



**Oral History Interview with
Arthur N. Levine, J.D.
Deputy Chief Counsel for Litigation
Office of Chief Counsel,
1970-1991**

**FDA Oral History Program
Final Edited Transcript
December 6, 2016**

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Oral History Abstract

Arthur N. Levine joined the FDA in 1970 and served as 8 years as a trial lawyer until he was promoted to Deputy General Counsel (and later Deputy Chief Counsel). In this interview he recalls the changing leadership and culture of the office, highlighting the shift towards the agency's increased use of notice and comment rulemaking. He discusses office practices for litigation, particularly working with compliance officers in the field and collaborating with a variety of officials in the Department of Justice.

Keywords

Food and drug law; Office of Chief Counsel; Office of General Counsel; enforcement litigation

Citation Instructions

This interview should be cited as follows:

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Interviewer Biography

Catherine Copp received her law degree from the University of Michigan, and worked in the Office of Chief Counsel and in the Center for Food Safety and Applied Nutrition (CFSAN) on legal and policy issues for over 30 years before retiring in 2011. In 2014 she joined the FDA History Office as a research historian, specializing in oral history.

FDA Oral History Program Mission Statement

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

Statement on Editing Practices

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

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Interview Transcript

CC: This is another in our series of oral history interviews for the Food and Drug Administration. This is Catherine Copp, and today I am interviewing Arthur Levine. It's December 6, 2016, and we're in the History Office at FDA's White Oak Campus. Welcome, Arthur.

Arthur, let's begin. You were an employee in the Office of Chief Counsel or the Office of General Counsel, as I think it was called when you joined. Let's start with that. Tell me how you happened to come to FDA and a little bit about your life before that, where you went to school, where you got your degrees.

AL: I graduated from UCLA in 1967, and I went to law school at UC Berkeley and graduated in 1970. That was a time when there was a lot of interest in consumer protection. It was the height of the Ralph Nader era, if you will, and I was interested in doing consumer protection law. I did a little bit of research in that field in law school, and when it came time toward graduation, I decided that I wanted to work at the Food and Drug Administration. I also had been very influenced by the Estes Kefauver book, *In a Few Hands*, which was the story of monopoly power in the pharmaceutical industry.

So I was interested in working for FDA, and I was interviewed in San Francisco by a representative of the Office of the General Counsel for the Department of Health, Education, and Welfare. And I subsequently got a job in the General Counsel's Office for the FDA.

Technically when I started, which was October 1970, there wasn't something called the Office of the Chief Counsel, FDA or the Office of the General Counsel, FDA. There was a General Counsel's Office. The General Counsel was the primary lawyer for the Department of

HEW, and that Department had nine working groups: one that provided legal services to the FDA, one that provided legal services to the NIH, one that provided legal services to the Social Security Administration, and there were six others. So I came to work for the Department of Health, Education, and Welfare in what was called the Food and Drug Division. At that time the Deputy General Counsel of HEW and head of the FDA division was Billy Goodrich. I came on just before Mr. Goodrich retired. In fact, I was the last FDA lawyer to be hired by Mr. Goodrich before his retirement.

CC: That's quite a distinction. Where was your office?

AL: Like most lawyers did back in that day, I started out by rotating for a couple weeks at a time through a number of the other divisions. So I went to the Food and Drug Division, but I also visited the Public Health Division and the Social Security Division out toward Baltimore. But I was earmarked for the FDA. When I got through doing my rotation tour, which was the practice at the time, I settled in at the FDA, and that was in the Parklawn Building in Rockville, Maryland.

The FDA and its legal office had moved to the Parklawn Building the year before. So they were just getting set up in 1970. And again, I started work for Mr. Goodrich. At the time I was the 17th lawyer on the staff of the Food and Drug Division of the Office of General Counsel at HEW.

CC: Who were the other managers or supervisors at the time you were hired? Do you remember?

AL: There was one other manager, the Deputy Alvin Gottlieb. He was in charge of the office essentially on a day-to-day basis. The most senior supervisory attorney and the only woman in the Food and Drug Division was Joanne Sisk, now Joanne Valentine. But basically the office was run by Billy Goodrich and Al Gottlieb. Al had been a staff attorney for Goodrich previously, and Goodrich had selected Al to be his deputy from among the other attorneys on the staff.

CC: Do you know what year Mr. Gottlieb was designated as deputy?

AL: No, I don't. I suspect it was in the latter half of the 1960s. He certainly had been a food and drug lawyer for a while, and I think at the time he must have been in his mid to late forties, and by virtue of his personality and temperament, he was an imposing figure, but I actually don't think he had been the deputy that long.

CC: When I interview Gary Yingling, I'll ask him the same question. He might remember.

AL: He might remember.

CC: Speaking of Gary Yingling, who else was on the staff at that time that you recall, other lawyers?

AL: Other lawyers when I joined in 1970 – the person who was hired just before me was Rick Blumberg so we were the two new kids on the block. In addition, already in the office at that time would have been John Young, Bob Anderson, Bob Wilmoth, Gary Yingling, Jeff Springer, Steve McNamara, Gene Pfeifer, Forrest Patterson. Those are the ones who come to mind most immediately.

CC: That's 12 people including Billy and Joanne and Alvin. Were they included in the 17 that you identified or were there 17 --

AL: I think there were 17 staff attorneys.

CC: That's interesting. Some of them were there when I arrived eight years later.

AL: Oh, and John Eldred was already there.

CC: Was Bob Spiller there?

AL: I don't think so. I think Spiller and Rick Silverman I believe came not too long after I arrived, but I could be wrong.

CC: At this point, those distinctions aren't particularly important. Of these people, the senior people were Anderson, Wilmoth, Youngmaybe?

AL: Well, Joanne was the most senior, and John Young was sort of her second in command. After that, most of the people had not been in the office all that long as I recall. I think most of them came in '67, '68, '69, earlier in 1970. Again, I could be wrong, but I think most of them were relatively new.

CC: I mean when I think about them, I think of many of them as being the same cohort.

AL: Yes.

CC: Steve, Gene, Forrest, Bob, Rick, and John. That's not completely inconsistent with what little I know, and I wasn't there.

Let's talk about the kind of work you did or the office did. Now the Chief Counsel's Office does both litigation of various types and does a lot of what they call program review – regulations and other non-litigation kind of work. Were both those present on your personal docket? What kind of work did you do?

AL: Well, both of those kinds of work were present, but the staff attorneys only did litigation. So all of the policy, program, regulations review, legislative work that had a distinctly legal component – all that work was done by Billy Goodrich, and it was done by him essentially alone to the best of my knowledge. He farmed out particular research assignments in support of that work to staff attorneys. But he did handle that whole side of the house.

Gottlieb was in charge of the litigation, and everyone did litigation. So we had 17 litigators, trial attorneys – supervised by Gottlieb. Then all the other work – regulatory policy, legislative – that was all done by Goodrich, farming out parts to the staff lawyers.

In fact, I did a research project with Rick Blumberg for Goodrich during the early months of my tenure, which led to a little bit of a minor incident. Rick and I were called into Mr. Goodrich's office by his secretary at the time.

CC: Could I just interrupt you? Did you call him Mr. Goodrich or did you call him Billy?

AL: Oh, absolutely we called him Mr. Goodrich. Joanne and Alvin called him Billy, but we all called him Mr. Goodrich.

CC: Did they call him Billy to his face?

AL: I think they did at least over lunch, but I wasn't in his office when they were in his office alone. In the office, often other people were standing around, and when other people were around, they called him Mr. Goodrich.

Well, Rick and I went into Mr. Goodrich's office. We didn't know why we were called in. You were rarely called into Mr. Goodrich's office. He had a big desk and two chairs in front of it – you know, like for guests, if you will – and he sat in a desk chair behind the desk. We came in, we sat down. He gave us a research assignment. We were taking notes like mad to make sure we got it right, and when he was through giving us the assignment we both got up and left.

Two things happened after that. First of all, Rick and I went to either his office or mine and immediately went through our notes to make sure that we understood what Mr. Goodrich wanted because he spoke fairly quickly and he assumed a certain amount of knowledge that neither of us had. We were both neophytes at the time, and Rick and I were petrified that we wouldn't get the assignment right.

The other thing that happened was that Rick and I got called into Mr. Gottlieb's office. As soon as we got into his office – this was an hour or two later – he read us the riot act because we had gone into Mr. Goodrich's office and sat down in the two chairs, and you don't do that. We did not understand that when you were being addressed by Mr. Goodrich, you were supposed to stand – the chairs were there if the Commissioner came down or a Congressman, but the chairs really weren't for the staff, and that if we ever went back into Mr. Goodrich's office, we should stand and not sit.

CC: This reminds me – and you may remember this – of Rich Cooper when he was the chief counsel telling us at a staff meeting or some group get-together that at the Commissioner's staff meetings, the chair to the immediate right of the Commissioner, who at the time was Donald Kennedy, that was for Paul Hile, and no one was to sit in it. I never knew if I had sat in that chair by mistake. So there was a lot of protocol I guess that wasn't necessarily communicated.

AL: Well, there was and it was also a sign of the times. You also have to remember that Mr. Goodrich had been the Deputy General Counsel, head of the Food and Drug Division, or as we would say now the General Counsel of FDA or the Chief Counsel of FDA, since 1959. Before that, he had been in the Justice Department working on FDA and related issues in the Civil

Division. He was probably the single-most knowledgeable lawyer in food and drug law in the country. So he was really more than the General Counsel of FDA. He was a well-recognized expert and essentially a walking history on most of the amendments to the Food and Drug Act. He worked heavily on the 1958 Amendments, the Pesticide Amendments, the '62 Drug Amendments. He was involved in everything. People treated him with a great amount of respect that was well-deserved and due. It was a slightly different time. It was a time of greater formality, especially among FDA lawyers. People got dressed up to come to work.

CC: I was just going to ask you that. Did you wear a shirt and tie?

AL: Shirt and tie.

CC: Did you wear a jacket?

AL: I don't recall whether I wore a jacket, but I wore a shirt and tie. Everyone did. There was an occasional exception. Gene Pfeifer tended to dress down and Blumberg did over the years, but mostly everyone was there in shirt and tie. It was just a more formal atmosphere. And, of course, Gottlieb wore a shirt and tie and a jacket, but he was the taskmaster over these 17 staff attorneys who all did trial work. As I said, Goodrich ran everything else with piecemeal assistance from the staff.

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AL: By the way, because of the way the office work was divided and because of the great respect that Billy Goodrich had in the Food and Drug community and because it was the practice at the time, lawyers in the FDA General Counsel's Office did not sign their own work.

Everything was signed by Mr. Goodrich. So you would prepare a document for court in support of a case that you were working on. Mr. Gottlieb would review it and provide comments. You would make revisions. You would have it prepared in final form, typed in triplicate with carbon paper by your secretary, and then there would be a place in the letter where you as the attorney would be named and your phone number would be given, but the letter would be signed by Mr. Goodrich. It would have his name on it, and either he would sign it or – he had a stamp or his secretary did it, but it bore his name, not yours. You were the staff resource. He was the general counsel, and that's the way it was until Peter Hutt became the chief counsel, but I'm sure we'll talk about that in a bit.

CC: If you said, I don't recall. What was Joanne Sisk's job?

AL: She was a trial attorney like the rest of us. She was a supervisory attorney. She handled her own cases, and, in conjunction with Al, she also would review drafts of motions for summary judgment, default decrees, consent decrees, and whatnot.

In that day, talking again 1970, 1971, until the Hutt era really got going, the Chief Counsel's Office handled about 350 cases a year, close to 300 seizures, about 25 to 30 injunctions, and maybe 20 or so criminal cases, and so every lawyer had a caseload. The cases were assigned to you by Mr. Gottlieb, usually in person. You would go into his office and he would tell you that the District Office had prepared a recommendation for a seizure, let's say,

and the District Office had prepared a draft of a complaint and it had been reviewed by the so-called Pleadings Branch of the General Counsel's Office, and that Mr. Gottlieb was assigning the case to you. He would tell you what to do, how to finalize the letter, how to be in contact with the Compliance Officer from the District who was assigned to the case, how to work with the Compliance Officer to have the case supported by the District Office once the letter arrived at the local U.S. Attorney's Office and was assigned to the Assistant United States Attorney who would be handling the case on behalf of the FDA with the support of the lawyer from the General Counsel's Office.

So in that, one is reminded that the responsibility of a trial attorney at FDA was always in effect a second-chair responsibility because the lead lawyer on behalf of the government was the local Assistant United States Attorney, who also ultimately had the power whether to file the case or not, although 95 plus percent of the time they did. But the lead counsel, if you will, at least technically, was the Assistant United States Attorney.

The lawyers in the Chief Counsel's Office helped promote the filing of the case. They worked on all the motions. They provided all the paperwork for filing in court in support of the case. These were all, you know, in theory subject to review and editing by the Assistant United States Attorney, but the members of the Office prided themselves on the fact that the work would be provided to the Assistant United States Attorneys in completely fileable form. It would be correct as to substance, it would be clearly written, it would comply with the local rules, and all the Assistant had to do was to sign it. That's how we were all trained, and we were trained to do that by Gottlieb.

The theory was that by doing casework, lawyers would learn about litigation, they'd learn about lawyering, and they'd learn about the Food and Drug Act, especially those provisions that

were involved in enforcement actions more frequently. We weren't so much studying every provision of the Food and Drug Act, but we certainly did a lot of work involving insanitary conditions in food warehouses, and good manufacturing practices for drugs and new drug issues and whatever that were the most frequently litigated. So that's how we learned the law, and that's how we learned the regulations, basically by working under Gottlieb's supervision.

He would assign you cases of increasing complexity as you progressed in your own knowledge and development in the Office. So everyone started out doing cases that Gottlieb knew were destined to go by default or consent because there wasn't a lot to be done, and default decrees and consent decrees were basically cookie cutter kinds of documents. As you got more and more experience, he would give you more complicated cases, cases that were more likely to be challenged, where you'd have to write motions for summary judgment; you'd have to take depositions again in support of the Assistant United States Attorney; you'd have to arrange for affidavits from experts, whether they were FDA in-house experts or experts at medical schools and places like that.

Gottlieb brought everyone along at a certain pace depending upon their apparent skills and aptitude, and that's how you learned to be a food and drug lawyer. Gottlieb ran that side of the office, all the litigation-related stuff and the relationships between the staff attorneys, the Compliance Officers in the Districts, and the Assistant United States Attorneys who handled the cases in the various judicial districts throughout the United States, of which at the time there were 96. It was up to the lawyers and the Compliance Officers to maintain good working relationships with the AUSAs who handled the cases in the various jurisdictions. There were also a lot of client relations and Department of Justice relations work as being part of a trial attorney for FDA.

CC: You mentioned that there were 96 judicial districts when you started. So did that mean you were traveling often? I know as a trial attorney, I spent time on the road. What was the travel like when you started?

AL: There was some traveling, but not so much in the day-to-day processing of the case. As I said, a vast majority of the cases were settled by default, which meant that the potential claimant never appeared, never claimed the goods that had been seized, and so the court ordered them destroyed. Or the claimant would come in and say in effect “Okay, I’m not going to challenge this, but I’d like to try to recondition the goods or I’d like to destroy them” and the goods were condemned by consent. There was no traveling involved in those cases.

But for contested seizures and for many of the injunctions (but not all) and for most of the criminal cases, there was travel. Usually that meant going to the U.S. Attorney’s Office, meeting with the Assistant U.S. Attorney, and doing whatever you and the Assistant felt needed to be done, whether it was interviewing an expert witness, developing a deposition, developing a draft of an affidavit, arguing a motion for summary judgment, arguing some other kind of motion. So you would go out and travel and do that. You almost never appeared in court on your own. You always appeared with the AUSA. Now sometimes the AUSA would take the lead. Sometimes the AUSA would say to the judge “Mr. Levine is here from the General Counsel’s Office of the FDA. They have the expertise on this question. I’m asking you to allow him to make this argument on this motion.” And then the Assistant would sit down and you’d argue the motion. This varied from Assistant to Assistant. But those are the kind of reasons why

you would travel, and there was some travel. It wasn't a constant diet of traveling, but there was traveling.

CC: My recollection from being in the Office and talking to people who have been around like you've been around for another decade is that there was some kind of West Coast office of the General Counsel's Office. What was that about and who staffed that?

AL: Just as I joined the office, there was a gentleman named Arthur Dickerman, who was a long-time colleague of Billy Goodrich's, who was a one-man West Coast Office of the General Counsel's Office of FDA. I don't know how it got started. I think it got started in the early 1960s. Dickerman had a hands-on relationship with the cases that were filed in the judicial districts out there, whether it was the Eastern District of California, Northern District of California, District of Oregon, whatever it was. He had supervisory responsibility for those cases. By the time I showed up, he was about to retire, so I don't know what it was like before that. By the time I showed up, those cases were assigned to attorneys in the General Counsel's Office in Rockville, and we worked them up on our own just like any other case.

CC: What about Jay Geller?

AL: Well, in the mid-1970s Jay Geller, who was a young staff attorney in the Chief Counsel's Office – I don't remember when he started – he had a desire to relocate to the West Coast. And there had been this tradition of having a West Coast lawyer. And after some consultation – I don't even remember who was the Chief Counsel at the time – Jay was assigned to go out to the

West Coast and be the primary contact for cases out there. And it was the same deal. He didn't handle all the cases out there, but he was the primary contact. He was responsible for relations with the AUSAs out there in that region and he had a closer working relationship with most of the Compliance Officers out there, but again it was sort of an overview kind of job. I don't know how long that office lasted. At some point – I'm thinking in the mid-1980s – Jay left the FDA and joined a boutique food and drug law firm out in California. There wasn't a desire to maintain that office I assume because it was costly to do so and also frankly because a trip to San Francisco or San Diego or Los Angeles was desirable for East Coast-bound FDA lawyers, that it was sort of a reward to be able to have a case out there. So I think for those reasons the West Coast Office was closed.

CC: My recollection is – and I came in September '78 – was that Jay was still on the staff at that time, but very soon after I came, he went into private practice and the office was closed. I never remember any relationship. You know, it could have been my cases, but I don't remember having any contact with him. Just he was sort of a name with a geographic location.

AL: Well, do you remember him as being already in California in '78?

CC: Yes. Yes.

AL: So, sometime in the mid-seventies, he went out there. And he would come back for once a year for staff meetings. Some of us knew him when he was a young lawyer among us in Rockville. But people like yourself who came in '78 and thereafter – and it was a big class in

'78 – just knew him as someone by reputation and that was that. So that was the West Coast Office as best I know it.

CC: You talked about cultivating relationships with the U.S. Attorneys. At the time you started, was there any relationship with the headquarters of the Department of Justice?

AL: No, not that I recall. That came later. There was, in the Justice Department in Washington in the Civil Division, a Consumer Affairs Section, later called the Office of Consumer Affairs, but it had always been at arm's length with the FDA cases. It was decided that that office would become active and they would exercise equal status, if you will, with the U.S. Attorney's Offices throughout the country. So starting in the late seventies, as best I recall, there were two Justice Department lawyers who were involved in every food and drug case to varying degrees – there was the Assistant U.S. Attorney as had always been, who was physically located close to where the case was and a lawyer from the Consumer Affairs Section of the Civil Division of the Justice Department in Washington. So one copy of a proposed FDA case continued to go to the U.S. Attorney who would assign it to the Assistant U.S. Attorney who always handled FDA cases in that office, and another copy would go to the Consumer Affairs Section. And then usually someone in the Consumer Affairs Section would contact the FDA lawyer and say "I've been assigned to this case.

If something happens other than a consent or a default, let me know so I can coordinate on behalf of the Justice Department with the Assistant U.S. Attorney," and that's basically how it went.

For many injunction and criminal cases, the Office of Consumer Affairs – well, first the Consumer Affairs Section was what it was called – got involved and then there were three lawyers – the FDA lawyer, the Assistant U.S. Attorney, and the Consumer Affairs Section (or Office of Consumer Affairs) lawyer. The two Justice Department lawyers were usually on the same page, but occasionally they had differences of opinion about the case. In its worst form, it sort of became a bit of a three-ring circus, but that didn't happen all that often, but it was one more Justice Department attorney to whom an FDA lawyer stood second in line. So instead of being actually second in line, even if the Assistant gave you all the authority in the world, you were still technically second in line.

Once the Consumer Affairs Section became active in a matter, you were technically third in line, but again, usually doing most of the food and drug work. The Justice Department lawyers concentrated more on, for the most part, local procedures, the judge's preferences, and the local dynamics and politics. But they did occasionally get involved in the substance, including the ultimate substance, particularly for a criminal case, which was whether the case should be filed or not because the FDA only made recommendations that cases be filed. They were always filed in the name of the United States, which is why food and drug cases are not styled FDA versus whomever; they're styled the United States of America versus whomever. So the cases by statute were always brought in the name of and by the United States of America, not by the FDA.

CC: My recollection is that there was a lawyer named Bob McConachie, who was the head of that headquarters Justice Department office when I came.

AL: Bob McConachie was the head of Consumer Affairs Section (or the Office of Consumer Affairs) at some point –

CC: I think he preceded Pat Glynn.

AL: Right. He may have been the first head of that office.

CC: He wasn't there very long in terms of my tenure.

AL: Bob was the first head of that office whenever that office became active. And again, I don't remember the exact year when it became active in FDA cases. He was succeeded by Pat Glynn. Pat had as his deputy, John Fleder. Pat stayed with the Justice Department until I think he retired, although toward the end, he took another job within the Civil Division. John Fleder was there many years and then he left and joined a law firm in Washington. But you're right, it was –

CC: Bob McConachie.

AL: Bob McConachie and then Glynn and Fleder.

CC: And not that all this minutia matters, but my recollection is that for some reason when McConachie was the director of the Consumer Affairs Section, the Section was actually in the Antitrust Division in the very beginning.

AL: I think you're right. I think it may have started in Antitrust. Then for a long time it was part of the Civil Division, and I think toward the end it actually got shuffled into the Criminal Division. So it moved around a lot, but from the time its existence mattered for FDA purposes, it was always part of the Justice Department, and there was a fairly constant set of lawyers. People came and went, but there was some consistency, just as there was in the General Counsel's Office of FDA.

One of the areas of some tension led to a meeting in '78 or '79 when Rich Cooper was the General Counsel. Rich had come to the General Counsel's Office from a private law firm in Washington, and he had a very distinct feeling that lawyers served clients, that clients made policy and program enforcement decisions, and lawyers found the best way to implement them, although the lawyers' views were always welcomed by the client. So Rich always viewed the FDA, including the Office of the General Counsel of FDA as the client.

CC: Of the Department of Justice?

AL: Yes, in relation to the Department of Justice. So he always felt that once the client, including its lawyers, including himself as the Chief Counsel, had made an enforcement decision, for the most part, it was the role of the Justice Department to implement that decision.

And we had some disagreements about some cases with the Justice Department. I don't remember now whether they were just about whether the case would be filed or not or how it would be litigated or what the theory of the case would be or whatever, and Rich became quite concerned that the Justice Department was exceeding the appropriate role as between clients and lawyers. I remember we had a meeting about that and we reached some accommodation, but it was always part of the tension, always part of the relationship between the General Counsel's Office of FDA and the Justice Department.

CC: I have just a couple more questions about that early period of both your career and the Billy Goodrich era. What was the pace of the work? Were people in the office on the weekends? Were you expected to be in on the weekends?

AL: Mr. Goodrich handled all the policy and regulations and legislative stuff predominantly on his own with the assistance of staff attorneys on various isolated research projects, and the 17 lawyers handled this caseload of about 350 cases. As a result, the pace was, I would say, constant but not hectic. It was constant because there was a lot of care and feeding to be done for a case – work on the case, relations with the Compliance Officer in the District, relations with the lead investigator on the case, relations with the AUSA, moving the case forward, keeping track of it, keeping Gottlieb informed of the progress. So there was constant work, and you were constantly working, but the pace was not hectic the way it became later. Even though there were more lawyers later, there was also a lot more work and so the pace tended to pick up. But there was plenty of work to do, and at the same time, many of us were also learning the law. We were doing the as-you-go Gottlieb tutorial method of training. So when you actually weren't working

on a case, you were expected to be learning. And so there were times you would go into the library and just do background reading.

I should add that in the very earliest years of my time in the Chief Counsel's Office, if you went into the library to get a book, you had to be very quiet because my office was in the library. There was no regular office for me. There was a library in the General Counsel's Office of FDA in the Parklawn Building. It was two or three different rooms that constituted this library, and my office was in one of the rooms of the library. I had a desk there and a phone, and my secretary was also in the library outside in another office.

CC: Was that Mary Amantia?

AL: No. That was before Mary. That was Linda Edwards. She was 17. She had just graduated high school, and I always remember joking to friends of mine that it was sort of like the blind leading the blind. I was brand new to law, I was brand new to food and drug law, and my secretary was brand new to working. After about a year or so, I did get a regular office and I moved out of the library, and I don't think they put anyone else in there.

CC: I heard comparable stories, not about the library, but I think our mutual colleagues Fred Degnan and Bob Dormer were first located together in a conference room, which then created some problems of sort of a legal nature because they were on opposite teams in a separation of functions on an administrative hearing or some similar action.

AL: Right. That sounds familiar to me. I don't have a specific recollection of where people were, but all the lawyers did not have their own offices for a number of years through the seventies. Again, in 1970 the whole FDA, including the General Counsel's Office, was relatively new to the Parklawn Building. We were on the sixth floor, which actually was great because you entered the building on the fifth floor, so you'd come into the building and you'd just bop up one flight of stairs and there you were in the Chief Counsel's Office. Very, very convenient.

CC: And that was doubly convenient because the elevators were sort of – well, slow doesn't describe them. So it was an advantage to be where you could walk.

AL: Well, you could get to your office in a reasonable amount of time. They were notorious, the elevators in the Parklawn Building.

CC: A couple more questions about this period. Was there any relationship that you were aware of between what came to be called "downtown," meaning headquarters of HEW (and then HHS) and the Chief Counsel's Office?

AL: On some rare occasions, staff attorneys would become aware of some direction that had come from the General Counsel of the Department down through the Deputy General Counsels who headed up the various divisions like the Food and Drug Division. There were probably a number of them that were more administrative in nature and we never really appreciated where the direction had come from. We just knew there was some change in the office. Every once in

a while, there would be policies that would have a more direct effect on us, but one of the advantages of moving with our client to Rockville, Maryland was that we were geographically removed from the General Counsel's Office, the Department General Counsel's Office, which was in downtown D.C. There was a time when all the divisions of the Department General Counsel's Office were in the General Counsel's Office downtown, so we moved away, and that physical distance contributed to a sort of working practical distance. And so there were not a lot of controversies.

When I became the deputy for litigation, I had a larger insight into the management of the Department as a whole, and I grew to understand the significantly greater involvement that the General Counsel's Office of the Department had in the other General Counsel offices that had client agencies within the Department – FDA, NIH, Social Security, whatever. But we were pretty much doing our own thing. That was the attitude – that we did our own thing, that we had an excellent reputation, that our Chief Counsel was highly regarded, and the Department left us alone. The staff lawyers were not apprehensive that someday the General Counsel from HEW would call them in and read them the riot act. If you made a mistake, Gottlieb would tell you.

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CC: You mentioned the Pleadings Branch, and I just wanted to ask you – the name I associate with that is --

AL: Frances McKay?

CC: Yes, Frances McKay. And I believe Phyllis Henkel was one of the secretaries in that unit.

AL: I don't know when the Pleadings Branch started, but there was a group, and I think it was there from the time I walked in the door, a small group that Frances McKay headed up that took proposed pleadings, complaints for injunction, complaints for seizure that the Districts would prepare and they would be reviewed and edited and revised by the Pleadings Branch headed up by Frances McKay.

AL: McKay edited what he got from the District offices by hand in pencil, and his pencil markup was then typed up and presented to Gottlieb who assigned it to a lawyer to review to approve to give back to Gottlieb to put on Goodrich's desk to be signed by Goodrich to be sent out in Goodrich's name as I previously discussed. But that's how it went.

CC: That's a good segue into one of my last questions about what things were like when you started in the Office of the General Counsel. Mag Card Selectric typewriters, carbon copies. Any other things? I mean it goes without saying there were no computers.

AL: Right.

CC: What about the phone system and conference calls; did you do stuff like that?

AL: We used the telephone like people used the telephone in the 1970s. We called. We kept in contact with the Assistants by telephone. We kept in contact with the District by telephone. There was rarely a conference call, except if what you mean by that is say you were having an important discussion with the Compliance Officer in charge of a case and the head of compliance wanted to participate. So they would both sit in one office somewhere out in the District, then you'd call from your office and they'd both be there in that office. Or they'd go visit the Assistant U.S. Attorney and they'd be sitting in the Assistant U.S. Attorney's office. The Assistant and the head of compliance, the assigned Compliance Officer, they'd all be in the AUSA's office. You would be in your office on the telephone and you'd have a call. That's how business was done.

CC: Did you have a speakerphone on your desk; do you remember?

AL: Not until I was a deputy. No, as a staff attorney, I didn't have a speakerphone.

CC: Do you recall using the FTS operator?

AL: No, I don't recall one way or the other.

CC: Federal Telephone System or whatever it was you'd call.

AL: Now that you mention the FTS operator, it rings a bell, but that's all it does, just as a phrase from history.

CC: One of my History Office colleagues is very interested of documenting – and this is before that – documenting the rise in the prominence of computers. So that was just one of the reasons I asked.

AL: Getting the work done was a real challenge, developing the kind of high-quality, ready-to-file work, which provided the leverage that our office had with the AUSAs. Most AUSAs got work product from lawyers, from regulatory agencies throughout the federal government, in draft, and the assistant would have to set aside time and work on the case before it would be filed. We prided ourselves in providing high-quality “fileable” work and developing a reputation with the AUSAs such that they were always very pleased to work on an FDA matter because the FDA lawyers always did a great job for them. That was what Gottlieb preached and that’s what we were trained to do. And that was the motivating thing about being a lawyer in the FDA the whole time I was there but certainly during the Gottlieb years.

CC: Do you think that Mr. Gottlieb or Mr. Goodrich was sort of the genius about the ready-to-file high-quality? I would agree with you – I think that gave us enormous credibility, particularly with the Assistant United States Attorneys. I’m just wondering who thought of it or came upon it as an idea.

AL: I don’t know. As I said, Billy Goodrich was an expert in the field and the most knowledgeable food and drug lawyer in the country. So he insisted that everything be right. Gottlieb felt that the way to develop the reputation of the office was to train good lawyers and

have them provide high-quality work. So I think it was both of them who engendered that attitude; and the two of them set that tone. Even after Goodrich left and Peter Hutt and Dick Merrill were, in succession, the next two general counsels and a lot of change came to the office, they both had a strong feeling that the office should provide high-quality legal work, although to a broader audience, which is sort of the next chapter.

CC: Right.

AL: After Mr. Goodrich left, Gottlieb continued with the staff attorneys in regard to litigation. By the time he left and Jeff Springer became the general deputy and I became the deputy in charge of litigation, all the Gottlieb tapes had been running in our head for years and they just kept running. So the principle of “fillable quality” carried on, as I think Gottlieb intended it would. It became part of the fun of working there and the pleasure of working there even as the different general counsels changed and tweaked the nature of the work and the relationship between the office and our FDA client.

CC: I was one of your first new lawyers. I think you were appointed maybe a week before I came to the office. I started September 10, 1978. Your description of so much of what Alvin Gottlieb did – I could go back and say the same thing about Arthur Levine’s training of new attorneys. I guess what I am trying to say is that I experienced the Gottlieb tapes running in my head, too. Mr. Gottlieb left quite a legacy.

AL: There was a consistency that was not by accident because we all signed up to the Gottlieb plan. Even while we expanded our work for the client through Hutt and Merrill, the Gottlieb plan always remained the guiding beacon not just on the litigation side but also with the emphasis on quality and thoroughness in the General Counsel's Office.

CC: And high quality regardless of the type of work.

AL: Absolutely. That was the way it was when I started as the litigation deputy in 1978. As part of the reorganization of the office, I was the first deputy chief counsel for litigation, along with there being a deputy chief counsel for hearings and regulations, a deputy chief counsel for administration, and a general deputy. The five of us, that sort of became the office management model going forward from about '78, but it all went back to Goodrich and Gottlieb and the kind of training and orientation that we all got during those early years.

CC: I think I've always known that I had a great debt to Alvin Gottlieb and, to some extent – I understood this less well – a debt to Mr. Goodrich because I had excellent training from you and the other senior lawyers, all of whom basically formed me and my practice. It's an enormous debt. I have no idea how many lawyers passed through the Chief Counsel's office through let's say the 21st century. But most of us were trained according to the Gottlieb plan, and then I turned around and trained the people that I supervised in the same way.

AL: Right. It definitely has a lineage and in a day-to-day sense, it all goes back to Gottlieb, and in a more overarching sense to Goodrich and Gottlieb. It has served the office well over the

years. Attorneys who work in the General Counsel's Office (or now the Office of the Chief Counsel, FDA) had a much more rewarding experience as practicing lawyers because of the sort of philosophy that Goodrich and Gottlieb instilled. And, as you know, it wasn't always an upbeat experience. From Gottlieb, you got tough love. But he respected the lawyers in the office. Sometimes people joined the office and it didn't work out, and they left. And I think Alvin's attitude was that if people weren't cut out for it, they shouldn't be there because he wanted everyone who was in the office to be drinking the same Kool-Aid. So that tended to work and over the years, for the many, many people who worked there 10 or more years, 20 or more years, they adopted that. There were certainly difficult periods between Alvin and Billy Goodrich's successors, but he left a very, very strong mark while he was there.

CC: I think that the tough love part of Alvin's approach got left behind because I never remember being afraid to go into your office. And I always sat down. I think that part evolved with the size of the office and maybe some other factors.

AL: I did that part of Alvin's job. Remember, Alvin's job was basically divided into three. Thinking in terms of today's structure, he was the Deputy General Counsel, so he was the number two guy on everything. He also functioned as the Deputy Chief Counsel for Litigation in the sense that he ran litigation. And he was the Deputy Chief Counsel for Administration in that he ran the office.

CC: Exactly.

AL: Goodrich was the Chief Counsel and the Deputy Chief Counsel for Regulations and Hearings because he ran that whole part of the office.

CC: Maybe we can turn to a little lighter subject now. Do you have a favorite story about Alvin Gottlieb? Or Billy Goodrich?

AL: You didn't have a lot of interaction with Billy Goodrich frankly as a staff attorney and I've already told you one story.

CC: Right.

AL: As for Gottlieb, his office and Goodrich's office fed into a large open suite where both of their secretaries were and possibly a couple of other support people. That was the front office. Often there would be outside counsel, high-ranking people in the agency, or other people sitting waiting to see Goodrich or Gottlieb; they would be sitting outside in the open area. You'd be in with Gottlieb and very often he would be speaking to you in elevated tones. So Gottlieb is yelling at you about some mistake you made and telling you how it should be done in his very bombastic tough-love style.

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Now, from the outside, people could hear through his door and could hear the tone, but couldn't hear the words. When you left his office, who knows who was sitting out there. I never wanted

to be embarrassed by walking out into a room of people sitting around waiting to see either Goodrich or Gottlieb by their knowing that Gottlieb had just read me the riot act over some mistake I had made. So I used to open the door to Gottlieb's office as I was exiting, and over my shoulder, I would say something like "Yes, Alvin, that's right" or "Exactly!" or whatever. I would say something in a loud tone of voice to make it sound like Alvin and I had been on the same page, not that he had been yelling at me. So I always walked out saying something that I thought was designed to leave the impression that Alvin and I had a mutual understanding, we simply both got carried away and were speaking in loud tones. So that was my trick.

CC: Forrest Patterson was the Administrative Deputy when I came to the office, and Bob Brady told Mike Landa and me, because Mike and I started the same day, that when Forrest doesn't talk, don't worry, he just speaks really slowly.

AL: Right.

CC: He just has a very different, sort of laidback, Southern personality.

AL: When he spoke, he meant what he said and it was good stuff and smart stuff, but he didn't talk a lot. He was a good listener and so often, there were not a lot of words spoken.

CC: What about Rick Blumberg? It seems like he had sort of the same temperament as Alvin.

AL: They would go at it from time to time. Again, over the years, Rick developed his own reputation in the office and so actually, he and Gottlieb were often on the same page.

It was a heck of a challenge to take these law school graduates and turn them into food and drug lawyers. The office was set up in '70 when I arrived to accomplish that objective. Mostly, all the FDA lawyers there were anonymous. It was always Goodrich, Gottlieb, and the staff lawyers. No one really had a reputation beyond the reputation you developed with a Compliance Officer in a district or maybe the head of compliance from that district or if the case was very important to the district, you had interactions with a District Director or maybe some people in one of the Bureaus.

You developed your own reputation as an individual as a food and drug lawyer. But because Goodrich signed all the letters and he and Gottlieb were the face of the General Counsel's Office, the lawyers there were basically an anonymous group of young lawyers trying to do a good job. And that, in its own way in the early years, helped I think create a certain bond between the lawyers, most of whom were very young, pretty much fresh out of law school.

Joanne Valentine and, I think, John Young was a little bit older also, but for the most part, the lawyers were a bunch of 20-somethings. And the fact that no one knew who we were and we didn't have reputations outside of the people we worked with on a one-on-one basis was part of being in the General Counsel's Office. We were the people who did the work. You took pride in your reputation with the District Offices and with the AUSAs who handled a lot of your cases, and that was very important.

[BREAK]

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CC: We're back on the record interviewing Arthur Levine. Arthur, let's move now to the arrival of Peter Barton Hutt, who became the chief counsel about a year or so after you arrived at FDA. What are your recollections of Mr. Hutt and the effect he had on the Chief Counsel's Office?

AL: Peter Hutt succeeded Bill Goodrich in the spring of 1971. I believe his appointment was endorsed by Mr. Goodrich. Exactly how Bill Goodrich became aware of Peter Hutt as a young food and drug lawyer at Covington [& Burling], I don't know. Hutt felt very strongly that the FDA would be a more effective agency if it spent a greater part of its time and energy on those legal matters which would have a proactive standard-setting kind of impact on the regulated industry. While he felt that enforcement of after-the-fact violations were necessary and should continue, the emphasis should be on getting companies to comply in the first instance not so much by enforcement litigation but by advising companies with greater clarity and specificity what the agency's expectations were and what the agency's interpretation of the law was.

In furtherance of this view, he felt that the agency could do a lot better job in promulgating regulations and issuing standards that would define what, in the agency's view, the law required. So he set about to modernize, if you will, the efforts of the Chief Counsel's Office in regard to the area of administrative law, and that resulted in a substantial change in the work in the Chief Counsel's Office.

CC: Did that affect everyone, the workload of every lawyer?

AL: It affected the workload of nearly every lawyer but in slightly different ways. What evolved through Peter Hutt's tenure – and it didn't happen overnight – was a greater emphasis on regulations and rulemaking, and especially notice and comment rulemaking as defined by the Administrative Procedure Act, the APA. More lawyers were needed and more lawyering time was needed to support the Centers in their efforts to issue guidance documents, issue interpretive documents, and engage in rulemaking, which is to say to write proposed rules, to get them published in the *Federal Register*, to receive and review comments on those proposals, to provide commentary on the comments, to change the rule in response to the comments or not change it and explain why, and to issue a final rule. This is basically the APA notice and comment rulemaking process.

CC: I believe that you said during – shall we call it – the Billy Goodrich era, Mr. Goodrich handled almost exclusively these kinds of matters, to the extent regulations were being written. This was Mr. Goodrich's job.

AL: Yes. Not only was it his job, but if you read an FDA regulation, say, from 1965 in the *Federal Register*, it would say something like this: “In November 1964, the Food and Drug Administration proposed a rule to do A, B and C, and it was published in the *Federal Register*. Seventeen comments were received. The Food and Drug Administration has reviewed those comments and today is issuing a final rule in the *Federal Register*. The final rule provides X. Signed, Commissioner of Food and Drugs.”

CC: Not a long preamble.

AL: Not a long preamble.

CC: Right.

AL: Okay. So that's how it was done, which is not to say that the agency and Mr. Goodrich didn't think through all the comments that came in and give them due consideration.

So – when Hutt put an emphasis on proactive rulemaking and rule interpreting rather than retroactive law enforcement, what happened was that the office essentially became divided into two working groups of lawyers and the office started to grow. All of the lawyers who did enforcement litigation, which was Gottlieb's domain – and he continued to run that just as he had under Goodrich and he had the services of about the same number of lawyers, 17 lawyers plus or minus – did litigation pretty much as before.

Hutt wanted lawyers to develop expertise in the various subject matters that the agency administered: food, drug, devices, biological – well, when he started, actually the agency didn't regulate biologicals – veterinary medicine and the like. And so Peter started assigning lawyers to work with the Centers to develop these draft regulations and do other Center work that had a legal, regulatory or compliance component. Peter wanted someone from his staff assigned to help develop those matters in part so that the agency would have the benefit of these bright young lawyers and because they would infuse into the process all the APA and administrative law principles that Peter wanted considered.

Peter started designating lawyers to do that regulations work. For a while, the trial lawyers simply did double time – lawyers would do litigation and then they would do Center work, they would do Center “counseling.” That worked for a while and people were working very, very hard. Sometimes a lawyer would have a case in a particular area, that lawyer would develop some expertise in that area because it was a contested case, not a consent decree or a default decree, and so there was a natural migration of that lawyer to become a counseling lawyer in that area, as well as the litigator. Although FDA staff attorneys generally litigated across the board – foods, drugs, devices, whatever – for counseling, Peter’s objective was to have dedicated lawyer counselors for each Center to develop expertise in the nuances of the law as it related to one type of product.

But that double time really couldn’t be sustained as the Centers came to enjoy the benefits they were deriving from having dedicated counselors who would develop much more in-depth knowledge of their processes and the aspects of the law that they were implementing. The Centers started getting very interested in having more OGC lawyers assigned to them to help them with their work and to provide this administrative and regulatory legal expertise. So Hutt started dramatically expanding the size of the office – he started hiring more and more people through the early seventies. People began to have this dedicated relationship with the Centers who became their clients in the same way that the Compliance Office of the District was the client of the trial lawyers. As a trial lawyer, your primary client was the Compliance Office of the District; as a Bureau or Center counselor, your primary client was the program and regulatory offices within the Center.

CC: About how many lawyers do you think Peter Hutt hired?

AL: In the four years that he was there – from '71 to '75, my guess is he hired in those four years about 15 lawyers or so.

CC: So he almost doubled the size of the staff lawyers?

AL: Yes. He would hire three or four a year.

CC: Who were some of the people that he hired; do you remember? Or brought with him – I'm thinking of Terry Coleman.

AL: Well, I'm trying to think of who joined in those early years, as opposed to who joined in the mid-seventies. Steve Terman and David Weeda joined OGC in the early seventies, and Bob Spiller, Rick Silverman, Charlie Raubicheck, Beverly Cherniak, Rick Shupack, Jack Woolrich, Fred Degnan, Bob Brady, Mike Taylor and a few other lawyers joined in the early seventies. And there were more. They were brought in, and for the most part, they started the way everyone started, which was the traditional path. They were assigned to Gottlieb, so to speak, and he gave them cases and started teaching them how to be a lawyer and about basic food and drug law.

But then Hutt started giving ongoing counseling assignments to the same group of lawyers, in the different subject matter areas corresponding with the different Bureaus or parts of the Bureaus. The office became much more active. Not everyone did dual work.

Some people were not interested in Center counseling, and in one way or another, let that be known. Spiller was a dedicated litigator and so was Blumberg, and there were others.

CC: What about yourself?

AL: Well, in 1972 the Division of Biologic Standards in the NIH [National Institutes of Health] was transferred to the FDA and became the Bureau of Biologics, and FDA became the home for enforcement of the blood and vaccine provisions of the Public Health Service Act.

I was asked to be their counseling lawyer and essentially help bring them into the FDA and integrate the Public Health Service Act provisions with the food and drug provisions so that the Bureau of Biologics would start functioning as a part of the FDA. Hank Meyer was the director of the new Bureau, and Paul Parkman was the deputy. They had been the management leadership of the Division of Biological Standards at NIH, and they became number one and number two in the Bureau of Biologics. They were both scientists.

CC: My recollection is that Drs. Meyer and Parkman were involved in the development of either the oral polio vaccine, OPV, or the measles vaccine. I mean, I think that together, they had some fairly significant scientific achievement in childhood vaccine development.

AL: Yes, they did. I don't think it was polio, but they were active researchers and helped create some of the childhood vaccines we have today. So they were practitioners, if you will, but they were researchers and academicians while they were at NIH. Then they came over as the head of the Bureau of Biologics and they became part of a law enforcement agency.

We would have sit-down meetings with them where we would put on seminars, Peter and I, about FDA law, and they would in turn help educate us about Section 351 of the Public Health Service Act pursuant to which biological products are licensed.

CC: I want to step back a little bit. How did the Bureaus react to this transition, suddenly having a lawyer involved on a more day-to-day basis in their business? I mean that both generally, if you know, and then specifically with the Biologics people.

AL: With Biologics, my experience was that they were overwhelmingly accepting, which doesn't mean they were happy every moment. It just means that, as a whole, they were accepting because they knew that there was a lot they didn't know about the FDA and they knew that they were supposed to get integrated into their new agency. So they were grateful to get educated, if you will, by Peter and me. But they had a way of doing business that was different from FDA's traditional law enforcement orientation.

The other Centers were glad to have the help, especially when Peter had succeeded in convincing them that they ought to publish regulations of the APA notice and comment variety because when they started to realize what kind of undertaking that was and they were not set up for that – they didn't have significant regulations management staffs, and Peter, as their lawyer was saying, “You know, you can't just promulgate a rule. You have to explain your reasons and you have to create an administrative record because that's what the court is going to look at.”

This was even before the *Chevron* case, but there already were Supreme Court cases concerning, if you will, the administrative record and administrative law. Peter

basically told them “If you do it that other way, the old way, your regulations will be challenged and they’ll be overturned. You’ve got to do it this notice and comment way and you have to be serious about it.” Well, once he had so declared, you know, given his legal opinion at the Commissioner and Director of the Bureau level, that was the way they had to operate, that’s just what the law required, at least if you wanted to be sustained in court. The Bureaus had a lot more work to do in writing these regulations and lengthy preambles and other policy documents and interpretative documents. So in that sense, I’m sure they were greatly relieved to have someone from Peter’s office because it’s one thing to have Peter describe it to you and then leave the room and to have someone from Peter’s office or a couple people from Peter’s office say “we’re here to help you on a day-to-day basis.”

At the same time, I’m sure they felt “Well, now Peter Hutt has put his people into our business,” and there were instances where I was aware of pushback. Lawyers would review drafts of preambles to proposed rules and they’d go back to the Center and say “You haven’t explained this and I don’t understand that and no one’s going to understand why we’re doing it this way.” There’d be back and forth and there was engagement, and whenever there’s engagement, there are going to be differences of opinion, and that was a process. But Peter defined what the target was for administrative law, if you will, to do administrative law right, and he set forth his staff to do it, the staff of the General Counsel’s Office.

CC: You said you and Peter Hutt tried to bring along the new Bureau of Biologics. What was it like to work with Peter one on one on that?

AL: Oh, he was very smart and always very well-prepared and had a wealth of background information, was always knowledgeable about the scientific or management background of whatever issue he was talking about. So it was very impressive to be with him and to have a piece of the presentation or a part of the action, if you will. He was a very dynamic, incredibly hardworking lawyer who had a vision of how the FDA could best operate with a more informed regulated industry that, in addition to getting whacked over the head from time to time by Gottlieb's litigators would be given the rules of the road by the Bureaus with the help of the FDA counseling lawyers.

CC: By issuing a regulation?

AL: In a regulation or similar document and that both of these ways – enforcement litigation and rule-making – should proceed together. There were certain enforcement matters where Peter was directly involved, in addition to Alvin, and Peter certainly could be as hard-nosed about enforcement as you would want a chief counsel to be.

Peter was, in general, supportive of the enforcement work, and was, in general, content to let Alvin pretty much run with that and handle that. But Peter had his own vision and he wanted to develop the other part of FDA's processes. Peter thought there was a part that was not doing what it ought to do and not being efficient or effective and that if that part could get up and running, then the Chief Counsel's Office would be more productive and by informing the industry, setting out what the rules were, making them well-known, there would be more overall compliance.

CC: His vision?

AL: His vision as best I understood it. And that vision included, by the way, not only substantive rules, but a set of procedural regulations (which were later successfully challenged because they were not issued by notice and comment rulemaking). Then the procedural rules were re-proposed and implemented. Peter developed the procedural rules almost singlehandedly, which is to say that he dictated them to his secretary, Linda Broadwater. He would sit in the conference room in the front office with Linda and he would recite the regulations in the Code of Federal Regulations format.

CC: For one of the OGC alumni dinners, I put together a list of questions and answers on OGC trivia. This was probably 15 years ago. One of the questions was about who dictated the procedural regulations and how many tapes it required. I contacted Peter to get the answer – I don't remember the answer now – but that story is not apocryphal. I've talked to him about the procedural regulations, and Peter really did just sit down and dictate them using a Dictaphone, I think.

AL: Yes. He sat down and dictated the procedural regulations.

CC: Over a weekend or something?

AL: No, not over a weekend. He may have done some polish over a weekend. He dictated them over a long period of time. Peter was also, of course, very hands-on in reviewing the work

product that came through the front office, as Goodrich had done, which leads me to my favorite Peter Hutt story.

CC: Oh, good.

AL: I came to the FDA from California, and I had a lot of friends and relatives in California when I came to the Washington area and began working at the FDA. Some of the people I knew in California were much older than I, and every once in a while when I was working at FDA, I would get a call at midnight or 1:00 in the morning. Unfortunately, a number of those calls were to advise me of some very unhappy news about a relative or a friend in California. And every time the phone rang in my apartment very late at night, I approached the phone to answer it with great fear and trepidation. That stopped when Peter Hutt was the Chief Counsel because if Peter was working on something – looking at a regulation or looking at a draft of a recommended criminal case – he would call you at your house to answer his question. Since he regularly worked until 1:00 in the morning, you would get a call from Peter at midnight or later and you'd pick up the phone – with great trepidation – and on the other end Peter Hutt would say as if it were two in the afternoon “Hi, this is Peter. I'm in the office and I'm working on X, and I noticed that you've got a note here that says A, B, C and I was wondering about that.” And, you know, you're trying to wake yourself up and, in my case, get my heart out of my stomach and answer his question. When it was over, Peter would say “Okay, I understand now” or maybe he'd say “Let's discuss this more tomorrow morning” or whatever and matter-of-factly, he would hang up.

Those were the calls you would get from Peter. And it was because of Peter that I stopped thinking that every time the phone rang at midnight that it was some catastrophe.

CC: How did it affect other people in their family lives?

AL: I think for the most part, we sort of all laughed it off. There was a joke that went around: One day, Bob Spiller was working very hard on a case and he stayed at the office very, very late at night to work on it, well into the morning. He went home and got a couple hours sleep and when he came back very early in the morning to finish working on it, Peter Hutt still beat him into the office.

Peter was very hardworking and his ability to focus on things intensely was impressive. He would just go from one thing to another and churn through the work, and as he churned through the work, the expectation was that his staff would churn through the work, and we did. We all started churning at a higher velocity because we had to keep up with his expectations as well as those of Gottlieb. So if Gottlieb said rewrite this brief and get it back to me tomorrow and Peter said rewrite this regulation and get it back to me tomorrow, then you had two things to get back tomorrow.

CC: Was there any “But I have to do X”?

AL: Sure. You would defend yourself and you would explain what else you had to do. And it’s not that Peter and Alvin were unsympathetic, but they didn’t have scheduling conferences. If you were busy on something for Peter and Alvin wanted you to do something, you had to explain

to Alvin what you were doing for Peter and in what capacity. Then Alvin would either say “Okay, I’ll get someone else to do this” or he’d say “Well, maybe next week would be fine” or he’d say “I want you to do it anyway,” but that was his prerogative – he was the Deputy – as it was Peter’s prerogative, and that’s how it was.

So the size of the office started to grow in the early 1970s, and at the beginning, everyone who came in came in got the Gottlieb training and then some migrated to Bureau counseling work and had more interactions with Peter. The other thing that Peter did was that the lawyers were authorized to interact with their counseling clients in writing (which usually meant short memos) in their own name.

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CC: And that was new.

AL: That was new, at least to the best of my knowledge. Whereas before, Goodrich had done all of that kind of counseling work and all the litigation had gone out under Goodrich’s name. Under Hutt, the recommendations for enforcement litigation still went out under Peter’s name. But the regulations work was all done in the name of the counseling attorney, so as a counselor, you could sign memos to someone in the Bureau expressing your view about something, and you could mark something up and then sign it and send it back to the Bureau or sit with someone in the Bureau and walk through it and discuss your views and comments and whatever.

CC: And that had weight and the support of your –

AL: Boss.

CC: Of Peter?

AL: Yes, Peter had sanctioned that, if you will. I don't remember whether there was a specific memo that said that, but Peter certainly let it be known that that was the reasonable and efficient way to do things and that he trusted all the counseling lawyers, and he felt that if they had an inquiry about some advice they were giving the Bureau they could come to him and resolve it and then they would be speaking with his imprimatur. So lawyers on the counseling side began to do things in their own name.

Now, this was not completely novel because litigators did things in their own name once the case was referred to the Justice Department. For example, I didn't call up and say to an Assistant U.S. Attorney "I'm calling on behalf of Billy Goodrich." I'd say "I'm Arthur Levine. You've just gotten a letter. You see my name is in it." I developed my own relationships with the AUSA, with the Justice Department lawyers in Washington, with the District Office, in my own name. When Peter came in and expanded the administrative law perspective of the agency, he blessed the counseling lawyers to go off and be on their own even more than Gottlieb blessed the trial litigators to go off on their own and work on their assigned cases.

CC: But I think there is a difference in a couple of important ways. You said a few minutes ago that Peter trusted the staff lawyers, and I'm wondering how he trusted them. I would say that he trusted both their legal acumen and judgment and also he trusted them to check with him

if it was necessary, if there were questions about the staff lawyers' advice? How did Peter develop that trust? Because he didn't work closely with everybody, did he, as Alvin had? I mean, it's always been really important to me to have somebody respect my judgment on the substance and on what needs to be run up the chain, so to speak.

AL: Right. Peter did work with the counseling attorneys. He worked with me, with the Bureau of Biologics. He had interactions with the counseling attorneys when their work product was presented to him for his supervisory review and he allowed the staff attorneys who were doing counseling to attend meetings that were at a level that he would attend. So there were interactions, and lawyers came to understand that he had a trust in them and that they were authorized to go forth and be counselors with his support and imprimatur.

And because he delivered his support and imprimatur in a style that was less intense than Alvin's, a lot of people came to enjoy doing the counseling work more than the litigation. It was also a lot more predictable. Litigation has its own pace, and when the judge wants to hear from the litigators tomorrow morning in Cincinnati, then you were in Cincinnati tomorrow morning. The Bureau work was more predictable in its pace, and there was also a lot of policy and a science component to it, which a lot of the lawyers found interesting and challenging. So a lot of lawyers came to favor doing counseling work. You developed a one-on-one relationship with a cadre of people in the Bureau. So it was a more manageable universe of clients than the Compliance Officers in the 21 FDA district offices. Finally, there was more feedback from the Chief Counsel himself and there was less travel.

CC: You mentioned, and I hadn't really thought about this, but the going to meetings, particularly when you're doing the counseling work, how did that evolve? I remember very early on – and I'm not sure how I got this project, but I had a project, and I went to the Commissioner's staff meeting when Don Kennedy was the Commissioner. Rich Cooper was the Chief Counsel, and he introduced me. I mean I had probably just three months in the office. I don't think that's the law firm model – that all the associates go with the partners to meeting with the client, so I found that sort of unusual. Did Peter institute that?

AL: Yes. Peter did that, and I think there's a little bit of a law firm model there – of having a young associate come along with the partner to meet with a client. Whether that's billable time or not is a different matter. But Peter brought people along, and I think he correctly perceived that that would be exciting for young FDA lawyers to be sitting at the Center Director level or head of compliance level or Commissioner level at a meeting with him. I think it was a very conscious decision on Peter's part and was very well-received by staff attorneys.

CC: It seems very generous. I mean, it served his long-term goal of having talented lawyers, but it seems very inclusive and generous.

AL: Yes, it was.

CC: I think Peter's reputation is that he doesn't lack for confidence in his ability, and maybe that's what allowed him to be so open with his staff lawyers. I mean he had reason to be confident.

AL: Right. He had confidence in his ability and he wanted to develop lawyers who would be confident and be capable of being independent. I think Alvin had the same objective, and I think he developed lawyers who were confident and capable. Peter just had a slightly different way of doing it and a different part of the office's operation lent itself to doing it in a slightly different way. To the extent that people associate Peter with the sort of Declaration of Independence for staff lawyers, I think that's true, but it does not preclude having a similar perspective about the way Gottlieb trained trial lawyers. It's just that on the administrative law side, it was a little easier to see – it was a little easier to see a young lawyer sitting with Peter at a meeting with the Commissioner and see that as independence. It was harder to see the relatively rare situation when a staff attorney would be sitting in a room with the U.S. Attorney as well as the Assistant U.S. Attorney, as well as the District Director or the Commissioner in a meeting about a case. It just didn't happen as often.

I can't remember when it started, whether it was Peter or Dick Merrill, who became the General Counsel in 1975 after Peter left. Dick Merrill was an administrative law expert as well as a food and drug lawyer and a constitutional lawyer who taught at the University of Virginia Law School and became the dean at some point in his very long career. But when Merrill came sometime in '75 until his departure in late '77, I think it was during that time that the counseling lawyers were given titles. For a while, everyone was just a lawyer, but as functions changed under Hutt and then during Merrill, I think people who did the litigation started to be called "trial lawyer" and people who did counseling work were starting to be called "associate chief counsel for" – for biologics, for drugs, whatever.

CC: Or assistant if you were a GS-11 or 12?

AL: Right, or assistant chief counsel. So there were Assistant and Associate Chief Counsels for counseling lawyers, and litigators were either called trial lawyer or, I think at some point, senior trial lawyer. That nomenclature evolved and it reflected the reality of the functioning of the office and the way it provided legal services to the client agency.

Also, during Hutt's tenure, the General Counsel's Office of HEW didn't have the requisite number of lawyer slots in its budget to provide the number of staff attorneys that Peter needed to do both the enforcement litigation and the administrative law and counseling work that he wanted to do. This need for more lawyers accelerated during Merrill's tenure. Initially, Hutt went to the Commissioner and said we need slots from your budget to hire the lawyers you need. That became the way things were done, that increasingly lawyers in the General Counsel's Office became employees of the FDA and were no longer employees of the Department of HEW. And the more lawyers that were needed, the more Hutt or Merrill, and probably Cooper, went to the Commissioner and said "if you want these things done, we need more lawyers and you're going to have to give us slots from your budget." So people were being brought onboard to OGC on literally FDA's dime.

Increasingly, when Dick Merrill was the FDA General Counsel, people did less double work. They were either counseling attorneys or they were trial attorneys, and there became a more distinct division of work. Some people still did a little bit of both, but mostly they just did enough litigation to sort of learn the ropes and then they became counselors. That was the

approach under Merrill, who continued the administrative law and notice and comment rulemaking proactive regulatory orientation that Hutt had started.

CC: I wanted to go back a little bit to the fostering independence of staff lawyers because I think that under the Goodrich/Gottlieb model, the fact is that you may send a lawyer to Federal court, which is not just a meeting in-house. I mean, it's before a Federal judge. And information is put on the record. I think that's the ultimate in independence. It's not like Alvin went out with you on every case. You tried cases by yourself. I know I did, maybe with an Assistant United States Attorney, but it wasn't as though Alvin was checking on your every move, your every motion, and every word you said to a Federal judge. So I think that, in many respects, the litigation side originated this model, this culture, of independence for staff lawyers and that Peter, and then Dick, built on it in terms of the administrative internal. Maybe staff litigators weren't signing papers, but they were the voice of the FDA in court.

AL: I agree with that completely. I think there's nothing more independent, if you will, than standing on your two feet in front of a Federal judge.

CC: Yes – been there, done that.

AL: Or a Federal Court of Appeals panel. Alvin rarely if ever traveled out for a particular case. You did the case with the Assistant U.S. Attorney or in some cases, the attorney from DOJ's Office of Consumer Litigation. You were out there and that fostered a lot of sense of responsibility and independence in your own name, which goes on the record.

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CC: I mean if you're held in contempt, it's you standing in the courtroom.

AL: Yes, and I almost was once. So I agree with you. But it was in part Peter's attitude and Merrill's attitude about the level of independence of the counseling attorneys that created that sensation that those attorneys were operating with greater latitude. Also, on the litigation side, while there is oral argument, almost everything comes off the paper – a motion and memorandum in support, affidavits and whatever. On the counseling side, there's a lot that's never reduced to writing and so there was less concrete attorney work product easily subject to supervisory review.

CC: At that time there's a lot that was never reduced to writing.

AL: Yes. It was never reduced to writing. So in addition to helping the Bureaus prepare preambles and write rules and whatever, the counseling attorneys were giving oral guidance, and I think that felt more independent because not everything was based on a paper that had been reviewed, whether it was by Hutt or by Gottlieb. Hutt reviewed all the paperwork carefully, but he also told his lawyers go out and be counselors. A lot of counseling is oral, and when it's oral, like an oral argument, although you're not standing before a judge, you're on your own. The client may push back and say that's not right or we don't agree with that or whatever, but you're out there verbally interpreting the law.

CC: In my experience, the client, whether it's the Center or a component of the Center, may not like the advice you give them, but they're not running to the chief counsel every time they don't like the advice you give and saying "I don't like this advice" – you know, "forum shopping."

AL: That probably happened less often on the administrative side than on the litigation side. If you were doing something with a case and the Compliance Officer didn't like the strategy or the approach and got the head of Compliance all riled up about it, then they'd just call Gottlieb and Gottlieb got it resolved. Often he would side with his lawyer and he would call the District back and he'd say, for example, "I've spoken to Levine and he's explained to me why he wants an affidavit from someone with this kind of background, and I think it would be very useful so you guys need to help him find someone with that kind of background to give an affidavit and stop whining that it's too much work."

CC: I think more often than not – and for me personally, this was one of the very positive parts of having the independence that I did have – I got backed up by you, by Jeff Springer, and other OGC managers. Although this was less about substance, I still remember that I was doing an administrative hearing. It was a clinical investigator hearing. The person from whatever the division was worked under Frances Kelsey. He didn't like anything that I was doing. And we were in the actual hearing, on the record. I don't think he was orally going on the record, but he was giving me a very difficult time during the hearing itself. There was a lunch break and I came up to your office and I told you what was going on. I was very distressed, and you, with

almost the same amount of calm that I had of distress, you dialed the phone and you said, “Dr. Kelsey, Arthur Levine,” and you went on to say basically your staff person is a problem and this needs to change. You just couldn’t have backed me up any better, and I think that happened regularly with both you and other managers.

AL: And it happened with Gottlieb, and I’m sure it happened with Blumberg when he was the litigation deputy. There absolutely was support. And nine times out of ten, Gottlieb would vote with his lawyer, just as nine times out of ten, Peter would vote with his lawyer.

Again it was a difference in style; a difference in emphasis. Peter believed rulemaking would create a deterrent and thus support enforcement litigation or reduce the need for it. Alvin thought regulations were helpful, but ultimately, everything that needed to be said was in the Act itself and it was the burden of lawyers to interpret it through enforcement litigation. So there was a difference of perspective, and Alvin ran the enforcement litigation side of the office and Peter and Dick ran the administrative law/rulemaking side.

There was something else that Peter did that I wanted to mention because it sort of runs in parallel with the way the lawyers started to increase their influence throughout the agency. The staff lawyers had a strong influence in the District Offices through the trial work and the enforcement litigation. Then the staff lawyers began to have a greater influence within the Bureaus and the Centers through their counseling work. But that was also going on at a higher level. Mac Schmidt was Commissioner of Food and Drugs from 1975 to ’77 during the Ford administration. That corresponded with Peter’s time as the General Counsel. Schmidt had a practice of having a weekly or biweekly high-level executive staff meeting, and Peter was invited to attend with the Bureau directors and associate commissioners. That staff meeting

morphed into something called the Policy Board, and the Policy Board became a forum for high-level decision making within the agency. As the agency moved more and more toward proactive administrative law, rulemaking, and other ways to interpret the statute for the understanding of industry, Peter's role on the Policy Board became more and more important because he was the keeper of the legal propriety of how to do these things. And so the Policy Board became not only a forum for high-level decision making within the agency, but, as best I know, a forum through which the General Counsel's Office's status and stature within the agency increased.

This elevated the position of the General Counsel's Office within the agency. And the lawyers were growing in number because if Hutt brought on four new people a year, certainly Merrill did, and more and more people joined the General Counsel's office. Many of them joined with the intention of working for the Bureaus/Centers as counselors even though they went through the traditional litigation "education" and had some litigation. Then, at some point, and I don't know if it was toward the end of Dick's tenure or the beginning of Rich Cooper's tenure, but as part of some other structural things that happened in the office, it was no longer required that lawyers start out as trial attorneys. Some people came into the office for the exclusive purpose of being a counseling attorney, and they would report not to the deputy chief counsel for litigation, which was the successor role to what Alvin was doing when he was overseeing the litigation, but they would immediately start reporting to the deputy chief counsel for hearings and regulations. Through Cooper's tenure, Nancy Buc's tenure, Tom Scarlett's tenure, and Margaret Porter's tenure – basically through the 1980s and '90s – that's the

way the office operated, with a fairly clear structural line between litigators and counselors, which was evolving through the seventies, through the Hutt/Merrill years.

CC: I would agree with all of that. I certainly recall when Margaret Porter was the chief counsel that not only did people come and start to counsel immediately – and I mean people right out of law school. I personally felt that was not the best model, but that’s neither here nor there. But I think it accelerated during that period, and part of that was the need for counselors because it was sort of like the pendulum shifted and there was substantially less emphasis on litigation and much more emphasis on regulations that involved the counseling side of the house.

AL: Right.

CC: Let me ask you a couple questions about the demographics of the office during the Hutt/Merrill period. You said there was one woman when you came when Billy Goodrich was the Chief Counsel.

AL: Yes, there was one woman in 1970. It doesn’t mean there hadn’t been more before. Joanne Valentine – Joanne Sisk – was the only woman in the office when I joined in 1970.

CC: How did you see the gender composition of the office evolve during the period from 1971 when Peter comes until 1977 with Dick Merrill’s departure?

AL: More women joined the office at that time. I wouldn't say there was a landslide of women, but there started to be more and more women who joined the office throughout the seventies. That accelerated right at the end of Dick Merrill's tenure, and in the first hiring class that Rich Cooper had, which was 1978, there were more and more women joining the office. There also wasn't much diversity in the office during the seventies.

CC: Ethnic or racial diversity?

AL: There were a small number of African-American lawyers, and a very small number of Hispanic lawyers. And again, that changed as well. I think the change was roughly parallel with both enrollment changes and graduation rates in law schools. There were more people coming out with law degrees who were not white males as the seventies progressed and into the eighties and nineties.

CC: How long did people stay in the office? Obviously, some people made it a career, but one of our colleagues, at least one of your colleagues – I think he was gone by the time I started my practice there – said that early in the Hutt era, lawyers would come to the office, work for two years, and then leave to go to the private sector, whether to a law firm or to a company. What do you remember about people staying?

AL: I think patterns of staying and leaving were pretty much the same in the General Counsel's Office as I experienced later in private practice.

CC: That's interesting.

AL: Some people came for a couple or three years. Some people would come for five or six years. Some people would make it a career, however you define that, 20 years, or so, not maybe the only job they had but a job of career length, if you will. I think there was a wide variety.

There were a number of people who came to the General Counsel's Office around the time that I did who stayed a very long time. I stayed 20 years. Springer and Blumberg stayed much longer. Spiller and Gene Pfeifer stayed for a long hunk of time.

There was something else I wanted to mention about where lawyers go when they leave the Chief Counsel's Office because there was a very important third option. They could go to a private law firm and practice food and drug law, they could go to a company whose products were regulated by FDA, or they could go into the FDA and become policy or program managers. This was one of the attractive offshoots, if you will, of the counseling role, people who became Associate Chief Counsel for drugs or whatever. We had people come to the General Counsel's Office, particularly in the mid to late seventies and early eighties, who left the General Counsel's Office but stayed at the FDA for varying lengths of time to take policy and program positions.

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Mike Taylor, Bob Brady, and Stuart Pape left the General Counsel's Office and all became Special Assistant to the Commissioner, and there are probably more. Gary Yingling left the office to head up the DESI review.

CC: I thought it was the OTC Review?

AL: Excuse me. I misspoke. The OTC Review. Joe Levitt and Mike Landa left the office and in each case, ultimately became the Director of the Center for Food Safety and Applied Nutrition. Linda Kahan left the office and became the deputy director of the Center for Medical Devices. Diane Maloney left the office and became an associate director in the Center for Biologics. Ann Witt left the office and took a high-level program position in the Center for Drugs. Catherine Lorraine left the office and took an associate director level position in the Tobacco Center, and there were others.

CC: Beverly Chernaik.

AL: Yes, Beverly Chernaik.

CC: Me – I went to CFSAN.

AL: Yes, there were others. Leslie Kux more recently, after I left the office. But this all started with the Hutt and Merrill model of lawyer interaction with the client, which migrated, as would be predictable, from purely legal issues to policy issues to program issues. All these people found a home – in some cases, for many, many years – in the client agency as a result of their work as counselors. One of the first OGC attorneys to migrate to the client was Mark Bozeman, who became the Director of Compliance for the Bureau of Biologics soon after that

Bureau joined the FDA. That was fun for me because I was the counselor to the Bureau, and one of my principal clients was my former colleague.

CC: And wasn't he also a Californian?

AL: Yes. He and I both grew up in California. So that migration was another consequence of the counseling process. It explains in some respect why more lawyers were needed in the Chief Counsel's Office because they kept leaving the Chief Counsel's Office and joining the client. But it also became a pathway, and there was no pathway like that on the litigation side. People didn't leave the General Counsel's Office and become District Director or head of compliance in a District. They might become head of compliance for a Center out of the Chief Counsel's Office. But there wasn't that pathway, and that also became an attractant to people who wanted to do counseling to come to the Chief Counsel's Office to do counseling/administrative law with the opportunity that they might actually become a working member of the FDA.

CC: Particularly at a high-level policy development position.

AL: A high policy level, absolutely. These were all GS-15 and later SES jobs.

CC: It's impressive when you start to list all the people. John Taylor was an advisor to Commissioner Hamburg and before that, he was the Associate Commissioner for Regulatory Affairs.

AL: And he started in the General Counsel's Office.

CC: Right. Right.

AL: And Phil Derfler left the General Counsel's Office and became head of the FSIS part of the USDA, which is not literally going to the FDA, but it's having a high-level policy position in the food area in the Federal government.

CC: And Phil then came back here to FDA and worked for a while for Mike Taylor.

AL: Yes. He had a short return tenure with Mike.

CC: So it's very impressive.

AL: Yes, it's a very long list.

CC: I want to ask you about the management team. Maybe we've already covered this – did Peter have any other managers besides Alvin Gottlieb?

AL: No.

CC: Just Alvin?

AL: Yes, just Alvin, and I believe that's also true for Dick Merrill. But either right at the end of Dick Merrill's tenure or at the beginning of Rich Cooper's tenure two things happened of significance for the future of the office. One is that Alvin Gottlieb left the office and went to work as part of the Office of Field Operations where he did a lot of work with the people who had always been his primary client, which was the District Offices. Instead of simply replacing Gottlieb with a new Deputy General Counsel, Rich Cooper reconfigured the management team to five members: the General Counsel, the Deputy (sometimes called the General Deputy), a Deputy General Counsel for Litigation, of which I was the first, a Deputy Chief Counsel for Hearings and Regulations (although the title changed a little bit over the years), and that was Linda Horton.

CC: That was Tom Scarlett first.

AL: Oh, right, Tom Scarlett, then Linda. And then a Deputy Chief Counsel for Administration, basically someone who ran the office in the same way a COO does in a company, and that started out as Forrest Patterson, then became Jess Stribling, and then Ken Baumgartner. But that structure of having a General Counsel and four deputies – or, as I used to call it using a basketball analogy, a one, one, three kind of organizational setup – was the way the office ran from 1978 until I left in 1991 and as far as I know continued.

CC: No, it's changed.

AL: I know there have been some slight variations in the last number of years, but it ran that way through the eighties and the nineties.

CC: Yes, until the millennium.

[BREAK]

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CC: This is the continuation of the interview with Arthur Levine. We've taken a break and we're now back on the record.

Arthur, I'd like to ask if you have any final thoughts or comments on what we've been calling the Hutt and Merrill years, which are basically the years 1971 until 1977. Do you have anything else to add, any other observations?

AL: No. I think we've talked about most of the major initiatives during their times. I'd like to say that the General Counsel's Office of the FDA has been very, very fortunate ...

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CC: The General Counsel's Office?

AL: The General Counsel's Office has been very fortunate to have the kind of General Counsels that they have had, starting with Goodrich, of course, and continuing on through during

the years that I was in the office. Lawyers, relatively young lawyers in the scheme of things, who were very smart and had a vision of what they wanted to accomplish and guided the staff toward producing a very high quality of legal work on behalf of the agency. Certainly Hutt and Merrill had all of those skills and attributes and really helped set the stage for what the office has been ever since the time that Billy Goodrich and Al Gottlieb got it rolling. Between Dick Merrill's departure and Rich Cooper's appearance on the scene as the Chief Counsel, Steve McNamara, a wonderful and thoughtful lawyer from the staff, very well-respected, was the acting Chief Counsel before Rich Cooper came in 1978.

CC: So let's talk about Rich's tenure. You talked about the restructuring or the creation of some structure with the five deputies or the five managers. It's not quite clear to me whether Rich created that structure or Dick did, but putting that relatively minor question aside, at the time, what was the thinking behind the creation of your position, the deputy for litigation and the deputy for, I think it was called, hearings and regulations?

AL: Well, again, when Al Gottlieb left the Chief Counsel's Office and went into the Office of Field Operations in FDA, there needed to be a deputy to manage the litigation as Al had done. And with the evolution of administrative work and regulation writing that had started with Hutt and Merrill, there was the sense that there also needed to be someone who would oversee all the lawyers who were doing counseling work and regulation writing and also, to the extent that it existed, some administrative hearings. Finally Al had also run the office from an administrative point of view – logistics. So, recognizing the evolution of the office and the significantly increased number of lawyers that were doing different kinds of work and the work that they were

doing, it seemed that, in addition to the general counsel and a general deputy, that there needed to be two function deputies, litigation and hearings/regulations, and that there should also be an administrative deputy to handle the logistics and all. So that's how that structure took place.

CC: That deputy triumvirate.

AL: Yes, the one, one, three basketball setup.

CC: And who filled those other positions eventually?

AL: Well, for the time under Cooper and then under Chief Counsels Nancy Buc and Tom Scarlett, I was the deputy for litigation. Linda Horton, for a long time, was the deputy for hearings and regulations. And Jess Stribling and Ken Baumgartner were, again, during that period, the eighties and most of the nineties, as I recall, the deputy for administration.

CC: Do you know who was the original, the first, Deputy Chief Counsel for Regs and Hearings when Rich first filled that position?

AL: In our conversation you've reminded me that Tom Scarlett had that position and honestly, I hadn't remembered that.

CC: You didn't get assignments from him – I did. And I think Forrest Patterson was the original administrative deputy.

AL: Yes, before Jess Stribling and then Ken Baumgartner.

CC: Right. So you became part of this group of five, the one, one, three. Were there formal management meetings? How did that group work?

AL: Yes. Starting with Cooper and continuing through Nancy Buc and Tom Scarlett and then Margaret Porter, we had regular deputies meetings in the Chief Counsel's Office, whoever was the chief counsel. We would discuss work priority issues and other office management issues and occasionally discuss substantive issues for which the general counsel might have wanted to sample some perspectives from more senior people in the office. We met regularly as a group. We also informally interacted with each other, especially on the question of assignments and especially at the beginning when some people were still doing both counseling and litigation. The litigation deputy and the regulations deputy would have to coordinate about human resources and which lawyers would be assigned to which matters. Once it became the rule that people did either litigation or counseling, then there wasn't as much need for constant interaction between the litigation deputy and the regulations deputy.

As the litigation deputy, I started doing organized training of new lawyers in my office in a seminar fashion. Also, lawyers were starting to come into the office dedicated to counseling work and never went through a basic FDA Law 101 kind of class. So I tried, to some extent, to duplicate what I had learned and distilled from years of being supervised by Al Gottlieb into a seminar process, including assigned reading. I think the office took in eight lawyers in 1978 and another five or so in '79, and had taken on four or so in '77. There was sort of an explosion of

lawyers, and Rich Cooper obviously was interested in having them get trained as quickly and as efficiently as possible. So I started having these seminars in my office. I continued that for a number of years, although I don't think there was ever a class as large as the class of '78, nor as many people joining the office all at once while I was there. And at that time, I think there were about 40 lawyers in the office.

CC: Were you the Deputy for Litigation when the class that included David Horowitz, Louisa Nickerson, and John Taylor came in?

AL: No. I saw John Taylor as a summer...

CC: Law clerk?

AL: Law clerk, that's it. Thank you. Yes, he was a summer law clerk. That was my exposure to him. He may have joined the office as a staff attorney just as I was leaving.

CC: I think that's the case.

AL: And so I think he did not go through my usual orientation program.

CC: At one point I think it was Margaret Porter who established a training committee to sort of take some of the training burden off of you and then I think you left.

AL: Right.

CC: I was on that committee and in fact, I ended up being the chair, but there were just a lot of people coming in that year. I always thought of them as the class of '91, but I could be wrong, but you left in the spring maybe.

AL: Yes, I left in the spring of '91.

CC: And they came in the fall.

AL: So whatever else happened that year, I don't know. But they would have come in the fall to the extent that they were immediate law school graduates.

CC: Right.

AL: Because they would have graduated, studied for the bar, and then joined the agency.

So Cooper came on in either late '77 or early '78 from Williams Connolly. He was not a practicing food and drug lawyer, but he was very smart, and he pretty much hit the ground running. He had the benefit of a lot of people in the office who had, at that point, several years of practice and seniority – when Rich arrived. The people who were there before I arrived. Many of them were still there. You know, Jeff Springer and Gary Yingling and Bob Wilmoth and Bob Anderson and John Eldred and Rick Blumberg and I were still around and had a number of years under our belt. And some of the people who came in the mid-seventies, Steve Terman

and David Weeda and Beverly Chernaik who had stayed for a while, they were all there and Steve McNamara who had been acting General Counsel between Merrill and Cooper. So these folks had a lot of combined tenure, and I think that benefited Rich as he was getting going. Rich was very supportive of the OGC lawyers and committed to providing excellence in legal guidance.

And the other thing that Rich benefited greatly from was having June Stephenson as his secretary. June had started being the secretary for Dick Merrill and was Steve McNamara's secretary when he was acting. And Rich Cooper inherited her as the secretary to the General Counsel. June was really more than a secretary. She was more what today we would call like an executive assistant. She not only supported the General Counsel in terms of his or her immediate work but also helped coordinate the various deputies and their interactions once Rich got that system going in '78. She also just did a lot of day-to-day interacting with the lawyers, many of whom would come in and discuss what was on their minds while they were waiting to see Rich or Nancy or Tom. She was the sort of hub of activity in the front office and its relationship with the staff. She was much respected and admired and she made a substantial contribution to the flow of the office and its getting from point A to point B efficiently and effectively for a number of years. She also was Margaret Jane Porter's secretary for some period of time. I left in '91 and June was Margaret's secretary on the day I left and had started with Merrill in '75. So that's 16 years right there. So Rich had June to rely on, and I know that they had many informal conversations where he would ask her about the people in the office. She facilitated Rich getting to know the staff. He also arranged to have a one-on-one

conversation with every member of the office during his first few months in the office and that was very helpful to him getting going in his role.

As I mentioned earlier, Rich had a very strong view that the Chief Counsel's Office should serve the client, and that the FDA, including the Chief Counsel's Office, was the client when it came to our relationship with the Justice Department and decisions that would be made about cases by the Justice headquarters and by the various U.S. Attorneys.

CC: So Rich supported his staff attorneys. We talked about this about Peter also.

AL: Yes, and the same was true for Dick. Rich Cooper was very supportive. He was a litigator at Williams and Connolly, so he had well-developed instincts about litigation strategy. Because I was the Deputy for Litigation, I was privileged to have a lot of interactions with him because even though I was the Deputy for Litigation and he was the General Counsel, he had a lot more first chair litigation experience than I did.

CC: Do you remember his ethnic bakeries in Boston memo?

AL: I do vaguely remember it.

CC: All I remember is that he couldn't understand why we kept bringing enforcement actions for insanitary conditions against ethnic bakeries in Boston.

AL: I guess when he first started, he didn't realize that each district office has its own enforcement personality and within the geographical jurisdiction of each FDA district office, there are types of industries. In New Jersey it's mostly pharmaceutical companies. In Boston it's mostly food companies or now medical device companies. He saw the patterns, and I think it sometimes amused him. He recognized that law enforcement is not uniform throughout the nation, that different kinds of businesses exist in different parts of the country, and that enforcement organizations like district offices have their own perspective on what kind of cases they want to do and bring.

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I believe he had an interest in a more uniform national litigation enforcement approach rather than one that was ad hoc on the preferences and particulars of each district office. He had interactions with the Executive Director of Regional Operations, the so-called EDRO, and the Associate Commissioner for Regulatory Affairs about this. But he didn't try to intercede too aggressively because he believed in the distinction between clients and the lawyers and the fact that the clients basically got to make their own decisions.

CC: When you became the deputy for litigation, there were several lawyers who were either your level or tenure. They had been colleagues because you were all staff attorneys and now you became supervisor. How did that sort of flow? Was that an issue?

AL: It really wasn't. Some of the people who had been senior to me had already left by 1978, whether it was into the agency or had left the General Counsel's Office. Jeff Springer was the general deputy. He had been a superior of mine, but now we were colleagues in management. I think there were some people who did litigation and, particularly, counseling people who would do litigation occasionally, who were older than I when they joined.

My most interesting interaction with someone who had been a colleague and then became a supervisee in a sense because I was the deputy was with Rick Blumberg. We had been staff attorneys for eight years together, and I knew his particular strengths and I knew his interests in enforcement litigation, and I tended to give him cases that aligned with his interest and his skills. We had a very good working relationship. And my relationship with Bob Spiller was the same; we went back several years together as equals. The vast number of attorneys who came to the office in that period, '77 to '90 were all young and I was very senior so I didn't have any issues about assigning them cases. That was my job to assign them cases, to supervise them, to train them, and I did and that was never an issue. The other people, even though they had been around for a while, were willing to accept me as the Deputy for Litigation and that was never an issue.

CC: When I came in September of '78 and became a trial lawyer – I mean I wasn't in trial every day – you were my supervisor of record, but on individual cases, I had different senior lawyers like Rick Blumberg and Bob Spiller, who were the supervisors and training me.. Where did that system come from? Was that something you instituted?

AL: Yes.

CC: I found that it worked very well because instead of modeling my work and behavior after one individual, which might or might not have fit me well, I had different people to observe and model myself after. I had Jeff Springer as a supervisor – I know Jeff supervised me. Sometimes they had different substantive backgrounds, but for me, the thing that was most useful was they had different personalities and different approaches to the law.

AL: Yes. For the most part I created a system of having supervisory attorneys for new attorneys. It was my way of building on what Joanne Sisk and John Young had been doing informally in an earlier era as senior supervising attorneys, under Gottlieb, although it wasn't nearly as structured. But when Alvin left and I became the deputy and we had this huge influx of attorneys, maybe 15 or so over a two-year period, which was a lot to absorb in an office that at the time had 30 lawyers, I realized that the newer attorneys doing trial work would need supervision that I couldn't provide as the deputy. I tried to spread the supervision around and I would assign attorneys with different supervisors to give them a different perspective on their cases from various people, and that worked out very well. At the time, Rick Blumberg really wasn't interested in being a supervising attorney. Now, Rick would sit in his office and do his work, and it was always excellent – I never really exercised any meaningful supervision over his work. I assigned him cases, but that was about it. There were some people who were more interested in being and more willing to be supervisors and some who were less so, and I found that out pretty quickly and I made supervisory assignments accordingly.

CC: I had forgotten that about Rick, which is interesting because then he went on to become not only a deputy but a very effective advisor or counselor.

AL: Absolutely, very effective. He became the deputy for litigation when I left in 1991 and served in that position for over 20 years. Like Gottlieb, Rick became legendary in his long and productive work in the Chief Counsel's office.

CC: Once, when he was supervising a case of mine, he said "Is this the standard decree? Then it's fine." whereas, Bob Spiller would sit in the library with a lawyer he was supervising and go line by line over a document. I remember one time Bob wanted me to do something that just seemed excessive – like make sure the product had been destroyed and it was moldy pineapple or something that wasn't going to be a major public health problem. It was the first time I said to him "Well, this is my case and I don't really think that's necessary." And I was surprised when he said "It is your case." And let me handle it accordingly.

AL: Yes. There were varying styles of supervisory oversight.

CC: Yes.

AL: I was aware of that. For example, I would rarely assign anyone to be supervised by Spiller several times in a row because his supervisory oversight was pretty intense but very informative and educational – that was the great thing about him in the office. He was so good and so committed and so incredibly thorough that it was such a benefit to have him bringing on the new lawyers.

You're talking about Spiller going over things word by word with you reminds me of one more thing about Gottlieb, and maybe part of the reason Mark Bozeman left the General Counsel's Office to take the job as the head of compliance in the Bureau of Biologics. Bozeman had a memo that he wrote for a case, and Alvin was reviewing it. Al also used to use a pencil to edit work. I happened to be in the office at the same time, I don't remember why, but I do remember that Al was working on a particular sentence in that memo that Mark had written and he didn't like it. But Alvin didn't want to embarrass Bozeman with a total rewrite so he took his pencil and he rewrote the entire sentence except at one point in the sentence the word "the" appeared. So he took his pencil and he brought it down under the word "the" and then back up so that the word "the" would remain; it would not be crossed out, it would be part of Al's redraft sentence.

I must say that the office was, I thought, a pretty forgiving, understanding place, in the years that I was there. It was the first stop for a lot of bright young lawyers who came from all over the country. The office seemed to meld them very well. There was a commonality of commitment to the mission of the agency and loyalty to the office, and I think that served very well. Alvin was part of instilling that. Peter and Dick in their own ways instilled that. And so did Rich and Nancy and Tom and Margaret, they all built on that when they were the Chief Counsel.

CC: Rich has an enormous intellect. When I introduce him now, I say, "Oh, one of his best moves was he hired me," which is of course completely tongue in cheek. Earlier, we talked about both sides of the house. Rich could also talk about two sides of the street. He was capable of-- he had the intellect -- to walk both sides of the street, both the litigation where he was a

tactician and that was his background, but also in regulations and regulatory policy, he was also very, very skilled.

AL: Yes. That didn't slow down at all. That train was out of the station and moving and by then the Centers had bought in and all these counseling attorneys from the Chief Counsel's Office, whose numbers kept growing and growing, they were all into the system.

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And also, you know, you're starting to get a little closer to the Chevron decision in '84, but the lower court cases were moving in that direction of deference to the agency and not second guessing the agency's decision making and having everything laid out in the preamble to the final rule. Rich was absolutely aware of that. The other thing was, as a litigator, he was quite capable of seeing both sides of a litigation argument. But the office just had a parade of really smart lawyers who were general counsel, and Jeff Springer who was very smart and extraordinarily capable as the deputy for many of them, and Gottlieb who, for all his bombast, was a very smart, and a tactically savvy lawyer and completely dedicated to the agency and its mission.

CC: And a great teacher and visionary.

AL: Right.

CC: They were all very capable, and that's just what we came to expect. I mean, when I interviewed Nancy Buc, who was the first woman chief counsel and followed Rich, I said to her, "You know, I worked for Rich for 17 or 18 months and then you came, so in my experience, 50 percent of the chief counsels had been men and 50 percent had been women." My point is that our experience can be a little narrow, and we don't realize some things of significance.

By the way, I was very struck by – actually, very moved by – your recollection of the life cycle of the Office of the Chief Counsel community. It is not lost on anybody, at least among our contemporaries, that there is one "the office" and that is the Office of the Chief Counsel. That is the way people talked about it and still talk about it.

AL: Absolutely. So you mention Nancy Buc. Rich was there for a couple of years and then the Administration changed in 1980, the Presidential Administration. And with that Jodie Bernstein became the Department general counsel.

CC: No – Nancy was the chief counsel during the last year of the Carter administration.

AL: Oh, that's what I mean. I'm sorry. I'm getting ahead of myself.

After Cooper left, and near the end of the Carter administration, Jodie Bernstein became the general counsel to the Department of Health and Human Services. And she had a mentee who was a lawyer at the Federal Trade Commission, Nancy Buc, and Jodie tapped Nancy to be the general counsel of FDA and Nancy became the first woman General Counsel of FDA.

CC: The first?

AL: The first female General Counsel of FDA. And Nancy's tenure was a little less than a year because in November of 1980, Reagan was elected president, and by the time of his inauguration, there were new Secretaries and new General Counsels.

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So Jodie Bernstein was out as General Counsel for HHS, and Nancy resigned as Chief Counsel at FDA and set up her own food and drug law firm. So she was only in the office literally for 11 months. She did certainly make an impression while she was there.

CC: How so?

AL: Well, she was smart, but mostly I think what struck people about Nancy is that she was very street savvy. She had an operational sense of programs and policy; insightful and pragmatic. As Hutt and Merrill and Cooper had been, she wanted to be an advocate for her client, the FDA, and she certainly was that. Her style was advocative, not professorial like Merrill, for example. And she had a very big personality.

I remember that once she asked Fred Degnan to write a memo on a legal issue. I don't remember what it was. Undoubtedly, it was in the foods area, probably something fairly sophisticated. So he wrote the memo and he gave it to her. It involved an area of unclear statutory interpretation and frankly turned on a question of one's perspective. And Fred had a

certain perspective, and Nancy had a different perspective. I don't remember how I became privy to this information, but I remember that Nancy's basic reaction to Degnan's memo was "Fred, this is an excellent and very courageous memo. We're not going to give this advice, but I understand how you reached your conclusion, but we're not going in this direction."

And that would sort of be classic Nancy. Someone would develop a position on some issue. She would have an insight that it wasn't the way to go. It would be very well-developed and all and then she'd come to you and say "I understand your argument. I appreciate it intellectually. I don't think the agency ought to go in that direction or I'm going to counsel that they do something different and here's why." And she always had a good explanation. And that's what we did because she always was looking at the operational aspect of things and always was trying to search for the best tactical or strategic outcome as she saw it. In making her point, she was known to swear occasionally.

CC: Occasionally?

AL: Often. She spoke very directly and she became known within the office and within the agency for straight talk and speaking her mind and not mincing words. I remember a particular Supreme Court decision that she sent, through June of course, to everyone in the office and called a meeting. I believe the decision involved the EPA. And the question for the meeting was what the Court's opinion stood for, you know, what was the court really saying. That's the question she put to this all-hands staff meeting.

CC: In the library. Probably sitting on tables.

AL: Yes. In the library crammed with lawyers. The office was probably 50 or 60 people by then. And of course in that kind of an environment people are very shy. She was new as the general counsel. And she asked some people what they thought about the opinion and somewhat hesitatingly, some people gave what might be called a lawyerly response to her question about what the case stood for. She listened to whatever comments were made and then she said “No, I think the EPA said to the Supreme Court ”F--- you” and the Supreme Court said back to the EPA “No, F--- *you*.” And that was her “analysis” of the opinion. Of course, you’ve got to know Nancy to know that there was a lot of thinking behind her summary, which we discussed later in the meeting about why she thought the Court had done what it did, but that was her opening gambit.

CC: That was her headnote.

AL: Yes. That was her headnote. And, you know, to some extent, that moment defined her tenure in the eyes of her staff, the General Counsel’s Office, during the time she was there. That’s what everyone remembered. But she was very effective and gave a lot of very pro-client, good strategic advice; she had a whirlwind tenure. It would have been interesting if she had stayed for three or four years or whatever, but she didn’t.

And then, after a brief period when Jeff Springer was the acting General Counsel, having been the sitting deputy for many years, in 1981, after all the national political dust settled, so to

speak, Tom Scarlett, who had been an FDA lawyer and a colleague of mine in the General Counsel's Office in the seventies and then had gone out to a law firm, was asked to return to the office as the General Counsel.

CC: Let me stop you there because there are a couple things that I think are characteristic of the Chief Counsel's Office that we're not going to find anywhere else.

First, about Rich Cooper. We used to have in the Chief Counsel's Office – and I don't know what the practice is now because the office is so much bigger – we used to have holiday parties, Christmas parties. And I have a very distinct recollection of not only being at the holiday party my first year – it must have been December 1978 – and, for some reason, sitting with Rich Cooper and Michael Peskoe and you did a humorous reading of Rich Cooper's resume.

AL: Yes.

CC: Do you remember this?

AL: Yes.

CC: I guess I want to get that on the record and any recollection you have of that as opposed to my recollection. My favorite line was that Cooper worked at a Washington haberdashery and would sell clothes to the judges on the Supreme Court and then his resume would say that he was “a clerk to a Supreme Court Justice.”

AL: Right, which Rich was, of course. He clerked on the U.S. Supreme Court after graduating law school.

CC: Yes, but you –

AL: Yes, but I made light of it. And Rich was a good sport about me spoofing his incredible resume.

CC: I'm sure there's a lot of in-group humor in different places, and what prompted me to remember incident that was David Adams wrote a song about Nancy, which I won't repeat on the record, but it played on her language.

AL: It played on her language, right.

CC: Those are some of my fondest memories. I think it was actually Fred Degnan, who you just mentioned, who told me he kept a folder, a file folder, that was called "Office Humor", and he couldn't believe I didn't have one. But can you say anything about the humor and the sort of – all I can think of is the Yiddish *hamish* --feeling of the Chief Counsel's office?

AL: Well, from the time I joined the office, there already was a sense of us and them. In other words, there were the lawyers who represented FDA and there was the industry, which always had to be kept in tow and was always trying to cut corners or whatever it was, you know, but it

was always us and them. We were always wearing the white hats. We were always the good guys. And that's a perspective that Al Gottlieb cultivated.

CC: And Bob Spiller carried that torch.

AL: Yes. And Spiller carried the torch very prominently. Bill Goodrich would get visibly upset when one of his lawyers left the office to work for a drug company or some other regulated entity. That attitude set the stage for a lot of in-office humor because when you're all on the same team, when you're all wearing the white hat, when you're all part of us and everyone else is them, then you feed on your own juices because it's all within the family so to speak.

As in many families, there was internal family humor (as well as internal family tragedies and internal family angst). Hutt was perfectly capable of laughing at himself and he knew that lawyers were telling jokes about getting calls from him at two in the morning and that sort of thing. Dick Merrill had a wonderful sense of humor and so did Cooper. And so it was perpetuated. The reason I did a spinoff on Cooper's resume was that when he was selected, everyone knew that he had this incredible resume.

CC: *Harvard Law Review*.

AL: Everything. Yes, head of the law review. I told him that I was going to do a spoof on his resume and he was perfectly comfortable with that – everything on his resume that was good I turned into something that was second class or whatever, and we all had a good laugh over it. And of course, everyone just went crazy over David Adams' song about Nancy and her expletive

deleted, which everyone in the office was capable of singing. To this day, David Adams can still sing it at the drop of a hat.

CC: So can I because I was part of the original trio. It was David, Jeff Friedman, and me were the original sort of Peter, Paul, and Mary who sang this sea shanty song about “Nancy L. Buc.”

AL: We did have office Christmas parties and occasionally, other office gatherings of a sort of a social nature. And I must say the office was very egalitarian in those events. There were attorneys and secretaries and other staff. It was never, you know, attorneys only.

Nancy fit right in. She was sort of a prankster, if you will. She was always telling jokes. She was quite capable of not taking herself seriously. And of course, she wasn't embarrassed by much of anything, so there wasn't any kind of hallway conversation that she wasn't willing to be a participant in.

After Nancy, Tom came back – he had been in the office during the Hutt and Merrill years. He had been a staff attorney, and as you remind me, he had also been the first Deputy for Regulations and Hearings. He became the Chief Counsel and had a fairly long tenure, about eight years, from '81 to '89. He was very analytical, often cynical, always questioning, rarely taking anything at face value. And he had a sly, understated sense of humor.

Like Gottlieb, Tom always challenged assumptions. One of Gottlieb's rules for lawyers was “never assume.” You'd be in his office and you'd be telling him about a case and then you'd say, “Well, I assume the reason they did that was,” and he'd always cut you right off and say, “Never assume.” And in a funny way, Scarlett had a little bit of the same temperament intellectually. He was always searching for the intellectually solid underpinning of something.

He really enjoyed the staff maybe in part because many of us sort of grew up with him. He was very supportive of the staff. He also had the benefit of June Stephenson as the secretary for all those years. In many ways, his dedication to the FDA lawyers cost him his job at the end of the day. And his approach, like Cooper's, was a mix of administrative law and enforcement. Tom felt strongly about both. He had a balanced approach. And like Merrill, he was an excellent writer and editor, very erudite. You'd give Tom a brief or something to work on, to look at, and he'd give it back to you and he'd make some changes and they weren't always numerous, but the things he changed, as soon as you read them, you said to yourself, "Yes, that's exactly what I meant," but he used a third as many words and made the point a lot more understandable, which is exactly the way you'd get stuff back from Merrill as well.

As Cooper had done and Buc had done, Tom continued to grow the office. I think at the end of Tom's tenure, by the time he left in '89, there may have been 70 or 80 lawyers in the office. He maintained the structure between litigators essentially on the one hand and counseling people on the other and continued the designation of trial attorney and assistant and associate chief counsel for drugs, biologics, whatever it was. So he was generally satisfied with the way the office was run and he continued to run it in that way and made his own contributions through his intellect, his commitment to the staff, and his direct hands-on participation in certain select matters that were important to him. One of his memos that I'm sure was in Degnan's humor file was a memo that Tom put out about certain word choices.

CC: Wasn't it "that" and "which" or was that Rich's?

AL: I think Rich Cooper's memo was about "that" and "which," which informed me quite a bit because I never knew the distinction.

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Tom had a different sort of bugaboo about some things that he saw in office memos, and he sent around a very funny memo in which he set things right, but not in a holier-than-thou way – and neither did Rich. The memo had allusions to Shakespearean phraseology. He made his point through humor, but he did want us to master that particular form of grammar.

CC: There are three things I want to ask you about Tom, things that happened during his time.

First, my recollection is – and I was the beneficiary so I'm pretty confident in my recollection – Tom was the chief counsel during a rather fruitful, shall we say, period of the women lawyers. I think probably in a four or five-year period – I could count on how many babies were born. I know Mary Pendergast, Beverly Chernaik., Diane Maloney, Peggy Miller, and Leona Marks all had children during the mid to late 1980s. I had two children during Tom's tenure. In fact, the second time I went to tell him I was expecting a second child, I shut the door and I told him and he said, "I thought that's why you were shutting the door."

But Tom was not married and had no children. So I think he had not been around children much, and yet he was the chief counsel – and this has obviously made an impression on me – who instituted part-time employment, which generally was four days a week, for women. By that, I mean it wasn't exclusively for women but was exclusively utilized by women with

young children. I also remember one time where you sort of threw up your hands and said “This is the first time I’ve got five litigators on maternity leave.” or whatever the number was. For me, it was such a gift because that one day allowed me to be with my daughters, and I think other similarly situated women would say the same thing, and yet continue to work and continue to do meaningful work. It’s not like suddenly, all I did was generate consent decrees – I continued to have the opportunity to do very challenging work.

I just would ask you to talk about that, Tom’s role in that, or how that came to be and how it was to have a staff that wasn’t necessarily in the office 24/7.

AL: Well, again, progressively, the office became more diverse in terms of gender, and this was true in terms of Cooper’s hires and Nancy Buc’s hires and Tom Scarlett’s hires. When you have an office that has a lot of young married women in it, you’re going to have an office that has a lot of young mothers in it, and Tom understood this. We talked about staffing kinds of issues and how to address this in our deputies meetings. I don’t remember the specifics about how the four-day-week process got started in our office. Certainly Tom promoted that within the office and I promoted it within the office. One of the things we talked about in our deputies’ meetings with Tom was human resource issues and we’d talk about someone’s upcoming maternity leave and how you covered for that and what cases and matters they had that would have to be reassigned. And then when people would come back to the office, what was a fair way to reintegrate them? By then, someone else has got a vested interest in that issue. Tom was very sensitive to that, and we worked on that as part of managing the office.

And so did Margaret Porter when she came in '89 as the Chief Counsel and that process continued because of the demographics in the office. When Tom left in 1989, the office demographics were so much different than when I had joined – you had to run an office in a way that reflected your personnel. So we did. And I thought that Tom did the right thing there, but I wouldn't have expected any general counsel in my history in the office to have done anything different than he did. But the fact is he did it.

CC: I'm going to challenge you a little bit on the assumption that you had to do it because I had many contemporaries who weren't given the opportunity not just to work part-time but to continue to do meaningful work. All I mean to say is that there was a choice, and you're right, Tom did the right thing. And I have confidence that his predecessors would have been similarly responsive. I mean, part of what made the office a wonderful place to work was that it wasn't just a factory and there were values other than work production.

AL: I understand what you mean and I agree with you that there were options to handle the issue of having a lot of young mothers as lawyers in the office. We made choices that were always driven by two factors. One, what was best for the lawyer, what would promote the lawyer's continued, meaningful legal work and legal development? And two, what would be the smoothest, most transitional way to do it for the client?

CC: Tom once told me that he thought he got – I don't know if he literally said – as much work out of his part-time people as full time ones. I think he realized that once you're working part-time and you want to be able to have the time that isn't supposed to be work-oriented, that

part-time people were often more – I don't know if he said more efficient, but he seemed to be satisfied with the amount of work that the part-time people handled.

AL: Oh, yes.

CC: You know, I think the part-timers were sometimes more efficient. I came in and did my work and I left because I had other things that needed my attention.

AL: I think Tom was very satisfied with the way the office was functioning, including that aspect of the office. And again, you know, when Margaret came in after Tom left, she inherited the office in that condition. She became the second woman to be the Chief Counsel of the FDA. She came over from the counsel's office for Social Security where I think she had been the deputy. She didn't know any food and drug law. And there was an educational process that took place that she greatly encouraged. She started her tenure with a strong reliance on the various deputies to inform her about the culture of the office, the culture of the agency, who is who, who knows what, who does what. For the first year or so, the deputy system that Cooper had put in place was absolutely essential to Margaret getting off and running. She was the Chief Counsel for 11 or 12 years.

CC: Before we go to Margaret, and I know we're getting down to the wire timewise, but I wanted to ask you because I was expressly asked to talk to you about change during the Tom Scarlett era in how referrals were made to the Justice Department. This is based on a memorandum ultimately issued by Paul McGrath, who was the then Assistant Attorney General

of the Civil Division. My recollection is until this memo issued in November of '83, all of our cases were referred directly to the appropriate United States Attorney with copies to the headquarters DOJ office, whatever it was called at that time. Then the process changed and we were able to continue to make direct referrals of seizure cases on public health protection grounds. But any recommendation for an injunction proceeding or a criminal prosecution now went to the headquarters of Justice. This had an impact on our role and how quickly things were handled. Maybe it's evolved a lot since then. But do you recall any of those discussions?

AL: Well, I recall the change and the fact that our non-seizure referrals were sent in the first instance to the Justice Department rather than the U.S. Attorney's Offices. In theory, this was supposed to centralize prosecutorial decision-making because it would all go through one Justice Department office rather than prosecutorial discretion being exercised in 96 federal judicial districts by 96 United States attorneys. And I guess, to some extent, it had that effect. And there were U.S. Attorney Offices that were not all that receptive to FDA cases, so to the extent that the people in the Office of Consumer Litigation of the Justice Department were familiar with our cases and basically endorsed the enforcement philosophy of the FDA, we probably did better with them than we might have with some U.S. Attorneys.

That said, the attorneys in the Justice Department in the Office of Consumer Litigation were charged by their superiors with making an in-depth review of our injunction and criminal recommendations. Nothing was taken at face value, and that's the part that got more intense because after the FDA District had answered all the questions that the FDA lawyer had about the case and then the FDA lawyer had answered all the questions that the Chief Counsel had about the case and a decision was made to refer it, particularly criminal cases, all these questions had to

be answered again for the benefit of the lawyer in the Justice Department's Office of Consumer Litigation.

They had their own squabbles with the U.S. Attorneys because often what happened is an Assistant United States Attorney would tell the United States Attorney "I'm aware that the District Office here for FDA has sent a case into headquarters and I haven't seen it yet. I wonder where it is." So the U.S. Attorney would ask the Justice Department headquarters attorneys "Whatever happened to that case that we understand was percolating through the system?" and the Justice Department attorney might say "Under the new system it comes to us first and we're reviewing it." And the U.S. Attorney might say "I don't care. I represent the Justice Department here in this District. I've gotten a copy of that referral letter. I'm going to file the case as recommended by the FDA Chief Counsel's Office." So there was tension within the Justice Department between the U.S. Attorneys and the downtown Justice Department about case decision.

And then there was tension between the FDA lawyers and myself as the Deputy Chief Counsel for Litigation and the people running the Office of Consumer Litigation in the Justice Department about the cases that we referred that were now first and foremost their cases that they then decided whether they would be active in the case or they would rely on the U.S. Attorney's Office to handle the way they had been historically – that the U.S. Attorney's Office had been the active participant on behalf of the Justice Department. Headquarters DOJ decided who would be the active DOJ lawyer on these cases and, of course, first and foremost, whether there would be a case at all. From time to time, there would be meetings involving the FDA Chief Counsel and myself with the Justice Department lawyers about whether there would be a case or not, or maybe they

thought there wasn't enough evidence in hand and they wanted a grand jury investigation rather than filing charges on the basis of what the FDA itself had investigated and found the facts to be, which was usually the compromise that would be reached between yes and no. In sum, there were frequent negotiations between FDA Chief Counsel's Office and DOJ about the handling of FDA referrals for enforcement litigation.

CC: What about the civil litigation, particularly an injunction? My recollection was that for injunction referrals the problem of the referral system was that by the time the General Counsel's Office had reviewed the case and then the Justice Department had reviewed the case, that the evidence was getting stale. So if you wanted to ask for a preliminary injunction and your evidence is six months old, what was exactly the big hurry?

AL: Exactly. There was, with some injunction cases, as you recall quite accurately, a question of timing. The Justice Department had a rule of thumb about timeliness. And so if a case wasn't timely within their perspective, then either we would not be authorized to ask for preliminary relief or the agency would have to go back and make a so-called update inspection to freshen the evidence and the results of that inspection would have to be moved along to the Justice Department quickly so that the case didn't get stale again. That was the fight. Do we file now with what we've got? Do we go back and make another inspection? How long will it take to schedule another inspection?

Also, the Justice Department had a policy of giving counsel for the defendant an opportunity to see certain elements of the case even before it was filed as a way to promote

settlement. Our policy in the General Counsel's Office was not to be that engaging with the potential defendant's lawyer pre-filing.

The "new" DOJ processing rules for FDA cases did change some of the dynamics. I don't think it changed the quality of life for an FDA litigating attorney all that much. It created some angst and, you know, the greying of hair. But while the challenges we got from the Justice Department were more than we would like, they were arguably less than we might have expected. And life went on. I did some fighting on behalf of the lawyers in the office with the Justice Department.

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I was the front line of the interactions with the Office of Consumer Litigation and had strong disagreements with John Fleder and Pat Glynn about various things. Tom sometimes took the lead and we'd involve the staff attorneys in most cases. And we'd have it out and we'd have to reach some kind of decision because at the end of the day, DOJ had the power. And the fact that they had the power and they were a centralized organization, as opposed to the 96 Federal judicial districts and U.S. Attorney Offices, did give them more leverage. Even though we didn't always succeed, it was sometimes easier to have a disagreement about a case with an individual U.S. Attorney, although we didn't win them all, than it was with the whole organization within the Justice Department.

For some lawyers who did litigation, it became an unhappy aspect of our work that, as an office, we had lost some leverage to the Justice Department by virtue of that case processing decision that had been made. And to that extent, it wasn't as much fun to

be an FDA litigation lawyer because this part of the Justice Department, which itself was staffing up in order to handle this first chair responsibility starting in '83. For some people, that bothered them a lot. I looked at it as the practice of law in Washington. I obviously got frustrated a lot and angry at times. But we always tried to do what we could to get the agency's work done. And the DOJ lawyers were often very helpful and contributed positively to the agency's litigation objectives.

CC: I was still a litigator at this time and I think for me and for maybe others as well, we looked at the U.S. Attorney's Office as being the local experts. The AUSAs knew the judges. They were trial lawyers. We looked at ourselves, I think and again rightly so, as the food and drug experts. And then you've got this person sitting in the first chair who was neither a local expert nor a substantive expert. That was why it rubbed at least me the wrong way. But it was in the end the decision and they did have the power, so we learned to live with it.

AL: Right. We knew what the U.S. Attorney's Office brought to bear, we knew what we brought to bear, and then the question is well, what was the headquarters Justice Department bringing to bear? In their mind, what they were bringing to bear was a national, evenhanded Federal law enforcement policy. What we thought they brought to bear was sometimes extraneous or dubious. Obviously, one more lawyer will give you one more perspective, and they had some good perspectives from time to time and they provided an arm's length assessment of things that we were involved in. They would often argue that we had lost our sense of perspective about things from time to time. It was challenging.

But again, our role, Tom's role, my role, Margaret's role until I left, was to make that relationship work to the betterment of the client's enforcement objectives to the extent humanly possible, which is why we argued with the Justice Department lawyers, because we were trying to bring our client's perspective and our legal assessment about the case to bear. But for me, it was an important but not a defining moment in the history of litigation on behalf of the agency.

CC: I want to go back to Margaret Porter and just give you a last chance before we conclude to say anything else you have to say about her tenure or working as her deputy.

AL: Well, as I mentioned earlier, when she came on, she was familiar with the Department of Health and Human Services and, being a Social Security lawyer, she had some sense for large programmatic issues in the law and had worked with some fairly sophisticated legal issues involving the interpretation of the Social Security laws, which is not for the faint of heart. But she knew nothing about food and drug law and knew nothing about the FDA as an organization and its culture. So we, her deputies, spent a lot of time at the beginning trying as best we could to be helpful and informative.

Margaret had her own style. Again, she appreciated the importance of enforcement. She understood the value of rulemaking and standard setting. She was very easy to work with, smart, very interested in the lawyers as individuals. She was engaging with the staff.

As you know, I was there for a relatively short piece of her tenure and I was sad to leave the office for many reasons. Certainly, one of them was missing the opportunity

to work with Margaret as she hit full stride. Because she was new, from a subject matter perspective, she tended to rely heavily on the senior lawyers in the office. She never, however, failed to exercise her responsibility to make decisions and lead the office. During the time I was there, she was very engaged with the growing number of women lawyers in the office and was sensitive to their perspectives on life in the office.

CC: Well, our time is more than up. Thank you so much, Arthur.

AL: Thank you.

[END OF INTERVIEW]

Curriculum Vitae

Born:

Brooklyn, N.Y., Oct. 23, 1945

Education:

University of California, Los Angeles, B.A., 1967

University of California, Berkeley, J.D., 1970

Work Experience:

Office of the General Counsel, FDA, 1970-1991

Deputy Chief Counsel for Litigation, 1978-1991

Partner, Arnold & Porter, Washington D.C. 1991 - 2010

Author and Editor:

FDA Enforcement Manual, 1992 - present. Thompson Publishing Co., Columbia Books.

Awards and Honors:

FDA Award of Merit

DHEW Distinguished Award

FDLI Distinguished Service and Leadership Award



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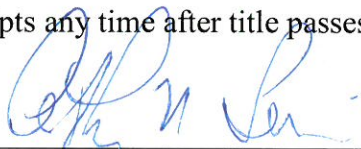
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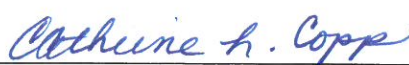
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Last position held: Deputy Chief Counsel for Litigation
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Date: 12/6/2016

Interviewer: 
Catherine L. Copp
Research Historian, FDA History Office

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