from outside because that's one of the issues of security.

CC: When you think about it, FDA is not only just a bunch of domestic field offices and headquarters. It's now got international field offices. Do you see that publication as helping bridge those geographic distances?

LB: Absolutely. Absolutely. That was really one of our main motivations in creating an internal newsletter was to bring together the broad FDA community. Roughly a third of the agency is the Office of Regulatory Affairs. They're just dispersed all around the country. It's always been a priority of mine to try and help make them – help them feel like they're part of the larger organization. I think ORA traditionally has had a really strong sense of mission and sense of belonging.

Moving toward concluding all of this, in my time at FDA, I've certainly seen that the field operations, the Office of Regulatory Affairs, as critical as they are to FDA's mission, is less visible than it was, certainly than it was 30 years ago, 33 years ago when I joined FDA, or longer ago than that. I think the image of the FDA is much less about investigators in the field on the front lines of consumer protection and investigations and inspecting plants. It's much more about

what FDA does at headquarters now reviewing applications and working on regulatory science and that kind of thing.

CC: What do you attribute that shift to?

SJ: User fees.

LB: I'm sure Suzanne has a perspective on this. The FDA grew out of – the field was the FDA. It was the policeman. It was the cop on the beat. It was the field investigator. Certainly, in the early days, too, it was combined, too, with the strong expertise in analytical chemistry. When I joined the FDA in 1978, the field was very visible at headquarters. People that I worked with day in and day out had come to the Parklawn building or to the foods center downtown from the field.

I mentioned earlier Theresa Hoog Stone, who had worked with me in OPA on admin stuff, she was a Consumer Affairs Officer – it used to be called CAO – in the Cincinnati District. Then that job series later became a Public Affairs Specialist, PAS. There's one of those in each of the Districts. One of my first supervisors in the old Office of Policy Coordination was a field investigator named Dan Brand from Arkansas.

Paul Hile was the Associate Commissioner for Regulatory Affairs. I can't remember if I said this in the first day of interviews, but the Associate Commissioner for Regulatory Affairs was in many respects a Deputy Commissioner because the enforcement and the field operation was so integral to what FDA did. I think as headquarters has grown, as the scrutiny of the FDA within the Executive Branch has increased, there's more – Michael Landa mentioned this in his

interview, I've alluded to it – the Department of Health and Human Services is much more aware and much more involved and much more controlling of many aspects of FDA's work.

There's just more at the top. There are a lot of highly graded civil servants in FDA headquarters. People with those same grades in the field would be a District Director with enormous responsibilities, lots of management, scientific, investigatory responsibilities. It's almost like the critical mass has shifted. It's a little bit hard to describe. I think Suzanne's mention of user fees, which have allowed certainly in the medical device and pharmaceuticals and animal drugs – human pharmaceuticals, animal drugs – has allowed FDA to increase its staffing in those crucial areas. So there's more focus.

SJ: One of the reasons that the field was so large from the beginning was the need to police the industry – to be out in the factories doing inspections. Once we moved away from case law and went toward administrative law, all the Peter [Hutt] preambles, and things like that in the '70s, I think that sort of started things in moving in the direction of expertise starting with probably legal expertise.

Plus, there were a lot of discussions beginning in the Peter Hutt era, having to do with FDA's expertise being questioned in some key areas. Well, anyway, there's a transition period. And I think user fees, though, were the nail on the coffin because about the same time ORA was going through an identity crisis, a serious identity crisis, because they needed to be moving more in international areas and they just didn't have the culture to do that without a lot of angst.

CC: I think another thing that happened is the shrinking – not literally, but shrinking – of geographic distance by electronic communication and people are closer together. So you don't

have to have so many people far away. I think how we communicate as an agency is reflective of how we communicate as a society. It seems counterintuitive on the one hand. You shrink distances and therefore, somehow, that has an impact on reducing the field. And then you do have user fees concentrating growth in headquarters. Also, there's a shift in the nature of FDA's legal authorities – it's not just the Peter Hutt shift from enforcement to administrative law and regulations – it's also that a lot of products are being controlled premarket. So inspections are secondary because we're not trying to regulate products so much post market by inspection.

I think it's a lot of dynamics.

LB: And the post-approval inspections are funded – those are funded by user fees, right?

CC: Or the preapproval.

LB: I mean preapproval.

CC: Yes.

LB: But before you can – the field has a crucial area there.

SJ: Right.

CC: You looked sort of puzzled when I was talking about the communications, but think about it. You don't mail samples anymore – you FedEx them. A lot of the field has been

consolidated because communications and other larger infrastructure changes allow us to. For example, we don't need a lab in every District anymore, and they're very expensive. So that has shrunk the field and the field's weight and influence, I think. I think there are lots of factors.

SJ: We also have the Office of Criminal Investigations, which because of Terry Vermillion succeeded, but there was a lot of angst in the field because you're drawing off inspectors and giving them higher levels, more responsibilities.

CC: Except that Terry Vermillion hired very few FDA people.

SJ: Well, that's just it. But you were cutting off people's career opportunities in the field. Some of them were leaving. It was demoralizing in one sense. We lost some good people, I think, because they saw no promotion potential at all.

LB: My sense is certainly for the first 10 or 15 years of the Office of Criminal Investigations, there was some tension between traditional ORA, maybe even for 20 years. I don't know. My sense is the last few years, and I've already been away now for seven and a half months, but that there was some effort to bridge that divide. I don't know how successful it's been, but I know there was talk about it.

CC: I think that one thing that's pretty clear about the Office of Criminal Investigations is that they're their own gig. They're off on their own. They do have a set of lawyers, but they work directly with the U.S. Attorney's Offices, so they're not coming through FDA headquarters.

They're not dealing with headquarters' Justice. It's not the same as the traditional enforcement thing. That tends to erode – if you have power and ability to actualize things that another component doesn't, I think the other component gets sort of eroded in its stature. It would be a fascinating study, I think, to look at the transition of the agency from its beginning until now and see that evolution because it was a field dominated office, even when I came in 1978, and that's no longer the case.

Paul Hile as the ACRA – this is the last thing I'll say. I thought you were going to say it. He was the greater among equals. I mean, there were lots of Associate Commissioners. And they all reported to the Commissioner or through the Deputy Commissioner. Certainly the ACRA, certainly Mr. Hile, was of a different order.

LB: Punching above his weight or of a different order of magnitude. He's the first among equals for sure.

CC: Right. First among equals.

LB: Then he was succeeded by Ron Chesemore, who I don't think came up through the field.

SJ: He came up through budget work.

LB: Then there was a fellow named Dennis Baker.

CC: Who came from Texas, I think.



SJ: Yes – the Texas Board of Health.

LB: State food and drug work. Then more recently, in the last ten years, there's been several heads –

CC: John Taylor – Mr. Taylor and then John Taylor III, his son – was the ACRA.

LB: Right. Certainly John Taylor – the first John Taylor – he came up through the field, right?

CC: Yes.

LB: So he was the last one in that tradition, was he? I was away from FDA at that time.

CC: No, I think you could be right. Now Melinda Plaisier, the current ACRA, came up through FDA's legislative office. Now, she did go out to a regional office.

SJ: Yes, she was a Regional Director.

CC: But Paul Hile was collecting samples when he first came to FDA.

LB: It's in their blood. It's in their genes. The only reason I'm raising it is one of the concluding themes is – just to emphasize the crucial nature still of the field operation and how

tough it's got to be. I think they get short shrift in attention from headquarters or in attention from the Department or anybody. It's a resource that needs to be nurtured and supported.

CC: One of the things that happened in my early years at FDA was that it was very common for somebody to move from the field to headquarters into certain areas, often to one of the offices of compliance in the different centers. As money has gotten tighter, relocation expenses aren't offered. It's much more expensive to live in D.C. People just don't do that. They don't move from College Station, Texas, to D.C.

LB: That's part of the factor.

CC: Again, there are multiple factors. When people were moving from the field to headquarters jobs, I think that had a melting pot effect. That's not disappeared, but it's significantly reduced, I think.

SJ: Well, that used to be a criterion for being promoted. You had to move. You were told when, where, and what. You were given almost no choices. But once we had two income families, it wasn't as easy to get people to do that. Plus, once we had women – women made a big difference – it was much more expensive to put a woman in the field because they couldn't share rooms. There were a lot of things that changed as a result of that. At the same time, industry was changing. We weren't doing the same – we were doing a lot more regulatory management than we were on the ground jumping in railroad cars and throwing 20 pound triers into the wheat to get samples. Not that we didn't still do some of it, but the very nature of the

inspections changed. That's when Paul Hile hired me to document this way of life that was going by the wayside so to speak and grab all the sieves and the grain triers and the black lights and the things that had traditionally constituted the armamentarium of an inspector.

LB: In that regard, in terms of the field-headquarters relationship, one of the first things that happened when I rejoined FDA in 1989 was the Office of Public Affairs hired the same woman, Theresa Hoog Stone, to be a liaison between the Public Affairs office at headquarters and the Public Affairs Specialists in each of the Districts. Back then they were empowered in the Districts to go on media and speak to reporters. It wasn't just giving speeches at Rotary Clubs or whatever. It was actually doing media relations. That was also an integrating exchange back and forth.

I think the fortunes of the Public Affairs Specialists have ebbed and flowed over the last couple of decades. Some District Directors didn't want their Public Affairs Specialists talking to the media. They wanted them out doing industry training or those kinds of things. It varied a lot from District to District. But we've lost something, I think, without those close ties. I know there's been a lot of effort in the last three or four years in ORA to manage its communications internally and externally. I just don't know where all of that stands. It's been an evolution in my FDA career with less visibility afforded to the field operation.

CC: One of my friends from FDA used to refer to the field as "the real FDA."

LB: I've heard that too.

CC: And you wouldn't hear somebody now – or you'd hear very few people say that. So I think that's, again, evidence of this evolution.

LB: They would say it with pride.

CC: Exactly.

LB: They were someone that had come to headquarters from the field and they'd say, "Well, I'm part of the real FDA."

[02:00:00]

The agency has lost something, I think, given that that's the state of affairs now.

CC: So where does that leave us? Maybe we're close to finished.

LB: We're close to finished. I did want to reflect just briefly on a couple of additional things, mostly I think to conclude the last major project that I worked on, which was a new uniform visual identity for the FDA. In the communications field within FDA, this is something we have been interested in and concerned about for a long time. The famous FDA logo that predates the CNN logo, although the type style is nearly identical, it's probably at least 40 years old now. I don't know exactly when it started.

SJ: Sometime in the '70s.

LB: It was designed by a freelancer – a contractor for the FDA later on. Currently that designer now is an employee of the FDA. It's the one standard thing we have. But if you were to go online today – not so much online – but if you look at various reports or publications, and even some of our online elements, from the Center for Tobacco Products to the Center for Drugs to the Office of Regulatory Affairs and you put these things on a screen together or on a table, you wouldn't really know that those materials, those communications materials, come from the same organization, from the FDA.

So a project that I worked on probably half time for just about my last year at the FDA, certainly the last six to nine months, was this uniform visual identity project which I think is about to bear fruit. I won't go into the details of the process, but about a year ago now, it was late July, early August 2015, after a long process, we identified a series of identity features, a standard FDA logo, a format for all kinds of communications materials and signage and awards and everything that will bring the agency together in a visual sense. If this were industry, we would call it branding.

It's a visual identity that should improve the way we communicate with the world in part because we are such a trusted purveyor of information. But if it's not readily identifiable that this is an FDA product, we don't get the full benefit of it. Anyway, that's a legacy that I'm still looking forward to seeing happen. I did notice on the way in today there's a new sign in front of Building 1 that says “FDA U.S. Food and Drug Administration Tobacco-free Campus.” That's a

new sign from when I was last here about a month ago, and it's got the new FDA logo on it. So it will be phased in, but that's an exciting communications project.

SJ: Let me play devil's advocate on that. It's received mixed reviews internally.

LB: Imagine that.

SJ: I'm playing devil's advocate on this. I don't have a position. What was the problem with just simply enforcing a current logo? One of the problems was that each of the Centers and Divisions and everybody else were creating their own logos. Certainly the cheaper option is just to say stop it, you can't do that. You've got to use the standard logo. You've got Zeb Rogerson on staff. Why not just assign him to look at creating something, put it online, and voting. We spent a million dollars and something on focus groups and all this other stuff.

LB: No, we didn't.

SJ: Okay. Good.

LB: We didn't spend that much. There's an FDA logo.

SJ: There was a decision process. I want you to elucidate that.

LB: There's an FDA logo. It may be more or less recognizable. There's some they would call brand equity in the current logo. But we don't have a visual identity system. There's no manual or no standards for even how you treat the current FDA logo. There's a webpage that says if you're going to use the FDA logo, these are the colors you should use. And if you use it in the conjunction with the HHS logo, this is where the FDA logo goes vis-à-vis the HHS logo. That's about as minimal – that's just basically a logo. This is a whole visual identity program.

SJ: Because you have social media and all sorts of things now.

LB: Yes. There's going to be a standard format for when we tweet, for when we're on Facebook, for electronic publications. They'll all use the new FDA logo. Right now if you've got ten employees that have business cards from FDA and you put those ten business cards on the table, I bet you'd have at least three or four different designs, different logo treatments. Some would say FDA only. Some would say HHS only. Some would say FDA HHS. This may not sound like a big deal, but it's really important for effective placement and communication. That just addresses the point of not having a visual identity, which is where FDA is now.

SJ: So we're not talking about visual identity as just a logo. We're talking about a visual identity as an entire new look at the way we present ourselves to the world in whatever fashion. So rethinking that was the key to the process, not designing the logo.

LB: That's right. That's right.

There's a lot of flexibility in the style guide, which is the term of art, and that will be available to all the designers across the Centers, across the various Offices. But it's down to the level of PowerPoint presentations. FDA has PowerPoint presentations online. We're trying to be transparent. We're trying to be open. Some of them say Center for Drug Evaluation and Research. Some of them say FDA. Some of them don't say anything. FDA should get credit for all the good work that it does so that it will be immediately apparent to someone on the outside who's looking at this what the source of this is. That's number one.

Number two, you're asking why can't we use the current logo? The process was quite exhaustive. When we started out, there were three kinds of logo designs initially proposed. This was in, I want to say, January or February of 2015. There were four treatments that used the current logo incorporating it into the proposed design. There was a middle ground where the current FDA logo was echoed. Then there was a brand new approach. There were four designs proposed in each of those three areas. They were subsequently weeded down in two stages from 12 to 6 and then from 6 to 3.

SJ: I believe you went out in the field and did some of the focus groups yourself or witnessed the focus groups.

LB: I did. I was involved in focus groups. They were in three different cities – no four: Philadelphia, Atlanta, L.A., and Chicago. There were four focus groups in each city. They covered industry groups, health care professionals, consumers, and a fourth constituency.

CC: State and local government?



LB: Scientists – scientists or academicians. It was quite well vetted. It wasn't like we were hell bent on coming up with a new logo, but we did want an identity system that would establish clear, uniform principles and give examples across the board. It was a very interactive process. The wholly new design won out over the more traditional.

CC: So what I'm hearing you say is that the benefit to the agency is – well it's not just to the agency – the benefit to consumers is that by visually identifying material as being from FDA, there's a certain credibility to that material.

LB: That's right.

CC: And so people find it believable. And as information multiplies with the Internet, we have to ask how do you sift through all this information?

LB: Right.

CC: Then there's also the benefit to the agency of getting credit. If you can identify by looking at something, people – particularly taxpayers – can understand this is something that my tax dollars pay for.

There's another point I want to emphasize because I think the visual identity project gets somewhat short circuited because people talk about it in terms of a new logo. Suzanne already

said this, but I want to emphasize it, that it's more than a logo. It's the totality of visual presentation.

LB: Right. It's a system for communicating visually. The other advantage that I'm positive will accrue to the FDA through this effort is that there should be, over the longer haul, there should be cost savings because set aside the aesthetics of you putting brochures from six different product centers on a table and they all look different in terms of where they come from. Every time, let's say, the Center for Devices and Radiological Health wants to do a brochure, they have to – whether they do it in house or especially if they contract it out, there's nothing to work from, so the designers have to reinvent the wheel.

Now there are standard visual elements, how you use the logo and where. And that's prescriptive. You couldn't do the new FDA logo in orange. There's an FDA blue color. That's the color you use for the logo. That makes good sense. You can reverse it out. You can have it on a black background. It can be in white type. But there's enormous flexibility in terms of the design of the brochure. So the idea was to standardize the look of the logo so that it would be clear where the publication or the communication was coming from, but to leave a lot of the creativity to designers, whether they're internal or external. But there should be a cost savings from that as well.

Anyway, it's an exciting project. You'll be seeing more of the results of it. The new sign, the visual wall in Building 1 to the right, the one that's got video playing now where I came in today, that's new since January because it wasn't here when I left at the end of December. That's got the new FDA logo in the lower left-hand corner as well. So this will be incremental as big capital projects or signage or whatever – it will be gradual, but there will be a date certain is my

understanding where all publications will start using the new look and feel. We won't say throw out 10,000 old brochures with the old logo. We'll just say when you exhaust that supply and you reprint, use the new logo.

CC: Sort of tying the beginning or near the beginning and end of your interviews together, when you were at the hospital association – I forget the precise name of that group – one of your jobs was creating a new corporate identity.

LB: That's right.

CC: Was there a visual piece to that?

LB: It's a nice kind of symmetry. I think the FDA's program is more comprehensive.

The organization was called Fairfax Hospital Association. It started in 1956. In 1987, the name was changed to Inova Health System. At Inova, there was a style guide and it was prescriptive: "Here's what the logo looks like. Here are the colors that you use. Here's how you say what Fairfax Hospital is under Inova Health System."

For FDA we have – there will always be U.S. There will be the FDA, the block blue with FDA inside. Then it says U.S. Food and Drug Administration in two lines. If you're from the Center for Food Safety and Applied Nutrition, your name goes under that. And it's always under it, never on top. Or if you're the Office of Foods, that goes under it. You can do three levels. That's all you can really do.

Suzanne mentioned some concerns internally. There were offices that were very intent on branding themselves. The Office of Regulatory Affairs is one. Other offices. They wanted their Office of – I'm just pulling this at random. It wasn't the Office of Medical Products and Tobacco, but let's say they wanted their logo to be prominent or their logo to be the only one. That's just not going to be allowed. No one ever says – tell me if you've ever heard anybody say the Center for Drug Evaluation and Research just approved a new product today. No. It's the FDA. That's who we are.

SJ: I have to laugh, though. The new logo. The typeface. That was what we were using in the '50s and '60s. I don't know what the typeface is called, but that block letter whatever is an absolute throwback to the '40s, '50s. Not even the '60s. Well, maybe '60s. For a historian, we look at it and go, oh my gosh, they've just reinvented the wheel. I'll have to find out what the typeface is.

LB: That's really one of the challenges, too. It would be in the style guide and you can find out from the Office of External Affairs. That's one of the challenges when you're doing something that you want to last that you not get sucked into the latest trend. All the appliances now are stainless steel and the accent color is black. It's been that way for ten years or so. But in 20 years, it's going to be, oh my god, that's a kitchen from the 2000s. Stainless steel. Isn't that awful?

To circle back to what you said about the health system, I was thinking about logos this morning. I pulled into the FDA driveway, and sitting right outside Building 1 was a truck. It had

on the side of it Inova Blood Donation Services. I thought, well, there's the other logo that I worked on in 1987.

CC: Maybe that's a good place to wrap up.

SJ: We thank you for all of your time. It's a long interview, but we've gotten a lot of material that we would not have gotten elsewhere or certainly in the same timeframe.

LB: Well, I hope it's not too long. I hope someone someday finds some of these stories helpful or illuminating. It's a little frightening. It doesn't seem that long ago I was a bright eyed young thing and all the senior FDA people seemed really knowledgeable and sophisticated and older. Here I am toward the other side of that.

There really has been in my career a cycle from the early days in the late '70s to the '80s where it was difficult, I think, for FDA to get the attention of the Executive Branch or even the public sometimes. In the '90s with David Kessler, that was no longer an issue. We got lots of attention. Then I think in the 2000s, maybe we got some attention that we didn't want to have for certain issues and certain drug safety things. Anyway, the agency now is two or three times the size it was in the late 1970s. It's certainly double the size it was even 20 years ago roughly. We've gone from 8000 or 9000 employees, I think, 20 years ago to 15,000 or so. Enormous changes. The culture is to some extent different. It's been centralized. It's been decentralized. There's just been a lot of ebb and flow, but I've been honored to be a part of it. It's a terrific agency.

SJ: Thank you.

CC: Thank you.

# Curriculum Vitae

May 2018

## LAWRENCE BACHORIK, Ph.D.

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### CAREER SKILLS/KNOWLEDGE

- FDA's Programs and Mission
- Strategic Communications Planning
- Media Relations and Strategy
- Speech Writing/Testimony
- International Public Health
- Stakeholder Relations
- Issue Analysis/Management
- Science Policy
- Crisis Management
- Staff Development

### COMMUNICATIONS, PUBLIC AFFAIRS, AND EXTERNAL RELATIONS

- I currently teach a course on FDA health policy, science, and regulation at the Foundation for Advanced Education in the Sciences graduate school at the NIH
- As FDA's Assistant Commissioner for Communications from 2007 to 2015, I directed FDA's communications program for consumers and other key external stakeholders. My portfolio included FDA Consumer Updates (100 web-based health articles per year), the FDA Voice blog (150 posts annually), speech writing for the Commissioner of Food and Drugs, FDA Link (the newsletter for FDA's 15,000 employees), and the FDA History Office. Throughout 2015, I led the development of a new visual identity for the FDA, an initiative designed to create a uniform "look and feel" for all of the agency's communications. This initiative was launched in 2016.
- From March 2005 through March 2007, I served as Senior Advisor for Policy and Communications in FDA's Office of International Programs, with responsibility for communicating about FDA's international programs and for managing FDA's relationship with the Organization for Economic Cooperation and Development and the World Health Organization. From June through August 2005, as a visiting expert to the London-based European Medicines Agency (the FDA's EU counterpart), I developed a strategic communications plan for that agency.
- As FDA's Associate Commissioner for Public Affairs from 1999 until 2005, I led the public affairs program of the agency responsible for approximately 20% of the U.S. economy. I managed media, communications, publications, and the FDA website; supervised as many as 65 employees; and served as chief spokesman for and media advisor to the FDA Commissioner. Accomplishments:
  - ✓ Designed strategic public health communications for FDA initiatives, product recalls, consumer advisories, enforcement actions, and product approvals
  - ✓ Oversaw the development of FDA's award-winning website
  - ✓ Devised and carried out a strategy to improve regulatory compliance and public health by generating increased coverage of FDA's enforcement actions. Integrated media strategy with enforcement work, as appropriate.
  - ✓ Served as Acting Associate Commissioner for External Relations, directing all FDA constituent relations and outreach for four months

- As FDA's Deputy Associate Commissioner for Public Affairs from 1993 to 1999, I developed much of FDA's day-to-day media strategy. I oversaw FDA's broadcast media relations, creating a broadcast media staff that responded to more than 2,000 inquiries annually, and supervised FDA's Freedom of Information operation. I analyzed complex scientific and regulatory issues for the FDA Commissioner, contributing to articles that appeared with the Commissioner's byline in peer-reviewed medical journals and FDA publications.
- From 1989 to 1993 I served as Director, FDA Speech Writing Staff. Then, and from 1982 to 1985, I researched and wrote scores of speeches, pieces of testimony, and statements for the Commissioner of Food and Drugs, raising the agency's consumer protection and enforcement profile and building support for the FDA's mission.
- As Director of Public Relations at Inova Health System in northern Virginia from 1985 to 1989, I managed all corporate public relations as well as media strategy for the corporate identity change from Fairfax Hospital Association to Inova Health System – a corporate identity still in place more than 30 years later. During that time, I served as Acting Assistant Vice President for Marketing for 16 months.

### **EDUCATION**

Graduate:	McGill University Montreal, Quebec, Canada Ph.D. in English Literature, November 1977
Specialty:	Restoration and 18th Century British Drama
Undergraduate:	Cornell University Ithaca, New York B.A., with distinction in all subjects, June 1971 Major: English Literature (60 semester hours completed); considerable work in Government (17 semester hours)

### **PUBLICATIONS AND REFERENCES AVAILABLE UPON REQUEST**





Deed of Gift

**Agreement Pertaining to the Oral History Interview of**

As a conditional gift under Section 231 of the Public Health Service Act, as amended (42 U.S.C. 238), and subject to the terms, conditions and restrictions hereinafter set forth, I, Lawrence Bachorik, Ph.D., hereby give, donate, and convey to the National Library of Medicine ("NLM"), acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at Silver Spring, MD on July 10, 2016, and prepared for deposit with the NLM in the form of recording tapes and transcripts. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

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Signed: Lawrence L. Bachorik

Last position held: Assistant Commissioner of  
Communications

Date: \_\_\_\_\_

Interviewers: Catherine L. Copp & Suzanne W. Junod

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