

History

of the

U. S. Food and Drug Administration

Interviewee: Linda R. Horton

Interviewer: Ronald T. Ottens
and
Robert A. Tucker

Date: December 28, 2001

Place: Rockville, MD

INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administration's History Office. The transcript is prepared following the *Chicago Manual of Style* (references to names and terms are capitalized, or not, accordingly.)

The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source, along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CASSETTE NUMBERS: 1, 2, & 3

GENERAL TOPIC OF INTERVIEW: History of the Food & Drug Administration

DATE: Dec. 28, 2001 PLACE: Rockville, MD LENGTH: 75 minutes

INTERVIEWEE:

INTERVIEWER(S):

NAME: Linda R. Horton NAME: Ronald Ottes & Robert Tucker

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FDA SERVICE DATES: FROM: August 1968 TO: December 2001

TITLE: Advisor to Acting Deputy Commissioner Murray Lumpkin

(Last FDA Position)

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RT: This is another in a series of FDA oral history interviews. This morning, December 28, 2001, the interview is with Linda R. Horton, adviser to the Acting Deputy Commissioner, Murray Lumpkin. The interview is taking place in the Parklawn Building in Rockville, Maryland. The persons interviewing Miss Horton are Ron Ottes and Bob Tucker.

Linda, as we begin the interviews, we like to have a brief résumé of your early history, your education, where you were born, and any pertinent information prior to the time that you joined FDA.

LH: Thank you, Bob. I was born in Louisville, Kentucky, December 1, 1946, a seventh- or eighth-generation Kentuckian. I'm a true baby boomer. This year, as I turn fifty-five, that means other baby boomers in the agency are reaching a similar milestone. I literally was born nine months after my father got back from the Pacific theater, where he'd been stationed in New Guinea and the Philippines and other places for three years—an old, reluctant soldier.

I was the oldest of six, and all my life had been interested in government service and international relations. I did things like collect stamps from all over the world, and constructed little models of plastic White Houses and the like, that my parents kept putting in front of me. So I think they were trying to send me off to Washington or something.

In college I majored in political science. I attended the University of Kentucky, graduating in 1968.

RT: Pardon me. You went to high school and so on at your home town of—where was it in Kentucky?

LH: I went to Eastern High School in Middletown, Kentucky, a neighboring town, graduated in 1964, and had a scholarship to the University of Kentucky. In 1968 it was quite an active political year, as you will remember, and I was a precinct captain. They needed a precinct captain for a precinct not far from my home, and I ended up being a delegate to the Democratic Convention that year, and I have this memento. I was a supporter of Eugene McCarthy, the peace candidate, and in Kentucky in those days we didn't have a primary, we had a convention, and the [Hubert] Humphrey people just absolutely steamrolled us. So somewhere I've got a political cartoon of the steamrollers that the Humphrey people used to squish the flower-carrying, pro-peace people.

I thought I'd be a journalist during my early college years, and then thought I'd be a high school social studies teacher. But student teaching was enough to convince me that I wanted to be around grownups more than adolescents, and was quite fortunate that one of my fellow student teachers knew about the Federal Service Entrance Exam. This wasn't something that my political science professors at U.K. were interested in. They were much more interesting in cloning future political science professors, and hoped I'd go in that direction.

RT: Your degree—you may have mentioned it—your degree from the University of Kentucky, what degree was it?

LH: A B.A. in political science, with a lot of courses in history and economics. Not a great deal of science, so I'm a little different from a lot of the people that you interview because my background is entirely in the politics and international relations kind of things.

RT: I think you came to the agency as a management intern. How was that arranged or developed?

LH: Bob, I just have to think that I'm one of the luckiest people in the world. I don't know how this came to be, but in June of 1969, a girl named Sue, who was a personnel intern at the Civil Service Commission, was doing a rotation at the FDA and going through people who scored high on the Management Intern Exam, and called me up, in Kentucky.

I remember I was working for a political science professor that summer right after I graduated, while looking for a permanent job. It was very unusual for me to receive a phone call in the political science department. I think my mother might have known that phone number, and somehow this very persistent intern, Sue, had chased me down in this professor's office. She asked me if I was interested in a management intern position in the FDA. She was very nice, and it so happened that I had just scheduled a trip to Washington to interview with other agencies. This was to be my first airplane trip in my entire life. My children flew when they were infants, but I was twenty-one years old,

having just graduated from college, and having just bought my first car. No, I hadn't bought my car yet, because I couldn't buy a car until I had the letter from FDA saying that I was going to be making \$6,891 as a GS-7 management intern, even to get the loan to buy the car!

I wasn't really all that interested in coming to talk to FDA. I really didn't know very much about FDA, I'm sorry to admit, but Sue pointed out that the FDA headquarters was very close to National Airport, where I would be flying in, and, indeed, they could send a car over to pick me up. I said that wouldn't be necessary, I'd be renting a car—again, my first experience renting a car as a dumb twenty-one-year-old—but I could drive over and have the interview.

This was really a miraculous day, because I got off my first airplane ride, rented my first car, drove something like 1.5 miles to Crystal City, and was interviewed by a succession of people in FDA, culminating in a job offer, and you know how strange that is. In '68 or 2001, it's really unusual to get a job offer that way.

I don't really think it's that I did that great a job or made such a big impression; I think they were sort of desperate to get this FDA management intern class started. They already knew they wanted some people from the field and some people straight out of college, and so I was the straight-out-of-college part. Somehow this dumb kid from Kentucky knew enough to ask for two weeks to think about the offer.

I proceeded to other government agencies and was not as impressed with any other agency as I had been with FDA, let me just say.

RO: Who in FDA interviewed you?

LH: Brynna Oman was in the personnel office, and had, I think, constructed the FDA management intern program. Her husband at the time, Gil Oman, was a young physician activist, and eventually became very well known in Institute of Medicine circles and the like.

Jack Markowitz was the head of the training branch in the personnel office of FDA, and he interviewed me that day. Most importantly, Mickey Moure, Rupert Moure, recently honored at Sharon Holston's farewell for later hiring her, also hired me, and it was he who made me the offer on the spot in June 1968.

One thing impressive about FDA, in making me an offer on the spot, was the "can-do attitude." When they heard that I was committed to working for the political science professor until August, they were a little disappointed, because they were trying to avoid a hiring freeze that was going to start on July 1, 1968. Mickey kind of rolled his eyes and pushed back in his chair and looked at the ceiling. He thought he could figure out a way around it, and this is, I think, characteristic of FDA. People try to solve problems rather than to be impeded by what seems to be a bureaucratic obstacle.

So I actually started on a Tuesday. You know how they're always wanting you to start in a pay period. Well, I started August 8, the day after my commitment for this professor was over, at FDA's headquarters in Crystal City, Virginia.

RT: When you first came in, were you in a training program or were you placed in a working job?

LH: Well, both, Bob. I was told to sign up for different kinds of training, and there were some government-wide programs for management interns that were offered through the Civil Service Commission. For example, I remember that in the fall of 1968 I attended a training program that took place in the auditorium of the Department of Commerce, the Hoover Building down at Fourteenth and Constitution.

What was remarkable was that the director of the Civil Service Commission gave a really sad speech, in which he condemned everyone who was antiwar and critical of President Lyndon Johnson. I would say three-quarters of the people in the room got up and walked out. All of us were recent hires to the federal government. I was very torn, because you know from what I've said that I was very antiwar, but in what is characteristic of me, I stayed on. The sponsors of the training program were very disturbed and seemed to realize that, "This is a different generation, and what are we going to do?"

We ended up disbanding the rest of the program and spending some time trying to figure out what the federal government needed to do to harness the energy of its young people, considering that many opposed the government initiative of the Vietnam War. This was before Lyndon Johnson announced that he wasn't going to run for re-election.

RT: Was your first assignment in FDA to the Office of Legislative and Governmental Services?

LH: No. My first assignment was in the personnel office. I worked for two months in the Employee Relations Branch. I worked on a revision of the FDA Ethics Rules.

At the time, FDA was forbidding GS-2 animal handlers from selling hot dogs at the baseball games. FDA knew that this position was extreme and the agency needed to come up with an exception. I did the first draft of what later became the rules that distinguish employees in sensitive positions from those who are in less sensitive positions, so that our clerical employees could do things like sell hot dogs or sell cosmetic products in their homes, and that sort of thing.

Then, for six months I worked in the FDA Training Branch. I worked with Brynna Oman and Jack Markowitz, the people who originally gave me a job offer. I can remember putting together training programs for FDA employees whose first language was not English, because the agency was beginning to have a lot of immigrant employees, scientists who were becoming American citizens and starting to work for FDA, but who were not always making themselves understood to their supervisors and coworkers. So we started an English as a Second Language training.

I can remember also putting together training on food standards and for food additives. I helped with the "charm school," the Executive Development Program, that was being put together at the time, and recall being an advocate for the selection of one of the women candidates in the program. Few women at the time were even in a position to be considered for that kind of program.

But I must say that, in general, I was somewhat disappointed with my FDA experience. I had come to Washington with a great deal of interest in "saving the world," and even though the people who'd hired me thought that being in the personnel office was the most exciting place to be, I felt differently.

I remember one day, when I had to be downtown anyway, I stopped by the Peace Corps to get an application to leave FDA and go into the Peace Corps. What stopped me was a man who loved me, Henry Ho, who later became my husband, and let me know that he would be brokenhearted if I went into the Peace Corps.

Fortunately, my eight months in personnel were about up, and I had a chance to go to Legislative Services, where I worked for you, Bob.

RT: That's true.

LH: And that changed everything. That kept me in FDA, because I had a very mission-oriented job.

RT: Well, it was an interesting place, in that you had a cross-connection with the whole agency, as relates to legislative matters. You were a very bright and enthusiastic intern, and captured the attention of your managers, including Associate Commissioner Ken Kirk and Deputy Commissioner Winton Rankin, as well.

RO: Well, of course, your interest in politics has brought you a little closer to some of the political issues.

LH: Yes. I think that legislative work is really a great place to get an overview of the agency, and it gave me a chance to develop my analytical skills and writing skills, because,

as Bob knows, a lot of the work that's done in those offices is written and oral communication.

Just to mention two categories of written communication, the legislative office prepares testimony and bill reports. In writing testimony for senior officials, we had to present the agency's views crisply and convincingly. In analyzing legislation for a bill report, we prepared a letter that goes from the secretary of the department to the chair of each of the committees in the Senate and the House, that has the responsibility for a piece of legislation, setting forth the administration's views.

There's a certain style to it that's a bit arcane, but it does make the point. "This is in response to your request for a report on this bill." And then you say whether the department is for or against the bill, and then you analyze why, with most important reasons given first. It's very good, persuasive writing. I think most people that do a tour of duty in a legislative office and are exposed to this exercise can improve their writing, because you have to be very, very succinct and persuasive.

RT: As I recall, you were asked, I think by Mr. Kirk and maybe others, to do some research on certain bills or issues. Do you remember what some of those might have been?

LH: Well, I had this exciting assignment when I was real new to that office. It had to do with cyclamate, and a scientific study showing that cyclamate appeared to cause cancer in laboratory animals. At the time, cyclamate was approved not only for use in packets, as

an artificial sweetener for the consumer to add, but it also was being put into canned fruits and other products, as one of our early weight-control products.

One of the issues that FDA was confronting was the enormous economic loss that would be suffered when FDA announced its finding that cyclamate was no longer generally recognized as safe, and had to come off the market. And so Ken Kirk asked me to very quickly research the issue of government authority to indemnify those with inventories of canned foods containing cyclamates. He was the Associate Commissioner for Compliance.

We used to eat lunch with Ken Kirk and Deputy Commissioner Winton Rankin, things were so informal. Remember this, Bob? We'd go across the street to a little muffin shop, and I would always have clam chowder and a muffin, as things were much more relaxed in those days. Often we would eat lunch with the *Food Chemical News* editors, Lou Rothschild and Ray Gallant.

RT: Yes, Ray Gallant. Actually, the legislative staff at that period was a rather small group of people, certainly not like the larger office of today. Maybe a half dozen or so were involved in the whole operation.

LH: That's right. Things were at a slower pace, and maybe we can talk about that later. But anyway, Kirk asked me to do research on indemnity and what authority the federal government has to give money to those producers who, innocently, would lose a great deal of money because of the government ban on cyclamate. After all, the canners of fruit

were not doing the testing on cyclamates; they were using a product that had been allowed on the market for some years, and they would undoubtedly lose a great deal of money.

I was to do this without attracting attention from elsewhere in the government, particularly the Department of Agriculture. So what I did was produce a memo that described existing authority and the limitations in those authorities, reasons why these bills may or may not apply to the FDA cyclamate ban. My conclusion was that new legislation would be needed to compensate the producers of these products, if that were Congress' choice.

Years later, I looked back on this study with some trepidation, because I had been such a dumb kid at the time I wrote it, but I couldn't really find anything wrong with it. I think it was correct, and I think it answered Mr. Kirk's need and probably confirmed his fear that when FDA announced its decision, there would be indeed a lot of people who'd lose money, and that it would take congressional action to create a program of relief for them.

RT: You served as a management intern for about two years before you really became a legislative analyst in that office?

LH: I guess it actually was only sixteen months, Bob, because I was supposed to take a third rotation that would have concluded my program. I was going to go to the FDA budget office, but the legislative office had a great need for a legislative analyst and a position available, and made a case to me that if only I would stay, I would be sure of getting this position.

I was loving the work, quite frankly, and so I became a "management intern program dropout." By then the other two interns had come on board from the field, Ron Chesemore and Art Norris, and so they were dutifully going through their three rotations without becoming dropouts.

RO: Who were the other ones?

LH: Ron Chesemore and Art Norris were the other two members of this cohort of management interns. I arrived first, right out of college, and the two of them came in during the fall of '68. I think it was late '69 when I left the intern program and became a GS-9 legislative services analyst in your shop, Bob.

RT: In the role of analyst you got into bill report-writing, and participated as an observer, I'm sure, at congressional hearings. Do you remember any particular pieces of legislation that you worked with at that time?

LH: Well, just to mention a few: the toy safety legislation of 1969; the Poison Prevention Packaging Bill of 1970; the drug abuse law of 1970; and the Egg Products Inspection Act of the same year, 1970. Then there was the huge amount of work on the consumer product safety legislation; Bob, I'm sure you remember that. 1972. I have a couple of newspaper clippings from that era that I can share with you.

We also did some work on subjects like fish inspection and different food safety bills, to give FDA records and reports authority. I might add that, in this year's

bioterrorism bill, we still have the same issue of the FDA inspecting records of food companies.

The Medical Devices Amendments of 1976 was probably the most important piece of legislation I worked on, and one that most shaped my later career.

RT: As you progressed on, then you became chief of the legislative branch. Is that not what followed?

LH: That's correct, Bob. My predecessor was Jim Corrigan, and when he took a job as director of the legislative office at HRSA, Health Resources and Services Administration, that created a vacancy.

Around the same time, there was a vacancy in the director position of the Office of Legislative Services. Here I might add that, when I joined OLGS, the Office of Legislative and Governmental Services, back in '69, the director of the office was Paul Pumpian, and Bob Tucker here was the branch chief of the Legislative Services Branch.

RT: When you assumed the responsibility for the branch, who was the director of the office at that time, do you recall?

LH: Yes. Bob Wetherell was the acting director of the office, and he followed several other people. In addition to Paul Pumpian, we had Pat Ryan. We had Gerry Meyer for one year. I think it was Bob Wetherell after that, and there was a delay before the

decision was made that Bob would be director. Once he was selected as director, he asked me to serve as director of the Legislative Services Branch, and that was in 1974.

I had started law school in 1971. I had decided that to really stay with this legislative work, I needed to be a lawyer. I started at G.W. [George Washington] University in fall of '71, and I've always been grateful that FDA paid for those courses that had some relationship to the work of the agency. I would guess that about two-thirds of my courses were paid for by the FDA.

RT: You pursued those studies while serving as a full-time employee, is that correct?

LH: That's correct. I never had time to study on the job, other than at lunchtime. I'd go down to the cafeteria, park myself in the corner at five minutes till two, and study for one hour. I finished law school in 1975, and was offered a job in the Office of Chief Counsel.

I actually was being pursued by a law firm, Morgan Lewis & Bochias, to work on ship financing law, of all things. I was on the *Law Review*, and was number three in my class at G.W., so I was a top law student. That was a class rank for the day students and the night students, combined.

RT: In the Office of the General Counsel, who was counsel at that time? Was [William] Goodrich still there?

LH: Bill Goodrich had left in 1971. I had a chance to work with him on legislation. In fact, on the Poison Prevention Packaging Act, we had this situation I regarded as

somewhat humorous, where he was dealing with the industry and I was dealing with congressional staff, indirectly through the department. You may recall a legislative attorney, Nancy Solon.

RT: Yes, I do.

LH: Ms. Solon was a very unique individual in the department. Basically, Bill Goodrich was going along with something the industry wanted, through backdoor channels, while Nancy and I were really insisting on a much stricter position on the Poison Prevention Packaging Act. She and I were unaware of Goodrich's discussions with industry, which were not done through the official channels used by Nancy and me. Our stricter position prevailed with congressional staff, and Goodrich and the industry were very annoyed.

But Bill wasn't communicating to the legislative office. Bob and I were in the chain of command on this thing. Bill was off doing his own thing, and I think he was somewhat embarrassed by the incident. But we ended up with a better law as a result of our through-channels activity. I might add that Bill and I were great friends.

Peter Hutt became FDA chief counsel in 1971, and I remember his first day on the job. We were having our annual meeting, going over legislative proposal ideas coming in from the programs. One of the nominated proposals was to ban unapproved uses of approved drugs. Basically, if the doctor wanted to use a drug for a certain use, it had to be on the label, or else it was illegal.

One of the things we did in the Office of Legislative Services was to try to figure out which proposals could be handled under existing law. You didn't want to go to

Congress asking for new legislation, if you could deal with it under existing law. So I had produced an analysis of how the agency could deal with unapproved uses of approved drugs under existing law.

When I described this to this assembled gathering of high-level officials in fall of '71, Hutt chimed in, first day on the job, that, number one, the idea of regulating unapproved uses was totally illegal and, number two, it would not be good policy, and this proposal should be killed. Everybody else in the room was silent and ready to fall back on their swords, but I disagreed with him on the authority issue. I think Peter was absolutely astonished that this bold kid was arguing with him. But that started a friendship, and during his time as chief counsel, legislation was very active.

[Begin Tape 1, Side B]

RT: You were talking about Peter Hutt.

LH: Legislation was very active during the 1971 through 1975 time period that Peter Hutt was chief counsel, and I, as either senior staff member or Chief of the Legislative Services Branch during that period, worked very closely with Hutt on the bills of that era, which included ones on food safety, the consumer product safety legislation, and, ultimately, the medical device amendments, which was passed in 1976, after Hutt had departed and Dick Merrill has come in as chief counsel.

Also, I wanted to recount one amusing episode during my time at Legislative Services. You'll recall, Bob, the toy safety legislation going through the Congress. In

those days, FDA administered a law called the Federal Hazardous Substances Act. It had been amended already in 1966, so as to apply to certain toys, but the law was too limited. By 1969 it was evident that the law needed to be changed. So the ranking members of the Senate subcommittee, and I believe the chairman was Senator [Phil] Hart?

RT: Phil Hart of Michigan.

LH: Phil Hart of Michigan was the chair of the subcommittee, I believe, and Senator [Warren] Magnuson of Washington state was chair of the full committee. They held hearings on the toy safety amendment to the Federal Hazardous Substances Act.

At the time, [Herbert L.] Herb Ley was the acting commissioner of the FDA, and he decided to present dramatic testimony on toy hazards, particularly mechanical hazards, and asked the field to conduct inspections and collect samples of hazardous toys that should be dealt with under this new legislation.

One toy that was sent in was a plastic lawnmower, and Herb Ley took a two-by-four, and leaned back like a lumberjack, and slammed it down on this little toy, and it shattered into a million pieces. At the time, Dr. [Howard] Weinstein, who was the FDA head of the Product Safety Program, commented that no child would have that degree of strength. A little footnote was, a few days later, I was heading off for Kentucky to visit family, and went to pick up a University of Kentucky alumna friend. She had two of these little lawnmowers that she was taking home to her twin nephews in Kentucky, and wanted to show me how cute they were. I commented that FDA had just identified these as dangerous toys, and she was dismayed that the government would use a test like slamming

a two-by-four, with adult strength, on a toy. I think about the scientific standards we apply today, and how in those days a test of dubious validity could create a wonderful news story for Commissioner Ley. Nowadays, I don't think any commissioner would get away with this. Our test would have to be much more reflective of the actual environment of use of a product.

RT: Linda, you then assumed the role of a trial attorney. Have any of the experiences you've been speaking of, do they fall into your role as a trial attorney, or is that other kinds of work that you did?

LH: Not yet. When I decided to turn down the law firm and stay in FDA, I decided I wanted to be a lawyer and move to the Office of General Counsel. I'd risen to a GS-14, Step 2, in the legislative office, and much to my annoyance, I had to become a GS-12 to be an attorney. Nowadays, I think FDA has found a better way to deal with this problem. So I was a 12, Step 10, and actually suffered a loss of \$2,000 to be a lawyer.

I continued to work on certain legislation, particularly medical devices, because I had such an investment in it and such institutional memory on certain issues. But I wanted to litigate, and for about a year, that's what I did. I handled the normal mix of FDA cases. I had seizures of adulterated products, such as cocoa beans with mold, and several cases involving misbranded, fraudulent medical devices.

I had a very interesting case in Florida, involving a pharmacist who was, in essence, compounding new drugs without complying with the new drug provisions of the act. That resulted in one of our few precedents on the unapproved-use issue, and it drew

the line between practice of pharmacy and the new drug provisions of the act. To this day, it's a key precedent.

One of the medical device cases I handled likewise became a precedent, the Accuflex case.

RT: What was that about?

LH: It was an electronic acupuncture device, and, as is so often the case with these crack devices, it bore a claim that the device was good for everything. Those of you who worked in enforcement are familiar with the kinds of problems FDA has dealt with over the years with crack devices. We secured a decision by the District Court for the Western District of Pennsylvania, in Pittsburgh, that this was a misbranded device, and that it could not be relabeled, and so it was taken off the market as a result of this case.

RT: This was before the medical device amendment?

LH: Yes, this was strictly under the 1938 provisions for medical devices. I think we actually had some adulteration charges, asserting that under section 501(e) of the Federal Food, Drug, and Cosmetic Act, the device did not have the quality it purported to have. And then we had the usual misbranding charges against the device.

In early 1976, it was evident that the medical device amendments were about to pass, and the Center for Medical Devices asked me to become their counselor. I had a

very good working relationship with a number of people in the center because of the work I'd done on the legislation.

Bob, an interesting little footnote. I can't resist. One of the offices that we always had to deal with in OLA was the budget office, because anytime we were proposing legislation or supporting congressionally initiated legislation, we needed to be able to say what the bill's budget impact on the agency would be.

Two things about the medical device amendments. One was, Bob told me to call up the budget office and get a budget estimate for a certain version of medical device legislation. So I called Bill West, Nancy Ross-West's husband, and he responded so quickly with this number that was something like four million, four hundred thirty thousand dollars. Bob said, "That was quick. How did Bill do that so quickly? What kind of estimates did he use?"

And so I called Bill West back again and said, "Bill, can you tell me more about the basis for your estimate?"

And he says, "Oh, Linda. We never know what these bills really cost. I was just giving you Dave Link's phone number." [Laughter]

It's a ridiculous story, but in some ways he was right. Actually, we had this little fight with Office of Management and Budget [OMB] in the White House. Do you remember this, Bob? Where I had to go down and deal with this official at OMB, whose name was Vic Zafra. That should ring some bells, because later on he came to FDA and became the Director of the Bureau of Medical Devices. Vic was really a very hard-edged guy. He was pretty hard-nosed.

The issue was whether we should send to Capitol Hill the draft bill that had been put together by Nancy Solon in the legislative part of the general counsel's office downtown, or should OMB approve the Commerce Department's version. Commerce always expresses the view of the industry, and had expressed fear that the pre-market approval provisions of the law would result in too much burden to the medical device industry.

Vic Zafra's concern was whether the HEW bill was so broad as to cost the government too much money. I was sent down alone to OMB to convince Vic Zafra to approve our department's bill, and what I told him was that FDA had just won some court cases, the Bacto-Unidisk case in the Supreme Court, and the Amp case in the Second Circuit Court of Appeals. These cases indicated that anytime FDA felt, as a matter of public health, that a medical device needed to have pre-market approval, all the agency had to do was declare it to be a new drug, and that this was consistent with a liberal construction of the Food and Drug Act, to protect the consumer, and surely Congress meant for this public health law to be construed so broadly.

So I told Vic that if FDA had to operate under existing law or the Commerce version, FDA would be forced into costly litigation every time FDA needed to declare a product as needing approval, if the industry took us to court. And so, with the draft HEW-FDA legislation, all we were doing was saving the government money, because the FDA would clearly have the authority to require pre-market approval of products as medical devices, rather than trying to force them into the new-drug category when their characteristics may not really fit.

In any event, FDA would have to do what was necessary from a public health standpoint, and if OMB insisted on the narrower Commerce Department description of FDA's pre-market approval authority, FDA would be forced to spend more money on litigation because the bill's narrower criteria would invite industry challenges to FDA's public-health-driven actions. Therefore, the HEW-FDA approach was the one that actually would conserve government resources. Vic looked as if a light bulb had gone on over his head, and right after that, he approved the HEW-FDA version of the legislation.

RO: In the General Counsel, you were talking about litigation. When Goodrich was general counsel, he used to like to use test cases a lot of times, for law. When Peter Hutt came in, he was the reverse. He wanted to establish regulations. Did you notice a big difference? Well, of course, you didn't work under Goodrich.

LH: I think the transition you're describing was pretty far along by the time I arrived in Office of Chief Counsel in 1975. [Alvin] Al Gottlieb was still there, and we had members of the staff who still subscribed to Bill Goodrich's preferred approach. Bill himself was already shifting positions. After the Abbott case was decided in 1971 by the Supreme Court, Bill had written a regulation to make the DESI program run more smoothly. The DESI program, of course, was the Drug Efficacy Study Implementation program. One of Bill's big concerns was what would happen if every drug company asked for a hearing every single time FDA moved to take the product off the market or to narrow its labeling. So he had written a regulation defining the meaning of adequate and well-controlled

studies. This was a term that Congress put into our statute in 1962 as part of the Drug Amendments.

Bill had decided that notice-and-comment rulemaking on this definition was unnecessary. FDA published this reg as a final reg, and the industry sued on the merits of the case and sued on the process. FDA won on the merits and lost on the process. The court said the reg was fine, but FDA's process was not fine, and so the agency needed to go through notice and comment. So I think in some ways the rulemaking era of FDA was launched at the end of Billy's tenure, and carried over through Peter Hutt's.

Peter argued that if he had been forced to bring a case every time he needed to take action against an over-the-counter drug, that the agency would be involved in litigation for the next fifty years. Now, as we all know, what happened was, we embarked on an OTC monograph rulemaking project that still is not finished thirty years later. My personal view is FDA needs some mix of rulemaking and litigation. There are some principles that you can establish only through court litigation, but it's pretty impossible to construct a program in which industry must glean their obligations by reading court precedents.

RO: Peter Hutt thought that if there were regulations or rules out, that the regulated industry would follow them. Goodrich, to begin with, didn't agree with that at all, with that approach, because that was the reason he wanted to use test cases. I think some of Peter's successors, Merrill and Cooper and some of those—and while we're talking about different general counselors, those you worked for, you know, your impressions of their approach.

LH: I was really quite blessed in having the opportunity to work with every chief counsel from Goodrich to Porter. I only recently met Dan Troy, our new chief counsel, and I think this agency has been fortunate in having had a succession of first-rate attorneys in this key position.

Bill Goodrich died a few years ago, I regret to say. He was consistent with every popular image of a lawyer in the American mind's eye. Bill presented that Perry Mason mystique, he was very charismatic, he had a booming voice. He was a short, stocky man, but with a great deal of presence. When he walked into a room, everyone took note.

Bill also was the last FDA chief counsel to be selected from within. Think about that. He became chief counsel in 1952, and not since then has an individual lawyer been selected from within. So people like me never had a chance to be considered for that position.

RO: What about Tom Scarlett?

LH: Tom had to leave FDA first. If you leave, you can kind of get your competence "ratified" on the outside and then be selected as chief counsel. Peter Hutt was chief counsel from '71 to '75, entering government for the first time from the law firm, Covington & Burling. Dick Merrill came in '75, staying for two years. Merrill, at the time, was a University of Virginia law professor, and that's where he is now. He had also practiced law at Covington & Burling, before going to UVA. He works for Covington now, one or two days a week. He was involved in the tobacco case. Dick Merrill, of

course, is an outstanding scholar who's contributed to food and drug law literature on virtually every topic, including food standards, drug approval, and food safety legislation.

Rich Cooper became chief counsel in 1977, when Secretary [Joseph] Califano would not accept Steve McNamara, the internal candidate, as a choice. Rich, at the time, was a brilliant lawyer at the law firm of Williams & Connelly, with no background in FDA law, but somebody that Califano had known since his own Williams & Connelly days. Rich was a quick study and a good leader in the office. He selected me to be deputy chief counsel in 1979. I had been a staff attorney for four years, working my way back up to a GS-14.

In 1979, Tom Scarlett announced that he would be leaving FDA to go into private law practice. This created a vacancy in the Deputy Chief Counsel for Regulations position. I received a phone call at home telling me about this opening. I was on maternity leave at the time, shortly after the birth of my second child, Colleen. I'd had Jonathan in 1976, not too long after the medical device amendments. I was told that Rich would be very happy if I would apply for the deputy chief counsel job. And I did, and later that year, was selected. This was after having served as a counselor for medical devices for about two years. And also I'd worked on the commissioner's Benylin decision on the drug, diphenhydramine hydrochloride. I presented the decision to Commissioner Donald Kennedy for signature on June 29, 1979, his last day at work, and gave birth to Colleen two days later.

So Rich was chief counsel till '79, and the then general counsel of the department, Jodie Bernstein, let Rich know that she would very much like to pick her friend, Nancy Buc, to be chief counsel. Nancy at the time was a partner at the law firm Weil, Gotshal &

Manges, another chief counsel chosen from the outside. So Rich packed up, Nancy Buc came in, and Nancy was chief counsel for a year, departing on the inauguration date of Ronald Reagan, January 20, 1981.

RO: She was flamboyant.

LH: She was a very colorful figure. Nancy was an interesting boss, but I learned a lot from her.

RT: Is she still in law, in private practice now?

LH: She is. I see all these people at Food and Drug Law Institute functions, or other similar legal meetings. Nancy has a law firm called Buc & Beardsley, and she practices before the FDA, the Federal Trade Commission, Consumer Product Safety Commission, and other agencies. She does a lot of work in the advertising area.

After Nancy left in 1981, Jeff Springer was acting chief counsel for a number of months, and the new Reagan administration looked around for a chief counsel. The job was offered to Steve McNamara, who had been passed over by Joe Califano just a couple years earlier. But Steve, by then, was already entrenched in private practice, so the job was offered to Tom Scarlett, and Tom came in as chief counsel.

During Nancy Buc's tenure, the Senior Executive Service had been established. She had designated the chief counsel job as political SES, or non-career SES. So when Tom re-entered government in '81, he came in as non-career SES. But Tom loved

government service. He had been in private practice of law twice before, once right out of law school at White & Case, doing antitrust work going through files, looking for behavior that would be a violation, or exculpatory, and came into HEW, first in the Welfare Division, and then in the Food and Drug Division, under Peter Hutt.

Then Tom had been at Morgan Lewis & Bochias for two years, starting in '79 through '81, but he much preferred government service and was anxious to return. Ultimately, he was selected as chief counsel of FDA in mid- to late 1981, and served in this capacity for the next nine years. So Tom was my boss and chief counsel for the largest time period in which I served as Deputy Chief Counsel for Regulations. I was Deputy Chief Counsel for Regulations for fourteen years, from 1979 to 1993.

RO: What were some of the major regulation areas that were developed during that time when you were Deputy Chief Counsel for Regulations and Hearings?

LH: That was a very active era. Number one, we needed to implement the numerous regulations required by the medical device amendments. I was not only the senior staff counselor to this program but later, as deputy chief counsel, I supervised other people working on these regulations.

Secondly, during those days, we really fleshed out our rulemaking authority. We issued the new drug GMP [Good Manufacturing Practices] regulations in the late 1970s, making use of the court precedents as well as the rulemaking challenge precedents, and successfully defended these regulations in court. We wrote the current version of food

GMPs, part 110, during that era, and I contributed to the legal rationale for the regulations.

In 1982 we had the Tylenol episode, a tampering incident involving a popular branded product. One of the things FDA needed to do was to write a regulation to bar tampering and to require tamper-evident packaging on certain products. This need generated many legal issues. I developed the legal theory that we ultimately used for the tamper-evident packaging, and that was derived from the U.S. v. Park case, that the industry obligation under the Federal Food, Drug, and Cosmetic Act encompasses prevention of violations, e.g., through tamper-resistant packaging. Again, this shows the interplay between litigation and rulemaking.

Park was a case that went all the way to the Supreme Court, involving criminal prosecution and strict criminal liability of regulated firms, under the Federal Food, Drug, and Cosmetic Act. I had remembered language from the Supreme Court opinion about how the Food, Drug, and Cosmetic Act is not only about going after products after the fact, once they're on the market, but also about preventing the entry into the channels of commerce of violative products.

So we used this theory in the tampering regulation. Other attorneys thought of a GMP theory, but that caused problems for products that may not be under a GMP requirement.

We also, during that year, worked on the Seafood HACCP [Hazard Analysis and Critical Control Point] regulations. In that regulation and others during the time period, I developed the legal theory for FDA issuance of a regulation that gave the agency authority to require records and inspectional access to records.

There had developed a belief that the section 704 provisions on inspection were the whole statement of FDA's records inspection authority. But through a number of regulations during the latter part of my period as deputy chief counsel, we developed another theory: if under section 701(a) of the act we could write regulations for the efficient enforcement of the act, and if under other provisions of the act, such as the ones on food adulteration or drug adulteration, we needed the industry to keep certain records, then FDA could write a regulation requiring a company to keep certain kinds of records that were needed to guard against the product becoming adulterated, or to allow action after the fact, and FDA's inspectors could inspect those records.

So we applied this theory to a regulation dealing with reports of adverse events from drugs that are not new as well as similar reports as to nonprescription drugs, so that we have such a reporting for all drugs. The seafood HACCP regulation pointed out that FDA could never enforce HACCP without its inspectors seeing the records of what was done at each critical control point.

RT: From there, you moved to the position of Director of International Policy. That was a little different scene, wasn't it?

LH: It surely was, Bob, and I think it's understandable that after fourteen years in one job, one gets a little restless and stale. I had done different things, such as teaching law at G.W. in the fall of '83, '84, and '85, which regenerated me. One of the things about teaching is it forces the professor to reread cases. If you tell your students to read a case, you have to reread that case. And if you reread a case, after having been a food and drug

lawyer for ten, fifteen years, you see things in it you didn't see before, and you synthesize this retake with other experience and new information.

I perceived a number of things. One was a whole body of case law dealing with delayed decision making. And so I created an outline for the benefit the people who worked for me in the Office of Chief Counsel, and for my G.W. students, recounting all the cases on delayed decision making and analyzing what the courts looked for in deciding what kind of action they would take, where FDA had taken a long time deciding whether to approve a product or in issuing a regulation.

Also, there had developed a whole body of case law dealing with informal due process. We all know about the cases on drug removal from the market. Once I started teaching, I realized that there was a whole body of oddball cases, dealing with topics like cosmetic ingredient labeling, and various types of procedures were being imposed on FDA by courts. If the agency has the authority and regulations to issue regulations having the force of law, almost like the Congress, we'd better have fair procedures. In a democracy, how could an agency have what amounts to lawmaking authority and then be able to jerk people around without fair process? Those two things go hand in hand—court cases saying FDA has a lot of substantive authority, and court cases saying FDA must follow fair process in using this authority.

RT: You were teaching advanced administrative procedures at that juncture. And then later, did you get into international food, drug, and medical device law? Was that after your going into the international office?

LH: Yes, really concurrent with it, Bob. Also during this time period, just a personal note, my husband, Henry, had died of lung cancer in January of 1987, and that was a great personal tragedy, very difficult for me and my kids. But I must say that I was very grateful to be working at this institution during that time period.

I was very grateful that, (a), I had my education. I hadn't sort of bought into the Cinderella syndrome that some Prince Charming would come along and rescue me and I wouldn't have to work; (b), I'd had this wonderful FDA career and FDA had helped me enhance my education; (c), FDA was very understanding during the time period when Henry was sick.

[Begin Tape 2, Side A]

LH: Henry died in 1987, and I continued to work in Office of Chief Counsel. I met Carl in 1990, and we married in 1991. He was a widower with two kids.

In 1993, the agency's global activities had begun commanding more and more of the agency's attention. When Dr. [David A.] Kessler came in as Commissioner in 1990, he reorganized the Commissioner's office and placed responsibility for international harmonization and bilateral inspection agreements in his new office of policy headed by Mike Taylor and later Bill Schultz.

RT: Let me interrupt you. "Harmonization" is used an awful lot. What does it really mean, as far as FDA is concerned?

LH: There are two meanings. One is a very precise meaning, and that would be every country adopting the same law. But that's very difficult. So I think harmonization would mean countries getting close enough to the same set of requirements, that the industry is not forced to engage in unproductive activity merely to meet unjustified regulatory differences.

Obviously, if the FDA has a good reason for demanding raw data on clinical trials, not just summaries of the studies, we're going to keep on doing this, regardless of the fact that European countries and Japan are interested only in summaries. But at least the companies can do a similar set of studies and satisfy the core requirements of the FDA and the core requirements of Europe, and then unwarranted regulatory differences are no longer forcing products to cost more than they have to.

If countries have different reporting requirements on injuries and deaths from a product, it's very easy for a company to become confused and report incorrectly. So I think governments can enhance compliance if we can agree on how many days after a death a report must be filed, or on what the criteria are for serious injury. Then we can have simultaneous reporting to all the different authorities, whenever there's a receipt of an injury or death report.

In spring of 1993, I was being courted by a law firm that wanted me to help build its food and drug practice. Luckily, I had a wonderful opportunity for an entirely new FDA international career.

At the time, I was getting more and more involved in the agency's international activities. For example, when Mike Taylor was given responsibility for international

harmonization by David Kessler in 1990, Mike put together a Task Force on International Harmonization. I was both a member of that group and the legal adviser to the group.

RT: In that work, you moved into the international sphere. Did that impose certain bilingual language skill development, or did you already have those abilities?

LH: I studied German and Spanish, but had largely lost that ability, due to non-use. I never traveled to a German- or Spanish-speaking country until I was in my forties. I was from a poor family and had to go to work and repay back college loans, so I never really had a chance to do much travel.

Bob, when I started working with other countries and their laws, I found it useful to learn enough about their languages to be helpful on legislative drafting. For example, I learned enough Russian to help Russian authorities with their pharmaceutical and medical device and food laws. I learned a little bit of French, because we were helping the French Ministry of Health and the French Senate in 1998 on their overhaul of food safety and medical product laws.

I learned a little Portuguese in 1999. By then I was studying Spanish again, and the two languages are pretty similar. But I was being asked to go speak to the Brazilian Congress on a bill, when the only copy I had was in Portuguese. With my little Portuguese dictionary, and what was in my head from Spanish, I translated the bill on the airplane trip down to Brazil, so that when I got there I could speak intelligently about this legislation.

RT: You're a quick learner, then.

LH: At the Congress, somebody handed me an English-language translation, but that was a bit late. I couldn't have sat there and read it. You learn some interesting things. Like "N-O" in Portuguese does not mean "no" as it does in English and Spanish. It is a contraction for "in the."

I also studied Spanish enough to develop a degree of fluency, because in the last two or three years I've done a lot of work with Pan-American Health Organization on different projects. But fortunately, for English speakers, the country that colonized us also colonized a lot of other parts of the world. English is the second language of choice around the world, and those of us who speak English as our native language can frequently get by in our language. Other people either speak our language or arrange for interpretation, so we're fortunate in that respect.

In '93, when Mike Taylor and Carol Scheman asked me to be the director of a new International Policy Office, I needed to be convinced. As I mentioned, I was being pursued by a law firm. I also was on the panel for an SES position elsewhere in the agency, and, ultimately, decided to take the international policy position. I asked Mike Taylor if he would pay for me to take a few international law courses, because I really wanted to understand how international law affected FDA, in a more scholarly and expert fashion.

At the time, several trade agreements were being negotiated and FDA, while expert on so many issues, from law enforcement to drug safety and efficacy, didn't seem to have mastery of the international law subject matter.

I thought it would be a matter of taking a course or two. It ended up being another whole law degree. I took one or two courses at a time from '93 to '97, and, really, at the end of it, realized that there wasn't a single course at Georgetown [University] Law School that really covered the things that we were working on at FDA. So I put it together myself, and now teach international food, drug, and medical device law at Georgetown. I've also given the course in-house to colleagues in Office of International Programs and Office of Chief Counsel, not wanting to force colleagues to go all the way down to Georgetown Law School on Capitol Hill to take a course for a fee that I should teach to them for free.

We, in fact, gave a thirteen-class course, not quite two years ago, to colleagues, and it's on tape down in the library in the Office of Chief Counsel, for anybody that wants to check it out from the OCC law librarian.

On harmonization, in each of the FDA product areas, there's at least one, and often two, international organizations working on harmonized approaches. The ideal of every country, if it has a law at home that it likes, is to try to export it. And we've had some successes. HACCP is one. HACCP was developed in the U.S. food industry, applied by NASA and the space program, included in FDA's low-acid canned food regs after Bon Vivant, and applied to seafood, meat, and poultry, and juice. HACCP became a world standard in 1997.

So what does this mean? Well, it's hard for a country to challenge our seafood regulations, which apply not only to processing of seafood in the U.S., but also in other countries where the seafood is destined for the U.S. market. Under international law, FDA has jurisdiction because the way the seafood is processed in another country or in

vessels out in the middle of oceans has an impact on our consumers. And therefore, under international law, we have authority. So our jurisdictional reach is not just the familiar map of the U.S., but it applies to anybody, anywhere in the world who's starting to produce product that's destined for the U.S.

We actually have a precedent, the so-called mushrooms case, about four years ago, where FDA had wanted not simply to detain some canned mushrooms from China that contained staphylococcus enteritidis, but to destroy them, because this was not fit food for any human on this planet. What FDA did was to take these adulterated mushrooms and move them into domestic status, where the agency had them seized and destroyed under section 304.

The claimant argued that we had no authority to do this, that our authority over imports was limited to section 801 of the act. We lost the case in the district court. We appealed it, and the Court of Appeals upheld FDA's action and held that the agency was not limited to 801; we could use the authority of 304 to seize and destroy the product, thus keeping it from being re-exported.

This opinion included wonderful language as to how FDA's jurisdiction applies in other countries. It applies to the practice of canning low-acid foods in China or elsewhere. Anyone who wishes to send product our way must meet our regulations. So this was a wonderful precedent that is part and parcel of our international initiatives in the last few years.

For pharmaceuticals, the International Conference for Harmonization has harmonized testing requirements, and for medical devices, we have the Global Harmonization Task Force. My particular contribution to these activities has not been in

the scientific area—that's not my background—but in the procedural area, namely, helping the agency to figure out the process that we use to adopt these international standards.

We have a need to comply with our own Administrative Procedure Act and our own Food and Drug Act requirements, and how do we respect and obey our own procedural requirements while playing in this international field.

This is a matter of great concern to industry and consumers, because, over the years, they've fought hard to have domestic rights to participate in rulemaking, and in open meetings and so forth. Do they lose those rights when FDA is working with other countries and international organizations to write the rules of the road for products? No.

During the last eight years that I've been working in different international jobs, we've secured a number of procedural rights. One was the need for balance in industry representation at transatlantic business dialogue meetings. We also reassured stakeholders that they would have a notice-and-comment process on any harmonized documents that we adopt. Whether we adopt an international standard through a regulation or through good guidance practice, FDA allows consumers, industry, all Americans, and all citizens of the world to comment.

In the European Union, there is not as yet the kind of notice-and-comment and docket approach that we have in the U.S. They're starting to get there, but they suffer what they call themselves a "democratic deficit," where there's often a mismatch between the rights citizens should have and the way in which European Union institutions conduct their business.

Here in the U.S., we have much more of a model. Just to use one rulemaking that I was involved in, tobacco, where Commissioner Kessler rounded up all the Food and

Drug lawyers who hadn't gone to private law firm jobs, and had us work on the tobacco rule. I was involved at the final rule stage on the most difficult legal issues involving the regulation itself, and also the question of agency jurisdiction over tobacco.

FDA had received more than 700,000 comments on the proposed tobacco rule, and still managed to get from publication of the proposal in January to publication of the final rule in August. This was done through priority and resources being given to a given project. People in other countries ask, "Well, how does FDA deal with all the comments it receives on proposed rules?" I say, "Well, we have dealt with as many as 700,000 on a regulation. Of course, it's difficult, but it can be done."

RO: Laboratory accreditation, meaning, the laboratories of the world are capable of doing the analytical work or the testing work, I noticed in one of the things you'd worked on, there was a laboratory accreditation.

LH: That's a very interesting question. Sometimes we're under pressure, Ron, to recognize another country's laboratory system through a Mutual Recognition Agreement. FDA has really stayed away from this. What we've said is, "We're not interested in having Mutual Recognition Agreements of other countries' laboratory systems, because we just don't even have the resources to go check out the system of another country. But let's do something else. Let's harmonize on the procedures followed in the labs as to the methods of analysis and sampling."

My good friend Bill Horwitz, who's been interviewed by you in the past, was the FDA delegate, or U.S. Government delegate, to the Codex Alimentarius Committee on

Methods of Analysis and Sampling. He continues to work with AOAC [Association of Agricultural Chemists], and then there's the International Standards Organization, ISO, which does some work in this area as well.

Through those activities the world now has a large body of methods that are used by labs. We have a practice of exchanging reference samples and doing split-sample testing that the AOAC has promoted. So we've said, "Let's harmonize in the standard. Let's have cooperation among the labs. We don't need to have this sort of political-level blessing of each other's system, where we each blindly accept each other's certificates of compliance. But what we want to do is build confidence, because FDA, as we all know, is only spot-checking a few products at the border, and we really need our foreign partners to do a good job."

If you think about how dependent we are on Mexico and countries in Central America and the southern hemisphere for fruits and vegetables, particularly during the winter months, we need our counterparts in those countries to do a good job enforcing food safety laws, because we can't possibly do the level of sampling at the border. Moreover, we all know that finished-product sampling at the border doesn't really work anyway. And does FDA have the resources to send inspectors all over the world? We don't. As an agency, FDA is struggling with the import challenge, which becomes more challenging each year.

In the lab area, I mentioned the work on methods of analysis. We also have a network of food labs in the hemisphere, that we put together in the last several years. There's a Pan-American Health Organization activity on pharmaceutical harmonization, and one element of that involves lab cooperation, and exchange of personnel. The Center

for Biologics Evaluation and Research [CBER] and the Center for Drug Evaluation and Research [CDER] have had scientists from other countries come into their lab, and have sent experts to other countries.

RT: We used to do that on a case-by-case basis. In order for them to export it, or import it into the United States, they had to assure us it had been tested, and we had to know what their methods were.

Another thing I was curious about was this precautionary principle. As far as equivalence concerned, are you concerned that some of the things might have an adverse impact on some of the foreign countries, so that you've got to be careful about what you're trying to enforce here?

LH: I think your question really presents three interesting questions. One is, what is the precautionary principle; what's this work on equivalence; and then what are the interests of the FDA with respect to U.S. exports? These are all very sensitive issues, and I'll sort of answer them in reverse order.

In the international activities of the FDA, we constantly discuss the precise scope of our international mission. When Mike Friedman was Acting Commissioner, he pressed for focusing narrowly on import compliance. He felt FDA lacked the resources to be a model to the world, nor did we have the resources to go to other countries and explain the U.S. system of whatever, such as testing meat for residues of hormones, or our system of approval new forms of agricultural biotechnology. He felt these were not activities that FDA could afford to do.

But Mike Friedman left, and Jane [E.] Henney returned to FDA as Commissioner, and Sharon Holston became Senior Associate Commissioner. Upon her return to FDA four years after her earlier tenure as Deputy Commissioner, Dr. Henney commented how much the agency had changed in that short time as it related to international matters. Almost immediately she had to send letters to the E.U., in which we were saying, "You're wanting our producers to meet very prescriptive European requirements. That's not what we want to do. We want you to find our system equivalent, because the approach used by FDA and U.S. companies is just fine. And we're not going to have individual FDA inspectors issuing certificates for each batch of product for export to the E.U. when there is no need. It should be enough that the companies are certifying to you."

Hormones. I've been in charge of the agency's trade activities for the last eight years. During that time period, U.S. Government brought the biggest case it ever brought, under the World Trade Organization [WTO] agreements, and this was against the European Union for refusing to allow imports of American beef from cattle that had been treated by FDA-approved hormonal growth-promoting product. This case was litigated in the mid-1990s. The Office of the United States Trade Representative [USTR] didn't realize at first they needed FDA, but it turned out that, at different times, we had five or six different people over in Geneva, as part of the U.S. Government team on this case. And it's not that FDA is a trade agency; it's just that nobody else in the U.S. Government knew anything about the approvals of these veterinary drug products.

So FDA sent various international policy experts and scientists to Geneva to make sure the government, U.S. Government, would speak expertly and competently on the subject matter, and know what science lay behind the approval of these products.

Secondly, we needed to have policy and trade law experts there, as we did not want the lawyer for the U.S. Trade Representative to make an argument that could come back and haunt the FDA later. Because—knock on wood—there has never been a challenge to an FDA regulation in the World Trade Organization, but we certainly wouldn't want to have another country making arguments against our rule that our U.S. Trade Rep lawyer had made earlier against somebody else's rule. So FDA needs to be involved in these cases.

With modern communications and the Internet, and with activists wired to each other by Internet, if we cannot clearly explain the scientific and policy basis of our approval process for biotech food, if our public doesn't understand that the forty-five varieties of agricultural biotech that FDA or EPA or Animal and Plant Health Inspection Service have approved are safe, and if European consumers are up in arms and burning fields and chaining themselves at ports to block shipments of American corn, etc., we're going to hear about it quickly over here.

RO: They are, aren't they?

LH: FDA knew we needed to do some outreach. The world is so small now, we needed to have people over in Europe explaining the FDA approval system, to make sure our consumers here at home don't start doubting our good work.

In the late 1990s, the E.U. was obsessed with the issue of food safety due to its "mad cow" crisis. In '96, '97, '98, there was a rumor in Europe that all FDA did was listen to industry, kowtow to industry, and approve anything the industry wanted. It was

in the context of the hormones litigation, which was very unpopular in Europe, because the U.S. Government won the case.

The consequence was that European exporters of unrelated products, everything from cashmere sweaters woven in Scotland, to caviar, to fine liquor products from France were saddled with 100 percent tariffs when they reached the U.S., because of the European refusal to change their requirements to conform to the WTO hormones decision. So you started having Ronald McDonald pelted in country towns in France, because the U.S. was viewed as trying to impose our lax food safety standards and American brands on European consumers.

Sharon Holston and I agreed that we needed to take advantage of opportunities to better explain FDA to the European public, and to counter the view that the U.S. system is less cautious than the European one. After all, we weren't the continent that had the mad cow [disease] problem; the E.U. was.

Europeans had developed a concept called the precautionary principle: if scientific evidence is uncertain and you need to be careful, the government is justified in taking action while awaiting the development of more complete information. It sounds good. The problem with the European approach is that they want to apply it at the political level rather than incorporate caution in science-driven decisions. There could be a scenario where, let's say, the scientists within a government had reviewed a certain substance or product or practice, and decided that it was safe, but then at the political level, somebody said, "Well, okay, but the consumers are concerned and I don't want to let this product on the market. I want to invoke the precautionary principle and keep it off the market." That's the way the Europeans are applying it.

So for the last two years, I've been at the forefront of explaining the U.S. approach to precaution. I wrote/edited a document that's on the www.foodsafety.gov Web site on how we use precaution in the U.S. food safety system. This, in essence, is an American reply to the European precautionary principle. We demonstrate, through case history, how we use precaution.

One of the key points we've made with the Europeans, one that has made a big impact on them, is that core to our system is the expectation that producers will take responsibility to produce only safe products. This seems very obvious to us. It's inherent in our basic legal system of torts and contracts in each of our states, and it's inherent in our food and drug law at the national level, going back almost a hundred years.

When our law makes it a crime to introduce into commerce an adulterated product, that really is pushing back to the producers of food and drugs, and now medical devices and cosmetics, the duty to place only safe products into commerce. This is so fundamental, and so missing in many countries, including the highly industrialized countries of the European Union.

The E.U. is now, as part of European Union-wide legislation, establishing a new framework for food safety following the mad cow tragedy and their problems with dioxin and other substances, putting in their legislation this responsibility of producers to only produce safe food. All the fifteen countries of the European Union will need to adopt the same principle in their laws.

Believe it or not, in France right now, as of two years ago at least, their law required *scienter*, knowledge of wrongdoing before somebody could be charged with wrongdoing under food law, whereas ours said, even if, in your eyes, you're totally

innocent, you didn't really know that you were introducing an unsafe food or an unsafe drug, you've chosen to go into this business of selling a product that has such an impact on people. We're going to impose on you a duty of care, so that you can't just plead ignorant innocence under U.S. law.

But France and United Kingdom, until very recently, they did not have this strict liability, and with the new E.U. legislation they definitely will have it. Outreach to other countries about key aspects of FDA's consumer protection laws is one of the best things we've been doing in the last few years, and, again, this has been under Dr. Henney and now Dr. [Bernard] Schwetz, certainly during the time period that I was working closely with Sharon Holston.

[Begin Tape 2, Side B]

LH: Bob, did you want to repeat your question about tobacco regulations?

RT: Yes, I was going to ask you that, what you thought of the FDA taking on the tobacco industry after all the years of saying we really didn't have the authority.

LH: In fact, since 1912, FDA's predecessor, the Bureau of Chemistry, as well as FDA has said that the agency possesses authority to regulate tobacco as a drug, if claims are made. The breakthrough during the 1990s was to assert that FDA has the authority to regulate tobacco, whether or not claims are made, because under another branch of the definition of drug or device, as the case may be, the agency regulates products that are intended to

affect the structure or any function of the body. That is what changed in the 1996 FDA regulation, due to evidence that the tobacco industry intended to affect the structure or function of the body.

The tobacco industry challenge resulted in a vote of five to four that FDA lacked authority to regulate tobacco. I thought the agency should present the tobacco rule as nothing particularly radical, and that we should acquaint the justices with the fact that since 1912 FDA has asserted jurisdiction over tobacco under certain circumstances. When you're making an argument to a court, particularly a conservative, strict-constructionist court, you don't want to be radical. You want to be incremental, and you want to follow precedents.

I had strongly suggested to Bill Schultz, who was Deputy Commissioner for Policy at the time, that we should forcefully remind people of our consistent assertion of authority over tobacco, if claims are made, and downplay the change that was being made in the tobacco rule simply adding another jurisdictional ground. Bill did not want to minimize the significance of what we were doing. He wanted to stress the revolutionary and precedent-shattering aspects of the rule, not its consistency with tradition.

When I picked up a copy of the Supreme Court decision, I was afraid that the point had been missed, and so I was, in a way, relieved when both the majority opinion and the minority opinion referred to the 1912 letter, as well as other precedents, in which FDA had consistently taken this position. I still continue to believe that if we had packaged our presentation to more strongly emphasize the continuity of our position, we might have swung the needed one vote to FDA's side.

With respect to my view of FDA taking on tobacco, I had initially been against it. It had been clear from a court case of around 1980, the Action for Smoking or Health case, that it was up to the FDA to decide whether its jurisdiction extends to cigarettes as conventionally marketed. In that case, an anti-smoking group had sued FDA after it issued a petition refusing to regulate cigarettes as drugs, except where they bear claims. The court had deferred to the FDA, but it was very clear from the decision that if the agency had issued the opposite ruling, the court also would have deferred to FDA. Because, remember, during this era the primary jurisdiction doctrine held that FDA was an expert agency and courts should defer to FDA matters within its area of expertise. During recent years, deference was not just on issues of science and fact, but also on interpretation of the law. Agencies like FDA were to be given deference on its legal interpretations as well as scientific issues, but the tobacco decision indicates a less deferential attitude.

In 1990, when Dr. Kessler came in, tobacco stood out like a sore thumb, as an unaddressed public health hazard. If you think about the universe of products, and what's causing death and what's causing illness, tobacco stuck out. You can talk about foodborne illness and you can talk about adverse events from drugs and even from a toxic drug like from chlormycetin, but cigarettes exceed all other product risks. One out of three people who start smoking will die prematurely of a tobacco-related death, prematurely. We're all going to die, but most people don't want to die earlier than would normally be their time, and this is what is happening with tobacco.

Dr. Kessler called a meeting, and I was at that meeting, where he went around the table, asking whether FDA should seek to regulate tobacco as conventionally marketed

(without claims). To a person, everybody in the room said, "Don't go near it, David, because it'll bite you." There was history where other agencies had tried to do something about tobacco—the Federal Trade Commission and the Consumer Product Safety Commission—and Congress turned around and slapped them and either provided weak authority or excluded them from tobacco jurisdiction.

David didn't give up, and recently he wrote a book (*A Question of Intent*) in which he described his own reasoning in going forward, and the arguments that he decided to use. Ultimately, FDA discovered a great deal of evidence that tobacco companies knew all along that they were intentionally addicting children, and that they were reaching out to children and marketing to children.

In my own case, I was a former smoker. Bob, I can remember smoking in this Parklawn Building many years ago, but I quit in either '73 or '74. I am mortified that I was creating second-hand smoke for other people.

My late husband, Henry Ho, had also been a smoker, although he'd given it up around the early 1970s also. But this disease has a gestation period of some twenty years, and in late '85, we learned that he had lung cancer. So this has shaped my attitudes because I saw this man I loved die a painful death over a thirteen-month period, in which his cancer, developing slowly for many years, became evident and went through its final stages.

I did not work with Dr. Kessler on the proposed regulation on tobacco, and indeed, that was so soon after Henry's death, I think I would have found it difficult to do so. But when Dr. Kessler and Bill Schultz asked me to work on the final rule, I was

delighted to do so. Enough time had passed and I was anxious to do something about this public health scourge.

I had that opportunity in 1996, and in my photograph collection, I've got some pictures from the Rose Garden ceremony, where President [William Jefferson] Clinton and Vice President [Albert] Gore [Jr.] announced the regulation, and I had a chance to shake their hands, and actually tell Vice President Gore how moved I was by his story about his sister's death, and that I, too, had suffered a great personal loss, due to loss of a loved one who had a smoking habit.

I personally think that FDA was right, and the minority of four in the Supreme Court decision also had it right, and that FDA does have authority to regulate these products. The difficulty is, what would we do with these products if we got them? We struggled with this issue in the tobacco team. We know that more should be done to restrict youth access to drugs. When I was a thirteen-year-old kid in Kentucky, I could put a few coins in a vending machine and get tobacco products. We have had, through other actions besides FDA regulations, some change in that area.

On the advertising side, there's a whole body of Supreme Court precedent dealing with commercial free speech that I, personally, as a lawyer, think was not intended by the founders when they wrote the First Amendment to the Constitution. Under this doctrine, it's very difficult for the FDA, or the Congress, for that matter, to ban the advertising of products to adults. It's still possible to ban advertising to kids, but in the tobacco team, writing the final regulation, it was very difficult to say which magazines were aimed at kids and which were aimed at adults, and we got into some pretty arcane distinctions there.

There are other democracies, such as France, that have banned the advertising of cigarettes. There's actually an international negotiation going on now, and I do hope that our administration can see its way clear to allow the framework convention on tobacco to encourage countries to ban advertising of tobacco products, even if our own Constitution, as interpreted in these commercial free speech cases, does not allow us to fully ban tobacco advertising in this country.

RO: When they started in to impose some restrictions on the marketing of tobacco in the United States, their biggest market was overseas, and I could just see what kind of problem that would pose for our international agreements.

LH: Yes, absolutely, Ron. I was involved in a White House task force dealing with international issues during the time period that a settlement of the tobacco legislation or litigation was being discussed, and it's a huge issue because our country has only 4 percent of the smokers in the world. Other countries have large youth populations, and populations where women's smoking rates are low, such as only 5 percent. The industry has a great deal of interest in those populations. "If half the women in China smoke, how many cigarettes would we sell in China?" As far as Chinese men, already half of them are smoking.

In a lot of these countries, cigarettes are domestically produced products, but American brands are the most popular ones. International aspects are clearly very important when it comes to tobacco, as with other products.

RO: You were talking about imports a while ago, and I want to make sure that I understood what you were saying, is that if we do not allow the entry of a product into the United States because it presents a hazard, they can't export them. We can seize that and destroy it here, where they're not allowed to export it back to the country of origin.

LH: Yes, that's right. FDA, in the early 1990s, developed the theory, and it was upheld in the mushrooms case, that when it comes to dealing with imports, FDA is not limited to section 801 of the act. If we were, we'd be limited to three remedies: voluntary destruction, if no one showed up to claim a product; re-exportation, which was treated as almost a matter of right; and reconditioning, which is sometimes possible and sometimes not.

When it came to these Chinese mushrooms, they could not be reconditioned. Perhaps you could open all the cans and turn them into fertilizer, but that wasn't very practical. The claimants wanted to re-export the product, but we did not want it re-exported. We have to work together very closely with Canada and Mexico about rejected imports anyway, and it's just too easy for bad products to go someplace else, and these products were unfit for human food.

So in this case, we had a chance to test our legal theory. We moved the mushrooms into domestic commerce so that we could use section 304 of the act, and we seized them and obtained an order of destruction. As you know, there's a difference between 304 and 801; under 304, we can more clearly order the destruction of a product.

And so the claimant said we were acting improperly, that concerning imports, we could use only section 801. The district court agreed with the claimant, but we appealed

the case and won the case in the Court of Appeals. And so this means that this is an additional remedy. I don't know how often we're using it, Ron. We still, as an agency, are trying to get a grip on imports. People like Steve Solomon, Ben England, and Carl Neilsen are working very hard on this, as well as people on my staff in Office of International Programs.

The other thing, too, has to do with jurisdiction, and that is, let's suppose another country said, "You don't have any business telling us how we do clinical trials in our country." And sometimes our agency will say, "You're right."

My response is, "No, if they want to submit data to us, we have jurisdiction. Read the mushrooms case."

Or another country will say, "You don't have any business telling us that our seafood processors have to follow FDA HACCP rules, and keep records the way you want them kept."

And the answer is, "You don't have to ship here, either. But if you choose to ship here, you have to follow our regs."

I think you can imagine that every country in the world can say the same thing. The European Union says it. This argument I described earlier, where we're resisting the idea of stationing an FDA person in the four gelatin plants, shipping to the E.U., to sign little certificates. We are instead saying, "We have this approach that's just as good as yours. It's equivalent."

The E.U. is the other 800-pound gorilla. Remember, our market is 280 million people, but theirs is 380 million people, and they're adding countries. They're adding ten

or fifteen more countries, and so they're going to get bigger and bigger. Their weight in the world likewise grows.

So we need partnerships with other countries, and we also need to harmonize our standards, so that HACCP—I mentioned it's a Codex Alimentarius standard, under the United Nations Food Standards Program. So there's two ways nobody can criticize us. Number one, it's an international standard. Number two, we have evidence that following HACCP helps in controlling your critical points in production. It helps to make sure the seafood is safe, and therefore we have an interest in how you produce your seafood. In international law terms, as well as under the U.S. Food and Drug Act, FDA has jurisdiction.

There's another whole body of international law that's been much more troublesome. In the tuna-dolphin situation, there's nothing wrong with the tuna, okay, but the people catching the tuna used a net that slaughtered a lot of dolphins. So the U.S. passed a law, some years ago, banning tuna that had been caught in a way that hurt the dolphins. Under the international litigation dealing with this issue in the predecessor to the World Trade Organization, the U.S. did not prevail. When there's nothing wrong with the tuna, trade rules make it difficult to tell other countries about how they catch fish, except as part of a treaty.

There's also one about shrimp and sea turtles, where some of the shrimp nets, or sort of boxes or something, catch endangered species sea turtles. And there's nothing wrong with the shrimp, we hope.

It's very hard for the U.S. to try to protect the dolphins without going through international treaties for conservation issues. So the reason why some countries will tell

us, "You don't have any business telling us how we process our seafood. Remember tuna-dolphin." One of the reasons why people like me have to understand international law is to have a defense, that, "No, the tuna-dolphin case was different, because there was nothing wrong with the tuna. Here, there could be something wrong with the tuna if you don't follow HACCP. It could have histamine, it could be decomposed, it could have microorganisms or filth in it." So it's proper for the FDA to impose HACCP requirements on other countries.

RO: FDA conducts foreign inspections, and years ago, we were starting to get agreements with some of the countries that their inspections were equivalent to ours. How is FDA progressing in that now?

LH: I think we've made a lot of progress. We now have agreements with several countries for exchange of inspection reports on drugs. We have old agreements with Switzerland, Sweden, and Canada. And then during my years in the international arena, we reached similar agreements with the European Union and its fifteen countries, with Australia, and with Japan. We particularly favor the agreements like those with Australia and Japan, which offer cooperation and exchange of information from FDA's Compliance Status database as well as disclosable information in inspection reports.

The European Union Mutual Recognition Agreement has been very challenging. I actually negotiated the medical device part of it, and that part's going very well. The pharmaceuticals part, I think, was flawed from the beginning, because it's one of those international agreements where certain philosophical differences were papered over with

words, and the European Union really wanted us to treat their system as a unit. We knew good and well that there were huge differences among the different countries, with respect to the rigor of GMP legislation, enforcement, and inspection. So we refused to treat the European Union as a whole, as a unit, and they grudgingly signed an agreement that allowed us to look at each country individually.

So here we are, three years later, and we still haven't made much progress on the pharmaceuticals annex, and part of it is the European resentment that we insist on looking at each country individually.

You asked me about equivalence, and I have become convinced, Ron, that equivalence is not a viable concept when it comes to regulatory cooperation at the international level, and this, for me, is a change of views. If you asked me in '93, '94, '95, I would say, "That's the benchmark. That's what we want to go for. We want to have agreements with equivalent countries."

But what's really tough in some areas is finding someone who's equivalent. Quite frankly, when it comes to the drug regulatory system of this country and the medical device regulatory system, we're second to none. There's nobody equivalent. I'm not saying that we can't learn from other countries, because there are some things we've learned from other countries. Indeed, we've incorporated them into our programs, like the Third-Party Accredited Persons Program for entities to assist CDRH in review of products. That concept was borrowed from the European Union. They borrowed device classification from us, and we worked together on the current version of the GMP regulation for devices. But if there's nobody equivalent, how can that be the benchmark?

Foods. I talked about the fresh produce in our grocery store all year round. That's coming from countries whose food systems are not equivalent. And if we say we only want food from equivalent countries, our diet will become very boring and perhaps not very nutritious during the dead of winter.

So, what is it we want? Well, what we'd really like is strict compliance. That's what everybody wants. We haven't really been forcing strict compliance. We haven't had the resources to do so. So, a country's message to other countries needs to be, can you please regulate your industries and only send us safe food and drugs and drug ingredients? And so that's been the challenge, and we still haven't found an effective way to deal with imports.

RT: Have we encountered resistance by other countries to the exportation of our products?

LH: That's a very interesting question, and I think it depends partly on whom you ask. But let's take the beef and hormone case, which is one of the most celebrated instances, or the agriculture biotechnology case, which is still current. Right now, the European Union approval process for foods derived from modern biotechnology is totally shut down. They're not allowing in any products, including ones they've already approved. So their system is completely dysfunctional right now.

And I can tell you, it's a mixed bag. Their consumers are concerned. If you look at their consumer surveys, half the consumers, or more, are very concerned about the safety of these products, whereas our consumers gleefully chow down the corn chips, and

as a whole, don't worry about the issue. Few consumers in the U.S. worry about this, but in Europe, it's still a big concern.

Hormones in beef. Many people our age or older in Europe, and some younger people, can remember dramatic photographs from Italian tabloids of baby boys with breasts, that allegedly were due to baby foods with hormones. This got planted in the European mind. They cannot think about hormones being used to promote growth in beef cattle without this image coming to mind, even though the level of hormone is either undetectable in the meat or is greatly exceeded by the natural levels of hormones in human bodies. And so, what is it? Trade? Or is it consumer fears or is it science? It's all of the above, and so it's hard to pinpoint.

The Food Safety Inspection Service says that every time they de-list three different Mexican meat products as out of compliance or out of equivalence with their requirements, Mexico de-lists three American plants. That looks like trade discrimination.

So I think the answer is, it's a mixed bag. Some of it is legitimate scientific concern. Some of it is not legitimate scientific concern, but it's consumer concern, which is often not science-based, and then some of it is pure and simple trade restrictions in the guise of consumer protection measures.

RT: I think the issue has been considered whether or not, in order to be a trading partner in the European market, this will tend to lower our standards in order to participate. Is that a viable argument?

LH: I think that's a concern. Here's the concern. Let's talk about the Mutual Recognition Agreement with the European Union. We entered that negotiation because of our frustration getting the resources necessary to do foreign inspections. Nowadays, we even have some other issues, where some of our inspectors don't want to be gone so long and don't want to go to certain countries. In some cases there's unrest in the country where we need to go, and we're reluctant to send people to countries where they're in harm's way.

So, going back to the early 1970s, we have been interested in being able to rely on foreign partners, whether they're equivalent or not, so that their people that could go forth and do an inspection for us or whatnot.

But, Bob, there have been some instances in the last few years where the FDA has done an inspection in Europe of a drug or medical device company, and found problems, and this came to the attention of senior trade officials. I think there's room to believe that certain politicians in Europe would prefer that FDA inspectors not conduct inspections in Europe, because we tend to find things wrong. And it's not as if European companies are the only ones who fall out of compliance with GMPs. I think if you look back in the last ten, fifteen years, FDA has, and our enforcement really has forced a lot of small and big companies in the U.S. to do a better job on GMPs. So it's not surprising that we're finding similar problems in other countries.

One of the issues that I have, dealing with foreign officials, whether it's Swiss officials or European officials, is "Why are you so anxious to keep us out?" Who's the "we" and who's the "they"? This should be we the regulators dealing with they the companies, who, increasingly, are multinational and transatlantic. Regulators need to

cooperate. We don't have the resources to stand behind a national border and say, "Nyah, nyah, nyah, nyah. You can't come and inspect our companies." That's not the way it works. We have to be partners in public health, just as the companies themselves are all married together and teamed up and have all kinds of arrangements back and forth.

If you, the foreign official, think the "we" and the "they" is we the Swiss officials protecting the Swiss industry from too many FDA inspectors coming over, that's not a partnership that's going to work well. So it's we the public health officials working together to effectively and efficiently regulate an industry that's increasingly transatlantic, and increasingly operating under global quality standards and global product standards.

So that's kind of a challenge for the future, and this has been another thing that's made me disinterested in equivalence, because when regulators are forced into a position of giving each other report cards on how good a job you're doing. That immediately tears down the cooperation. It's much better if we can sit around a table, like we're doing, and harmonize what the requirements should be, what the inspection reports should look like, and what bulk-drug GMPs should look like, and we can share information on how we do inspections. We could do some joint inspections as a learning experience.

But once you start getting into—and this is what the Mutual Recognition Agreement for pharmaceuticals says—an obligation for FDA to normally endorse the inspection reports of another country and empower the other country to say, "Time out. You can't come over, because we have an agreement, and you're supposed to normally endorse our reports."

We say, "Time out again, because don't you see this safeguard clause, where we said we could come in?" That's just not good. If we're truly regulatory partners, partners

don't include this language that seeks to compel endorsement of each other's work. We should view each other as somebody that can help us do our job and save resources, not somebody who's going to harass our native industry, because, increasingly, there's not a native industry; it's a global industry.

RT: You will be retiring next month, officially, as I believe you indicated, after which you—

[Begin Tape 3, Side A]

RT: Linda, I was about to ask you, as you look forward to the conclusion of your career with FDA, whether you professionally will be active in this or other fields of the legal profession?

LH: Yes, Bob. At this point, I might mention some of the outside activities that I've been involved in and will stay involved in. I've been very active in the Food and Drug Law Institute over the years. I was chair of their Editorial Advisory Board for the journal for a couple of years.

I've also recently become very involved with Regulatory Affairs Professional Society, and now serve on their board of directors. I was the FDA representative on a wonderful RAPS mission to Brazil two years ago. That was the time I spoke to the Congress. It was a public-private sector partnership. Each member of the U.S. delegation from a company gave a quick history at the same congressional session of a challenge that

his or her company had been presented with, and how they dealt with the challenge, and how things then improved.

One described a tampering episode involving an infant formula product. Another member of the group was from the American Red Cross and described the manufacturing practice problems and ARC's success in reducing the number of adverse inspectional observations. Somebody else talked about challenges with a product launch, and how they worked with the agency. The message to the Brazilians was, "Don't just look to the government to solve all the problems. Companies need to take on board the responsibility for the product, wanting to have a good brand name with the public, wanting to avoid adverse publicity, wanting to be a partner, wanting the product to be safe and effective, and, again, not standing behind that wall and daring FDA to take action, but really working together with the government to make sure products are right."

In '99, the Food and Drug Law Institute gave me a marvelous award, and during my acceptance speech at the annual meeting I said that through my legislative work with Russia, which was coming out of seventy years of communism, I had come to understand the role the private sector plays. I had to explain to Russian officials why American food is safe, despite the fact that we were only inspecting food companies an average of every seven or nine years. I had to explain to them how there were legal obligations that apply to the food industry whether FDA exists or not.

I started thinking some more about this, and formulated this idea that the regulatory affairs people in the companies, and the food and drug lawyers, and the other people in the private sector who make sure that companies meet requirements are the eyes and the ears of the public good when the government is not watching, which is most of the

time. Even for drug companies and blood banks, where we inspect more often, most of the time it's got to be the people in the companies who are making sure of compliance.

So as a government person in RAPS, or soon as a private-sector person, I really see this army of 9,000 members in RAPS as being people who help to reach out and multiply the effectiveness of the FDA by making sure that the submissions to the pre-market approval programs are in compliance, by making sure that the quality systems for devices and GMPs for all products are in compliance. Now, RAPS members don't always just sit back and comply. They also make useful suggestions to FDA on how to improve regulations.

Bob, I'm going to be going to the law firm of Hogan & Hartson, which is the largest, oldest Washington, D.C., law firm, which has a major FDA practice. A number of my former colleagues from Office of Chief Counsel are there, like Bob Brady, David Fox, Rick Silverman, Howard Holstein, Marc Bozeman, and other people I have worked with over the years. They're looking to me to build the international practice for Hogan & Hartson, which now has an FDA practice that's second to none. They have a reputation with the agency as being nice people and not being argumentative and hostile. They also refuse tobacco business. I did not interview with any law firm, that I know of, that represents tobacco business, and I stayed away from some of the other big firms whose names are very well known, because they do have tobacco clients.

It's because I'm going into Hogan as a partner, and when you're a partner in a partnership, you're sharing profits, and there's no way that I can wall off myself from tobacco-related profits if I went to a firm that represented tobacco clients. And this is a conscious choice of Hogan, driven in part by the fact that they have a large health practice

and they represent the American Heart Association, the American Lung Association, and a lot of the other health groups. They've chosen to stay on that side of the border.

I'm convinced that, as a food and drug lawyer, in large part I will be helping people to find their way to the fold of compliance. Also, in the international sphere, I can help to make harmonization a reality, maximize the benefits of harmonization, assist companies with submissions that meet requirements of foreign governments as well as FDA requirements, and deal with problems involving approvals or inspections in other countries.

Our initial focus will be on the European Union and probably on medical devices as an initial focus, because of some of my recent expertise and experience as well as industry needs. But I'm also going to be active in some of the food biotech issues and the pharmaceutical issues.

RT: So this law practice has among its clientele a number of foreign producers. Would the foreign governments also be likely to have legal advice of this nature?

LH: It's an interesting question. The current clients of Hogan & Hartson are predominantly domestic, but not entirely. We also have this global, multinational phenomenon, particularly in the drug industry and the larger device and food companies. Just to give you an example, I think there's a large number of medical device companies represented by Hogan, and three-quarters of them are in the U.S. and one-quarter are foreign. There are hundreds of firms. The foreign firms are predominantly European or Israeli, and I think there's probably some interest in the firm in expanding Hogan's Asian

presence. I think there are some Japanese drug and device companies that are interested in better understanding FDA requirements.

But my main emphasis will be not on compliance with FDA requirements, but helping U.S. and foreign firms to meet foreign regulatory requirements, particularly in these harmonized areas.

RO: Are there restrictions imposed on you?

LH: There are. I'm under a number of different restrictions that apply to FDA officials when they leave. Number one, I'm senior, so that means I'm under the one-year cooling-off period, where I cannot appear before FDA to try to persuade FDA to do something, for one year. I can have lunch with friends, and I can ask for general information, such as, "Has that regulation been published?" But I can't say, "You should not be prosecuting my client, because—." And I think this is actually a good requirement that helps avoid uncomfortable situations for agency officials or me.

There also is a lifetime bar against working on particular matters, such as approvals or court litigation. Luckily, I stopped working on individual product approvals in 1993 when I left the Office of Chief Counsel. While I was there, I handled only a relatively small number, mostly signing off on *Federal Register* documents for certain approvals in the animal drug and medical device area. But I have really done no work that's case-specific in eight years, and most of the medical device clients of my future law firm did not even exist eight years ago because of the technological change in that area.

RT: Linda, we certainly wish you success in your continued legal career.

LH: I also hope to continue to do some of the international legislative technical assistance work, and I'm quite sure that I will be able to, because lawyers have an ethical obligation to do pro bono work. Pro bono, of course, means "for the public good." The most useful way for me to make a contribution is in the legislative technical assistance area. I've felt for some time that some of the work of which I am most proud is the legislative work in recent years with Russia, in particular, but also France, Brazil, Mexico, and other countries.

RO: Is there anything else you'd like to add to this interview?

LH: No. Just, in the words of Rodgers and Hammerstein, sometime in my girl- and boyhood, I must have done something good—to work for this agency, and I think we're really blessed to work in an area that's so vital to the public health. I've had a marvelous thirty-three-year career with the FDA on legislation, regulations and other legal matters, and international activities. I leave with the warmest feelings about this institution and my colleagues.

RT: We usually ask the interviewees what they think the prospect of the Food and Drug Administration is, since there's always the argument on the Hill about disbanding it, carving up the Food, and putting it one place or another.

LH: I think our future looks very bright. I think that Secretary Thompson appreciates this agency. I've had the chance to meet him and work with him on a couple of things, and I'm very impressed. He's wonderful. He's under the gun right now to get a Commissioner in place. I don't actually know what's going on there. I think it would be helpful to have a Commissioner in place, although Bern Schwetz and the other people on the fourteenth floor, including my boss, Max Lumpkin, are doing a wonderful job right now.

On the single food agency proposal, I think it's going to be very hard for that to move forward because of industry opposition and the way that Congress is organized. As we know, Bob, each committee of Congress feels it owns a certain piece of the bureaucracy, and so the agriculture committees are very oriented toward the USDA food agencies, and the commerce and health committees are very oriented toward our world. As long as Congress is organized the way it is, it's going to be very hard for them to make major institutional changes on food safety regulation.

I'm also not convinced that there's a dire need for a single food agency, but I won't go into that in any great detail. Scarcely a day goes by that FDA is not in the newspaper, and we have new concerns like bioterrorism. FDA's role is at the forefront as to approval of new smallpox vaccine, new uses of doxycycline and Cipro[®] for anthrax treatment, and improving surveillance of food so that it's not a medium for terrorists to harm our public. You look at the surveys, and the public hold FDA in very high esteem, so I think the agency's future is great.

The challenges are great, too. Our law is ancient, and even with creative interpretation, it has some gaps. This import problem needs to be reckoned with, and the international challenge is still there for my successors, that's for sure.

RT: We certainly appreciate this interview.

LH: Thank you for the honor of this interview.

[End of interview]