History

of the

U.S. Food and Drug Administration

Interviewee:	**Michael M. Landa, J.D.**
Interviewer:	**Suzanne W. Junod, Ph.D.** **Catherine L. Copp, J.D.**
Date:	**March 9, 2015**
Place:	**Silver Spring, MD**

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Date: 5/3/15

Michael M. Landa

Last position held: Director, Center for Food Safety and Applied Nutrition

Date: March 9, 2015

Interviewers: Suzanne White Junod, Ph.D., and Catherine L. Copp, J.D.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

TOPIC OF INTERVIEW: History of the Food and Drug Administration

LOCATION OF INTERVIEW: FDA White Oak Campus

DATE OF INTERVIEW: March 9, 2015

INTERVIEWER(S): Suzanne W. Junod, Ph.D. and Catherine L. Copp, J.D.

INTERVIEWEE: Michael M. Landa, J.D.

FDA SERVICE DATES: September 1978 to
January 2000 to December 2014

TITLE AND ORGANIZATION: Director, Center for Food Safety and Applied Nutrition

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Interview with Michael M. Landa

March 9, 2015

SJ: This is another in a series of oral history interviews for the Food and DrugAdministration. Today is March 9, 2015, and we are interviewing Mr. Mike Landa at FDA's White Oak Campus. This is Suzanne Junod, and Catherine Copp and I are conducting the interview. Mike, start with telling us a little bit about your early history and how you came into the food and drug law area.

ML: I studied law at the University of Virginia and at that time Dick Merrill was teaching there. Dick had clerked in the D.C. Circuit and then been a food and drug lawyer at Covington & Burling for a period of time and then came to the University of Virginia to teach. And when I was there, which was '72, '73, '74, I guess or thereabouts, Dick was teaching a food and drug course among other courses. So I took the course with him and became interested in food and drug law. And after law school I went to work for a private advocacy group for a couple of years, a group that focused on automobile safety and mobile home safety.

SJ: With Nader?

ML: Yes, Nader and Consumers Union had established it, but by that time it was independent. It still exists, it is called the Center for Auto Safety. Clarence Ditlow started running it within a year of my arrival and is running it to this day. But I retained an interest in food and drug law and went back to school. The Food and Drug Law Institute at the time had some number, two or three, I don't remember, of fellowships at NYU [New York University], which offered a master's of law in trade regulation. And so I applied for it and got that and spent a year at NYU in, I think '77 and '78, getting a master's. And from there went to the Chief Counsel's Office of the FDA in September of '78. Catherine and I started the same day – it was September something of '78.

CC: September 10th.

ML: Okay. We were part of what was called at the time I think the "Brady Bunch" after Bob Brady who was the senior lawyer on that floor. It was the 7th floor of the Parklawn Building. Most of the lawyers I think were on 6, but not a small number on 7. And at that time the practice was you would start, when you started at FDA, you would start by doing some litigation. I think that was principally because the chief counsel at the time was a litigator, Richard Cooper. And I think that was grounded on his view that it was a useful thing for lawyers to know a little bit about litigation and also it was a way of moving you around the statute, to get a sense of the whole.

SJ: And to see if you were any good at litigation?

ML: Maybe, or if you wanted to do it, perhaps; that you were both good and wanted to do it. But I think within a year –

SJ: And how many came in with the Brady Bunch?

ML: Around that time, sort of plus or minus a year that Catherine and I came to FDA, Joe Levitt had come, Beverly Chernaik had come and those were names that come to mind immediately. A little bit later, but it could have been two or three years, Phil Derfler and Ann Wion – I have the feeling I am missing a couple in the plus or minus a year or two, but those are names that come to mind.

SJ: Was this in any way related to Project Hire?

ML: Not that I am aware of, no. Then as now attorneys in the Chief Counsel's Office attorneys are excepted service, so I think they just must have gotten some money. The office wasn't very large, maybe 35 lawyers – it could have been 33, it could have been 38. It was certainly much, much smaller than it is now.

CC: I think there was a group of about eight of us. People who aren't around anymore -- Vicki Goldberg, Nicki Goldbach, and Jenny Lyman, and Marsha Gardner transferred from the OTC Drug Review office -- and then the people you mentioned.

ML: Yes. So after about a year, give or take, of litigation, Richard Cooper asked me to do medical device work which I agreed to do starting in, it would have been ’79, probably late in the year, but that is as definite as I can be, thirty-four years later or whatever it is.

SJ: You are far more precise than many of our interviewees.

ML: Well, I remember it partly because I think there was a perception in the agency – Don Kennedy was Commissioner at the time – that the device bureau, it was then a bureau I think -- was somewhat hostile to the law that it was supposed to be administering.

SJ: Was this after Link had left?

ML: Link I think was still there. His immediate successor was a guy named Vic Zafra who had come from OMB who was a very bright guy, but certainly knew nothing about device regulation. He knew about management or leadership, but I don't think had any substantive expertise, experience, knowledge in the area of medical devices.

And so I think the idea was they wanted, Rich Cooper in particular, but for all I know he may have talked to Kennedy or somebody else about this, wanted somebody they perceived who was willing to knock heads a bit. I had come from a private advocacy organization and those organizations tend to call themselves public interest, but they are really just private advocacy, but it had a certain point of view and I think there was a desire to get some of that point of view into that Center. And I am quite sure that was – whether the word “hostile” to the statute was used by Rich Cooper in my presence, I don't know -- but I am quite sure that is what was going on.

SJ: Well, there’s a lot of history in the development of devices.

ML: Yes, there’s a long history there of not very much regulation.

SJ: Were you aware of the fact that there were plans to put a Center for Biomedical Engineering in PHS [the U.S. Public Health Service]? I’ve got a proposed org chart.

CC: I was just going to mention, from a time standpoint that you are talking about 1979 and the medical device amendments were passed I think in the summer of 1976. So implementing those amendments was a priority and so the recalcitrance of the Bureau of Devices was important.

ML: Also it reminds me, Catherine has mentioned the passage of the ’76 amendments, my recollection is that every lawyer who was relatively new when we came, which was September ’78, was assigned to review a batch of classification regulations. As you may remember, the law had required the agency to classify pre-Amendments devices by notice and comment rulemaking.

SJ: Which is a tremendous undertaking.

ML: All the devices on the market. And there were these classification panels and of course there were offices in CDRH[1] that reviewed panel recommendations and then wrote up regulations and whatnot. And the lawyers, the relatively new lawyers, all drew a substantial number, a batch of these. I was one, Catherine was another.

CC: Which panel did you do, do you remember?

ML: No, the only thing I remember about it, if my life depended on it, I couldn’t tell you which panel, which type of devices. But I do have a very clear memory of one thing which is that these were basically boilerplate notices of proposed rulemaking, but they still had to be reviewed to make sure that everything that is supposed to be there is there. And so under one particular category in the notices, let’s say its basis of recommendation, I don't know, there was set language. And I remember seeing a bunch that deviated in some small way, the verb deviated and bringing this to Tom Scarlett’s attention. And I remember Tom sort of smiling and saying he thought it was not meant to convey anything different, it was just sort of an accident of whoever happened to be writing it. A very strong memory of that, of seeing that difference and Tom’s reaction to it.

CC: Tom, at the time, was in which position, do you recall?

ML: He was what Linda Horton became and then Ann Wion, it was basically the deputy for regulations and hearings, for regulations, as a practical matter, the hearing work

[1] Editor’s note: FDA’s Center for Devices and Radiological Health (CDRH) was the successor organization to FDA’s Bureau of Medical Devices.

generally got done on the other side of the house – the litigation side. So those are the early days. I mean, what else can I remember? In terms of the hostilities, no doubt – I was in my late 20s, early 30s, more than half responsible for the difficulties that ensued.

But there certainly was not a great desire to regulate, not a great desire to pay attention to the statute. I mean, there were some very bright people there. Bob Sheridan, who ran the Office of Device Evaluation, was a very bright guy but he had his own views about what "substantial equivalence" meant. I think to his credit, he was probably consistent in his application, but whether his application, whether his understanding, had much to do with the law is a different question.

I mean, I can recall two things just in terms of the hostility, before I forget. One was a company had gone out and marketed a bifocal contact lens which FDA said required pre-market approval. The company said basically go pound sand. So FDA seized the product; the company sought to enjoin the enforcement; and FDA then filed a complaint for injunction. Long story short, we won the case and I will go to my grave convinced that Vic Zafra was disappointed that we won. That is one story.

SJ: Now this was under the '76 amendments?

ML: Yes.

SJ: Because there was a mention of soft contact –

ML: Yes, there were transitional provisions and soft lenses, which had been regulated as drugs, were automatically class III requiring pre-market approval. Certain hard lenses I think were, too.

SJ: Because they had been on the market for a substantial period of time?

ML: Yes. But this, I think, was a soft lens where a company – Wesley Jessen was its name – had taken different types of approved soft lenses and basically combined the elements into one bifocal lens saying it had approval for A and approval for B. So A and B is C and we have approval for C. And we actually went – it was litigated through the preliminary injunction stage. At any rate, the government won. That was one thing I remember. The other was, and

this probably shows the depth and the level that I was not aware of distaste. At some point, in trying to show devices what a proper preamble looked like, appropriate level of detail and of explanation, I sent over what I thought was a model of how you do it. The model was a CVM document, the subject of which was recycled animal waste.

SJ: I trust they didn't think this was a commentary?

ML: I suspect they did and certainly at a conscious level I am, to this day, capable of doing that. But at that time I was not aware of meaning anything, but maybe at some level I did and I would not be surprised if they took it that way. Yes, there was a lot of tension. It wasn't just with me, it was with other lawyers in the office. It was a problem. And I don't know how current, through what period of time your interviews go, but I would guess that if you would talk – I'll put it more strongly – I would be surprised if the lawyers doing device work today don't tell you the tensions remain high.

SJ: The lawyers and engineers – the engineers were definitely afraid of cutting off innovation and there was concern that the '62 amendments had done that for drugs. I think they feared a scenario that would have never happened for devices, though.

CC: Do you recall any explanation for how the Bureau of Devices was staffed or where the people came from and whether that contributed to some of this?

ML: The only thing I recall is that, it is fairly obvious that they had a number of people with familiarity with radiological devices because those are sort of the, it was the old Bureau of Rad Health that formed the foundation of the medical device, including its leadership - it was John Villforth and Jim Benson after Zafra. And I don't remember whether there was a device center in the radiological health center and they were merged, which is, I suspect, what happened.

CC: That is my recollection. At the time we arrived, the biologics and human drugs organizations were separate. Then they were combined. The same happened with rad health headed by John Villforth and the Bureau of Medical Devices where David Link was the.

ML: Right.

CC: And then they were combined.

SJ: Well, David Link in particular was very leery of –

ML: Link's tenure didn't overlap by very much. I mean, Zafra was definitely next and then it was Benson and Villforth. And they did not have much interest in enforcement. I mean, that was –

SJ: Speaking of enforcement, the first pre-market approval for a class III device I believe was for the notorious Shiley heart valve. Was this responsible for any of the tensions, did you have any involvement with it at all?

ML: That was after I was advising them or someone else worked on it. I remember working a lot on contact lenses.

SJ: Was this a reclassification?

ML: This was a reclassification thing, right? Yeah. I remember working on approval of the first lithotripter.

SJ: For the kidneys?

ML: Yes.

SJ: Was it used for anything besides kidney stones?

ML: I don't think in this country, at least at that time. I think it may have been used abroad for use in breaking up gallstones. But even if that is right, I don't think it has ever been approved for that use here – maybe in Europe – although I am not sure. Actually, I think it was first approved in Germany for kidney stones. But I remember that, I also remember working on approvals of the first what were then called nuclear magnetic resonance (NMR) devices, subsequently magnetic resonance imaging (MRI) because they concluded, the companies, I guess, that the word 'nuclear' scared people so they changed it to MRI. Which is accurate – there was never anything "nuclear" about them as the term is commonly understood. But not Shiley no. The only heart device I remember was the Cordis prosecution.

SJ: For the pacer leads?

ML: The pacers and pace and leads, it was a long investigation, a long trial, and nothing much to show for it.

CC: Was there a trial?

ML: Oh, yeah. The company pled and paid what at the time was a large amount of money, 500 grand. It may have been, at the time, the largest or one of the largest amounts ever paid by a corporate defendant in an FDA criminal case. The grand jury investigation lasted I think close to two years. It wasn't every week, but it was a huge number of trips to Miami. And the trial, my recollection, the trial was close to two months with a couple of breaks, one for Yom Kippur and Rosh Hashanah. I think it started in August. And we convicted not a single individual. My brother used to refer to the case, as "the government's triumph in Miami." There were four or five individual defendants and we convicted not a single one.

SJ: Because they were going after high level officials?

ML: There was a vice president, I think, and not one of twenty VPs, or if he was one of twenty, he was first or second or third among equals, a guy named Hershenson, Harold Hershenson. There was a guy named John Pagones who was sort of head of regulatory. And I think there were at least two and possibly three defendants who were lower in the food chain, engineers. In fact, I am certain of two because I don't think I could pull up the names.

CC: You might be interested to know that in preparing this interview I located the referral letter in the GC library just poking around in some old historic documents. So should you want to know the names, I could –

ML: There was a Dean something or another [Ciporkin] and there was another defendant, I can't remember his name, but I remember – he probably at a personal level, his family, certainly his lawyers were deathly afraid we were going to try to get in evidence of a prior conviction.

CC: I was just going to ask if you tried the case.

ML: Yes and no. There was a guy from the Department of Justice, Ray –

CC: Ray Phillips?

ML: Yes, Ray Phillips was the lead lawyer and Bob Spiller was second and I was third. But we all put on witnesses and did direct and cross. I am sure I had the smallest share and Bob would have had been in the middle and Ray would have borne the brunt of it. The U.S. Attorney's Office blew hot and cold. They were then, as I suspect they now are, interested largely in drug cases down there, violent crime and whatnot. So they, in the end, my recollection is, didn't provide any assistance even in the form of guidance. I don't even know if they sat at the table with us.

CC: What was the sense of – why did the jury refuse to convict?

ML: I mean, what I can tell you, the impression that I was left with was that – it was a couple of things. One, even when pacers don't work, most of the time it doesn't matter from the point of view of life or death. I mean, I forget what the figure was, 98, 99, 99.5 percent of the people with pacers are not going to drop dead if the pacer dies. They may have some problems, but they can get to a doctor, but it is not what you think, sort of the ordinary conception of the need for a pacer to function properly in your life and if it stops, you are gone – that's just wrong. So I think that was an issue.

I think the case was highly technical from a legal standpoint and covered many 510(k) and maybe other submissions. The rules surrounding 510(k)s are a little muddy as it is. I remember the defense had three or four lawyers because they had several defendants. And I remember one of the lawyers in the opening statement at one point, wheeling, literally turning, wheeling and pointing to me as having sat in some meeting at CDRH where allegedly the Center had told Cordis you don't need to submit a 510(k) for these leads. That's all I remember, I don't remember whether the guy got it right. But there was a memo of the meeting and, I attended the meeting, I don't remember whether it was relevant. So there was that. And then finally I think, and it is my strongest memory, is we basically got out-lawyered. I mean, these were people who earned – the lawyers on the other side were people who earned their living by doing criminal trials. We didn't, Ray didn't.

As good as Bob was, Bob didn't and I certainly didn't. They had an old hand from a major law firm down there as their lead. There was also a woman who had been an Assistant U.S. Attorney for a number of years who was sort of second. And I remember his name was Ted, I can't remember – her name was Rebecca, I think, Poston. He gave a close, one or both of them gave closes that lasted an hour without a note.

I mean, you could have put them on television, only not for five minutes of really gripping theater, but for an hour. We weren't up to that, we just weren't. I mean, not that there aren't government lawyers who are up to it, but OCL [Office of Consumer Litigation of the Department of Justice] in those days, they didn't really earn their living by doing trial work in the sense that these people earned their living by doing trial work. And I don't know how many trials they had done, but they sure as hell had done a whole lot more than Ray, not to mention Bob or me.

That was my strongest recollection, we just got out-lawyered -- out-lawyered orally; on the writing we were fine. Rules of evidence we knew, but would have to call them up. I mean, for them it was second nature. The objection or the counter to our objection was out of their mouth almost instantaneously and for us it was just much harder. We just didn't do enough of that kind of work. And it was complicated and we probably in retrospect – I think another thing is we probably bit off more than anyone could reasonably could chew.

SJ: It was an early case?

ML: It was a 50 page indictment, and I am making that up, it probably should have been 5 – just too much there. IDE, 510(k), PMA –

SJ: And you did not have much experience with the new regulatory system either, is that correct?

ML: Much experience?

SJ: In the system of interpreting what these things meant?

ML: You know, I think it was less than the other factors. It was complicated and in some ways it was a little muddier than we thought. I do think we were out-lawyered. I do think that was a large part of it.

CC: I don't want to jump way ahead, but I think I'd like to get your sense of, having then come back to OGC – so this trial must have been 1987, '88.

ML: Actually I think it was later, I think it was maybe – I left at the end of '92 or '93, so this would have been –

CC: So let's say 1990 and I am just going from when I know the referral was. So ten years later you came back to OGC and then you were the acting chief counsel for a period in 2009.

ML: Right.

CC: Do you think that out-lawyering changed or was that always a possibility?

ML: I think FDA, OGC is better equipped to do trial work by virtue of the existence of the lawyers who do work for OCI [the Office of Criminal Investigations] and the experience some of them have gotten. Most of them have done some trial work and some of them came in having done some trial work. So I certainly think the gap I perceived, I was describing, sort of my perception, has been narrowed. Whether it has been narrowed completely I think is a different question.

And it's not to do with the intelligence or the inherent capability of people; it's how do you actually earn your living day in and day out for 35 or 40 years? The guy who was the lead trial lawyer in the defense in Cordis was remarkably comfortable in the courtroom. I mean, I don't know what you have read about Paul Clement – I have never heard Paul Clement argue; I met him once or twice in the course of my government career.

And what is said about him apart from the fact that he's a really smart guy with a lot of experience is that he is able to engage the Justices [of the Supreme Court] in a kind of conversation. Not that he's their equal, he isn't, but he engages them in a conversation. If you do a Hill hearing and you are lucky, that is what you are able to do. Instead of just being bashed,

you are actually in a conversation. Well, this guy was in the courtroom as if he were having a conversation. You know, that takes a lot of practice, a lot of experience, and maybe some innate skill.

I mean, by way of analogy, it is sometimes said that a musician makes something look easy. My brother is a professional musician, he is an oboist, he has played in the symphony orchestra for forty years. And he has been lucky enough to have, his orchestra has had, as guests some major performers, including Yo-Yo Ma. And what he said about Yo-Yo Ma is not that Yo-Yo Ma made the cello look easy, it's that when Yo-Yo Ma was playing the cello he might just as well been speaking English as a native speaker of English. As well, I am sure he practices hard, but there is real gift there.

And my impression to this day of this trial lawyer was he just that comfortable standing up and giving a one hour summary of the case or his colleague – I think it was Ted Knight and I think hers was Rebecca Poston. Whichever one of them gave the close, it was that good, it was that comfortable to make it look easy. And in a sense, it was easy for them, I don't mean that they didn't have to work hard at it. But we didn't have that kind of skill then. I rather doubt that the OCC has that level of talent today just because it is not its bread and butter.

SJ: But this was a criminal case, too, so you know, the incentive for the company to get the best was, of course, pretty high, correct?

ML: Maybe. And look, the government, in the apple juice case [against Beechnut], where it was primarily DOJ lawyers opposing Brendan Sullivan of Williams, Connelly & Califano, at the time – won. It was reversed on appeal, but it's not as if the government is without resources or ability in this area.

CC: But it was a jury trial or not?

ML: Yeah, that was. But I mean, it's like anything else, there is a reason the Solicitor General's office argues almost all the Supreme Court cases. Not all, I think the Department of Labor and maybe a couple of others that argue their own. I mean, there is a reason for that. It's a particular forum and if practice doesn't make perfect, at least it makes better.

SJ: Or at least not getting rattled by questions interrupting you.

ML: Yes.

CC: Now we can go back to 1990.

SJ: Does that wrap up your conception of what you were doing in devices?

ML: Yes. I am sure I was at least half responsible and maybe more than half responsible for some of the difficulties with the client, I was relatively young and not, I think, anywhere near as sensitive as I should have been to their perceptions of the world and nowhere near as skillful as I should have been in dealing with those. There would have been some disagreements, inevitably, that probably could have been handled much better.

SJ: What led you away from device work?

ML: I was tired –

CC: I just wanted to ask one thing about the contact lens case because I think it is, for me, emblematic and maybe it's just an example of a common problem in FDA. But in the contact lens case -- I think Suzanne has put a copy in front of you -- it seems like there were four or five opinions within FDA about the product. Can you speak to that, because I think it is maybe a more common problem than –

ML: I am glad you asked that because I will give you some recollection of the history. And when I say recollection, obviously there are perceptions woven in with that. My recollection is that whoever was running the Division of Ophthalmic and something else devices at the time, there was a definitely a division with ophthalmic devices, my recollection is that it essentially promised the industry that it would reclassify these rigid gas permeable lenses from [Class] III to II.

That was sent over, and this was, I can't remember the statutory provision, but it had to be done by rulemaking and my recollection is they sent over a draft that was just not close to publishable. They didn't have the goods, they didn't have the evidence, neither did the industry, which I presume was the trade association, nor did the device Center. I can tell you that I wound

up writing the proposed rule screaming every day. That this was a subject of a Hill hearing, fairly unpleasant, with I think [Representative] John Dingle and then Representative Albert Gore.

Ultimately the decision was to publish the proposal, I remember, which I had basically written because [the Bureau of Medical] Devices was unable to produce it. They could not produce an acceptable draft and the clock was ticking. And I can remember being so upset that I went into the parking lot for the Parklawn building and cried. I didn't weep for hours, but I shed real tears.

I remember that when the comments came in saying where is your evidence, I mean the conclusion was what I had thought, and I wasn't the only lawyer who thought this, we don't have the evidence and what we did was to withdraw the proposal which led to this lawsuit which we won in the D.C. Circuit. The industry petitioned for cert [*certiorari*], I think, and the cert was denied and that was the end of my involvement with it anyhow.

But CDRH had to assign different people to do the withdrawal document. Al Van De Griek, who had, I think, been in rad health, I don't remember Al's background. But I remember, I am pretty sure this is right, that I am remembering the Federal Register Notice withdrawing the proposal and not the proposal itself. I think Al sent over an envelope with a copy of the blue sheet and instead of the signature – well, instead of the normal, it was 'for an encore I'll have a heart attack' and he signed his name. Sort of a joke, because it was very stressful. He was as unhappy as a device person at what had gone on as I was, as the lawyer assigned to it.

That's what I remember. I think people in devices, they meant well. I am sure they sincerely believed there was not any safety problem or effectiveness problem warranting pre-market approval, but I think they also did not pay attention to the need to justify reclassification with more than their sincere belief and there just weren't any data.

SJ: As I recall, it had something to do with constituents as well. Part of the problem with regulating devices was reportedly that FDA didn't really have the expertise in-house to evaluate components, we didn't have any polymer chemists, we didn't have specialists in those fields. Do you remember that being any kind of factor?

ML: No, I just don't remember that.

SJ: Okay.

ML: Actually, there is one other matter I remember which involved a device called Drionic, D-R-I-O-N-I-C. And there is a D.C. Circuit opinion on this which was Ann Witt's primarily, but I think at that point in her career, I was supervising her. It was a device that, it was supposed to treat people who perspired profusely. I think the fundamental question was whether in the absence of evidence of effectiveness, if the risk was fairly minor, was it nevertheless unreasonable. I think my recollection is that the court said yeah, you're right, if there isn't any evidence of benefit, then almost any risk is unreasonable and reclassification is not to take place. But that was a big deal. That was one where I think the lawyers and the client were aligned.

SJ: That's good.

CC: Was that a reclassification matter or an enforcement case?

ML: I think reclassification. I am pretty sure.

SJ: I gather FDA was having a lot of reclassification hearings at that time or not?

ML: I guess there were a fair number of petitions, some rulemaking, some via order. Because by then, remember, probably the bulk of classification had been accomplished.

CC: I think probably reclassification was finished by 1980, maybe 1981 because I ended up with …

ML: An extra batch, perhaps?

CC: The final rules on the OBGYN devices and I was still living in my first apartment. I can remember sitting on my sofa working on them.

ML: So that was the logical reason for reclassification and for some a manner of enforcement, when is pre-market approval required, so that contact lens case. There was also a huge flap over – I barely remember this, but it was the lack of investigational device exemptions (IDEs) for studies of certain types of lenses. And most of what I remember about that is John Villforth and Jim Benson being unwilling to enforce and getting them to the cusp of enforcement and then they would pull back. Catherine remembers my screaming – if you were to talk to Ann

Witt, she might remember – I would have had to have talked to her about this, and here's why. We had a meeting with Villforth and Benson when they were still in, not in the Parklawn Building, but in the building on the other side of Parklawn.

SJ: Chapman?

ML: Yeah.

CC: Wasn't it one of those little out-buildings on Twinbrook Parkway? Chapman is closer to the Pike, I think. One story which had been rad health. And I remember we were having our meeting number 9,000 with them trying to come up with some enforcement scheme and it just all dissolved. Again, this is my recollection. And I remember because I was really close to losing it, I was so angry I just wanted to punch somebody. So I didn't punch them, I went into the men's room and just about put my first through a ceramic tile – that I remember. Depending on how close that men's room was to that room, they might have heard it. From my standpoint, it was just impossible.

Jim Benson, I remember, was constitutionally incapable of enforcing anything. Whatever it was about him, I don't know, but he simply could not bring himself to enforce the IDE provisions. And John was sort of "Mr. Outside," so it wasn't really his bag anyway.

SJ: I guess my question was that by that point Peter Hutt had been in the agency just a few years in the '70s, but he had really moved administrative law forward. It seems to me as if in the device area we were moving back to the model of setting precedent, taking cases to court to set precedents before the administrative law issues could take over. But that is just a retrospective perspective.

ML: Well, I think there is something to that, but I think it was largely because there weren't regs by then. I am pretty sure there was no pre-market, no PMA reg, at the time the contact lens case arose, for example. For the reclassification cases, though, contact lens and Drionic, there were regs, but they were not terribly detailed. I think there were regs, but if that's right, they were not terribly detailed.

And 510(k) [section 510(k) of the Federal Food, Drug, and Cosmetic Act] to this day I think, I guess I should take that back, I haven't followed that stuff closely enough for fifteen years, but for many, many years, there was a 510(k) reg, it was pretty broad, didn't tell you a whole lot, didn't answer sort of the critical questions, for example, what is the significant change warranting submission of a new 510(k) for a device that had already had 510(k) clearance. I think to this day people are arguing about that. Not that you can eliminate all arguments, but I don't think the regulation provided a whole lot of guidance.

CC: Before we go forward, I just wanted to invite you to talk about other early litigation, whether you want to talk about Michaelis or the Community Nutrition cases, if you have any recollections of either of those. As far as I can tell, Michaelis is the only Bivens-type action that has ever been brought and defended or certainly was one of the first because I think Michaelis was itself an early '80s case.

ML: I got Michaelis after the government had either once or possibly – no, no I think the government had done two things. One, I think it had executed a search warrant against [Otto Steven] Michaelis which was thrown out. And I think there was some sort of action related to the seized property and I think the motion was granted. It's called a motion for return of seized property – that's what it boiled down to. Then the government seized civilly and the government lost that case.

Then Michaelis sued the U.S. government, Leonard Farr, and at least one other individual who was then based in Atlanta, and the Secretary of HHS and/or the Commissioner of Food and Drugs as well, I don't know. And I wound up with that case supervised by Gene Pfeiffer, who had been the lawyer in both of the preceding matters.

SJ: Was this laetrile?

ML: Yes, sorry – Otto Steven which was for Otto Steven Michaelis, who was a pharmacist in Ohio and was a proponent of laetrile. And then he sued us, yes, and almost all of the issues were dismissed. But the Bivens action survived. It was an interesting case, this was

circa 1980 and Nancy L. Buc was chief counsel at the time. And I remember that because at one point I must have talked to her or maybe showed her some of the papers.
I probably showed Nancy some of the papers because I got back a note saying this one has got it all, all from sort of a first year or second year law school perspective because of a combination of jurisdictional issues. I had an individual based in Atlanta who I argued did not have sufficient contact with the matter in Ohio, inter-state, for federal jurisdiction and the court agreed with that. And there were a whole bunch of little wrinkles.

We were left with one individual defendant, Leonard Farr [an FDA field compliance officer]. And that did not go to trial, which was I think disposed of in a motion for summary judgment, which was granted. I remember two things about that. I argued it. The first time I went out I got on a plane early in the morning and I learned never do that again because I went early in the morning and got there and the judge was sick. So I had coffee with the Assistant [U.S. Attorney] and flew home. And then the second time, I argued the case and Leonard prevailed on summary judgment, but I think the judge did not – somehow or another the case against the United States survived. And I remember that because we settled it, we settled it from my recollection as 20 or 25 grand.

SJ: On what basis? It clearly wasn't on the merits of laetrile.

ML: No, it was a Fourth Amendment violation issue.

SJ: Is this the Bivens issue you are talking about? I need you to clarify that for those of us who are not familiar with it.

ML: Against the individuals was Bivens, it had to be.

SJ: So Bivens means against an individual?

ML: Yes, it was for violation of Fourth Amendment rights.

SJ: Okay.

ML: And the defense was you had to have, at the time, you had to have a reasonable belief that your actions were lawful and you had to have, at the time, a subjective belief that your actions were lawful. The [Supreme] Court ultimately threw that out -- "who cares what was in

your heart." And so Leonard was able to establish that he had relied in part on advice he got from Gene Pfeiffer or somebody else in the Office of the Chief Counsel at the time, and that was good enough. So the government, I think under the Federal Tort Claims Act – again, this is really hazy – all I am quite certain of is that we did not get that dismissed or get a ruling on summary judgment because we settled it.

SJ: What's the essence of the Federal Torts Claim Act?

ML: The general rule is the sovereign is immune from being sued, the only exception being when the sovereign consents – implicitly or explicitly -- to be sued. And that is what the Federal Torts Claims Act is, it is a consent to be sued for money damages with a number of exceptions, and that is about all I can tell you. And whatever exceptions we argued applied, if I am remembering correctly, we did not prevail. And whether we flat out lost or maybe we were facing – my guess is we were going to be facing a trial on damages. The [FTCA] exceptions must have been deemed not to apply and then the question was, what are the damages here? And I have a vague recollection they were somewhere between 20 and 25 grand. We settled.

SJ: Okay. And what was the other case?

CC: Community Nutrition Institute.

ML: There were basically three issues, if I am remembering correctly. One is whether 406 [Section 406 of the Federal Food, Drug, and Cosmetic Act] requires FDA to set tolerances or simply authorizes FDA to set tolerances. Another was whether action levels as defined at the time could only be set by notice and common rulemaking. We didn't do that at the time. And the third was whether we had discretion to permit blending of aflatoxin in contaminated corn. So the contaminated lot –

SJ: Which we normally define as adulteration?.

ML: So the resulting lot was under the action level. And I think, I suspect we won on all counts in the district court, but don't really remember. In the Court of Appeals the first time around, I think we lost on 406 and maybe the court did not reach rulemaking, although I don't really remember, and maybe it didn't reach the enforcement discretion issues.

So the Supreme Court reversed the Court of Appeals on the 406 issue, the Supreme Court said you are authorized, but not required to issue tolerances. Went back to the Court of Appeals which said action levels as we then defined them were rules and therefore had to be done by notice of comment of rulemaking but upheld our exercise of the enforcement discretion. I think I have got the history right.

I don't remember – what do I remember about that? One thing pretty sharply, a pretty sharp memory which was – two things. Art Tsien, for reasons I don't remember, wrote the letter to the SG [Solicitor General] requesting appeal. Everybody thought it was a long shot, but the SG agreed to take the case to the Supreme Court. And again, for reasons I remember, I remember working on the Supreme Court case. I suppose it had to do with his availability and mine at the time. And there was a fair amount of industry interest in this.

And we put into either the main or appellate brief sort of a grammatical point that I think Olsson, Frank, and Weeda had made about the structure of 406, a sentence in 406, the key sentence. Which I remember thinking was wrong, but was a plausible argument. It got a vote or two, if not four or five, because we won that case, I think eight to one or nine zip, I don't know.

Actually, I remember one other thing about it and that is Bill Schultz in the course of the argument – and Bill is a terrific advocate, but things happen. Somewhere along the line in the argument he conceded that the government's position was reasonable or not unreasonable. And you could hear people gasping because that was the end. This was post-Chevron – it was over. Statutory interpretation, he is conceding that our position is reasonable and that was it, that was the end. Bill Schultz represented the plaintiffs, Community Nutrition Institute.

SJ: Can you clarify Chevron?

ML: Chevron deference? Basically, if a statute is clear as clear can be, you are stuck with it. If it's not – is the agency's interpretation reasonable? And somehow or another Bill came, either conceded or came close enough that it didn't matter, to concede that there was some ambiguity and the government's position was reasonable. It was just all over. I am not kidding,

there were audible gasps – I mean, it wasn't a scream, but you really could hear people saying – what?

SJ: Well, maybe he was being honest?

ML: Yes.

CC: You mentioned Bill Schultz, and he is now the General Counsel of HHS. One of the things about the Food and Drug bar is that it's a small group and lawyers often oppose former colleagues, which I think makes it a little unusual. This really isn't a question particular to Bill, but about your interaction with him and other people that were colleagues and then were on the other side.

ML: I think the quality of the interactions had less to do with whether people were former colleagues than whether for one reason or another, and that could be a reason, you came to trust people in a special way. I mean, I remember learning fairly early on from people who were senior to me in the Office of the Chief Counsel sort of who to trust and who not to trust on the outside and for very special purposes.

So for example, one might reveal what could be said to be a client confidence to lawyer X on the outside who would do the same and you would do that because you trusted each other and you concluded that that would help the two of you achieve something of mutual benefit to your respective clients. So you would learn there were people like that you could trust and there were people you could not trust at all. And I don't know if there was any particular – one might think there would be some connection between a former colleague -- somebody you actually worked with in the office – as opposed to someone you never worked with in OCC, but I can't say I found that to be true. Not that it was particularly false, but not particularly true.

SJ: How does a lawyer decide to make a shift? You shifted out of devices to do other work. Were you shifting on the basis of being a litigator and they needed litigation done in a particular area, or had you tired of working with devices?

ML: Okay, I had had enough of devices and for all I know, devices had had enough of me. At the time and it was certainly true for a long period of time and it may still well be true at

OCC, the Chief Counsel would from time to time issue calls for expressions of interest in doing particular types of work. And of course, one was always free to say to your supervisor or the Chief Counsel --it was a relatively small office -- I would like to do such and such work. And I remember asking to do CVM work.

I did want to get out of devices, I did go back to litigation and I did some litigation for CVM, some administrative, of which was nitrofurans was the first big one. And I also did some work involving interim marketed sulfa drugs and that sort of became an entree, got to know people better in that Center and wanted to do work for them. And then ultimately there was either enough work or someone doing CVM work moved onto something else, so I moved into that.

CC: Well, talk about nitrofurans a little bit.

ML: I guess probably my two best experiences as a lawyer were CNI vs. Young in the Supreme Court on one hand because I got to work very closely with the Solicitor General's office – in fact, I wrote the reply brief, which is extremely rare now. The Solicitor General's office did with that reply brief what it apparently does with every brief written by anyone and given to it, which is thank you very much, this is very nice and then goes off and writes its own brief.

That's what they typically do, they get their initial briefs from civil appellate, thank you very much and now we are going to write our own brief. But it was recognition of my expertise in the area and it felt good and I had a great time writing it and then they set it aside. But it was okay because I understood that's what they did.

The lawyer there was wonderful, he was a guy by the name of Paul Larson, who was relatively new to that office, really smart, and I never met anybody who could work as hard. This guy was reading legislative history at 3 in the morning. And I was treated well by a couple of Deputy SGs, I was down there enough working with them and got to know them a little bit, and it was just a wonderful experience. But mostly by myself, sometimes with Paul, sometimes with somebody else. Ken Geller was his name, was one of the Deputy SGs, Larry Wallace was the

other one. I think Ed Needler has now argued more Supreme Court cases than anybody on the planet, but at one time, Larry Wallace had argued more cases than anyone on the planet.

The other one was a much more sort of team experience which was nitrofurans. I mean, there were six or seven of us, Bob Spiller was the other lawyer, Dick Geyer, another OGC colleague, did a couple of witnesses for us I think on economic cost, but basically it was Bob and me for OCC [Office of the Chief Counsel] and then five or six people from CVM [Center for Veterinary Medicine] -- Charlie Barnes, Nick Weber, Judy Hauswirth, Suzy Fitzpatrick, Bob Benson. Suzy and I remain friends to this day, it's 30 odd years later. Charlie Barnes was our methods guy, I think he was a residue chemist and Nick was a chemist. Suzy, I think at that time, was functioning as a compliance officer and not as a toxicologist. I think the toxicologists would have been Judy Hauswirth and Bob Benson. Benson was I think a chemist by training, but SOM [Sensitivity of the Method] was his basically.

SJ: And this group worked together closely on the hearing?

ML: Yes. I mean, we worked – at one point, close to three straight months seven days a week and it was nonetheless a great experience. Really we gelled as a team, not that people didn't lose tempers -- I did -- and tell each other off, they did. I remember Bob Spiller came in one Saturday or Sunday in the midst of what I think was three solid months of work. Joanne Spiller, Bob's wife, comes in with [their son] Christopher – I don't know that Steven [Spiller] was born yet. And Bob announces they are going out to lunch and people just kind of lost it – what do you mean, you are going out to lunch? We aren't going out to lunch; we are here to work. And it was a long haul. I mean, it was a long period of preparation once the hearing notice was issued, the hearing itself went on for a while. It was a fairly long period of doing a post hearing brief. My mother died at that time, which would have been February '87. I knew by the fall that she was terminally ill, so it was a very hard time. But for personal and professional reasons, it was the best group experience I ever had.

SJ: Would you summarize the issue of nitrofurans?

ML: Well, there were four compounds that were used in poultry and swine that were sort of the DES for the poultry and swine industries. And our position that they were all carcinogens and left residues. And so under the Delaney clause and under the general safety clause, they had to be removed from the market.

They had been approved I think circa 1950 and if you went back and looked at those at NADAs, you find a quarter inch of material. But they had been extensively studied and a number of bioassays, carcinogenesis bioassays had been done, I think in the late '60s and early '70s. I think the first time the agency issued a Notice of Opportunity of Hearing was circa '72.

I fell into this in '78 or '79 when I arrived. The managers concluded, probably wrongly, that as a relatively new lawyer but with some dangerous amount of knowledge in the environmental area I should take the lead on whether there was a real environmental issue here. I don't remember what it was. I do remember FDA did not do an Environmental Impact Statement, but we wound up doing this 150 page [Environmental] Assessment, which in those days was just a humongous environmental assessment. Ultimately turned out not to be an issue, but my mucking about probably cost us a couple of years and then the Commissioner issued a notice of hearing and we did a trial.

SJ: Were these drugs removed from the market?

ML: Yeah, the administrative law judge ruled in our favor and we negotiated a phase out period for the drug. I guess the Commissioner did write an opinion. I'm sorry, there was an appeal to the Commissioner by the companies. The Commissioner did agree with the administrative law judge, at least the bottom line. The Commissioner may have reversed or not certain findings, I don't remember. And then I think we negotiated with the companies a phase out period in exchange for their agreement not to go to the Court of Appeals.

SJ: Now we would use our administrative law judge, I presume?

ML: Daniel – Judge Davidson was the ALJ.

SJ: I have always been curious as to how that system works. He is independent?

ML: Yeah, he is assigned to FDA, but he is independent and can be assigned elsewhere and in fact did work for CPSC and some other agencies, I think, because he used to complain that we never had enough work for him, we meaning FDA and he was right, we didn't.

I think he is retired now. I actually had business with him circa 2000 when I came back to OCC. I think this was before Dan Troy. I think there was some Hill pressure/interest in FDA doing more clinical investigator disqualifications. And one of the problems we had was finding presiding officers, people who were knowledgeable and competent in the area. You know, there were plenty of people with the appropriate titles under the FDA regulations, RFDD [Regional Food and Drug Directors] or whatnot, but what did they know about running even an informal investigator disqualification hearing? And these were busy people.

And so I went to Judge Davidson because I knew him. You know, you spend eight weeks in front of somebody, you get to know him and our paths would cross in the building occasionally. So I remember going to him and saying would you be interested in being a presiding officer? There is a provision in the ALJ law allowing for this and you need permission and we had to revise the FDA Part 15 reg, but it is doable. And he said yeah and it was partly again, reiterating a theme which was he didn't have enough work, so would be happy to do it. And he did some of them, I don't remember how many.

CC: I think he had a good memory for lawyers that appeared before him because I was in Montgomery Mall with one of my daughters and he recognized me and introduced me to his wife. And I actually was pregnant at the time I appeared before him. And he asked me is that the daughter? In fact, it wasn't.

SJ: Richard Merrill, just as an aside, had this concern about Judge Davidson wearing a robe. I think he thought it was horribly pretentious. You had a couple of other interesting observations.

ML: Animal drugs I think are worth mentioning. After nitrofurans, presumably after the briefing or somewhere in the '80s anyhow, I worked with a small number of people on a number of interim marketed sulfonamides. CVM had, by regulation, provided for the interim

marketing of a number of sulfonamide drugs. I can't remember why they were thought to be effective, but there was some flaw or inadequacy in the effectiveness data. But as with many regulations the FDA issues, this goes on and on and on.

So at some point somebody at CVM certainly with a great interest in and perhaps with my prodding decided that twenty years of interim marketing were enough. So we yanked the regulation and at the same time initiated proceedings to withdraw, god knows, 100, 150 NADAs [New Animal Drug Applications]. And the regulation that terminated the interim marketing was the subject of a Court of Appeals case that would have been decided in '86 or '87.

It was published and I remember that because I was asked to argue the case, but Michele and I were committed to a vacation in Mexico at the time, so Gerald Kell argued it. The reason I remember the case is that we had considered but rejected the idea of arguing that you could extinguish a license by rulemaking because a license is usually revoked or terminated the way it is granted. The Court of Appeals basically said no, you can extinguish a license by rulemaking in the context of the case, at least that is my recollection of the case.

I was also involved in – this never came to a hearing, but did involve fairly complicated notice of opportunity for a hearing for dimetridazole and some other five nitroimidazoles, which I think were thought to be carcinogenic or mutagenic or both. And then the last, the fluoroquinolones, which was much later, my second tour of duty in FDA. I was nominally head of the team, Bob Spiller and another staff lawyer tried it. And the reason I am mentioning all of this is that every time, and I think this applies to FDA in general, it's not just CVM, the prospect of doing a Part 12 hearing rears its head and the head is always seen, it's not just ugly, but hideous beyond hideous, we can't possibly do this. It will take resources for a century and on and on and on – it's bullshit. It is doable – it is hard, but it is doable. People just don't want to do it.

And if you look at some of the drugs, DES is off the market because of Bob Spiller. That's a major accomplishment. I don't know what resources went into it, but probably an incalculably small amount in relation to the benefit when you consider the damage that drug did. So it is just nonsense – it is just sheer nonsense. It is hard, it is hard work.

SJ: When you put 150 drugs on the market, I mean, you know there is going to be pushback and you anticipate legal action, correct?

ML: What we have is a system, we have a legal system that is much more process oriented than substantive outcome oriented. And so as an example it is very hard to get a license from FDA or an approval, but it's very hard to yank the license and that is the flip side. And typically what happens on the human drug side is if there is enough pressure, people don't fight, it is exceedingly rare. A little less rare on the animal drug side. On the antibiotics, there's this voluntary approach, I hope it works.

I mean, we will see, but my point with these examples is it is not as if that could not have been taken on five years ago if we really think we could prove the science of the antibiotic resistance. It could have been taken on and it would not have required a small army.

CC: Maybe you will react to this: part of the problem is there's a cadre of people who work on a hearing. They acquire skills about how to do it as well as the substantive knowledge and then there's no other hearing. Bob Spiller is the exception in being a lawyer that did more than one hearing.

ML: I think it is part of the problem, but my point is that the work is not impossibly difficult. If it's important enough, you just do it. You're not going to lose thirty people for a year. You may lose three or four people for a large chunk of the year, you know. Fluoroquinolones is interesting of course because there were warnings about it at the time it was approved. Within a few years of its approval, I think, we proceeded to withdraw its approval.

SJ: And I know you didn't have a lot of involvement in that, but could you just identify what the particular public health/scientific issue was?

ML: It was antibiotic resistance, theoretically, at least. I mean, the belief is making antibiotic drugs less effective in humans than they would otherwise be.

SJ: And this was used in poultry?

ML: I think that is right.

SJ: I want to go ahead and move maybe a little further down your career path. Why did you leave the agency for a short period of time?

ML: I left in ’92 or ’93 and came back in January of 2000.

SJ: What prompted that and what brought you back?

ML: Two things prompted it, really. One is the desire to do something different. I had been at FDA for fourteen or fifteen years as a staff lawyer. And I remember at the time looking at people occupying management positions and it was relatively flat at the time – there was a Chief Counsel, which is political, and a deputy and which you could think of it as the principal deputy, and then a deputy for litigation and a deputy for regulations and hearings. And the people occupying those jobs had been there for some time.

I don't know, Rick [Blumberg] was relatively new in ’92 and I left in ’93, but he was not much older than I was and clearly was going to be there for the duration. And so there weren’t a lot of opportunities to run something and that wasn’t going to happen. So that was one reason. And the other was money, I just wanted to make more money.

SJ: And you were a 15?

ML: Yes, I wasn’t a 15/10, but I wasn’t going to make appreciably more money if I stayed the rest of my life, so I left. Actually I left – those were the reasons, I didn’t beat on myself to look. I got a phone call in the fall of ’91 or ’92, I don't remember when it was, from a firm I had never heard of and it turned out to be a West Coast high tech firm looking to build a biotech practice. In the course of nine months and flying out there a couple of times and talking to people in its D.C. office, I decided to go, so I did.

SJ: And how was that experience working on the other side?

ML: It was good. I mean, I made some money, which I wanted to do. I got to see the world from a different perspective, which was extremely useful. Interesting, intellectually interesting, and useful to me as a lawyer. I liked both firms very much and was particularly fond of various colleagues in the second law firm. I mean, the law firm model is pretty simple, it’s you have got to get the business, you have got to do the business, you have got to bill for it, you

have got to collect on what you bill. So a very simple model. I mean, there can be all sorts of variations and people are experimenting with things other than the billable hour, but the basic model remains the same, you've got to get the business. And you are selling your time – your time, your expertise.

I did not like the getting the business part of it and was not terribly good at it. Was not forced to do it, I was a full equity partner, but basically a service partner with a small book of business. In retrospect, probably not a smart thing. I mean, I was treated well enough, but ultimately if it's not your client you don't get to call the shot if it gets sticky. I can't say I had any particular problems, but that is sort of the way things work. And I had some very interesting projects but by and large I think the stuff was more intellectually interesting in the government.

When Jeff Springer was going to step down and that deputy position in OCC opened up, I decided to apply – it was a logical position for me given that I had wanted to do something different when I left in ' 92 or '93. I wound up running Fenwick and West's D.C. office for a couple of years or at least the human relations part of it, the rent and equipment were the responsibility of a colleague of mine, both of us were of counsel at the time. There was a change of leadership in the D.C. office and we kind of – tag, you're it. So the opportunity to come back to OCC in the Deputy position opened up and I remember thinking it was now or never because those positions don't open up very often. So I applied and was selected and came back in January of 2000 as deputy chief counsel.

SJ: Into what position and what did you find to be different?

ML: Well, one difference was that Margaret Jane Porter, the chief counsel at the time, placed a huge emphasis on vision and values, (perhaps called values and vision?). It was among other things an effort to make the place more collaborative than it was perceived to have been. I mean, in the time I was there I never found it to be particularly competitive or people not sharing information. I am sure there were disagreements among managers, but in my experience they certainly never got really bitter. I think the office was small enough that even a newbie like me

would have known. And as the years wore on and it got larger and I was more senior again, I think I would have known.

I think Margaret perceived some problems that she judged needed addressing. There certainly were some problems with the managers not getting along and I remember hearing about it from the outside so she brought in some people to help with that. I don't know whether that morphed into a larger effort or she had a larger effort in mind and that was the first step. That was new. Although I will say by the time I was there I think there was not a whole lot of energy for it. There was this small committee that met fairly regularly and tried to attend to various problems.

SJ: How many lawyers are we talking about at this point, roughly?

ML: I would guess 80 to 90. I don't think it was 100.

SJ: That is a tremendous growth from when certainly you and Catherine started there. I have heard said about her tenure that she was shifting things into more into an advisory role and employing more of a staff lawyer model.

ML: Yeah. I had worked under her for a number of years and I can't remember any –

SJ: Well, with that many new lawyers, with that many lawyers, you have got to have a new way of organizing, I would think, and managing. And still just having one deputy seems like –

ML: Well, there was a principal deputy, although not called principal, and that was Jeff Springer. And then there was Ann Wion as the hearings and regs deputy and Rick Blumberg as the litigation deputy. There were no deputies at the intermediate level, what I came to call an intermediate level manager, below Rick and below Ann. I mean, I think what happened with Margaret Jane Porter, she became more interested in management, in coaching, than in law. She was a fine lawyer, but I think as her career evolved in the federal government that is what she became more interested in.

In fact, when she was removed as Chief Counsel for political reasons-- George W. Bush came in and they moved her out and she went to the immediate office downtown – I mean, two

things happened. One, she went FEI [Federal Executive Institute] for a year, and I think that was sort of to develop, in part to develop, coaching skills because that is what she wanted to do. And then when she came back, that is kind of what she did in the HHS Office of General Counsel before she retired. So it may be partly a function of size and partly a function of the office as it grew under her and partly a function of what she perceived as not working well. But I think it was also her interests which had evolved.

SJ: What challenges did you immediately face?

ML: I think one is fairly conventional or commonplace, which is becoming the boss or supervisor of people who used to be colleagues. So people have expectations that you may not be meeting, may not be able to meet. People might have felt threatened because Jeff Springer is a terrific lawyer, but was not very active towards the end of his career in the practice of the office. He was largely, I think his principal role was hiring, which he did really well, but I think he devoted a huge amount of energy to that and was not deeply involved in a lot of the substance of the office. I think when I came back it was okay, what the hell is Mike going to do? I have had my niche for X number of years now. So I think that provoked some anxiety.

CC: On Jeff's part?

ML: No, because Jeff by then had been moved out – I think some on Rick's part and I'll get back to that in a minute. And I think it was a little hard for Ann, who was very gracious but had competed for the same job and not gotten it and that is never an easy conversation. I think where this manifested itself with Rick -- and Rick and I were friends before I left OCC in '92 or '93, and remained friends until he died. He had not had much of an interest in generic drug litigation and had not made a secret of that fact. As he would put it, he didn't give a ****. So people started coming to me because they wanted someone to talk to who they thought might have something to add even as a sounding board.

It was some time after that he became more interested and I think it was because he had in a sense been able to get away with not being interested. I don't think people were going to Jeff for whatever reason – Jeff is a terrific lawyer, but I don't think people went to him about these

issues. I don't think they were going to Margaret with these sort of random issues and so the staff lawyers were doing the work and that was the end of it.

Generic drug litigation hadn't been of interest to Rick and I think he felt odd, and maybe somewhat threatened – okay, if this is step one, what is step two going to be? So there was some of that sort of integrating into a place that I had known pretty well and people knew me. Most people – obviously, there were a number of new lawyers in the seven years. I mean, other than that, I mean Margaret was great. Her conception was that the job would be sort of quasi-civil service and that at least as things stayed that way, she would leave and I would become chief counsel. So we doubled up on almost everything and most every meeting that she went to and I had any interest in or she thought I ought to go to, I would go to. That, plus she had me do a lot of budget stuff which was really useful.

SJ: So you weren't really doing much litigation at this point?

ML: No. I mean, at that level you shouldn't be. The second firm I was with was run by a wonderful lawyer, incredibly smart, fine person, who once told me he held onto a case or two after he became chair. He was a major anti-trust litigator, national reputation, and, I learned from him, was roundly criticized by the partners for not immediately giving up all his cases. Because, they said, you are running a $300 million dollar business, we don't need you trying anti-trust matters or whatever he was trying. And they were right, he knew ultimately they were right.

And in fact I remember when I came back, a case upholding a provision of the statute concerning industry dissemination of information about unapproved uses of approved drugs. I have long since forgotten what provisions or when they came into effect, but they were in effect by 2000 and it was litigation over their constitutionality. And the government offered a reading which essentially stripped out enforcement.

So if you see the statute, it imposed requirements if industry wanted to disseminate information about unapproved uses; disseminate without meeting those requirements and you were in violation of the law. The government read that out so basically it was a safe harbor with

no penalty for leaving the safe harbor. And we were trying to figure out exactly what the decision meant.

The D.C. Circuit issued its opinion I want to say January, February of 2000. And we were trying to figure out what to do, what do we tell the world? So we did a Federal Register notice which I took the lead in drafting. And a former colleague, Linda Kahan, who at that time was the Deputy in Center for Devices said do you really think this is the kind of work you ought to be doing? And it was a subtle way of suggesting that it wasn't, and I think she was right.

There wasn't much harm because it didn't take me that long to do the notice, but a point well made. I mean, the only -– tension is too strong a word -- but I remember as kind of the source of some tension was we had decided to increase the number of managers, to add two or maybe three, but I think two on the counseling side and one on the litigation side. And we got permission to make them SES and we advertised and we competed and the tension basically was who was going to make the choices, was it Margaret Jane Porter or me.

In retrospect why I ever thought it should be me I don't know. Her career in OCC was winding down but there was no guarantee I was going to get the job and besides, she was Chief Counsel. If she had announced she was leaving the next week or the next month, okay. In any case, they had hired a guy named David Coleman, who was a psychologist, but they hired him as a coach. I guess he had been brought in because the managers before I arrived had trouble getting along and he was trying to sort out what was going on.

SJ: He was also a lawyer?

ML: No, I think by training a clinical psychologist and I think at that point in his career maybe had patients, but he was certainly functioning in the government as a management consultant, advisor, coach. So I remember talking to David a good deal about this issue of who is going to decide and I am sure he was talking to Margaret Jane Porter about who was going to decide. In any case, she quite generously let me decide. And it made a difference because she had different views about what qualities were important.

I mean, we had a candidate she had wanted to apply for one of the jobs or I should say a potential candidate. The person had not applied and just decided not to apply. Well, Margaret Jane Porter wanted to reopen the whole thing, which a number of us thought would have been unfair. There had been plenty of time to apply, nobody came asking for more time so it sort of sorted itself out. Or I should say I think David helped sort it out.

CC: And how long did he stay?

ML: He was on contract. I think he had worked with Rick, Ann, Jeff, and Margaret to help them function better as a group. And when that started I don't know and when it ended I don't know, but that was sort of kind of the prelude to Margaret's suggestion that I work with David. That was fine, he was very good. And actually I remember having lunch with him at some point well after he stopped working with us and he suggested that I might do well to think about doing something other than law. And within a year or two I got moved to CFSAN – it all worked out quite well for me. Not what I had anticipated.

SJ: Did he say why he thought that you should be doing something else?

ML: Just that it might interest me, just something else to do. At least as I remember lunch, it was nothing about having failed or not a prediction of failure, just I guess maybe observing me and thinking that maybe I would run that stream.

SJ: I know what I was going to ask. I try to get gauges on this because honestly, my records are kind of weird. When you left the agency was not computerized. Now I don't know if the Office of Chief Counsel was or not, I would assume you guys would have been one of the first to get desk station computers or whatever. When you came back there certainly would have been, right?

ML: When I left there was certainly no email in '92 or '93. But there were, lawyers had their own, not a PC, whatever the heck they were. I didn't do my own word processing, but a number of lawyers did, maybe even most sort of engaged. I used to use my little stickies and that's how I used the screen, but I distinctly remember having one.

SJ: But it was definitely a word processor?

CC: Our first word processors for individuals – the secretaries had Wang I think or – not Wang, what was the other one?

SJ: Lanier.

CC: Lanier. But then we were going to get individual desktops and what they got us instead of word processors were computers but we didn't have communication function. But I started doing foods work in '88 and at some point I got hooked up to the CFSAN system -- CFSAN had some email communication -- but I don't think it was in '88, it might have been around the time you left.

SJ: I am trying to get a timeline down a little bit better. That was one of the conditions of me being hired, as a matter of fact. I worked for Lanier Business Products for a while in Atlanta before I went to grad school. And that was one of the conditions of me coming onboard was that I get my own computer. In fact, Ron Chesemore at that time had one and so this was a big deal. So I ended up getting his secretary's word processor and I do think I was probably one of the people that pushed it along at ORA because I made that a condition to employment which seemed perfectly normal to me, but apparently really was unusual.

ML: I have a strong recollection of having a small monitor and using it – full of stickies.

SJ: Post-it notes, yes?

ML: Yes.

CC: Well, at some point, I know I acquired some knowledge of the Lanier and there was one Lanier that was about the size of a small refrigerator that had a printer on top of it. And they were going to get rid of that one and I got that one in my office so I could start doing my own – I was sort of the counterweight to Mike. But I can't tell you when that was.

ML: When I came back it was closer to four years than three and I have got to say I don't have a really strong recollection of that period. I mean I remember being acting chief counsel, but I couldn't tell you what came up. I remember when Dan [Troy] came. I mean I knew there was no chance –it was worse than a snowball's chance in hell that I was going to

become chief counsel. It simply wasn't going to happen. But I still remember however small the levers of power as acting in that circumstance, I remember it was hard to give it up. I remember a few instances of unpleasantness with him. A couple of them were really just, I guess a function of the relationship that wasn't very good. I will give you an example. He wanted a special assistant and it wasn't a practice in the office for most of its history, but he was chief counsel. So he brought in one person who had worked with him at his law firm and I think it turned out she wanted to work three days a week and that wasn't going to work for him. And then he brought somebody else, who he ultimately hired and I remember saying to him I thought she would be fine as a staff lawyer, but really wasn't, didn't make sense [as a special assistant] for various reasons. And then I remember he polled sort of the group and I said the same thing and he came in just livid because he thought I had changed what I had told him. And it really was based on a misunderstanding. I mean, maybe I hadn't been as clear, but certainly in my own mind I had been clear and fully consistent. However, he became very angry one or two other times, over relatively small stuff.

On some First Amendment notice there was some rush to get out, I am sure it was, in retrospect, for political reasons and someone above him was interested in it. And I said we really should give people more time to comment internally and he came in, again, very angry, I mean way out of proportion to whatever offense I had committed.

And the final one was probably the final straw – I shouldn't say probably, it was the straw that broke the camel's back. I had taken upon myself to write, on 90 plus percent of my own time, a First amendment analysis of various FDA programs. It was like a 90 page memo which I had shared internally for comment, not with him, until it was done. And so I gave it to him a day or two before I left for vacation thinking he would have time to digest it. I mean, what's the big deal, I hadn't sent this anywhere outside the office. I came back and he was just beside himself and issued a memo.

SJ: Now do you have a copy of the paper that is releasable?

ML: I honestly don't know. What I probably don't have is a copy of a note he left me saying I was not to do any substantial writing again without his prior permission. It was just – I think it was borne of his fear that I was going to send this out publicly or something because there had been, I think some of his advice perhaps, written advice, I am not sure about this, to devices had been divulged to the Hill and he had been called up to testify.

I don't do business that way, I have never done business that way; if I wanted to embarrass every administration I have worked for after my early years, I could have done it. We all could have done it as lawyers, there is always something floating around that makes people look silly because we are all silly, occasionally. I just don't do business that way.

But he was just – that was kind of the beginning of the end. He left me a note saying you are not to do any substantial writing without my prior permission. And yes, I had not engaged him on this paper I was working on, but he was going to be engaged. What I presented him was a draft, not a final piece for publication, circulation or anything else. I thought the office then and maybe to this day had been remiss in never trying to take a look at First Amendment issues before they all arose.

SJ: I remember going to a Food and Drug Law Institute meeting during that period and seeing a mock trial on First Amendment issues. It was very enlightening and it must have been around the time that you were, you had been doing work related to it. I will have to look the year up on that, but it was fascinating. So clearly whatever you had written or whatever was being talked about had taken root by that point.

ML: I don't know, it was just a strange. I honestly didn't have it in for the guy. I mean, I think we all have our reasons and I am sure he had his for his reactions to me. And you know, I would not be surprised if he could point to things that I had done that I would say in retrospect were out of order. But the three I identified were just not in my view. A couple were the product of misunderstandings and some to this day that I don't understand. Yeah, I wrote the memo without telling him. Why would I tell him? It was almost entirely on my own time, I wasn't

hiding it, he got the product in the form of a draft, what do you think about this, can we make some use of it?

He was very upset and it manifested itself in this note. And then ultimately they moved me out and there's no question that it was Dan and it was Alex, Alex Azar, who was the [DHHS] General Counsel. It sure as hell was not Lester Crawford, who was the Commissioner – he could have cared less. Crawford had no interest in sending me anywhere; he was directed to do this.

SJ: To go to CFSAN?

ML: Well, they wanted me out and Lester Crawford asked me a couple of times about would I be interested in going, I think, to CFSAN, maybe it was Bob Lake's job because Bob was going to be retiring. I said I was flattered but no, I want to stay in OCC. There was at least one such conversation, maybe two, I don't think three – probably two. And then I get an email one day, an email from Crawford saying, "as discussed, I am reassigning you to CFSAN" because I think you would be better able to meet the agency's needs at CFSAN, blah, blah, blah. There had been no such discussion.

SJ: Because you are SES, they could do that?

ML: Right, but there had been no such discussion. He had asked me a couple of times if I wanted to go, I said no and then he wrote this – he didn't write this email, someone wrote it for him. And so I wound up asking Alex Azar to, I guess, I asked Alex if he concurred because I guess technically we were his employees. I guess in my position as deputy, I am trying to think of who paid me, for sure I think the Chief Counsel is paid by the Department and all or almost all the other lawyers are paid by FDA.

In any case, I found some reason to ask Alex Azar to either reconsider this or to talk to Crawford or do both. Alex was plainly not happy. We met and it was all very civil, but it was plainly not what Alex had in mind.

SJ: Intervening?

ML: Yes. In any case, if he did talk to Crawford at all, it was to no avail, no big surprise, and I was moved to CFSAN. Bob Brackett was the Center director and I was moved

over. They created a second deputy slot. There had been one deputy, Janice Oliver, and they created a second deputy for regulatory affairs and that is what they moved me into.

CC: Any understanding of why CFSAN versus anywhere else?

SJ: Or any speculation?

ML: The only thing I can think of, a couple of things. One, I had been pretty heavily involved in qualified health claims. And whether Mark McClellan wanted to do this or was directed to do it, I don't know, but there was some initiative, more information for better consumer health, I forget what it was.

There was a report and I was on that committee and I was probably one of the first authors because CFSAN basically just decided it wasn't going to play, even though by this time there were several cases involving qualified health claims. So I had been pretty heavily involved in that. There was also an obesity initiative, a report, a committee and a report that I was very heavily involved in that.So I mean, I suppose that was a fit. It may well be that to the extent I had stuck my nose into unapproved uses and First Amendment issues and litigation issues, they wanted me out of that, I don't know. The very last thing I remember was, there was 9th Circuit litigation about, all I can remember is that it involved, in some way, drugs and the First Amendment, very broad. And there was some discussion internally about whether to cite a D.C. Circuit case which was helpful to the government's position in the 9th Circuit case.

I remember writing the email saying basically 'I know it's the D.C. Circuit and the 9th Circuit certainly isn't bound," but I thought it would be unethical not to cite this case and to make something of it. It caused quite a stir. A meeting that had been scheduled by Dan to discuss the Ninth Circuit case was cancelled. A couple of people sent me emails saying you're really being brave. Of course by that time I knew I was going to be moved out so there was no bravery involved; there was nothing for me to lose.

If my memory is serving me well, it was his special assistant who was leading the charge in favor of not making anything of this D.C. Circuit case. I think it was because they would have preferred, in their perfect world, the government to have lost the case in the 9th Circuit, or for it

to have issued a favorable decision on the grounds most restrictive to FDA and I think I said, Yes, you are right that the 9th Circuit is not bound to follow what the D.C. Circuit says, but it is sheer madness to represent a client when you have a case that is helpful and not cite it. It is just totally inappropriate.

CC: Maybe you want to just elaborate on the – I think, whether it's not the code of professional responsibility *per se*, but the obligation to cite to a court precedent, adverse or otherwise. And it certainly goes to the credibility of the remainder of your brief. So mean, this wasn't making something of nothing.

ML: And I had also had a – before he came to FDA, Dan had represented or his firm at least had represented a plaintiff suing FDA over a regulation I think requiring pediatric studies under a fairly broad reading of intended use and the district court had ruled against the agency. And so Dan was recused from working on any appeal.

And at one point I instructed his special assistant to stay out of the case. She had not been involved but had been involved in related issues with HHS OGC. And so I said you are a special assistant, for his sake, you just can't be anywhere close to involved in this case.

SJ: Did you have any sense that Dan did have his own – he was a political appointee so he is entitled to his perspective, but did you get the feeling that he was really pulling us in an identifiably political direction?

ML: He was one of the higher ranking politicals, along with Amit Sachdev, who was head of legislation at the time, and Crawford. Crawford is a bright guy but my perception was that this was a reward to him for years of service, including at USDA. And so I think Dan and Amit, my perception at the time, they were the sort of political powerhouses of the agency more than Crawford. McClellan may be a different story.

SJ: But there was more overt political machinations going on, say, than there was with Margaret Porter.

CC: If I can just interject, when Mike and I were hired, Rich Cooper was a political appointee. He was followed by Nancy L. Buc, who was a political appointee and then Tom

Scarlett. However, during Scarlett's tenure, the Chief Counsel position became a civil service position and Margaret was civil service, not a political appointee. At least this is my understanding because I remember asking Tom about his status when he got the boot over the generic drugs scandal. And when Dan came, the position was made a political appointment once again.

ML: I think what happened over time is political edges have become harder. I mean, I knew vaguely that Rich Cooper had been a partner at Williams, Connelly and Califano, and Califano was Secretary of HHS. Califano, I think he had been in Defense and Rich had worked for him there maybe, but certainly that was the connection.

CC: Definitely Democrat.

ML: But I never knew until very late in the game that Scarlett was not only a Republican, but pretty conservative. It just wasn't an issue in the office. I mean, nobody ever asked an incoming, of people applying or looked for signs that they were members of some Democratic interest group. Whereas Dan was thrilled to see – people obviously figured out if I write on my résumé that I am a member of the Federalist Society or the American Enterprise Institute or whatever, that was a big plus because they had the "correct" attitude towards government. That was never in my experience part of the office until Dan got there. And I don't think it was because I was – it's true I was in a much higher position, but it certainly wasn't under Margaret Jane Porter and I don't think it was when I was a senior lawyer as opposed to junior. Were there more sort of Democrats than Republicans? Probably, but nobody cared.

CC: Nobody took a count.

ML: Nobody cared. Nobody thought for a nanosecond about Tom's politics. There was work to be done and the law is the law – you give your best advice re: what is and is not legally reasonable and/or legally defensible -- and one serves the client.

CC: I do remember at one point during Dan's tenure being somewhat taken aback when I realized that his mug had the Republican National Committee logo on it. And he freely used it in the office.

SJ: It was somewhat jarring to see it, I guess?

CC: Yes.

SJ: What would be the driving force to get him in, does anybody know, to get Troy in? Somebody would have been pushing for it -- he certainly wasn't known to the Food and Drug law community.

ML: I assume somebody decided that the Food and Drug Administration needed to be reined in, similar to the way, if there is a Republican administration in 2017, it will reign in EPA.

SJ: Could you talk to us about the situation with CFSAN. We have interviewed Joe Levitt but we have not interviewed Bob Brackett yet.

ML: Well, as I say, I was sent there. I think Brackett was happy enough to have me because of my experience as a lawyer and because of what I knew about Parklawn. Well, it just hadn't been his experience so it was useful to have someone who had some insights into what went on at OCC and the Office of Policy and Legislation and the Commissioner's Office. And I will say that, with one exception, whatever skepticism there may have been about how I would fit in, I know there was some, none of it was voiced. People were just willing to see how it worked out.

The exception was someone who again, this happens, someone who felt threatened by my ties to OCC. At least initially instead of wanting to take advantage of them was worried that I was going to take over an area, which was not my intention. Ultimately the person was assured, but there was at first great concern. But that was the only exception, there may be others, but that is the only one I observed.

The one thing that I remember from my early time there was that Dan had assigned a lawyer to work on a guidance about the meaning of "structure/function" language in the drug and device definitions. And Dan, I think before he came to the FDA, was part of the tobacco litigation, had wanted, as his clients had wanted – it doesn't matter, he came to want a reading of that language that included intended therapeutic or medical benefit. I disagreed with it. And I

got a chance as the client to comment on the guidance, which was circulated in draft form to the Centers.

SJ: He couldn't say anything about it?

ML: I was commenting, as requested, as a client. And they were fairly obvious points. I mean, if there has to be some intended therapeutic gain, what's a production animal drug? DES' principal (maybe only) use as an animal drug was to fatten cattle. Is that not regulatable by FDA as a drug? What about a breast implant if it is non-therapeutic? Some are therapeutic in a sense, but plenty are not. What about a scalpel? I mean, there are scores of examples which I of course wrote down in my comments on the draft.

CC: Dutifully counted.

ML: With great delight. Not to mention that there is a DES proviso in the statute. That had to have meant something – Congress knew it was used as a production drug. So that guidance never went anywhere, but it was a little Walter Mitty-ish being able to write for the Center this fairly extensive set of comments and circulate them to other centers, of course, before I sent them off. I think what happened is that he was, and I think this is true for OCC in general, in a position to stop things, but not to force things out.

SJ: That is a very good observation.

DR-100-0026

SJ: Our research shows that you started at CFSAN on August 4th, 2004.

ML: Could be, it was very early in the month, that I remember. When Crawford sent me the email saying, "as we discussed" and reassigned me to CFSAN, I don't think they had given any thought to how much notice I was entitled to, or what form of notice. So I went to talk to the head of management, Jeff Weber. I said look, I understand I am moving, this is after I had spoken to Azar and asked him to intervene and that had failed. And I just said I want to talk to

you about a start date, so Jeff Weber and I worked out a start date which was early August of 2004.

CC: So when did you get, about when did you get the notice you were being moved?

ML: The first or second week.

CC: I ask only because I think there were no rumors until the official email announcement.

ML: No, I had a head's up or did I have a head's up? I guess the answer is I didn't have a head's up. I mean, I subsequently learned that there were a couple of people who knew that it was coming and chose not to, for better or for worse, tell me. Actually one of them may have told me something beforehand, one definitely did not.

CC: In OGC or just in the agency?

ML: One in and one out and then I knew a number of people, I knew enough people to find out sort of the obvious that it was not Lester Crawford driving this.

SJ: And who took over for you in the agency?

ML: I think Jerry was brought in pretty quickly, Jerry Masoudi. He had been at Justice, I think. I am not sure, but he was brought in pretty quickly.

SJ: My impression was that when PDUFA [Prescription Drug User Fee Act] came along in 1992, there was a sort of perfect storm in CFSAN. You had people who were eligible for retirement and FDA had to show that it had money invested in the human drugs program and that that had a huge impact on CFSAN. And of course Joe Levitt worked really hard to use re-orgs and get things back on an even keel. But that's a gross over-simplification –

ML: By the time I got to CFSAN the user fee issue had pretty much dried up. And we were during much of Brackett's tenure dealing with cuts, in fact, for two years in a row we had to pay people to leave. I forget what it's called, you get permission from OMB to do buyouts.

CC: Early out?

ML: Early out. It can be retirement but it doesn't have to be, it can just be leaving for another job or just leaving --here's a check for whatever you are entitled to under the formula. I

don't think it was an unusually large number of people retiring. I think by 2005 or ’06, we were paying people to go. So who took an early out that I remember? Lou and Karen Carson, retired. I mean, they were eligible to retire and they were going to retire fairly soon in any case. Who else? Again, I don't know if these people took early outs.

CC: John Kvenberg?

ML: Yes, John left. Well, during my first tour of duty at CFSAN between 2004 and 2009, [Terry] Troxel left I think in that period, John Kvenberg, I think he retired, the Carsons, Terry Troxel.

CC: Did Alan Rulis leave?

ML: I think Alan left in that period, although I think it was past the early out and he just decided to retire.

SJ: He waited until the Centennial?

ML: Could be. Those are the names that come to mind, there may have been others. I guess in 2009 Janice retired and Laura Tarantino. Because I went back to OCC in April of 2009 and by the time I went back to CFSAN in January of 2010 Laura had retired and Janice had retired.

SJ: Those were huge losses?

ML: Yes.

SJ: Big losses, at least in terms of the institutional memory and experience?

ML: And talent. But to get back to Brackett’s tenure, I mean, my strongest memory of it is really budget cuts and Bob steering us through a very difficult time. I think at the height of the food safety initiative CFSAN had about 950 FTEs [Full Time Equivalents], that’s what I remember hearing. We were somewhere around seven and a quarter – maybe not as a budget ceiling, but as bodies on board, maybe it was 735, I don't know. It was brutal. We were paying people to leave and it was working. I mean, I think 60 or 70 people over the two years in the buyouts left.

CC: You know, as part of my personal development in this position have been reading some of the existing transcripts. And I was pleased and I guess a little surprised to see that in Andy von Eschenbach's interview, he talks about arriving at FDA after Crawford resigned and, seeing FDA's budget and thinking that somebody had left a zero off of the budget, on the left side of the decimal. And he talked about a meeting with all the Center directors in which Bob Brackett spoke up -- and this is Dr. von Eschenbach recalling it -- and Bob Brackett said 'we are so over doing more with less' or something to that effect. I thought it was interesting that Bob was willing to say that, particularly given what was going on at CFSAN as opposed to Drugs and Biologics where they had the user fees.

ML: They were relatively quite comfortable.

SJ: Do you remember any particular cuts in particular programs?

ML: I think my guess is that Compliance and the Office of Food Additive Safety probably went down substantially because OFAS had had at one point 140 FTEs and I think they went down to around – I think it was 110-115 or something, but they went down quite a bit.

SJ: Was there any reason for that in particular?

ML: It was one of the larger offices. They only have two mandatory programs -- food contact notifications, which runs sort of like clockwork, and food and color additive petitions, but we don't get a whole lot of those. The GRAS [Generally Recognized as Safe] stuff, a lot of business, but it's all voluntary and the same with biotech consults.

CC: The other issue with the food contact substance program is the way that is set up legislatively. There has to be a certain amount budgeted and if that is not budgeted, the program doesn't operate. I only remember that because I believe that by then Laura Tarantino was the Office director and her predecessor, Alan Rulis, put this program on the table for cutting, and I think she was pretty taken aback by that. And I think people legitimately thought that was what was going to happen.

ML: Cosmetics shrank. We actually went to, with Bob Brackett I went to von Eschenbach and I remember Bob asking for permission to zero it out and the Commissioner

wouldn't let us, but we cut it in half. Again, it may have gone from 20 to 10, the non-color certification part of it. And also Brackett reorganized the place. What had happened is that there was a model which dated I think from the early 1990s, from Kessler's time, a model of CFSAN with a bunch of program offices each of which had its own reg writing, compliance, and research capacity. That model probably required a CFSAN of 1500 people.

With all due respect to whoever developed that model, he or she just didn't understand it was never going to happen. And so it was bad enough when the model was stood up, but four years later or a decade later when you had gone from a high of 950 to 735 your chemistry research group in one office might be two chemists. That model wasn't viable at 950 and at 730, it was a joke. So you would have clumps of researchers in various program offices unable to accomplish anything. So when Brackett reorganized the place, we created a research office in the Wiley building and pulled all the chemists and microbiologists and geneticists together. Which saved some number of FTE because there were supervisors – there weren't a lot of them, but there were some who were supervisors no more and the positions were abolished and some of those people tended to drift away.

DR-100-027

CC: Any other thoughts about the years with Bob Brackett as Center Director?

ML: I wouldn't say Bob was the most forceful leader, but my hat's off to Bob for, I think being terrific at giving people information, as much information and as early as he could. I mean, there were some unhappy facts – and I think his candor was appreciated. I remember one all hands where he got a standing ovation after it was over and it wasn't because he was delivering good news, but people appreciated that he told it like it was.

SJ: Because he was being honest?

CC: As I listen to you on different things and sort of go back to that time, I would have been one of the people sitting in the audience during that and I think people did find him credible and empathetic and just what you say. Your perception of how the masses felt was right.

ML: So there were the budget difficulties, there was the reorganization which took a lot of Bob's time and energy and mine and Janice's too. There were efforts to deal with outbreaks. There was more and more information coming to light about foodborne illness and about the source of particular outbreaks, the food source, the bug. And it was actually, it was during Bob's tenure that the Center started to develop – I don't know how far people got -- but were working on regulations for produce safety. I mean, the notion that this all started with FSMA [Food Safety Modernization Act] is a figment of the imagination of a number of people, but it would do a real disservice to people like Bob Brackett. Not me, I mean, I was there, but this was Bob's leadership.

SJ: But was that was part of the packaging issue? That was one reason that you could downsize packaging, correct? Because there were changes made in the safety modernization acts that lessened the requirements for packaging?

ML: No. I'm talking about people – Bob had people start on regulations for produce safety on the farm. This is what's now part of FSMA. This didn't – people were working on that stuff well before FSMA got passed, well before the bills got introduced.

CC: I went to the Center in April 2004, and I remember Bob came to me with something someone had written on produce safety and asked me if I could revise it, condense it, or whatever. So you're right -- as early as April 2004, Bob had staff working on produce safety. And there was a guidance on fresh cut produce.

ML: Yes. And then the Good Agricultural Practices guidance issued - I don't know either '98 or '99 or 2000 or something like that. So, work in those areas started before I got there and certainly continued. But there were major impediments because we had no – we didn't have people and we didn't have money.

CC: I think one of the things that I saw as you mentioned here, we didn't have people. We did eventually acquire some people who had more particular experience in produce and produce safety.

SJ: There was someone who came in that I worked with for a while. British –

CC: David Acheson?

SJ: Yes.

ML: Yes, David – there was - in one of the offices that came out of the reorganization was the Office of Food Defense, Communications and Emergency Response (OFDCER), which was an odd conglomeration of units, put in one place really because of David. David had come from I think FSIS and he was at Tufts before that with I think expertise in food defense, food safety, and emergency response and he was a very good communicator. And so there were again, there was an odd conglomeration in that office.

But OFDCER was established as it was because of David, he was its director. I mean he wasn't – he may have run the food defense team, I forget, before that office was established. And then von Eschenbach moved him up after the 2006 outbreak due to E. coli 0157:H7 in spinach from Salinas Valley. Von Eschenbach moved David up and made him, I don't know, Assistant Commissioner and then Associate Commissioner for food defense or food protection or something. It wasn't too long, maybe a year after that, Brackett left.

CC: And, with the election of President Obama, von Eschenbach left and David I think was moved out fairly quickly.

ML: Yes, David – I'm trying to think – yes, after Brackett left, I think Brackett went to GMA, Sundlof came in.

SJ: And that was when von Eschenbach was still Commissioner?

ML: Definitely, because it's one of those things, you always remember. So, von Eschenbach announces that he wants to meet with the senior folks at CFSAN to discuss Brackett's successor. Whether Bob was still there, and I don't remember, he'd certainly announced his departure. So, Andy is asking us all for what would you like to see in the next director - scientist, industry experience, and a whole range of attributes and experience and expertise. This lasts for about an hour and a half, maybe a little less, and then Andy announces, well, it just so happens I found exactly the right person for you and at that meeting he announces that he has selected Sundlof.

Now personally I liked Andy because I had butted horns with the Office of the Commissioner to the point where he'd complained to Brackett about me a couple of times and I always would circle back with him and say, sorry, I maintain my views, but I am sorry about the way I framed it. And he always said then that, you know, no problem. And a lot of people can throw punches but they can't take them. And he could have squashed me if he wanted to and quite the contrary, he was not unwilling to let me go off the track a year or so later. But that meeting with Andy was really quite something, I mean, he wasn't listening obviously to anything we said.

ML: He had already chosen Sundlof, who had no industry experience and didn't know really much about human food regulation except for the animal end which USDA regulates anyhow. Yes, it was a striking meeting. And then, you know, right after Obama won, they brought Mike Taylor in, I think by the spring, as sort of senior advisor for food. David felt terribly mistreated, I mean, I know from a short conversation we had.

SJ: David Acheson?

ML: Acheson, yes. He felt that he was treated very badly. I don't know the details. He left and then – Sundlof left in roughly April 2010.

CC: May, I have down May in the time line that I constructed.

ML: It would have been April or May 2010, because that's when I became Acting, I came back from OCC. Yes, I went over to OCC in roughly April or May of 2009, to run it as acting chief counsel at Sharfstein's request - insistence might be more like it. I mean, he must have felt that he was drowning because you know, he asked me on a Friday, and could I start Monday. And I said actually there are some things that I have to finish up here and I would certainly be available to you, but. And I was there until January 2010, when Ralph Tyler started. I went back to CFSAN and Steve Sundlof decided he wanted – by that time, Janice Oliver had retired, I don't remember exactly when, but by January of 2010, she had retired. When I got back there, I think – Laura Tarantino was still there as opposed to retired, it was not for a very long –

CC: She'd retired at the end of the year. I think she was gone.

ML: Okay. Leslye Fraser may have been identified as acting. Sundlof wanted – he reportedly said he wanted a one deputy system. What did I know? What did I know, it wasn't my choice. The job was mine unless – well, a deputy job was mine, they would have had to have abolished it and found something else for me. So I came over in January 2010 and by that spring Sundlof was gone and he was gone because Mike didn't really want him. Basically he was pushed out.

CC: Were you present when he announced that he was leaving? Were you in the auditorium? Because it was absolutely clear to everybody that he was not leaving willingly. He sort of finished his sentence as he walked out of the room – nobody had to circulate rumors.

ML: Again, I think I did – I don't know what conversations Mike had with Steve or when. It was obvious watching the two of them in meetings that this was a marriage made in hell. I mean, Mike doesn't like to say no and he will just ask the same question in lieu of saying no. And there was a contract –

CC: He doesn't like to say no or he doesn't like to get no as an answer?

ML: Both. But what I was saying is he doesn't like to say no in this circumstance. We had let a contract with an outfit to collect and analyze huge numbers of samples in order to get baseline data. How prevalent is listeria in X, salmonella in Y, e. coli in Z? We were looking for a needle in a haystack, and so lots of produce samples were required. For whatever reason Mike didn't like that, but he didn't want to or wouldn't stop it and so there would be what felt to many people like endless conversations. And in one of those conversations Sundlof basically said – he didn't say "screw you," but it was basically here's what it is and I've had enough. I mean, it was pretty blunt.

CC: Endless and fruitless conversations?

ML: And in my own mind that was sort of the beginning of the end for Sundlof. I don't know that I thought that at the time, I thought it fairly soon thereafter because there just wasn't anywhere to go.

CC: And what did Mike want to have happen?

ML: I think Mike really didn't want the contract to go forward. It's like whole genome sequencing which is now the rage. CFSAN is a world leader in that domain for foods, period. It is provable. Jeff Farrar, who was and still is in the Office of Foods and Veterinary Medicine, was really skeptical about it, and CDC was really not keen on it (for foods) for the longest time. CDC is now full bore in. Before this is all over, CDC will have created this from the get-go but that is just not the truth. In any case, there were a lot of communications about sequencing, whether and if so, how much in the way of resources should we be devoting to it, etc. So, too, Mike really was not convinced about the value of the contract to obtain baseline data and so you would have conversation after conversation after conversation about it. Mike was skeptical about the extent to which CFSAN wanted to invest in whole genome sequencing generally – equipment, people, time. This work is done principally in the Office of Regulatory Science in the Wiley Building. Sequencers are closer to $ 40,000 or $50,00 now than $ 2 million, but you go back five or six years and you would be spending a million or two for sequences – tabletop sequencers didn't exist at the time.

CC: And Steve really thought this was useful, I guess, or he supported it?

SJ: Who was the advocate?

ML: Well, the advocate for the sampling and analysis, which was a different issue, but Mike reacted the same way. Just to use an illustration, he didn't like all the sampling and analysis, which we were hiring someone to do. We were hiring an outfit to do the sample collection and analysis. He didn't like the amount of investment in whole genome sequencing, but he would never say stop, he would just always want to come back and talk about it.

CC: Do you know what Dr. Sundlof's background was in particular? It seems to me that he might have had some background in genetics.

ML: I mean, he was a DVM PhD so I don't remember what his PhD was in. But the particular meeting I remember was not about whole genome sequencing, it was about this

contract with an outfit that was going to collect and analyze samples of produce using whatever technology and I don't remember.

SJ: When was this the most successful? There were several outbreaks, do you remember which one it might have been tested on and proven? The Office of Criminal Investigations established itself on Pepsi, so was this?

ML: No, there was an outbreak which was – I want to say there was some type of luncheon meat and a red or a black pepper and I think we were able to determine it was the pepper.

SJ: Well, we can certainly go back and check on that.

ML: This technology is this decade. There were other technologies and CDC is still using them, pulsed field gel electrophoresis -- PFGE. But the whole genome sequencing is newer. It has now taken root, it is going to be, it will supersede PFGE. There is no question about it. But again, it is the kind of thing where Mike isn't sold on it and he doesn't say no and that's because he doesn't like to say no. But he didn't say yes either, and so you find yourself struggling. That particular day Steve Sundlof had clearly had enough on the subject of the contract for sampling and analysis and he was not willing to get into another conversation and essentially said "buzz off."

CC: And that was the beginning of the end?

ML: Yeah. I mean, it was an odd moment -- not that we didn't understand his frustration-- but just to be that blunt. It wasn't Steve's style.

CC: I was going to say it wasn't particularly consistent with his personality which is perhaps suggestive of how frustrated he was.

ML: So sometime after that Mike started talking to me about running CFSAN and they gave Steve a deal at the University of Maryland for a couple of years, it was a two year deal under an IPA [Inter-personnel Agreement] or whatever they are called. By August of the same year [Don] Kraemer and [Roberta] Wagner are acting deputies.

I went to see Peggy basically to tell her two things. One, that ideally, I thought a scientist should run CFSAN. But the scientist has to be able to lead and manage, it's not enough to be a scientist. I also told her that I thought Don and Roberta and I were doing pretty well at stabilizing CFSAN and it was important to let us continue that until the end of the year. So if they were going to make the change I would both advise, I would advise, request, and appreciate it if you would wait until December, January – a perfectly pleasant conversation. But it took her another year, it took her 19 months to get me the job on a permanent basis and I think part of what happened is that Mike approached me about taking the job without talking to her first. I don't know that for a fact, but I think that it is true.

CC: Well, would she have any reason to object?

ML: Well, first of all, she might have wanted a scientist and might have had someone in mind, I don't know. Second, just as a matter of protocol. Yes, he's the Deputy Commissioner and the Center Director reports to him, but she's the Commissioner of Food and Drugs. Also at that time I don't know that the Directorate had even been established.

CC: I don't think so. I think that happened after I left, that reorganization or near the time I was retiring.

ML: Most of the rest of the history for me is FSMA [Food Safety Modernization Act], FSMA, FSMA, and also trying to find dollars and people to do other things.

SJ: Other than FSMA you mean?

ML: Yes. I had this debate with Mike, I've had it with Mike in front of Peggy. I have never had it publicly, although I am hoping to soon. The numbers don't lie, there are far greater gains to be made in public health in this country from doing better nutrition than FSMA for the next 100 years. The figures just don't lie.

If you look at partially hydrogenated oils alone, just assume that all the estimates from CDC are accurate: CDC says you will prevent 3,000 to 7,000 deaths per year if you get partially hydrogenated oils out of the food supply, 3,000 to 7,000 deaths per year. The number for all of food safety is 3,000. Now a lot more morbidity on the food safety side. But now look at

something like sodium. I mean, the figures are staggering regarding what could be done to reduce morbidity as well as mortality by reducing sodium in the food supply.

SJ: But the latest study said no, that healthy adults shouldn't eliminate their?

ML: The dietary guidelines scientific advisory committee has looked at all of that stuff and concluded yet again that we ought to be reducing sodium. I don't know what the truth is, but if you are the Federal government and you have an advisory committee on this issue and it reaches a consensus, I think that is what you have got to go with. I mean, otherwise what are you left with? I think you are left with you can't govern which is a whole other issue. So I spent a lot of time trying to find dollars for nutrition broadly defined to include what is in the food supply that is not a contaminant, sodium is not a contaminant and industrially-produced trans-fat– we get it from partially hydrogenated oils -- it is not a contaminant. So I spent a lot of time and energy in those areas.

SJ: You said you had done some work on obesity and I know Alan Rulis worked on that as well.

ML: I think it is fair to say that Alan Rulis, Ann Crawford, Paulette Gaynor, and I wrote the report.

SJ: And the recommendation, as I recall, was that calories do count. Alan's presentation of it to me was just really, it is "calories in" and "calories out."

ML: Well, prominence of calories is - one of the things we recommended in that report was that calories be made more prominent in the Nutrition Facts label, which was one of the things that was proposed. I mean, that is when Brackett or Joe Levitt was Center Director and that predates my time in CFSAN because when I worked on that it was from my perch at OCC.

SJ: One problem seems to be a question of how do people know their baseline. Obviously calories are determined by individual metabolisms and right now we don't have a good way for people to measure that kind of thing.

ML: But you know in general that if you are taking in a huge number of calories, it's not a good thing. And the label is really not designed in a way that highlights total number of calories and we proposed to change that, I don't know –

SJ: There was a proposal at one point to make a special exception, with specific information about people over 50. Was that something that you had anything to do with?

ML: No, it doesn't ring any bells.

CC: I assume the people in CFSAN had a view about where the dollars should be spent in terms of public health impact?

ML: Right.

CC: And the Office of the Commissioner had a view. I don't know what to ask about that other than it sounds like –- who is in charge here?

ML: Well, a couple of things. I mean, FSMA directs us to issue a whole range of regulations and we can't issue them without trying to implement them. So certain financial consequences flow from that. Most of the dollars, almost all of the dollars that have been appropriated – and Mike Taylor has done a fabulous job of obtaining funding -- have been for food safety which is generally not thought to encompass nutrition. We did put together in CFSAN, and this could be five or six years ago, I don't know, a rather ambitious nutrition initiative, I think $40 or $50 million is the number that sticks in my mind. I don't think we got it out of the Agency. A year or two ago we put together a much less ambitious initiative for maybe $7 million and my recollection is it got out of the Agency but did not get out of the Department.

SJ: These are for supplemental funds?

ML: No, these were part of the regular budget process, not supplemental, proposing budgets.

SJ: So what do you do when you get turned down?

ML: We're stuck.

SJ: Come up with something new?

ML: Well, you come back the next year, but you can't – our boss is the Commissioner of the Food and Drugs, you can't go to the Secretary and say overrule it.

SJ: Are the funds lost?

ML: You don't get them, these were for increases. You just don't get them. So it was a $40 million or $50 million, this goes back five or six years and went nowhere. I am pretty sure it didn't get out of FDA. And I think last year the $7 million proposal got out of FDA, but did not survive the Department. No, I mean there is nothing to do but stitch together whatever dollars you can and that depends to some extent on – I mean, if the Deputy Commissioner for Foods and Veterinary Medicine, it could be Mike, it could be Jack Jones or Jane Jones, or whoever wants all available funds to go to X, they are going to X, with the possible exception of statutory mandates. So user fees for color cert are not going to food safety, they have to pay for color cert, some fees have to go to food contact substances. But there is huge flexibility in where money goes. And I myself if I were king would devote more of available dollars to nutrition than we do and I would worry less about shortfalls in food safety because I don't think that is where the big payoff is.

SJ: Were there difficulties between CFSAN and CDC over the obesity "epidemic" and how we were going to handle the public health aspects of it?

ML: Not that I can recall. I guess what you would say is that we are redoing Nutrition Facts, and we are going to emphasize calories. I think you would say we did issue menu and vending machine labeling which was part of the Affordable Health Care Act, we did that. We did a proposed rule, we finally got a final rule out. I just think there is more that can be done and I think if you look at FDA's own figures about net benefits, it is really striking. I mean, I think if you look at the net benefits from the nutrition activities, and broadly defined to include sodium and to include partially hydrogenated oils, industrially produced trans-fat and labeling, Nutrition Facts, serving sizes, I think we are talking on the order of $100 plus billion per year over, I don't know, twenty years, over an extended period of time. For all of the food safety rules, you are talking about 0.40 billion dollars.

SJ: In terms of loss?

ML: Annualized net benefit, $400 million as opposed to $100 plus billion. Now there are lots of assumptions on all those figures, but it is probably going to be easier if we could get voluntary reduction levels out for sodium that most of the industry would pay attention to. Because that is the problem with sodium, we are all used to eating a lot of sodium in processed food. There is pretty good evidence if you cut it down gradually we will all get used to it, we won't miss it and it will be a health benefit.

Even people who published recently on sodium would not dispute that going from 3400 to 3000 would be okay, they worry about going to 2300 much less to 1500. Even going from 3400 milligrams a day to 3000 would be a benefit. It is going to be easier to do that than to make sure that every farmhand washes his or her hands before picking fruits and vegetables.

But that aside, 100% compliance is never going to happen. You assume certain compliance rates when you do your economic analysis, but some of them bear some relationship to reality and some don't. And so it's like current good manufacturing practice – I mean, you are never getting 100 percent compliance. But you actually can force things out of the food supply just like you can force ingredients out of the drug supply.

Yes, occasionally someone will flout the law, but by and large when FDA flat out bans or even puts out a guidance, don't use such and such an ingredient because it poses certain problems under certain circumstances, I mean basically everybody falls into line. Much easier to get compliance there than in CGMPs. I think probably people would say -- a counter argument is -- that food safety is in some ways easier to accomplish certainly politically. I mean, who the hell is not for food safety – it's motherhood and apple pie. The food companies don't live by selling pathogens in food; they live by selling taste – for example, sugar and salt. You start limiting that, then you got a real brouhaha. You don't get a brouhaha about food safety, you argue with the margins, but you don't argue the basic principles - there is nothing to argue about. But to get back – I think there is a fair amount, I think a relatively small number of people actually have accomplished quite a lot in the nutrition area.

CC: It is impressive, particularly when you read the list. I just think that it's curious that – I mean, there are a lot of curious things that go on, but just that The First Lady has this initiative and yet things that dovetail with that initiative don't seem to get support.

ML: Right, although I think Nutrition Facts got a boost from her interest. I think partially hydrogenated oils/industrially produced trans-fat got a boost from the interest of probably a couple of people on the DPC [Domestic Policy Council] and probably from Sam Kass. Because again, unlike – I mean labeling is fairly easy relatively speaking even though there are people who kvetch about it because of cost. After all, it is just providing information, people can pay attention or not as they see fit.

But it is still, I think, seen as more disruptive than most of the food safety measures. For example, most of the preventive controls principles have been in play for ten years or twenty years. Think HACCP, for example. These are not radically new ideas. Regulating on the farm is, but I think it's unclear just what we are going to wind up doing on the farm. I mean, composting now, we are doing a lot of research and we have decided we don't have enough to do much.

CC: To develop a guidance on composting?

ML: To actually put it in the reg, how many days does the manure have to sit in a pile and that kind of thing. USDA has organic rules but USDA concedes in preambles that on composting they are not grounded in food science.

SJ: I was wondering why USDA wasn't more involved than we would be?

CC: Because the compost gets put on the fresh vegetables in the field and there are microbes in the compost. The issue is: are there microbes in the compost? And FDA regulates the produce so we are focused on the conditions in which the produce is grown.

DR-100-0028

SJ: Well, you think we need to look more carefully at concentrating on nutrition as a component of public health and as a component of what FDA does to ensure proper nutrition?

ML: Yeah, I think as important as food safety is, as important as FSMA is, CFSAN needs to be careful not to be so focused on it that the focus becomes a fixation and nutrition is given short shrift. And I certainly hope that Susan Mayne, with her expertise in nutrition, can lift, help lift nutrition in CFSAN because if you look at the numbers, that is really where the public health gains are to be made. If you look at the benefits from getting – I am assuming a conclusion here about the safety of partially hydrogenated oils even at tiny, tiny levels.

If you would assume that conclusion, then there are substantial gains in morbidity and mortality to be made by getting partially hydrogenated oils out of the food supply. There are very substantial gains to be made by reducing sodium intake across the population. Just accepting all the models and the figures as accurate from the economist make the food safety gains look basically puny. You are talking a $100 plus billion per year compared to $400 million.

CC: Are there any other substances that you think could be focused on and could offer huge gains?

ML: I think probably, I mean beyond partially hydrogenated oils and at least when I left the agency was under a court order and had agreed to reach a decision on that by June. I mean, CFSAN finished draft sodium reduction targets – I don't know, two years ago. I think they have been at the Department for a year or a year and a half, I don't know how long – a long time. Getting those out is important in my view. I mean beyond that, I think –

SJ: Well, in the meantime I think Walmart has already voluntarily –

ML: But I don't like the idea of turning over to private enterprise a determination of what I think the Federal government ought to be doing in the area of public health. I don't want to discourage Walmart, but I don't want to turn over the obligation to Walmart.

CC: But I think there’s a risk – the metaphor I use is if they fill the field, if they get in first and establish a standard and it turns out there ought to be a different standard, you both have to put aside whatever level the industry has said is appropriate and then justify the level the Federal government thinks is required.

SJ: Do you think FDA has the legal tools, not just the scientific information, but the legal tools to address obesity and other public health issues?

ML: For ingredients, it certainly does in my view and the food additive amendments which is how it has approached partially hydrogenated oils and how it could approach sodium. Sodium is much more complicated because there are real benefits to sodium, antimicrobial, there are functional benefits and it is across the food supply. It would be very complicated, the sodium reduction targets that have been developed are across 150 odd categories of food. The Agency is not ready to publish regulations tomorrow if the White House said go. FDA doesn't have enough information.

SJ: What about something like fiber -– certainly it is listed on the label. Is there a way to encourage, we certainly put out rules mandating certain levels of folic acid. The levels themselves were controversial, but our conservative efforts won the day and we have seen real public health benefits. Is there something – I am just trying to think of something, some other things that can be accomplished?

ML: I don't know if fortification with any particular amount of fiber, I don't know what evidence there is that that would accomplish, a particular goal – I just don't know. And the only other, I mean beyond sodium and PHOs [partially hydrogenated oils], what comes to mind is taking a look at least at saturated fat. You are not going to eliminate it from the food supply obviously, but I don't know whether it's in the food supply in levels that are higher than they need to be or should be. Someone might certainly look at that and there is a fair amount of research going on there.

SJ: What about trying to go to more the macro level and encouraging a better diet?

ML: I mean, FDA could do that. I think it could do it partly through Nutrition Facts. I think it could perhaps do that through some of front of pack arrangement. I mean, one of the standard, I am not quite sure what the right word is, I'll say things for communication is to an audience, is it understandable, is it actionable, and do people actually act based on the information?

I think FDA by and large worries about is it accurate? I don't think that is just foods, by the way, I think it's across the board – is it accurate. I mean, look at some of the drug labeling. My God, does anyone believe physicians in general actually read these treatises? I don't believe it. I bet there is pretty good evidence they don't. But the foods world is the one that I have occupied myself with for the last decade at FDA and I think there was more concern about is it accurate than is it understandable, for what purpose, is it actionable, for what purpose, do people actually act on it. So the evidence is really solid that people can look at using the Nutrition Facts to compare one product to another.

If you are on a low sodium diet, it's pretty helpful to look at the Nutrition Facts. If you are trying to construct a daily diet, I mean, come on – not for yourself, not for your family, not possible. Maybe once Nutrition Facts is revised, one could devise a subset of Nutrition Facts to go on the front of the pack, I don't know. It may be legal and would have to figure out whether –

CC: You do think it would be legal?

ML: Yes, a subset, yes. It wouldn't be a traffic light system, but it would highlight certain nutrients.

SJ: Well, we have always had concerns about endorsement. We all know that fresh fruits and vegetables are better on all counts, but that might counter commercial interests.

ML: I don't know why you can't, I don't think there is any prohibition. There is no legal prohibition, I don't think.

SJ: I am just trying to think what FDA could uniquely do. The National Cancer Institute did the five a day program that I think was pretty successful and CDC has been the one pushing the exercise component of it.

ML: Well, exercise I wouldn't have FDA engage in. It has no expertise in it and there are plenty of other people who do. But in terms of the food supply, we have the expertise. And I think trying to devise some system of food labeling, and it might be front of pack, that is more helpful for people in actually planning than Nutrition Facts in my judgment could ever be, that is something that FDA could engage in. I mean, it is thought about.

We did a public meeting, a part 15 hearing, on front of pack maybe seven or eight years ago. In CFSAN, certainly there was interest in learning about it so we had this meeting, but there was no interest in going forward. There was an effort in I think spring 2009 or '10, CFSAN actually developed some front of pack guidance. I don't remember the details. But it either didn't get out of FDA or more likely didn't get out of the Department. There was some concern that it was not backed by enough consumer studies and I forget the details.

But I think you could, once you get the Nutrition Facts finalized, begin to think about whether some subset of that for front of pack would make sense. And you know, you would want to accompany that, if you could, with some campaign and you would want to do that with the food companies if you could.

I can't believe the food companies, the bigger ones, are not looking at two things, I mean among tons of things, but two things. One is tobacco litigation and whether they are at some risk down the road of being accused of 'making us all fat' and getting illnesses associated with obesity. And the other thing that I think we ought to be looking at is the margins are really small, it's really tough to make a buck in the foods area compared to other areas FDA regulates. So what could they do that really would make a difference? I don't mean in dietary supplement style claims which are supported by thin air, if any air at all, as far as I can tell. I don't even know what half of the claims mean -- "boosts your immune system" what does that mean? And so start to look in a serious way at what you could do with food, either by subtracting or taking out things that aren't good or reducing them or by adding things that are good.

A company came in to see us sometime in the fall with a proposal for a medical food – in some ways my mind is like sieve because I can't remember a thing about the meeting except that it was a proposal for a medical food. But what the company was proposing to do, I mean its basic pitch to us was here's a population inadequately served by conventional medicine for indication X. Here's why we think it doesn't work. Here's how we think we could deliver what does work through a food product. And the company asked us do we think the experiments they have

designed, if the results were the ones that the company wants, would establish this product as a medical food.

Because if the answer is that we agreed with the company, it would do the additional research. If you FDA think we are crazy, we are not going to spend more money on this, we've got other things to do so we want you to take a look at our hypothesis, we want you to take a look at the data we have assembled, published and non-published. We want you to look at our studies and let us know what you think.

I mean, that is not the food supply in general, but it is food, and it is an example of where, if the company is right, it struck me as a serious effort to find an area where you could add something important.

SJ: Real value?

ML: Yes. And how much of that is – I don't know. But I would be surprised if major food companies aren't having that thought. Because how much more fat, sodium, and sugar can you market to people? Without – and still make a lot of money, and without a litigation risk, and without China at some point saying, no more Western fast food, thank you very much. And I really am, I mean, I was an advocate for putting nutrition expertise as one of the expertises that would make a person suitable as a candidate for Center director. So, Susan Mayne certainly fits that bill. And I hope she gets a chance to work with people in the Center in bolstering the nutrition effort. That's going to require some money. And that's a fight she's going to have to make at this point, because there hasn't been money for nutrition.

The nutrition program staff in ONLDS has roughly the same number of people in it as the strategic communications group in the Office of Foods and Vet Medicine, which really tells you something - it's like 15, 16, 17 people.

CC: Wow, that's impressive.

ML: Yes. Now, there are other people in CFSAN who do nutrition, but there are other people in CFSAN and CVM who do communications. And so, yes, the ONLDS nutrition staff is

an appallingly small figure, I've used it with Mike. As I say, I'm hoping to have some fun with it publicly because I think there ought to be a debate about this.

SJ: The argument was made of course that FDA has always endorsed the idea that all foods can be accommodated in a healthy diet. Jerald Mann, who served under Kessler, was ballistic over the concept that there were no "junk foods." He believed that people of normal stature, for example, cannot eat pecan pie, that kind of thing. That wasn't going to fly as a policy, either. But, I believe there was dispute within FDA at the time about exactly what we could be seen to be saying about nutrition.

ML: Well, it's one thing to say, don't eat X; it's another to say, you know, eat A, B and C. I don't think there's any prohibition on encouraging people to eat A, B and C.

SJ: Unless it's a processed food versus a natural food?

ML: Whatever it is, whatever food FDA thinks – I mean, FDA is not going to do it by brand; it's only doing it by type. I mean we always say eat a balanced diet. This is just general advice that's always given no matter what shows up in the food supply. I mean, the stock answer is, eat a balanced diet.

SJ: Can you briefly discuss the dispute over BPA?

ML: I think a couple of things. Scientifically I'm not really competent to hold an independent view. But I think if someone looks at the history of this twenty years from now, what's going to happen is this is going to be seen as sort of a stalking horse for people who think endocrine disrupters are bad beyond bad. I mean, Linda Birnbaum is certainly a smart cookie who runs NIEHS and has a passionate interest in endocrine disruption. And that is fine. But I think there are some people there for whom BPA is just evil.

SJ: Where is she?

ML: In the National Institute of Environmental Health Sciences. There was a guy there who was so anti-BPA that when FDA was trying to identify some peer-reviewers and his name came up, an agency expert, not from CFSAN, and who was no fan of BPA, conceded that this guy should not be a peer reviewer -– that he had gone so far around the bend on BPA. And

so I think there's that. I think a lot of people have decided this is what's going to prove that all the concerns were valid. And of course that means they are bitterly disappointed whenever there's some test result that doesn't fit their model. I think there's a lot of that.

I think also people may be writing about BPA as an example of where science really went south. Science isn't free from the normal run of human pettiness and vindictiveness and bias and prejudice. But science as a discipline has not been seen the way lawyers are seen, as advocates. So I worry that BPA us going to be a rather unhappy turning point, evidence of a rather unhappy turning point in that discipline.

CC: In science?

ML: In the discipline of science.

CC: You mean a loss of objectivity or reliance on empirical evidence?

ML: The former. They're just interested in proving outcomes. They're not interested in finding out what the answer is. I think with BPA a lot of people doing the work are just interested in proving an outcome and I actually don't think those people by and large are in CFSAN. I think people in CFSAN don't have an agenda. If it's safe, it's safe; if it's not, it's not. But you know, study after study after study, there's nothing there. And I don't know how many tens of millions have gone into BPA. My guess is it's over a hundred. You've got nothing better to do than spend our money on BPA?

I mean, yes, I think somebody ought to be – people have already started to write about this, but as advocates from one side or another; I think if you find somebody to step back and look at it, it's not going to be a very happy story, even if it turns out the people who are worried about BPA are right because the amount of money that's going into this is insane. I mean it's already out of baby bottles, it's out of sippy cups - the amount of BPA we're exposed to is really trivial.

SJ: Was that one of the reasons why Laura Tarantino left when she did?

CC: No, I think she worked – she worked a huge amount of hours and I think she'd had enough.

SJ: She was the one I initially started talking to about it and we never had a follow-up conversation.

ML: I think she liked what she did, I think she'd done her time. I don't know to what extent the new regime – you know CFSAN is less independent than it was, and that would be true even if Mike Taylor were a completely different human being

SJ: You're saying the layer needs to be there because of the leadership?

ML: Whether it does or doesn't, so long as that layer exists, it's almost – almost – certain to make a difference in how you do your business from a perch in CFSAN. Not certain, but almost certain. Because people don't occupy senior positions in OFVM to amuse themselves. They are high level jobs. I have a high level job, what am I going to do with it? Typically people do not answer that question by saying 'nothing.'

SJ: Where, in CFSAN now, is FDA strongest scientifically?

ML: Microbiology and chemistry, analytical chemistry, world class. I spent a fair amount of time trying to figure out how to get toxicology more in line with Center needs and I think progress has been made in that.

SJ: Were you responsible for some of the work – you have hired some very good statisticians to interpret some of this stuff. Is that part and parcel –

ML: We needed to get more people in bioinformatics and so we decided to staff up some there. I was responsible for saying yes to Steve Musser's wise recommendation to do that. It was his idea.

CC: He is now a Deputy Center director?

ML: He is the Deputy for Scientific Operations.

CC: You started to say something about toxicology and I was interested in what you were going to say.

ML: Yeah, I think that – what happened in toxicology in CFSAN is you have to go back a number of years to when Tom Cebula was running OARSA. Well, when I got to CFSAN and this had been around for a while, Bob Buchanan was the senior science advisor and he ran

the Office of the Senior Science Advisor – more or less that was its title and it had several functions. But it also had within it a whole other office called the Office of Applied Research and Safety Assessment [OARSA] out in Laurel, Maryland in what is called Mod I; Mod II, as you know, is the CVM research facility out there.

Tom Cebula was a molecular geneticist and I would say the consensus was that Tom was a superb scientist but kind of did what he thought he should do but others thought OARSA was insufficiently linked to program needs. So the story line, and I think there is some truth to it, is toxicology kind of got devoted to what Tom saw as the needs for genetics, for molecular genetics and toxicology, as such, kind of lost its way. So we have spent, with a few other people, a fair amount of time in the last years trying to orient it to here's the kind of work we need done. So for an example one of my favorite projects, and it wasn't done before I left, was we had the dietary supplement people identify a number of compounds of significant concern in the dietary supplement world and concern with respect to cardio-toxicity. And we had the OARSA folks figure out a relatively inexpensive animal model for testing purposes and to talk, to confer with OCC about whether, if those results showed cardio-toxicity, that would be enough to either A, remove the product from the market or B, require a warning. And the answer was yes. And so they were doing those studies and again, they are not finished. But to me that is a good model for OARSA toxicology and if it's inexpensive, it's an even better model than the government spending money because if it's relatively inexpensive, industry is likely to use it before launch, do some 30 day or two week studies on 20 rats, whatever.

SJ: Now we also have not given you the opportunity yet to discuss dietary supplements overall.

CC: Before you go to that, when you are talking about reorienting toxicology, are you talking about the research arm or the analytical, when the studies are presented to the Center in support of an ingredient's safety?

ML: No, the research, what the researchers are doing. I don't – I think they are fine at reading, interpreting the results of research, it's what research should they be doing. They had, as

an example and who knows, Susan [Mayne] may disagree with me, but they were looking at a particular form of worm called a nematode, *C. elegens* as a model for some cheap tox testing. And years ago when Brackett was still around but was unavailable, I made a couple of decisions about how much more we would invest in that effort – they were just outraged about how can a non-scientist be doing this. Well, somebody has got to do it. Five years later we finally pulled the plug on this because other people with more expertise in that type of model had abandoned it, and still others had much more capacity than we ever would, so it made no sense for us to continue doing this work.

CC: Do you mean OARSA?

ML: Yes, it was after Tom Cebula retired. There was just no sense for us to be pursuing *C. elegens* into year seven. I mean, I am a great believer that some of the research that CFSAN does should not dictated by a program need at the moment, that it is sort of exploratory. I think it's good for the program. We got into whole genome sequencing because Steve Musser applied for a grant when Frank Torti was Deputy [Commissioner] for Science or whatever and Steve got a grant. That is how whole genome sequencing started in CFSAN. If all we did was analysis and methods development, we never would have gotten into that business. But after some number of years in the case of *C. elegens*, I thought seven was enough and just stop.

SJ: I don't know if you had any feelings about DSHEA [the Dietary Supplement Health and Education Act], which has been highly criticized. What is the evolution of your thinking about dietary supplements?

ML: The authority is weak, but it is not nonexistent. I will give you one example of things we can do which is try to figure out from published literature and any other sources we can get our hands on where there are compounds that may present problems and find a cheap way of studying them and either confirm that there is a problem or exonerate them - I don't particularly care which.

I think we can do a better job of enforcing the new dietary ingredient notification requirements, I think that is going to require another year or two to get the guidance out. That

will remove a lot of industry hand waving about we don't know what it is you want. I mean, it is not legally dispositive, but it is difficult to weave your way through, particularly with Hill interests. So if you have better guidance out, that will help.

I think doing more on claims would be useful. That is going to require more resources and probably more work with OCC. I mean, there are a number of regulations on the books which OCC is really not prepared to enforce.

CC: Why is that?

ML: Well, for First Amendment reasons. Often some of the health claims, where we have authorized health claims by regulation, you go too far outside the boundary and you're unauthorized? Well, there are often real struggles with OCC about whether there is a First Amendment right to make the statement even if it is not within the four corners of the regulations.

CC: So what do you think we can do better in the way of clarifying?

ML: I think there are two parts. Some of that has to be clarified internally, and when I left we were trying to do a warning letter initiative for claims in conventional foods. And it was painful, it was painful to get the information, it was painful to write it up, it was painful to get it through OCC. And if we started with 20, by the time I left, 7 had been killed, 4 or 5 had been issued, and 8 were the subject of discussion. You can't do business that way. I mean, it's not good for CFSAN and it's not good for OCC.

CC: You are a student of the First Amendment. Do you think this is risk adversity or what?

ML: I think there is probably some aversion to risk, I think that is probably some of it, although I don't think that is most of it given how poorly FDA has fared in the courts. I mean, in the foods arena and well outside the foods arena, of course, into the drugs arena. I think some of it is due to underlying concerns in OCC about some of the labeling regs. And I think some of it is because there is sometimes a little bit of, sort of academic beyond academic view in CFSAN. So no one has ever said this to me, but it will illustrate the point. Now the reg says you have to

say 0.5 grams. That means you can't say one-half gram. Well, that is crazy, it's just crazy. You are not marching into court over that. There are occasionally things that I have seen, we were worked up over that kind of difference. Unfortunately a huge amount of effort would have been put into finding the label, reading and viewing the label in the context of the regulation, and writing up why this was a violation and then having a back and forth in OCC. And then I wind up in a meeting with OCC and they are saying we're not proceeding because the company said one-half instead of 0.5. It wasn't that bad, but it was bad enough.

SJ: Is there any relation in your mind between excesses in dietary supplements and the obesity crisis?

ML: No, I think it has to do with, I suppose three things. One is skepticism about conventional medicine and another is cost of conventional medicine and I think a third is – the most clever people I ever ran into in private practice were marketers. They are very clever –you will feel better, it doesn't cost very much, and what the hell, it's not going to hurt you.

SJ: And scientific illiteracy by many of the public?

ML: Yeah, I suppose, but I don't know that it's any worse now than it was fifty years ago.

SJ: When they were writing implementing regulations, Bob Temple and Janet Woodcock told me that they were tasked with coming up with some meaningless claim with n medical relevance that they could use as an example in the regs and that is what they came up with.

ML: 'Boosts the immune system.'

SJ: Or 'Supports a healthy immune system.' And they thought it was kind of a joke and they were shocked that the industry itself took it up.

ML: I mean, the other thing – it's a weak law and obviously there is no meaningful pre-market approval except for new dietary ingredients and supplements containing them, but is the difficulty in proving that something is false or misleading as unsubstantiated. It's hard, it's very hard.

At one point, one of the drug companies came in. It had purchased a medication that it wanted to take over the counter – that much I remember. And of course maybe it had already made the purchase or maybe it was thinking about it, I think it had made the purchase. And of course what it wanted from us was to go after dietary supplements with similar, but not prohibited on dietary supplements, claims.

And one of the things we said to the company was we are not unsympathetic, but you need to understand it is very hard to find people who are going to stand up and say those claims are unsubstantiated. Not because they are aware of substantiating data, but because they don't know. The law doesn't require this stuff be published and people don't know what is unpublished and maybe there is some viable theory, some viable scientific hypothesis as to why something might work. So finding people, academics or people at NIH to do this is really tough. You find some names for us, we would be happy to go ahead and my recollection was we didn't get a bunch of names.

SJ: Do you have any observations with regard to nano-technology?

ML: No, I think my general sense from the OFAS people is that we have probably put more time into developing and issuing guidance than the problem warrants. That's an impression and I can't offer any more than that.

SJ: Let's take a break.

DR-100-0029

CC: I guess we were talking about how you had separate tours of duty in the Office of Chief Counsel.

ML: Right.

CC: You have stayed in contact with the OCC organization. How do you see that whole organization evolving over time?

ML: I think it is part and parcel of what has happened in the Federal government in general which is increasing control from higher levels. So at the Center level it's the White House, OMB, the Department, the Commissioner's office, the Office of Foods and Veterinary

Medicine, the Center. I think Liz [Dickinson, current FDA Chief Counsel] probably has more dealings on a more regular basis with Bill Schultz and David Horowitz of HHS OGC than any of Liz's predecessors. At one point we talked, it's pretty rare, but we talked occasionally and Liz said you know what it's like. And it is one of those things in a parking lot so I didn't get to answer it, but the answer would have been no. Even though I was acting and even though Alex Azar [HHS GC] I am sure was concerned when I was dealing with some cases that Dan was recused from.

I mean, after Margaret left Alex didn't know me from Adam and they bollixed up Margaret's removal. They basically, it got to the press before they talked to Margaret. And Alex just felt awful about it. So Alex had nothing against me and I don't think was suspicious. But even when maybe he had some concerns, I did not experience in any of my acting tours the degree of control that Liz now appears to experience from Bill and from David. It just wasn't part of it.

CC: Do you think some of that is her seeking guidance?

ML: I think its Bill's history with FDA, he was Deputy Commissioner for Policy. Bill is a terrific advocate. And I think because he has such a history with FDA, not only working at FDA but handling FDA cases – 35 years. So no, I am sure she values his opinion and I sure as heck would, but I wouldn't want to be talking to him every day or however frequently. I don't know how frequent it is, but I gather from the scuttlebutt that it's mighty frequent.

CC: That is what I have heard.

ML: And that just has an unfortunate effect.

CC: What brought that about and how did it evolve?

ML: With respect to Bill Schultz, I can't tell you. I think what has happened since I came back to the government which was in 2000 is there's been, I suppose there is just an increase in political interest in what FDA does, increasing recognition of the amount of the economy it regulates and the volume, the dollar volume.

Society has become obviously much more split, a much sharper division, much harsher lines – conservative, liberal, progressive, however you want to describe it. So there is much more suspicion. The Democrats, in my view, and for reasons I really do not understand, I have no clue, are 'Know it alls' in my experience in the way that Republicans are not. I mean, the Republicans have their ideological view and the Dan Troys of the world, but I would bet – I mean, look at what happened with, I will get that thought out first which was that there's a lot more worrying about drug approval decisions by the Obama/Hamburg administration than there was by the Bush/von Eschenbach. I don't know that, but I would bet it.

And for all the liberality, look at what happened with Plan B. I mean, the Democrats did exactly what the Republicans did, which was stuck their nose in it in a political way and they got caught and they got sued and they lost. I mean, it is staggering. I mean, Sam Kass is a bright guy, do you know who Sam Kass is?

CC: Yes. He was a personal chef to the Obama family and also a staff member at the White House.

ML: He was apparently an important advisor there on nutrition. What's that about? Well, I gather he has got a master's in nutrition, but you know, why is there so much scrutiny from the White House of the agencies' expertise? And by the way, I believe that he was helpful on partially hydrogenated oils [PHOs] because someone I know and trust says he was helpful. CFSAN and FDA drove PHOs to the White House, but we couldn't drive it out. He also was actually very decent; he did some tours for CFSAN and other FDA people who worked on PHOs and another nutrition matter or two.

But I think it is crazy that the White House chef should play a critical role, assuming he did, in getting PHOs through the White House. I mean, what is that about? So it's part of a trend. On the Democrat side I don't understand it, I don't understand why they have to micromanage everything and I don't understand why – and of course, it spills over.

Mike Taylor who was rightly upset about the interferences would deny that he micromanaged anything yet he does it, too, in relation to CFSAN. And the effects are terrible

because it makes it harder and harder to get good people to come or to stay because at a certain level of expertise, talent, experience, and sophistication you are going to know. You are going to ask around and you are going to figure out that you'll have little if any authority or independence. So whatever one may think of Peggy's situation, it isn't at all like Donald Kennedy's.

CC: And why are you comparing her and Don Kennedy?

ML: Because Kennedy was Commissioner at a time when I think there was a lot more freedom.

CC: Got it.

ML: He was an academic hotshot, brilliant guy; I am sure he had some political connections, but he was not part of a political class which she clearly is. And the political connections have advantages for the system (and the individuals) but disadvantages, too, principally the risks of undue deference, insularity and "group think."

CC: Remember back in '78, we used to talk about "downtown" and Peter Libassi was the general counsel of HEW when we started? Libassi came out to our division maybe twice during his tenure -- that seemed to be the extent of his contact with the Food and Drug Division. That was when Donald Kennedy was Commissioner and FDA functioned much more separately. I don't know that you could say that the decisions then were any less solid. I don't know that we lost more cases or did less public health protection or whatever. It really has been a dramatic evolution.

ML: I think it has followed from what has happened in society. I mean, I don't know what Rich Cooper thought about the Chief Counsel as a political appointee when he was Chief Counsel, but I know what he has said publicly because he said it in a FDLI session which is in his view, it is appropriately a political appointment. I don't know if he held that view thirty years ago and even if he did, I am not sure he would attach the same meaning to political when he was Chief Counsel as we do now.

CC: How do you think, if at all, the 24 hour news cycle, affects things? It seems like nothing happens without everybody knowing it instantaneously.

ML: I think that is probably part of it, but also people choose to make it so. The last head of press for public affairs, Virginia Cox, I recall attending some meetings with her and with the Commissioner [Margaret Hamburg] and Mike [Taylor] and three or four others, a relatively small number, about foods issues. And Virginia, from my standpoint, of course it's what I wanted to hear so she became the voice of reason.

But it was essentially you know, this will be bad news for a day and then it will disappear, can we please calm down about this? And people can't calm down about it. There is no blog which should go unanswered. Some of this we made. I am thinking of Mike Taylor doing some visits to farms - I don't know, there was going to be a blog about it. I mean, who really wants to follow that? Seriously, we contribute to this. Look, he's a really smart guy with enormous expertise, and FSMA is really close to his heart, but the nation is scarcely on pins and needles about FSMA.

I am on the email list for Constituent Updates from CFSAN so I get this stuff, I tend to look at it. He started one blog about "the country is waiting for FSMA." I mean, it's like – my point is we contribute to this in two ways. One, by never, by seldom, never being able to just say you know, that is an unfortunate story and people will forget it in a day and a half and we're done. And the other is by tweeting and retweeting and blogging and to a degree, who is our audience for this stuff? I don't know. Our families? I don't know.

SJ: I think one of the criticisms has been and sometimes continues to be that we're not going on record much of the time. We used to have something like FDA Consumer that was citable. We knew that at the time it was published that it was cleared by everyone in the agency. It could be as general as possible, but people needed that touchstone of authenticity. Certainly historians needed it to know and date official policy positions.

ML: I am not saying none of it, but I'm not sure what purpose it is really serving and I think the clearances, I think, are a function of the politics and the fear of saying or proposing or

finalizing something that is going to set off some important constituent or constituency. I think on the food side for strategic communications, a huge amount of energy is spent keeping people – quote unquote – "in their seats" and it's a phrase, it may be 'chairs,' and it is a phrase Mike uses fairly often and so does Sharon. And look, these are smart –

CC: Sharon Natanblut?

ML: Sharon Natanblut. And these are smart people. So political judgments are made about the need to give this and give that to keep people from running to Congress and undermining FSMA or whatnot. I think what gets lost is what happens to culture – in quotes – when that becomes a way of doing business, when you become afraid of offending anyone, really. What's the cost if that is your practice for five or eight years to get your rules out and your implementation plans in place?

And even if you are just trying to buy time ultimately you want to be able to enforce the way you think you ought to be able to enforce it. Can you actually throw that switch five or eight years down the road? I am not convinced you can. I mean, FDA's budget has never been as healthy, I mean overall.

Maybe it is worth it, but there are counterarguments to be made and, as an example, I would point to raw milk. I wish we would do something about raw milk. If you look at outbreaks from raw milk, it's a temporal association, but it's quite striking. We step down, outbreaks go up. We stepped down because there was a great fear that we were going to repeat what happened shortly after Mike came, he started threatening – well, the Gulf Coast perceived him as threatening to do something about oysters and post-harvest processing -- and the Hill went bonkers.

And we backed off right quick – we didn't say it, but we did. I think it's a fear with raw milk. But one could make the argument yeah, it's horrible and it's horrible that it is mostly kids who are drinking it and it's horrible that they get sick and occasionally die, but we are much better off if we leave that alone because we can use all this money we are getting for a much greater benefit.

SJ: For FSMA?

ML: Well, for FSMA or drugs or whatever. I mean, it's not a crazy argument. I think there ought to be a lot of debate about internally and I don't think there is. I think there are some people who understand that is what we are doing and they just do it. I also think there are elements of personality in this as well as tactics and strategy. But it all fits together in terms of – the more you are that way, the more you are likely to find people above you who are going to poke at you.

CC: We have not interviewed many people that have served in the Office of the Chief Counsel, and one of the reasons the History Office was interested in my coming to work for them was to try to work on that. So as long as we have you captive, I guess I'd like to sort of probe some more specifics, even though it is the early part of your FDA career. And you probably hinted at this, but maybe you can expand on it. How do you see the evolution, if there has been one, in the role of the staff attorneys and are there changes that either enhance or reduce people's interest in coming to work for FDA or staying in OCC?

ML: I suspect there is less independence on the part of the individual lawyers by and large and I think that is a function partly of size. I mean, to go from what I think was 35 or so, maybe it was 38 in '78 to what, triple that? In 2014, you have got to have more controls in place, you have to have more managers. It is, I think, a more complicated world, both from a regulatory standpoint and politically. It is harder to navigate and I think that is part of it. I think there is probably less tolerance for making mistakes. It is just a hunch, I can't point to anything.

CC: By making mistakes, you mean giving the wrong opinion?

ML: Yes, or an opinion without sufficient caveats. I struggled with this at CFSAN and never really figured out what to do about it, but I sensed that people were afraid to make mistakes, were afraid that they would be penalized somehow, and so didn't speak up for that reason. And fairly early in my tenure and almost literally on my way out the door -- I hit send on my last all-hands email 15 minutes before I walked out the door -- I quoted a story, it's true, it's not a story, it's about Warren Buffet when he took over Solomon Brothers after a bid-rigging

bond scandal circa 1990. And he actually said this on the Hill, that's how I know it's not just apocryphal. He essentially said to the assembled traders, he said more or less, there's probably not one of you who is not going to lose money for us from time to time, and some of you are going to lose a fair amount of money and that's not a good thing, but that's just going to happen, don't worry about it too much.

But if you do something to stain the reputation of this place, you'll be fired before you know it. That was basically his message. I don't know if that ever took. But I think – in CFSAN because I tried it - I said to people I'm not going to worry about moral "crimes" here, but if you want to worry about something you'd get fired over, that's it. It's not about making a mistake because we all make them.

I just think there's more fear of making a mistake in general unless it's – whether it's grounded in reality or not, you know, I gave the wrong legal advice. I mean I used to give a huge amount of informal legal advice to CVM and people appreciated it. I think it's harder now to do that. Over the phone it's more likely to produce five internal phone conversations. It may not produce a memo, a lot of which OCC used to do but no longer does because of the press of work or other reasons, but I think it's more likely to produce five internal conversations which automatically reduces independence.

CC: Do you mean with supervisors, with colleagues in the same area, or?

ML: With supervisors, with managers.

CC: So, by my count, you worked either for or with ten chief counsels.

ML: Ten?

CC: Cooper, Buc, Scarlet, Porter, Troy. Then, as deputy chief counsel, and then as the client.

ML: Right.

CC: You, Troy, Bradshaw, Masoudi, Tyler, and Dickinson.

ML: Yes, that's right.

CC: Do you have any thoughts about any of them, all of them? I think you're very insightful about how they conceived of their role, how they saw the role of OGC, their strengths, their drawbacks?

ML: Starting with Rich, I mean, Rich is a little hard because I was new and he was just so smart. He's like scary smart. But I suspect Rich was probably of the group the best combination of lawyer and manager because part of that role is to lead and manage the office, and part of it is you are the Commissioner's lawyer. And his tenure was, his was only a couple of years, ours probably only overlapped by a year, but my guess is he was probably the best at that. Tom is certainly scary smart, but Tom, I mean, he wasn't a people person. He certainly had some good instincts, but he didn't really manage.

SJ: Nancy L. Buc?

ML: You know, her tenure was too short. I think Nancy, it was like nine months.

CC: Nine or twelve months. Rich retired in the winter of '79 and I think she was Chief Counsel until Reagan's inauguration.

ML: Yes. I mean, my impression is, and I had sort of business with Nancy on the agency and occasionally some small business. I mean, very effective I thought, as a lawyer, a really effective advocate. I think she –

CC: She bit my head off more than once.

ML: I think she did – I was going to say come on too strong sometimes with lawyers and with a client. And I think, you know, she was relatively young at the time as was Rich, but different people grow in different ways at different times. And also she was a she – the first -- which may have made a huge difference because she may have felt extra pressure.

CC: She was the first woman Chief Counsel.

ML: Yes, so that may have made it. But some of the –

CC: Do you know what Bob Spiller said about her? Well, it wasn't about her so much as he observed that for the first time in his professional life there were three women between him and the President because it was Nancy, Jody Bernstein, and Pat Harris

ML: She could be rough on people, and I think sometimes dismissive where she just didn't know food and drug law and for some reason or other was just at that point in her life unwilling or unable to defer to a staff lawyer.

CC: Did you work with her at all on TSS?

ML: Yes, I worked with her very closely, it was a wonderful experience - Toxic Shock Syndrome. Yes, we negotiated with Procter and Gamble over withdrawal of Rely tampons. And she was there, and that was late at night at the Department. Procter and Gamble had flown in its lawyers and some pretty high officials on its private jet. Yes, Nancy was there, I was there as the staff lawyer. If Jody Bernstein wasn't there she was available and this was a big deal.

I learned a lot from Nancy. I never had – the only time I ever had – it wasn't really sharp but it had the potential to be sharp. I had written some memo to her but the audience was really devices about it, the reason for doing rule-making. And I got this why, it was certainly from Nancy, why the lecture on rule-making? I said it's not for you. Yes, this is to you, but I know it's going to the client and then she was all right with it. But she clearly was a little tight because I had written this memo explaining why we should do rule-making here.

No, I didn't have any trouble with her. But I knew of people who did. But my, as I say, my personal experiences with her were very good, really good.

CC: We talked a little bit about Margaret and a lot about Dan. Did you have anything more to say about Tom? He was Chief Counsel for –

ML: A long time, yes. I think Tom was much – I mean, I came to realize very late in the game that he was much better than I had thought when I was much younger because I had tangled with him a fair amount and more over style than substance. He always seemed to me to be very passive. Not that he wouldn't deliver an opinion I thought was right, but it was always so diffident.

CC: Very contained.

ML: Without punch, without force. People do react to what you say in part by how you say it, not just are the words eloquent, but is there something behind the words? Now that

wasn't Tom so it's not a question of fault or blame. I'm not going to blame me for not being 7'6". No, I am not seven feet six inches tall.

And I guess what I really liked about Tom apart from his incredible analytical strength was one, he was really quite witty. You didn't see it very often, but a very sharp wit. And the other thing was you know, I mean I came to believe eventually that he was a fairly conservative Republican, but he didn't salute when nonsense was run up the flagpole – bullshit was bullshit.

If there was a Republican cant coming out of someone, he would be the first to disregard it that way. Not with a lot of fanfare but in his own quiet way-- he didn't have any use for it and made it clear he didn't have any use for it, didn't expect people to pay any attention to it – go do your work and just forget this crapola. He would be more eloquent and funny about it. And I appreciated that, appreciated the honesty and the trust. And the trust because it reflected trust in us. We weren't going to tell on him.

SJ: Dan Troy is probably one of the most controversial chief counsels certainly that I have ever known while I have been at FDA. I am interested to hear your take on his ideological grounding, but also people's reaction to it.

ML: Well, I think he was the most, up until that time, I would say I think continuing through this day, but certainly up until that time, the most frankly political Chief Counsel and the most ideological. I mean, as I mentioned earlier, as his deputy, one of my roles as is logical, a well-established role, was to play a large hand in hiring and going through résumés and looking at recruitment and materials and whatnot.

And I don't think it was an accident that during his tenure, we get these cover letters preaching fealty to AEI [American Enterprise Institute] or the Federalist Society, or whatever. Granted, I probably saw more of those letters in that role than I had at any other time except when I was deputy to Margaret Jane Porter, but I don't think people used to write that way when seeking employment with OCC. It just wasn't regarded as important. It was regarded actually as irrelevant at best.

No, I mean, the law isn't physics, but you are expected to find a way wherever possible to read a law, to read the law in a way that allows the client to accomplish its goal with an eye towards – this may be more me than any Chief Counsel and something I developed as a way of thinking about the role as opposed to another Chief Counsel – but with an eye towards preserving the client's discretion and making sure the client doesn't commit itself to something it can be sued over for failing to do without thinking about it 10,000 times. So just in general.

It was never what's your idea of the proper role of government, it just was not part of the office. And it became part of the office because Dan was interested in it, what was people's conception of the proper role of the government. In that sense it was political and ideological and that was new.

CC: I think he hired at least three FODs, Friends of Dan. And I never remember that practice before or after Dan. And I don't think any of them survived.

ML: Yes, so there was that, it was the most frankly political, it was the most ideological, there was – I think the political power certainly perceived, but I think it was real. There were ties to the White House which were probably real because his brother was there and there were some other ties. I mean, to some extent real – I mean, how real all of this was, I don't know.

ML: I think he was a very smart guy, very able lawyer. So how real were the ties to the White House – were there some? Yes, because his brother was there. How real were they really? I don't know, but they were certainly perceived and he was there when, not so much with McClellan, but when Crawford was the Commissioner, it was –

SJ: How were his relations with people? My sense was that many people found him irritating, but that is obviously from a distance.

ML: I think people - one way of looking at it is in trust and the other is a matter of confidence in his ability to distinguish a policy preference he had, in which he may well have been given license to execute as opposed to what the law allowed. And once in a while you

would see that and I can't remember the specific issue except it was in biologics and he became persuaded that the law did authorize something or another that biologics wanted to do.

But it was sort of – "I don't want to do that." At least that's honest. And I think one has a right to expect that much. We understand you have the power and that is what you are deciding – okay, don't twist my arm to read the law a different way. Concede that the law allows the interpretation I have given you and just tell me that the client, and if you are the client, then you are the client – that's alright. I don't think he wanted to do that, I don't know why. Maybe Dan wasn't entirely comfortable with us as a group, with the careers, just being that frank.

Three other things I recall. One is Wyeth, where Dan jammed into a preamble to a final rule an argument/determination re: preemption. The Supreme Court, in an opinion that is not a model of persuasiveness, rejected preemption. I think there was such fervor about it that the proponents of preemption forgot just how little mileage FDA would get out of an argument/determination that appeared for the first time in the preamble to a final rule.
The second is that when we decided a Washington Legal Foundation citizen petition on unapproved uses and the First Amendment – a response I had worked on with Alex Azar because Don was recused – Dan's response was that "it didn't make [him] sick."

The third is that when he had wanted to give a speech suggesting that FDA needed to take on less. He asked me for my thoughts and I agreed with him. But someone above him decided that he should not give the speech – perhaps he was seen as the wrong messenger.

More generally, Dan's focus on closely reading the statute was appropriate as was his concern about risks of running afoul of the First Amendment. But I think he was perceived as so political and ideological that the sound messages were not welcomed, and were even mistrusted.

CC: Sheldon Bradshaw?

ML: Very little business with him. My impression was that it was hard to get an answer out of him. I had a few matters at the Center where I needed an answer and it was just spitting down a well. You just couldn't get anything out of him. You could get a no, you just didn't get a yes.

CC: You and I worked together on the status of compliance policy programs, not compliance guides, under the Good Guidance Practices.

ML: That is to carve something out to make it easier –

CC: Right, I am still waiting for that memo. We were told it was in draft, I think we even got it in draft, but we never got an answer.

ML: Bradshaw was sort of a cypher – seemed pleasant enough and smart, but beyond that –

CC: I think people thought he was a nice guy.

ML: Yes, a decent guy. But I meant sort of as a functioning lawyer for the Center, I mean –

CC: Didn't see it?

ML: No.

CC: Jerry Masoudi?

ML: I really liked Jerry. I liked him personally and I suppose we got off on a good foot because, for two reasons. One, shortly after he came onboard, he invited me, he said let me take you to lunch, I would just like to pick your brains about the Office, about what you think the job was. And it was a nice thing to do and it was also a smart thing to do. He could have been told I was the devil, but I held his job for four years, talk to the devil. So it was a nice thing to do and a smart thing to do.

And he was a lot of fun to debate with. We used to debate on intended use issues in emails, and stuff that I was interested in and that he was interested in. And they were not long debates, but they were fun. There wasn't a mean bone in him. I mean, I identified one particular area where he gave us, he had thought of a problem with an interpretation which was sustainable, but he thought would cause real problems and he presented his arguments and he was right and we said yes.

CC: Well, that requires are some skill when you are going to tell somebody 'no' who wants to do something, it takes a certain amount of skill to communicate that in a way that other party can hear you.

ML: Yes.

CC: And he didn't ram it down your throat. I mean, I don't want to put words in your mouth, but the sense I get is that he didn't ram it down your throat, he counseled you and he was skilled at counseling whereas some people just imposed.

ML: Yes, and he was funny.

CC: I think he was really well liked by the staff.

ML: He was, I think, sometimes too quick to decide things. Not that his decisions were wrong, but I think he was built for speed, and a very bright guy, so not surprising.

CC: So his mind was moving quickly. And he is at Covington and Burling now?

ML: He is one of three heads of their food and drug practice, but the youngest. What else can I say about him? You had the impression that he was a decent guy and a Republican, but not a little unlike Tom in the sense I think he had no use for Republican cant. Probably more conservative, maybe more conservative than Tom, but no use for the ideologues or holy wars.

CC: And Ralph Tyler?

ML: Very little business with him. I think he did himself a disservice. Any time there was someone new in a reasonably high leadership position in OC [Office of the Commissioner], CFSAN and I would try to get him or her to meet with our management council -- office directors, deputies, and some senior advisors. Sort of a meet and greet so maybe for the Chief Counsel, how do you see your job, sort of the standard questions for all the lawyers. And he spent some amount of time basically dumping on his own lawyers, insufficiently service oriented or whatever.

I mean, having spent almost twenty years in that office, I figured I knew a fair amount about its strengths and weaknesses -- not everything and I had my own biases and prejudices--

but it was just an odd way to start. But he is certainly, in the few dealings that I had with him, he was always fine. Pretty quick turnaround.

CC: We haven't talked about Liz Dickinson.

ML: I didn't have a lot of business directly with Liz, much more with Pete Beckerman who was the – I don't know what his title is, but he was effectively the deputy for foods and vet medicine. And I was one of the people who recommended hiring Pete into OCC after I came back in 2000 so I knew him fairly well from his first day and then he left for the Office of Policy and then came back for the OCC job. In fact, probably was, I can strike the probably, I was consulted. My views were sought about whoever the candidates were, he was one of them.

The little I hear which I indicated before which is that there's a much different reporting relationship between the Chief Counsel and the General Counsel and the Department than there used to be. And I can't believe – I mean, Liz has known Bill I think as long as I have and she may well be friends with him, but I can't imagine she enjoys reporting.

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It's now apparently the nature of her business, more may I do this? Most of us would, at a certain point in our careers, not want to ask 'mother may I?'-- we just want to be able to do stuff.

CC: Any final thoughts?

ML: I would leave you with one thought about the Commissioner. I spent roughly half of my career in OC, I spent about thirty years at the FDA.

CC: Thirty or 38?

ML: Thirty, 3-0. It's like 29 years and 9 months or 10 months or something, roughly 20 in OCC and roughly 10 in CFSAN. There is something I used in CFSAN to try to bolster spirits there and I believe to be true; it wasn't just to bolster spirits. And that is that what I think people in the Office of the Commissioner generally fail to grasp is that if the Office of the Commissioner disappeared tomorrow, FDA would still exist.

If the Centers disappeared tomorrow, there would be no more FDA. That doesn't mean the Office of the Commissioner isn't terribly important and it doesn't mean that it doesn't approve Center work products. There is a whole range of things it does. But fundamentally, the Centers are the factories. No Center for Drugs -- no drug approvals in the United States. It is fairly profound, a fairly important fact. If we don't have an FDA strategic plan, the sky will stay up. We don't get any drug approvals out, there will be incredibly horrible consequences.

And the one job I would want to do at FDA would be to spend some time trying to figure out what the Commissioner's Office ought to do, how it ought to be organized, and how it ought to be educated.

And one of the educational points I think everybody ought to have in there is just think for a minute what happens if the Centers disappear. And then think for a minute what happens if you disappear. Profound differences in consequences. And I don't think people in the Commissioner's Office begin to grasp that basic fact. I don't think it crosses their mind.

And again, it is not that dealing with legislation is not important, dealing with strategic plans – a lot of that stuff is important, but fundamentally the taxpayers to the extent they think about us at all are not thinking about strategic planning or IT management or, or, or. They are thinking about is the food supply safe, are drugs safe and effective, are biologics safe and effective and the list goes on.

CC: Well, as I listen to you, I am struck that until 2009 (or whenever the new level of management, the Deputy Commissioner for Foods and Veterinary Medicine, was created), all the program stuff happened. What you have now is more control, but I am not sure that you have better decisions, more efficient decisions, more effective resource allocations.

ML: No, I don't think you do and the resource allocation question, we have had contractors in, contractors have been hired, let's do this better. Not that we can't do it better, but I did tell Deloitte that if we were truly allocating resources on a basis of public health benefit, I said wouldn't pay you a nickel because it's quite simple. You figure out – if you assume that you

could actually accomplish something by putting those million dollars into nutrition, you put them all into nutrition. Goodbye. They were not used.

Not that there isn't a big if there, how much can you influence? I mean, some things you can influence. Obviously if you remove industrially-produced trans-fat it is gone, if you actually reduce sodium, it's a benefit – let's assume it's a benefit to have a reduction to some level and one could argue about the level. In terms of getting people to follow better, more healthful dietary practices is a different issue.

END OF INTERVIEW