

History
of the
U.S. Food and Drug Administration

Interviewee: Joseph Levitt, Esq.

Interviewer: Ronald T. Ottes
Suzanne W. Junod, Ph.D.

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Place: Gaithersburg, MD

Interview with Joseph A. Levitt

December 23, 2003

TAPE 1, SIDE A

This is another in the series of FDA oral history recordings. Today we're interviewing Joseph A. Levitt, Esq., retired director of the Center for Food Safety and Applied Nutrition. The interview is in his home in Gaithersburg, Maryland, and interviewing Mr. Levitt are Suzanne White Junod and Ronald Ottes. The date is December 23, 2003. The tapes and transcript of this interview will be placed in the National Library of Medicine and become a part of the FDA oral history recordings.

RO: Joe, we'd like to have you start with a little biographical sketch of where you were born, educated, and any relevant work experience prior to coming to FDA.

JL: Very good. First of all, let me thank you both for coming out here. This is a real joy for me to be able to participate in this, having lived in and mentored by so many of FDA's former leaders.

My biographical sketch is pretty straightforward. It's simple. I was born in Dover, New Hampshire. Both my parents are from New Hampshire. When I was in the first grade, we moved to Long Meadow, Massachusetts, where my family still is in the same house.

I went all the way through school there, went to college at Cornell University, graduated with a bachelor in arts *magna cum laude* and went on to law school at Boston

University, where I was on the *Law Review* and graduated *cum laude*, and came straight to work at the FDA. So my only adult work experience is at the Food and Drug Administration.

RO: So rather than take your career from the beginning until the end, we're going to start at the end and work forward.

JL: Sounds good. That's where my memory is best.

RO: Okay, just start.

JL: Okay. I have a few notes to help me.

I began as CFSAN director in February of 1998. February 2nd was my first official workday. And I came in at a time when the food program was front and center. There had been, under President Clinton, what was called the Food Safety Initiative, the President's Food Safety Initiative, and that had started a year or two before. It had actually been several years in the making.

If you go back and ask people, as I did, why -- I asked them, "Why is food safety such a big deal now?" and they said, "Well, because it was all about microbiological hazards in the food supply." That's where all the attention was. And they said, "Well, you know, if you go back into the 1980s and ask about food safety, and they care about pesticides and chemicals, and if you ask them about bacteria in the food supply, they said, 'Well, that's just a stomachache. That's all that matters. It's not a big deal.'"

But in 1993, very early in that year, right at the very beginning of the Clinton administration, three children went into a Jack In The Box restaurant in the Pacific Northwest, ate some hamburger and died, and that was a catastrophic event on the same level, I think, historically that other major FDA events had been, where they go back to thalidomide in '62 or elixir of sulfanilamide way back in the early part, in 1938. That was a groundbreaking event. It might have been over a product regulated by USDA, not by FDA, but the reverberations were soon felt because we realized the problem wasn't just in the meat. The problem was in the environment and in the bacteria, the pathogens, that were available in food. And as time went on, there was an outbreak in apple juice made by Odwalla in about 1996. There was a major outbreak in imported raspberries from Guatemala with a parasite called cyclospora. There was a major outbreak in strawberries contaminated with hepatitis A, which we've recently seen a revisiting of. And all of these outbreaks led to a clear realization that the food supply, the safety of the food supply is a major issue and needs a major new approach by the government. And from that was born the President's Food Safety Initiative.

There were basically several items. People were asking, "Well, why was food safety now a big deal?" It's not just the quick off-the-hand. It's not a bellyache anymore once people are dying from it.

We went back and realized there were several very distinct reasons why food safety was such a problem. Number one is that people's diets had changed. It wasn't just meat and potatoes, buy food from your local market. People's diets had changed. From eating potatoes to more seafood, to more fresh fruits and vegetables, and they're not just getting it locally, but they're getting it from all over the world. And so that just

introduces a lot more food that is not processed and a lot more steps in the food-distribution chain where contamination could get in. And so we have a much different source of our food supply. And it's coming not just from all over the country, but literally all over the world. The trade agreements in the early 1990s that opened up the borders for free trade also opened it up to just a deluge of food from literally -- you can get now produce in your supermarket from, you know, 12 months a year from places all over the world, so that introduces a lot more opportunities for contamination.

RO: Joe, what do you think about country-of-origin labeling?

JL: Oh, I see a country-of-origin label, like a lot of things, is an idea that doesn't really hit the mark, because what a consumer wants, what a consumer wants is safe food. The consumer doesn't want to do their own investigatory reporting. The consumer wants to go to the markets and expects that the food they buy is going to be safe, and it doesn't matter where it's from. They want to have that confidence, and the government _____ now.

So we have food coming from all over the world, different diets. We have a population that is aging. Vulnerable populations for food-borne illness are anyone that is elderly, very young, immune compromised, or women who are pregnant. That's 25 percent of the population. All of a sudden 25 percent of the population is highly susceptible to food-borne illness.

And we have a lot more foods being eaten or prepared outside the home. I was astounded to learn that 50 cents of every consumer dollar spent on food is on food

prepared outside the home. That's not just restaurants, but it's also institutions: nursing homes, hospitals, daycare centers. Again, you get into the vulnerable populations.

And finally, the number of pathogens in the food supply has grown exponentially. We went back and did a comparison of the 1940s versus 1990s. The 1940s, there were half a dozen pathogens; in the food supply in the 1990s, it was 30 or 40.

And so you have all these factors. It's almost like the perfect storm, all these factors coming together that really made a compelling case that the government's _____ food safety has to be dramatically different, and that's what we set out to do.

By the time I took over, a lot of legwork . . . _____ the government agencies had prepared a blueprint called Farm to Table. That was the notion. You got it all the way from farm to table. You know, when you think of FDA historically, we don't do much at the farm, we don't do much at the table. We do almost everything in the food processing plant. But the realization is you've got to look at the whole food supply, and we started doing that.

The government developed a whole . . . I think, looking backward, there were three major thrusts. Number one was newer surveillance systems. Through Centers for Disease Control, there were developed a series of mechanisms to track foodborne illnesses, something called FoodNet, set up sentinel sites in hospitals across the country, in states across the country closely linked to public health hospitals. I think it moved finally to nine states, which represents about 10 percent of the U.S. population. And we now can track and have tracked food-borne illness since 1996. We also developed something called PulseNet, which was DNA fingerprinting, and I'm going to come back to that in a minute. But the first key issue was better surveillance systems, early-warning

systems, know what's going on, be able to track it.

Number two was stronger prevention programs. The first cornerstone became public health HACCP, Hazard Analysis and Critical Control Point. It was done in FDA with seafood. It was expanded to USDA for poultry, and we then expanded it to juice products and are always looking for ways to expand that concept further. But the idea is, instead of just looking at sanitation throughout your plant where the points where contamination is most likely to occur, put your energy and effort both on prevention and on inspection for those points. That's it in a nutshell.

RO: Remember Dr. Angelotti? He came up with that HACCP.

JL: Yes.

RO: But he was a little before his time.

JL: Well, the low-acid canned food regulations from the early 1970s, after the Bon Vivant incident, really were a forerunner of HACCP.

So we developed stronger prevention programs and increased that good agricultural practices for fresh produce on the farm, a stronger import strategy, looking at retail through something called the food code, which is really model legislation for the states where they do the regulation in restaurants. But the FDA puts out the model food code. And so step by step, we put in place stronger prevention programs across the board.

And finally, just faster outbreak response. The advent of PulseNet became a revolutionary change, the single biggest technological improvement dealing with food safety. And what it is -- it's DNA fingerprinting. So we can now take a sample of food or a specimen from a person from California and from Connecticut and see if they came from the same source. Now that food is distributed just so far and wide so quickly, we'd better be able to put the pieces together, and that has brought the epidemiological investigations much, much quicker than they used to be.

CDC went back and did analysis of the original Jack In The Box, where there were about 750 cases overall of people that were sick, and they estimated, if they had had PulseNet in place then, that would have been cut by two thirds. So that gives you a sense of how dramatic that change is, actually, the PulseNet, which was led by CDC, but FDA had significant involvement in the scientific development of it, won the Ford Foundation Innovation Government Awards, which is probably about the most prestigious award that is given to government programs.

RO: The CDC, FDA, and USDA . . .

JL: And USDA was involved in that as well. Exactly. Almost everything in food safety involves all those agencies as well as EPA, as well as the states.

But that three-part approach -- newer surveillance systems, stronger prevention programs, faster outbreak response -- became the backbone of how to strengthen food safety.

To support that, we had invigorated research programs as well as strong public

education programs both geared at the public and at food preparation workers that work in restaurants and institutions and so forth, developed some safety months every September, developed a Fight Back campaign of a four-part program to keep your food, your surfaces clean, your food cool, your food cooked well, and to avoid cross-contamination. Those four simple themes have been played again and again and again to reinforce the food-safety message all the way to the table.

We actually funded some research that showed that people, even people that are very good cooks, nevertheless do not practice good food safety practices. We actually went back and videotaped people in their kitchens, so you'd think they'd be careful. And nevertheless, you know, you'd have a little towel over the shoulder and you'd slice the raw chicken and wipe it off on the towel, and then use that same towel to wipe your hands after you've washed them and just spread that contamination again and again and again.

One of our sayings is that it's not your grandmother's kitchen anymore, that just the food system has changed so dramatically. And so this was a time of just major change throughout the food program. It was a time of some increase in resources, a stronger focus on research, a stronger focusing of inspections. We in FDA had an inventory in the field of about 59,000 establishments, from warehouses to food processors, and with a small inspection cadre, we were looking at everything maybe once every 10 years on average, which is clearly not acceptable. And so one of the first things we did was say, "Well, where is most important?" What are our priorities? What is most important? And we established _____ for high-risk foods and where that food is processed and how. And that only came up to about 6,500 establishments. Well, we

could do that many inspections each year. When I started, I think we were probably at 8,000 or 9,000 inspections. And so those are most important. We could get those done. And the field realigned and figured out how to get those inspections done in a timely way.

SWJ: _____. Can you mention the people that you worked with? It doesn't have to be people solely within FDA. Some may have been active in the sciences, for example.

JL: Okay. Well, the -- I'll give maybe half a dozen people as they jumped into my head. Within CFSAN, the person I depended on the most was Dr. Bob Buchanan, who actually started at FDA the same day I did, and was a little concerned when he came in and found a director _____ who wanted to hire him.

RO: What was his last name?

JL: Buchanan. He actually had come from USDA from an ARS laboratory up in Philadelphia, and had worked previously at FSIS, a microbiologist, very strong background, and had headed up CFSAN's research program.

Maury Potter, who came from Centers for Disease Control and was the food safety FDA liaison for a long time. Actually, I hired him as FDA's food safety director. But, again, very strong epidemiological background.

In the laboratory, Farukh Khambaty -- K-h-a-m-b-a-t-y, I believe, but you'll have to look that up and verify it -- was our scientist on the front line, just did a lot of

groundbreaking research in PulseNet.

Those are the three that come to my mind right off the bat.

And if you'd like me to think of other key people that were fairly engaged on the education side, the whole Fight Back campaign, Marjorie Davidson was there from the beginning and did a wonderful job and also recruited Mort Fox and Howard Seltzer [sp.].

And that education, they developed much of the Fight Back campaign, and they ended up developing a higher K-12 curriculum on food safety for science teachers and worked with the National Science Teachers Association. And so now we have in the schools throughout the country much more rigorous education on food safety that's brought right into the schools. In fact, one of the programs that was developed, one of the video programs, won an Emmy Award for educational TV, so we felt quite proud of that.

But a lot, a lot of work.

When I first took over, the slogan I used was that, just like with the realtor, your priority is location, location, location, _____ food safety director and as the food safety initiative, your priority is food safety, food safety, food safety. And that's what we focused on almost exclusively for several years.

The first major jolt for that was, of course, the terrorist attacks on September 11, 2001, and that had a profound impact on everyone in the nation, without question, but certainly not the least of which was because we recognized that food safety, food is a vehicle for contamination.

All of the talk about food safety, I forgot to give you the CDC numbers. But the numbers on food safety from active accidental contamination are estimated to be, each year, 76 million illnesses, 325,000 hospitalizations, 5,000 deaths. Those numbers -- 76

million illnesses, 325,000 hospitalizations, 5,000 deaths -- that became one of the main rallying cries to show them this compelling health problem.

All that came by accident. And the food, we know, is a ready vehicle for contamination, and could it be used intentionally? You know, we'd go back in FDA and think about the Tylenol episodes, those over-the-counter drugs that nevertheless we know the history of tampering on a very small scale, but great worries on whether it could happen on a much larger scale.

And so we immediately refocused our efforts to what else is needed, and while last summer, almost two years later, we put out a status report where we looked at our 10-point program, beginning -- it really began first with trying to get a sense of how big a problem this is. We started doing vulnerability assessments because we, in the beginning, it looked just like us. The food supply is so vast. Where do we start? Well, _____, you've got to start somewhere. And all the way through, we tried to set priorities.

And so we conducted vulnerability assessments, we developed guidance for industry, good, reasonable steps they could take to increase security, because you have to suddenly look at the food supply as you look at a different light. We used to be looking at it through, how is bacteria getting from the environment or from people carrying it? Now, how does it get in by intruder? And so you're as much worried about fences around, about security cameras, about supervision of employees as you are about food sanitation and about critical control points in the tradition of food safety.

SWJ: So you have to look less at pathogens and processes and more at people and procedures...

JL: Well, yes. So the vulnerability assessment actually is -- I joke about this, but it's true -- which is you have to think back to the board game Clue. And you'll remember, Col. Mustard with the wrench in the kitchen. Well, Col. Mustard, which food are you talking about? The wrench: which weapon is it? Which pathogen, which chemical? And where in the food supply? Which room is it in on the board? And we have actually to do the analyses three different ways and put them together in order to rank, because some things if it is detected early, if food goes through pasteurization and it kills it, you don't worry about it. You only have to worry if it enters later. And so those vulnerability assessments became a cornerstone.

Unfortunately, once we prepared them, it was quickly recognized that there was too much good information, and they all got classified. And it was even so bad that the people who wrote them could no longer read them. And so we had to then go back and get security clearances for everyone, to be able to operate within it was, just a new world that we were _____.

We got a lot of help. Secretary Thompson went to Congress and got more resources for FDA as well as new legislation, and they both became major cornerstones to our food safety, food security effort. The resources -- it was \$153 million to FDA, of which \$97 million was for the food program, of which \$90 million went to the field, and the field hired, with that, 655 people, the biggest hiring since 1970. And I will always look back and feel that was one of our biggest accomplishments. While you hate to think it took something like 9/11 to catalyze that, nevertheless, the rebuilding up the field. I think history will look back and see this time just like it did in 1970 under Project Hire as

one of the rebuilding of the FDA field force, and the hiring of _____ these two leaders becomes very, very important.

Looking back over the last couple of years, including security, we have made dramatic gains, and we also realized how much we had to do, and so we now have the blueprint and put out a document, which I'll just here incorporate by reference, that did lay out a 10-point program. It involved stronger FDA import people, a particular focus on imports, the vulnerability assessments I talked about, four emergency response exercises, implementing to do bioterrorism legislation. We just came out with major regulations to register every facility, to require prior notice of imports. And in the spring, FDA will be coming out with final rules on recordkeeping and on administrative detentions. And so these are probably, for foods, the most significant set of regulations since NLEA 10 years ago and required a major, major effort.

So we feel good. We have a system in place. We're developing a nationwide food laboratory response network, what we call FERN, Food Emergency Response Network -- I have to get the words right -- between federal and state laboratories. When the anthrax episode hit, the nation had to test over 150,000 samples of white powder during a month. For the FDA, that's not a month's work; that's a lifetime of work.

If you think back to your times in the field, you know, our goal for pesticides this year is 8,000 samples. Well, 150,000 compared to 8,000, you know, astronomical. So the new buzzword became _____, and that is what that is geared to do.

We also have found that it's necessary to get a dedicated research team, that there's an enormous amount of research that needs to be done, and OMB did provide us \$5 million this past summer to get that started. And you need to both look at how does

the agency detect select agents in food as well how to control and prevent them. _____ both on the detection side as well as on the prevention side. You know, a lot of food is pasteurized. Well, what does that kill, what does it not kill, as well as basic understanding of what is dose response, what foods or different agents do they stay alive in, which do they die in anyway, you know, the same kind of information we know on traditional agents like salmonella, listeria, we have to have, unfortunately, on all these _____. So all that is ongoing.

Finally, over the last year, a major effort on our applied nutrition side, you know, where, The Center for Food Safety and Applied Nutrition, but the reality is for the first several years of my directorship, it was food safety, food safety, food safety _____, you know, a little bit at the end. And major resource shifts, because as people left from the nutrition side, they were hired on the food safety side.

Well, all of a sudden we find ourselves facing an epidemic of obesity, and how do we shift gears towards that? But we've already done a substantial amount. We've put out regulations on trans fats to the food label, the first major change in the food label in a decade. We developed a framework for additional health _____ information to apply on foods, and we're now in the throes of developing a whole series of recommendations, broader recommendations on what FDA's role is in fighting obesity. And so this is all the upturn.

So in my last address to the staff, I laid out on, when I came, I had a chart that just said food safety, food safety, food safety, and kind of three mounted, and now the last chart has food safety, food security, applied nutrition, and trying to make that a coherent whole. And tried try to figure out how to allocate resources in a way that's consistent

with that three-pronged mission.

SWJ: Let me ask you a couple questions about how you interpreted applied nutrition. Obviously, you weren't thinking about it a whole lot when you first came in. But obesity seemed to hit the press quickly as an emerging issue. I remember working with Surgeon General's Report on Health and Nutrition edited by Marion Nestle, and it took forever to get clearance on that report. Why do you think it took so long for people to, see this as a public health crisis? Why did this all of a sudden pop up? I mean, clearly, the obesity epidemic took quite a while to manifest itself.

JL: I've asked the same question myself. I don't really know. There was not a single event that catalyzed it like you have in the other areas. It just broke through. And it did break through with a vengeance. There was the Surgeon General's report.

SWJ: And it took forever getting that out.

JL: Well, the honest answer is, I don't really know. I just worked through it.

TAPE 1, SIDE B

JL: I'll state that again just to be sure it got captured and not lost in the turning of the tape.

When Mark McClellan became commissioner, he said very clearly that Americans can do more good for their long-term health by making sound dietary choices

than almost anything else they can do. Drugs are good, but you're always sick by the time you need drugs. So the prevention side of the equation is our _____, and that plays in consistently with what the secretary had been saying. But it just suddenly broke through.

I know I have joked in speeches and said, "Why is this that?" Three years ago, we were all unsafe. Two years ago, we were all not secure. A year ago, we're all fat. What's going to happen next year?

SWJ: Maybe it's avoidance of the first two that led to the latter.

JL: And I don't know why some things have suddenly a breakthrough into the public consciousness, how other issues kind of get in the way or just take front page. I can tell you, during my six years here, the first three and a half were totally dominated by food safety. And then the next really two years were dominated first by food security, but then by the obesity and nutrition issues, with food safety kind of establishing its mainstay in the program.

RO: Where do you think we're going to go on this obesity as far as FDA is concerned?

JL: Oh, well, I think time will tell. I think we'll find that there's additional things we can do with the food label, additional things we can do with public education, different things we can nudge the restaurant industry to do. I think there's a lot of possibilities. But I think time will tell. You'll have to ask the next director.

RO: I see one of the things that they're looking at now is serving size.

JL: Well, there are some things that just don't pass the lab test. You can get bigger bottles than . . . And you've got one of these 20-ounce bottles _____ gets from their vending machines, and it's actually two and a half servings. And it says a bottle of sugar soda might be, say, 110 calories. Well, it's not really 110 in that bottle. It's really 270. So why doesn't the bottle say 270? Now, it does if you do the arithmetic, but who does the arithmetic? And so that's an example, and people realize that. They say, "Well, there need to be some changes in the system so the consumers know what they're getting."

But I think it needs to go beyond just knowing what they're getting, and there need to be incentives for companies to develop a broader range of foods that fit a better nutritional profile; that both have reasonable levels of calories, fat, sodium, and so forth, but still fit within people's taste what the world eats, because people do know the difference between an apple and a doughnut, and they still eat the doughnut. And so the question is, can there be additional . . . It's a real challenge, I think, for the food industry, how to shift their marketing towards what is now consumer needs _____.

I'd like to talk for a minute, if I can. Everything I've talked about so far has really been the FDA to the outside world. A large part of what I feel has been my contribution within the foods program is reinvigorating the internal health.

When I came, the feeling was that the food program was down. The food program had often felt to be somewhat of an orphan within FDA. Commissioners were usually physicians, cared about drugs. I was in the commissioner's office. I understood

that. Resources had gone steadily down. Actually, during, when I came, the peak of resources in CFSAN was 20 years earlier, and, ironically, in 1978, the first year I started at the FDA, was the peak of the foods program, and just about 1,000 people, actually 998. Sandy Miller was the director. And when I took over, it was only 75 percent of that, or about 750. And so there had been a long period of decline. The belief was that there was just too much to do and not enough capability to do it, and yet not a priority on a big scale. People were calling for a single food agency. And we needed to inject, we needed to turn that around and inject what I call a can-do attitude, and we did several things that were progressive at the time.

The first thing we did is I established something called CFSAN Pride and announced that in my first all-hands meeting after I was there about a month. And CFSAN Pride stands for -- the P is for public health and safety, because public health and safety organization, and that's where our focus needs to be. R stands for respect, and we need to have high respect for our stakeholders, for the law, and for ourselves. I is for integrity. We have to have the highest integrity at all times. D is for dedication, a dedication to the mission, and not just to the mission, a dedication to E, to excellence. And we -- I talked about that wherever I went. And you know what? People liked it. People wanted to have pride in the work, and they wanted to see that it was recognized and it did mean something.

We then took that and said, "We've got to establish priorities. If you've got too much to do, you're not going to get anything done." And I've always felt, in my whole career at FDA, that was FDA's biggest downfall. We have too much to get done, we can't ever get it done. I always say it's like trying to push a hundred pebbles up a

mountainside at one mile an hour. After 50 years, all you've got is a mountainside of rubble and nothing to show for yourself. Can't we establish with a fewer number of boulders and get them up and over the mountaintop?

And so we established an annual _____ process. I began with public meetings to get input from stakeholders. In subsequent years, I did that through just sort of register announcements. I worked with each office and we developed what became known as the Yellow Book because its cover was yellow.

But everybody understood. We had our A list, which was the items that we said we were going to finish this year -- not try to finish; we were going to finish them this year. And then we had another B list for items that we'd work on, but no promises made, but at least try to make progress, show _____. And we did this each year for the six years I was director, and the results were, in retrospect, somewhat remarkable, probably better than I would have expected.

Our goal each year was to accomplish 90 percent of our A-list items, and we were with that, plus or minus 5 percent each year for five years. But also, the actual numbers. The first year, we finished 78 out of the 80-something. This last year, we finished 138 out of 150. So from 73 to 138, that's almost double. The productivity increased each and every year and almost doubled over five years. And a lot of that was done _____.

What I find as a leader, clarity brings efficiency. If people know this is what is expected, people try to do it. If people don't know what's expected, everybody's running around trying to do whatever they think is important but is not part of a clear movement forward. And I think one of my major contributions was to establish clear movement forward. This is what's most important, and that's what we're going to finish. And it

built up a lot of credibility both on the outside and on the inside.

We had a number of other things. There was a lot of concern that we had just -- there was not strong management within the center; that supervisors were not backed up; that a certain number of workers were carrying everybody else. And I brought in a consultant, and she said, "Well, what you need to do is you need to establish a new day."

And I said, "What's that mean?" And so what it means is that, whatever happened in the past is past, but today's a new day, and these are the rules from here on forward. And we had enormous interest in it. And _____ I lose track of time. It was not -- I came in February. It was not the first June; it was the following June, and then we, I think, had to postpone until September, when we actually announced it, so it was about 18 months after I was here.

But we set up another all-hands meeting, which we do periodically, and we called for a new day in CFSAN. And we said, "Whatever's past is past. That doesn't matter. This is what we're going to do, and this is how we're going to do it together," and people responded, let me tell you. And that generated a sense of optimism.

And we then took that to the next level, and _____ people . . . It's very interesting what people relate to, because I threw out lots of ideas, and most of them, you know, kind of fall on deaf ears. And I let them go. I don't worry about them. Nobody has time for all these ideas anyway. But every once in a while, you find something catches on. People say, "This is real." And if you say to somebody, "I found the phrase that caught people's attention even more than new day" -- and that was the phrase world class, world class.

Foods is the most international of FDA's programs? Codex; had a long tradition

with them, foods. Food is made all over the world. It's traded all over the world. Foods has the biggest international presence. When Sandy Miller was director, people feel that they were the gold standard for the world in risk assessment for cancer-causing agents and for other things. And if I say to people, you know, we had a go-a-way, and on this wall we listed things as they are: just what is reality? And then we'd say, "Is that world class?" and everybody would know immediately whether that was world-class or not. So on that wall we wrote, "What would it mean to be world-class?"

And with that, we set our goal of building a world-class organization, and it had three very simple components: number one, a strong science base for good decision-making; number two is that we have the capacity to follow through on those decisions in a timely way; and three, that we have a culture of accountability, but also cooperation and respect, again the spirit of working together. And that mantra of building a world-class organization with strong science, strong follow-through, and strong accountability and cooperation became the cornerstone of what I think will be my, hopefully my most important legacy at CFSAN.

And if you talk to anybody within the center now, they know that that's how you want to be viewed, and that's what we've tried to do. We've tried to do that through recruiting top people, by putting in a staff college, by building in good systems. We have systems of risk assessment, systems of risk management, building communication capabilities. We're now building a leadership development program. All of these things are underpinnings that make for a strong, vibrant internal organization. And you know what? Why shouldn't FDA be world class, that we should be the world standard. Why should anyone be better? I would say to people, "No one had a reason." So we said,

“We ought to be.” And you see that. You see that when the bioterrorism regulations came out on time; you saw that with our _____ risk assessment that just came out, the first of its kind in the world. They’re all looking, the world is looking to us on how to do it, and that is how it should be.

Now, everything wasn’t easy. In fact, I’m not sure any of it was easy. Probably the most difficult thing I dealt with during my whole time as director was an incident right within our own building, when we had the anthrax where the mail room, and that will always be my most memorable -- I’m not sure it’s the right phrase -- but . . .

SWJ: Unforgettable?

JL: But certainly unforgettable. Everybody remembers this; it was after 9/11. It was the incident at the Brentwood postal facility. A couple of postal workers had died. Every day in the paper, you’re seeing different buildings being tested positive and closing down. The Ford Building, which is right next to us, the Congressional Office Building, shut down. The Supreme Court shut down. And one day, a Wednesday, a couple of guys in Commissioned Corps uniforms came through, and visited the mailroom and quietly handed the workers there medications, just as a precaution, just as a precaution. And somebody came in and took samples to send out to the lab.

Well, the next day, since the Brentwood postal facility had been shut down, and with no mail coming in, somebody put up a little sign that said, “Mailroom closed.” Now, our mailroom is in the basement. Hardly anybody goes to the basement. It took about two seconds for everybody in the building, and no one has told them what’s going

on. And I was at Parklawn at the time, and Thursday is my Parklawn day. And they called and said, "Joe, you've got to do something." I said, "I'm at Parklawn. I'll deal with it tomorrow." They said, "No, you've got to deal with it today." So I put an announcement today that tomorrow we'd have a meeting, an all-hands meeting, and we would go over everything, and I spent that time trying to figure out what was going on. What was going on was that all the government mailrooms that had received mail from Brentwood had, you know, they were going and doing testing and all to see how far it spread, and that seemed sensible it would be nice to follow it. But it seemed sensible once you understood it. But everybody immediately, of course, jumped to the conclusion, it's going to be positive and we're all going to die. That is what people thought.

And so Friday I had an all-hands meeting. I didn't have answers to any questions, but, as you know, this is something we would all be looking at.

Sunday night, I got the call that our test came back presumptive positive, but only presumptive. It wasn't definitely positive, it was only presumptive, and so the buildings would stay open. Well, that relieved people for sure. Ha, ha, ha. And so that just spun off a lot of panic, and I didn't do anything that entire week.

They said review would begin with anthrax in the building. We had hour long webcast -- I'm not sure we did webcast to be honest. I'm not sure we had that capability.

But we all, everybody _____ into that room in the basement at FDA. All came down. And we brought in every expert we could find. We brought in experts in infectious disease to talk about what the symptoms were. We brought in an expert from CDC to talk about how they do the epidemiology; we brought in the building engineer to talk

about how the airflow of the building went; we brought in a physician on-site so people could go talk to a doctor if they wanted. We granted flexiplace, flexitime, flexi, flexi.

And I remember, by Wednesday, by Wednesday things had started to calm down a little bit because somebody asked again, what are the symptoms of cutaneous anthrax, if you get it on the skin. And so they said, "What about inhalation that's worse?" "Well, I'm not worried about that anymore." _____ a big sigh of relief because, you know, the worries have gone down. We didn't hear till the following weekend that the presumptive positive was negative.

What was most important during that week was the credibility and trust that we'd built up with the staff, because I guarantee you, if you took a poll at the beginning of the week as to whether the government would be honest with them, if something was wrong, it would have been overwhelmingly no. I mean, look at the situation. The Post Office was closed but we're open, you know. They don't want to create a panic or we will be the guinea pig. That was the feeling of everybody. But through that time, we built up trust that whatever we told them at the end, because it was important to believe it's negative, that it's negative, that if it's positive, it's positive, and we accomplished that. We actually did, not for these purposes, but we did some focus-group testing in the Center.

We're getting ready to move to College Park, and so I wanted to get some baseline information on how anxious people were. And so we were doing it around that time anyway, and afterwards -- to me it was so remarkable -- people actually said that during that week, after that week, they actually had greater internal cohesion within the unit than they had before. And, again, if you ask anybody who was there my entire

tenure, they will all point to that week, that from an insider's point of view, it's really when the center came together, because that's something that's totally egalitarian, you know. Anthrax wasn't just going to pick on the leadership or just pick on the rank-and-file. They're going to pick on whoever's there. And it really put us all in the same boat together, and we came through it together.

Let me pause.

That then became a springboard in terms of moving to College Park. We all had things we had to do to move out there. We had, you know, what the order was. Everybody had to have their _____. They all had to pack up. We did this every week for about four months, five months: November, December, January, February, and March. Five months it took us, moving FDA out there. But, again, we developed cohesion and a way to do that.

We had a few people that didn't, couldn't fit in College Park. College Park was built when we were going, we were already going down, and the planners, you know, back then, you take two years and extrapolate to infinity, and don't account for corrections for up or down.

But we -- I said we started at about 750 when I started, and when I left in September, it was about 960. So about 200 more people on net and over 350 that were new since I came. So we brought in a lot of young talent, a lot of people that would be there, hopefully, for a long time.

We also had secured another new building for the people that wouldn't fit in College Park. That's what I was saying when I lost my train of thought. Two groups that fit, one is our Office of Food Additive Safety down on Vermont Avenue, and the other is

the Office of Cosmetics and Colors, which is now split between Vermont Avenue and the Color Certification Group, which is in an interim facility out in Chantilly. But there was a new building being built right on the other side of our parking lot.

In terms of names, Jeff Weber was really the person most instrumental in securing that for us, and I have often thanked him for that. That's going to be open in another year, supposed to open in November of 2004. And then all of CFSAN will be together in College Park, together with the research unit just a few miles up the road at _____.

RO: And you're going to abandon FB 8?

JL: FB 8 is already abandoned. FB 8 is totally closed. It's only being -- what's the word, not decontaminated, but there's a phrase.

SWJ: Decommissioned.

JL: Decommissioned.

Well, the _____ process will take care of that, I'm sure. But it will be a milestone to get all of CFSAN together out in College Park.

And then the final thing I want to say about internal management and culture.

I did something -- I can't say by accident because I attempted to do it, but I didn't intend it to quite have this impact -- and that is, at my first all-hands meeting, you know, these people didn't know me from Adam; a few people did, but not very many. I'd been six years in Devices, and while I'd worked on food labeling when I was in the

commissioner's office, you know, by then a lot of those people had left. There were a few people like Bob Lake who knew me from before, but not very many.

And so I tried a lot of different things in that first all-hands meeting, and one of them was, I read from a Dr. Seuss book. Now, if you were to predict, just sitting in the audience and then predict, what is the new director going to read from, you know, maybe he'd read from the _____ or maybe he'd read from *The History of FDA*, but who could have predicted -- not even me -- that the new director was going to read from Dr. Seuss. Well, I had a four-year-old daughter at the time, and I spent a lot of time reading Dr. Seuss, so it was on my mind. And I used the story, *Yertle the Turtle*, because in *Yertle the Turtle*, Yertle builds a pile of turtles, and, being king, and the higher he goes, the more _____. And as he makes it higher and higher, the people down below get tired and more tired and more tired, and say, "How long do we have to do this?" And, of course, Yertle the turtle is having fun up there. And finally they rebel and the whole thing collapses.

But the point, the reason I read the story was to make the point that if I'm up at the top of the center, I want to be sure that I keep in touch with those at the bottom because that's really where the work gets done. That was the point of the story. Nobody got the point.

What they all got was here was a guy who read Dr. Seuss, just like me. And it became a connection. Somebody came up to me and said, "My father read me that story," you know, a woman in her forties.

I went to talk about egg safety, and people pull out *Green Eggs and Ham*. I go somewhere else and someone's got a shirt that says *One Fish, Two Fish*. And everybody

knows this. And it became, in every one of my all-hands speeches from then on, I got such feedback on it. But I always found a Dr. Seuss story to use as a point. But it became, again, more of a community of people who basically all have families, all have something at a very basic level to relate to. I tried very hard always to emphasize the importance of family life as well as work life, and probably one of the things that people have quoted back to me often

My wife has been a schoolteacher all these years, and schools start early. She was in high school, and the high schools start first. She starts early. She leaves 6:30 or something. And when my daughters whichever it was at time, they'd wake up six in the morning. I'm the one home. And the kids just call and say, "Hey, come home." You know, you're home, she's at work. And I have a momentary wonder, "Oh, my gosh," you know, "what's the FDA going to do without me today?" But then I think about it and say, "You know what? The FDA has 10,000 people to figure out how to do work today. My daughter's only got me." And so I was always the one that stayed home, you know, at least on the first day. We'd trade off depending on how sick she was. And people, again, very much understood that, and the notion of the importance of family became an important theme.

And the importance of employees and the importance of the nurturing of them to me is something that FDA -- and I don't mind being quoted on this because it's true -- FDA has never done well. FDA has an enormous strong culture of public health, of consumer protection, of getting the job done. But it's not of nurturing employees. It's like get the job done.

And in my last talk, I reflected back that when I was brand new in general counsel

-- and we'll get to that maybe someday on this tape -- I was in a van pool. I was young, we had one car, my wife took the car to work. I was in a van pool. We had to be at work 8:00 to 4:30, pretty standard FDA hours. But the general counsel hours are from 8:45 to 9:15, but _____ and it was very nice and considerate. But a new general counsel came in, and, maybe, his name was Yertle, and declared all lawyers will, all lawyers will work 8:45 to 5:15. And I was summarily evicted from the carpool. And, you know, the saying was, "Well, if the secretary . . ." You know, "You have to be there in case the secretary calls you." Well, sure. But I've been here 18 months. What is the chance of the secretary calling me?

And I thought it was unfair, and I felt that somehow the FDA, the task came first, but not looking out, and I've always been a strong supporter of NTEU. I think that work is important because . . . And I only came up with this in my last talk, so it will be quoted back, I can assure you, because it already has been. And I call us -- we should be called Employees R Us, because that's how the work gets done. I don't understand this management-employee business. It's not like a factory. It's an organization with a coherent whole, and we have to nurture that, and you have to nurture the family end, you have to nurture the professional end, but you have to nurture just the human decency end, and that's something that I've worked very hard on, you know. And that does help _____, that helps the food safety, and it helps the food security, and it helps applied nutrition because it gets, makes people more feeling uplifted and feeling empowered and feeling that they matter and feeling that people care, and I just felt that's terribly important, but hard to do in the FDA because of all the outside pressure.

On my last day, we had a senior staff meeting, and the theme of it was Dr. Seuss,

and every person came in with a different Dr. Seuss quote, and they were given three minutes, and it really was a lot of fun. But, again, it was just an example that it didn't have to be Dr. Seuss, it could be anything. But people need and want a connection. They want a way to feel part of a _____, and all the things we try to do, setting a center-wide set of priorities, establishing a new day, trying to be a world-class organization, working together through things that are difficult, moving together -- all these things are organizational health. And it is just so terribly important in any organization, and that I've tried to foster.

I'm going to take a deep breath.

RO: Was there any apprehension from the staff when they brought a lawyer in there to head up CFSAN?

JL: People would ask, they'd say, you know, I was the first lawyer ever. The only one that would have been close was Michael Taylor, who was head of Food Safety Inspection Service. And while it wasn't FDA, it was food and was well known to people. But within FDA, I was the first.

And people asked me, and I said, "Well, this job is a big challenge. I have two daughters . . .

TAPE 2, SIDE A

JL: What I was saying was that it just gave me a much better feeling of what it's like to work with the field.

These cases also were the groundwork for the good laboratory practice regulations, so that's really the historical significance of that.

I had a couple other cases. I had an injunction case out of Chicago, had a mass seizure in Gulfport, Mississippi, but I had to get home on Christmas Eve. It wasn't easy. I had an injunction case up in Reading, Pennsylvania, with an animal feed mill. But through this I had some work from drugs, medical devices, veterinary medicine, foods, so it was a good cross-section. I stopped doing that. It was too much traveling. It was a little too combative for me. I always said I never saw a case I couldn't settle, or thought I shouldn't be able to settle.

And so I converted and did more work, you know, counseling work. I ended up working on the commissioner's team for cyclamates. The main issue had to deal with whether or not cyclamates, which then were being petitioned to come back onto the market -- they had been taken off in the early '70s, artificial sweetener -- whether or not they caused cancer. But there was a second issue of whether or not they might cause genetic defects, and that was my issue. That's what I worked on.

The commissioner's team is an unusual thing because there's separation of functions. It was an administrative hearing, and so you couldn't talk to anybody in the Bureau of Foods. And the agency had to get experts, so you had your record. You're like an appellate, a court for an appellate judge. You've got your record and you've got your experts you can talk to, but you can't talk to the people who are actually involved. And that position came out from Commissioner Goyan.

But then whoever was the lead lawyer on that didn't do that anymore, and the next artificial sweetener that came up was aspartame. Then I became the lead lawyer on

that. And that was much more controversial because then the Bureau of Foods had wanted to approve it. There was an objection from a researcher named John Olney and a consumer group that went to a, instead of an administrative law judge, the cyclamate _____, this went to what's called a public board of inquiry, which is like an advisory committee. A three person panel. And they recommended against approval, saying the evidence was not sufficiently strong enough that it did not cause cancer. And so all of a sudden you had the Bureau of Foods saying one thing and this expert panel saying another thing.

SWJ: What expert panel?

JL: It was provided for in the regulations and had been used once before for a drug called Depo Provera. And everything I know about Depo Provera, but they used it once for there, and so it was in vogue at that time. And they felt it would be more scientific, I guess, for whoever got to choose. But, again, there was -- by the time I got involved, it had already had . . . It had already selected a panel, it had already had the hearing. The panel had issued a report. And we had a brand-new commissioner. Actually, when the report first came out, probably Mark Novitch was acting commissioner, and Dr. Hayes came a little later in the spring. But there was a team that was assembled, and I was the team leader. We had statisticians and we had toxicologists and all, and went through it in excruciating detail. Briefed the commissioner multiple times, and the final decision was to approve it and to agree with the Bureau of Foods, but not with the Board of Inquiry. And, again, that decision has withstood the test of time 20 years later.

RO: You're talking about aspartame.

JL: Aspartame, right. All that what I said. If I didn't say aspartame, all that discussion was about aspartame.

And I think from that experience, number one, I got to know the new commissioner, and I established an ability to work on things, something that's controversial, with a group of people.

And so one of Dr. Hayes's first main initiatives was to review the new drug review process and establish a big task force, which he chaired, and I became the staff director for that. We had a group of 5 people. Billy Don Weaver was actually the executive secretary, and he's since passed away. But he did all of the logistical things, got the meetings set up, got everybody appointed, and I had a group, and every two weeks we'd present another paper for review, and we did that for about a year.

The main thing that came out of that -- in fact, I was recently quoted correctly, because, in fact, they called me physician .

RO: Yes. I was just going to mention that.

JL: I was just . . . And what I was going to say it's consistent, because I went back and read that, and it was what I said. Except for the fact, I'm not a physician, that is probably the most significant thing that came out of that was the thing that Dr. Hayes rejected or were viewed as the big ideas at the time. One was to get rid of the

effectiveness standard and he said, I'm a physician and I want things to work. Another was to delegate phase one testing for Institutional Review Boards (IRBs). I've been on an IRB. You don't want to do that. They aren't staffed with toxicologists and so forth to do that kind of review. A third was to really shift the review to outside advisory committees like they were doing in England, and he said, "No. I've been on advisory committees, and they don't have the time and attention to really do the detail work that needs to be done." And the fourth was to approve drugs much earlier and do testing in phase four. He said, "No. I really think you need to have the larger trials done so we know that these things are safe and effective." So he really stood up, I think, very courageously and said, "I want to improve the process, but I want modified improvements. I'm not going to do anything to dismantle."

And so what came out of that affirmatively was the Investigating New Drugs/New Drug Approval (IND/NDA) rewrite that I worked with first when I was a general counsel and then finished when I was in the commissioner's office. But that was really my transition from working with him on aspartame and then a review process. He asked me to come up and work on the commissioner's staff, and I began there in, May of 1983, when I made that official transition. But I had essentially been working up there since the fall of 1981.

Of course, he left shortly after that, and Mark Novitch was acting commissioner. And the most significant thing I was involved in during the year that Dr. Novitch was acting was a follow-up on a drug called E-Ferol. E-Ferol was a tragedy. It was, again, a product that came onto the market through an old grandfather provision in the law. It was an injectable and killed several dozen, I think it was 30-something, premature

infants. And, again, we assembled a team of people from the commissioner's office, from the field.

Remember, Dick Davis was regional director for the Philadelphia region at the time. I remember Hank Dausch from legislation was on the group. I don't really remember everybody on the group.

And we had a short intense assignment, what happened, I'm going to stop it, and I'm not going to let it happen again. And we figured out that it came in through kind of a loophole in the regulation, so we closed that. I remember Dick Davis saying, "Well, one thing we can do, we can inspect." We went out and inspected, in the course of a month, every *in vitro* manufacturer that made that kind of product to be sure there weren't other things going on. And we changed the rules, which I can only vaguely remember, for reporting of adverse events, because somehow, while the company should have reported, we believe, when they find a problem, they're actually weren't required to by the regulation. Again, it was another loophole.

And I've always felt that, while nobody but me remembers I even worked on that, I've always felt that was one of my most significant accomplishments in my entire FDA career because it was taking a real public health problem that nobody had any idea why it happened, figuring out what the problem was, and fixing it, and to me, that's what we're about at the FDA. It's not just doing what you were trained to do. It's how do you respond to the unexpected and deal with that? And I think probably how FDA responds in those cases is more significant than kind of doing all the daily work. So that's what I remember most from the year that Mark Novitch was acting.

Frank Young came in, and by then I was up there. I'd been up there for a little

while as a special assistant. We called it program advisor to the commissioner. And that -- let's see. There was a whole lineage of lawyers that had come before me that had all had the title executive assistant to the commissioner. It began as Stuart Pape with Don Kennedy, and then Michael Taylor with Jere Goyan, and then Bob Brady with Arthur Hayes, and then Jeff Stribling with Mark Novitch. And then, when Frank Young came, Jeff Stribling left, and I moved two offices over.

SWJ: The same Michael Taylor?

JL: Same Michael Taylor, same Michael Taylor, yeah. That's who he is.

And a lot of the executive assistant commissioner I think . . . No, it had to be -- Frank Young must have been there, because Jeff Stribling wouldn't have left till after he got there. But in any case, I was there to replace that as part of that lineage.

And then I helped Frank Young develop a so-called Action Plan. Remember the Action Plan? Well, that was the final draft for the final Action Plan. And he then started giving me a lot of work, and I was only one person. So instead, he put me in charge of an office, and he put me in charge of the executive secretariat and I formed another group in addition to that. We called it Office of Executive Operations, and that was really the position from which I worked for most of the time. That probably would have been -- let's see. Frank Young came in '84, so that would have been in the summer of '85. We did the Action Plan in the winter -- and that would have been in the summer, and essentially became, I was dubbed the chief of staff. Even if that wasn't the official position of record at that time is how Frank Young referred to me and everyone else.

And, you know, we did a combination of getting high-visibility projects done as well as keeping daily work going, and did that for a long time. I guess that was '85 all the way through to when Frank Young left in '89, in November of '89. And probably what I was most involved in had to do with, again, a follow-through on all of the drug review work.

FDA suffered under the euphemism, drug lag, you know, they are approved faster everywhere else except the United States, the U.S. has to suffer, and always Europe will _____. And so there were a whole series. First were the IND/NDA rewrite, and then what happened is the AIDS epidemic started, and that brought a whole different notion to urgency. And you might remember, there was that demonstration in front of the Parklawn Building, and the fact that there's nothing for these people. They're dying. And while the same is true of other chronic diseases, nevertheless, these people were young, and the course of the disease is quick, and it just brought a whole different dimension.

And so first we developed something called the Treatment IND, which was to provide promising drugs late in the development process just for the ill patients, but where there was still reasonable evidence of safety and effectiveness. I forgot the exact standards that were used.

And then there was something called Subpart H, which is nothing more than, in the IND regulations, where we wrote it must have finished just before H, G _____, but it had to do with expedited development. It had to do with much greater collaboration with drug sponsors to try and design trials that would show needed results quickly.

What companies had to do was they had to be willing to put in more money quicker, because one reason the drug review, the drug-development process takes so long

is most drugs fail. And if you're a company, you want to limit your losses, so you go slow. So when it drops out, you don't put much money in. This really was an attempt to put more money in earlier, and you've got a gamble, but FDA would work with you to do that.

There was also something called a parallel track, which was devised particularly for AIDS patients, and that was purely access earlier in the process. And I think one of the great achievements of FDA accomplished with the AIDS community is the recognition through time that it's not just about access, it's about _____. And the AIDS activists became some of the biggest proponents of high-quality studies. I think that was one of the most significant achievements during that time.

And when Dr. Kessler came, it was another round called Accelerated Approval, which had to do with approving drugs based on what was called a surrogate endpoint, and then doing more studies post-marketing.

And so that whole lineage of trying to get good drugs developed more quickly, get access to patients who need them more quickly, was a theme for about an entire decade.

And FDA's quandary, I always thought, was best summed up by two congressional hearings that I attended just as a back person watching very early in my career. It would have been at the early part of the '80s. One of them had to do with a drug called Isoprinosine. I remember one FDA official called it a drug in search of a disease. FDA did not think it would work, but there were anecdotal reports, and I can remember a father testifying with his daughter. You know, the drug saved her life. It was very compelling testimony. And the question is, why isn't it -- why is FDA so slow?

Then six months later, a drug called Oraflex got put onto the market, hurt a lot of people, got pulled off the market.

Oversight hearings. Why did FDA move too fast? Too slow, too fast. And how do you get that balance, how to get that balance of being _____ as fast as you can, but doing a good job? And that's always a balance FDA _____. And I think probably not until PDUFA was the FDA able to achieve that relief _____ because they finally decided to give the FDA enough staffing to do the job. And FDA in turn put a lot of effort into both getting out _____ to industry _____ new studies on, put together applications, and say the FDA would be timely. And FDA did meet the goal, but I wasn't involved in PDUFA at all.

But, again, I see that as both a model that the government can do a good job if they give us enough people, money and people to do it; and that FDA can be both timely and of high quality. And I think a lot of _____ program.

RO: What was that first drug again?

JL: It was called Isoprinosine, I-s-o -- and I'm making up the rest of it -- something like I-s-o-p-r-i-n-o-s-i-n-e. That would have been the early '80s. I don't remember what it really was called.

SWJ: Inosine pranobex is the generic name.

JL: That would have been before Frank Young. That would have been -- Hayes

would have been commissioner of record. Or possibly Goyan. I don't think so. I think it would have been Hayes; I think it would have been Hayes, because I wouldn't have been there if it was Goyan. That's when Dick Crout was still head of the Bureau of Drugs. I remember that.

Dr. Hayes liked to reorganize, and so I would say the CDRH reorganization was a successful one. And under John Vilforth and Jim Benson, they brought a much greater rigor to that program, and both good and bad, they reprogrammed -- the only really successful reprogramming of government resources I've seen in my 25 years for Radiological (referred in transcript as Rad) Health and Medical Devices, because I looked at it and _____ medical devices are so vast, we can't justify keeping all these people in Rad Health. And only the people in charge of Rad Health could have done that. If anybody else had tried to do that, they would have instinctively pulled back and said no way. But because they weren't charged, they realized what was more important, and they had made a lot of progress on Rad Health. Unfortunately, now they've got _____ so much, now the agency is trying to find a way to move out of Rad Health. But that overall was successful. The drugs and biologics were not. They tried it for a while it was too big, too many different things, two different cultures that didn't work well together, and they got separated back out.

And then there was the ORA reorganization that combines the Executive Director for Regional Operations (EDRO) and the Associate Commissioner for Regulatory Affairs (ACRA). You may have different, you may have your own feelings on this, and I'm sure. But it was successful, it was. And I didn't really know FDA from a senior level before then, but I could see how those positions could become competitive, between

enforcement and the field allocation and implementation. And while the ACRA now is a big, big hard job, no question about that, nevertheless it's a very important . . . And I would say that reorganization has worked.

So, two out of three, that's not too bad.

I worked on some food matters while I was up there. Sulfites was one of the most visible safety issues I worked on, in the commissioner's office. In both salad bar as well as packaged foods. And what we did was we banned them from salad bars and we labeled them on packaged foods on the principle that a person knows if they're allergic, but they've got to be able to know, and you can't feasibly label salad bars, but read the label, you can.

Another thing I was involved in, but only at the tail end, was the whole issue of aspirin and Reye's syndrome, and most of that happened before I was involved, but I was involved with the final labeling of aspirin that's still there today. And the language, it was worked out, accomplished, all me.

RO: Two commissioners were involved in that, both Dr. Hayes and Dr. Young.

JL: Right, exactly. So that took a long time.

I was also involved in direct-to-consumer advertising. And at that time, direct-to-consumer advertising was an issue whose time had not yet come.

I remember there was a turning point on that issue with a major conference that we held, and they did something very interesting there. They had audience participation and voting. You could ask questions. And at the beginning of the conference, they asked

the question, “Do you think direct-to-consumer advertising of prescription drugs is inevitable?” and people overwhelmingly answered yes suggesting that’s why they came to the conference.

And then the head of Upjohn comes at the time. This was before Ted Cooper. I can’t remember his name, but I can remember his face. Stood up and said, “I know what all these other people’s issues are, and some of the consumer groups may not like it and some of the physician groups may not like it, but I’ll tell you, as head of a prescription-drug company, I don’t like it for business reasons. I can’t afford all this advertising. And, you know, trying to compete with these Over-the-Counter (OTC) drug giants, you know, it’s not going to be a good competitive position, and I’m not going to have anything do it.” And after that, we voted again on how many people thought it was inevitable. Way down.

And that conference was a turning point, the only conference I’ve ever been in. But if I thought hard, I could probably think of another one. But at least one of the very few conferences that the conference itself was a major turning point.

And then I remember Dingle’s committee came out with a report. I think it was the first one on a subject like that, direct-to-consumer advertising issues _____. Now, a decade later, it did come and it’s fine. But in the time I was there, that is what happened.

And then, finally, before Frank Young left, the last major initiative he started was revising the food label, and we had all the issues around Kellogg’s All Bran and health claims and started having a series of meetings around tartrates, and there had been a whole food-label initiative in the late ‘70s which kind of just abruptly ended, probably with the change of administration. But it didn’t go anywhere. But there had been a lot of

ground work done.

And there was amazing interest among everybody _____, more than I would have guessed to be perfectly honest with you. And what I thought was going to begin as a pretty modest thing for the food label, from like adding fats and saturated fats became an overhaul of the label, and it's been one of the FDA's lasting and most significant achievements. And we actually put out and not always remembered so for historical purposes, I will note it. But FDA issued a whole series of proposals, proposals on revising the food label, which were then ratified by the NLEA. And in retrospect, we wondered why Congress had to do it if we were doing it anyway. But in reality, it put it in law so it was good. Even if you had to propose it again _____ again under the law. That was after I left for Medical Devices. But that was when Louis Sullivan, Secretary Louis Sullivan, gave a so-called Tower of Babel speech at The Press Club. Then the food labeling becomes the Tower of Babel, all in languages nobody can hear, understand, it's a mess. We have to clean it up. And at Scarborough was the head person there, so Derfler for general counsel just did amazing work through all of that.

Bill Hubbard from the commissioner's office, on my staff at the time, was involved, and, of course, Mike Taylor just took that over after I went over to Devices. But probably the food label was another just major, major part of the history that I played a part in.

And then probably the final thing would be -- I'm not sure exactly how to characterize it, but the year that Jim Benson was acting commissioner, Frank Young had left, we had had, were in the throes of the generic-drug scandal, one of the low points in FDA history without question. And that was a very intense year. Jim Benson was acting

commissioner. I functioned as acting deputy commissioner. He actually moved into the commissioner's office, I moved into his office, and it was intense!

I remember the first week we were down in the department working among different subjects every day because there was great concern on what would happen to the FDA. And coming back to, you know, pride and integrity, I think what Jim Benson brought more than anything else that year was restoring the sense of integrity to FDA functions. And the generic-drug scandal was horrible and we wish it wouldn't have happened, but we're not going to accept that as our norm, and we'll do whatever we need to do to deal with that, and there'll be complete investigations and follow-through and prosecutions to the extent needed, and there were.

But then we also were able to get on, and we moved on with things like food label proposals. And we banned red no. 3 that year, after it had been extended forever and ever and ever and ever. And I'm sure there were other things that happened that I, my memory's not as clear on. But what I'm vividly clear on, what I'm vividly clear on is that was the prime period for restoring integrity. And I think there's no one who could have stood for that better than Jim Benson.

I think that's a good note for me to finish on.

RO: Well, thank you very much.

JL: As I say, two hours isn't quite enough, but . . . Let me just . . . Why don't we try to say one o'clock?

TAPE 2, SIDE B

JL: I've worked for, directly for 10 commissioners or acting commissioners in 20 years. That doesn't count my early years as general counsel, and there have been several more that I didn't have this close or a personal relationship with.

So, what would you like to ask me?

SWJ: Just a little bit of your characterization of the commissioners you worked for.

RO: Differences in enforcement policy and priorities.

JL: Well, when Paul Hile left, he came around. I know you're _____ -- and he was in my office, and I asked him the same question. I said, "Here's my chance." He was an icon and he was also on the 14th floor, and the EDRO and ACRA for 15 years, I think, maybe longer. And I said, "Who's the best commissioner?" He leaned over and he said, "Joe, each one brought something different to the job." And I thought, "What a copout!" But he was right. He really was right. And so I guess what I can do is try to describe what I think each one brought to the job.

Dr. Hayes brought a willingness to make decisions. He'd say, "We can't wait till every shred of data is in, because that will never be," and aspartame was a good example of that. And as I mentioned earlier, he had the courage to make unpopular decisions by rejecting what were viewed as good ideas, like the drug review process, really weren't. And he had the courage to say no to them. And you don't get much public credit for the things you don't do. But I think his biggest achievement were the things he didn't do, in

addition to the ones that he did. And, of course, some of his reorganizations have been quite lasting and significant.

RO: First he did away with the Patient Package Inserts (PPI).

JL: Right, he did, and he did that right when he came in, and that was part of a transaction.

RO: That was part of Goyan's legacy.

JL: Right. But I really didn't have any involvement with that one way or the other. Except established _____, whatever that's good for, the National Education Association (NEA) or something like that.

Mark Novitch. There's nobody more decent, no more decent human being than Mark Novitch. And he gave -- remember that year of acting? He gave that his all. And I remember that he had _____ talked about earlier happened on his watch, and he said, "Joe, we've got to do whatever we have to do to fix them." And one of the most pleasurable persons to work with _____, and has always, I think, stood out in my mind are some of the, one of the very best for the FDA.

Being acting commissioner is a thankless job. Not one of them has gotten the job as permanent commissioner. Every one of them wanted it, whether they would fully admit it or not, because you're doing the job _____. Hey, I'm doing the job. In fact, some of them did the job as long as the ones who got the job. So I think anyone who serves as acting commissioner actually deserves even an extra bit of gratitude because

they get all the pressures and few of the rewards.

Frank Young, I worked with the longest and the closest because of the length of time, and Frank Young is a great example of someone who evolved more and more in time and got closer and closer to the agency; and I remember I wrote a speech for one of his Food and Drug Law Institute (FDLI) annual drug on the state of the nation in drugs for the FDA commissioner, and I can only remember vaguely but it had to do with various ways and what happened during different times.

But what I will remember most about him is how he acted when his son had that accident. He had five children, five children. The youngest one was in high school, and at the time, was a wrestler, and had a terrible, what they thought was going to be a life-crippling accident, broke his neck, and was medevaced and thought he would be in a wheelchair the rest of his life, if he did that. And I remember every night after work, he'd go to the hospital, day after day, week after week, how long it took him, and how somebody could do that and still maintain all of the pressures of the job, you know, it was remarkable. One of the things you see kind of from a staff point of view is not so much of what they do but what they're like, and he was a person of deep faith. He was a person of deep, deep faith and enormous dedication.

Work-wise, he believed strongly in trying to get drugs faster to desperately ill patients. Treatment IND's, he would still say, was one of his biggest achievements. A big believer in biotechnology. He was a scientific expert in biotechnology and helped foster that technology getting off the desk. He had his own product-tampering incident that Arthur Hayes had with Tylenol, not quite as visible, but that kind of makes you more of a warrior. And it was unfortunate that the generic-drug thing happened under his

watch, because it really wasn't anything he did. But these things happen. But he, at that time, he was FDA commissioner longer than any commissioner in history, and it is a hard job with pressures in every direction.

And he also probably did more for my personal career than anybody else by moving me from kind of a personal assistant advisor to somebody in charge of something. And that was probably one of the big shifts in my career.

Jim Benson I've already mentioned. I'm probably personally closest to Jim _____. It was during that year that it was like being war buddies. I was a member of the military. But I know that the people who are, if you were in combat a short period of time gets you a very close connection. And the year that he was acting commissioner was that kind of year. As I said he stood for integrity and restoring that to FDA. He helped keep the Seafood Program in FDA, when I became associate director. Many years later, I'm grateful. And probably what I remember learning the most from him, I was madder than a hornet at him. Sometimes that's when you learn the most.

When I was in the commissioner's office, what I was best at was getting specific special projects done. The commissioner needed an IND regulation done, you do that. Or they needed a Reye's syndrome regulation, we would take care of the very high-visibility stuff. And it's true. There are other places in FDA that could have done them, also known as the center in charge. If the data was food labeling, if it was drugs, it wouldn't matter. In everything we worked on, somebody else could have been doing it. But that wasn't our mission. Our mission was we worked for the commissioner and the Centers had other things to do, and that was what we did.

And I remember Jim Benson said to me one day, he said, "Joe, your work is good,

but it is destructive to the organization.” He didn’t say harmful, hurtful -- destructive. And what he meant was -- I didn’t talk to him for a week, and he picked me up off the ground -- what he meant was that, in running of -- and he’s absolutely right, he’s absolutely right -- in running a large organization, you have to think of two things simultaneously. One is you have to get today’s job done. But, two, you have to think of the long-term capacity-building of the organization. And when you do somebody else’s job for them, you rob them of that capacity-building. You’re going to leave and they’re not going to know what you did, and they didn’t grow from it, they didn’t learn from it, they weren’t part of it. And so you’ve got to both get the job done, but build the capacity at the same time. If you do one, you rob the organization of overall growth and strength. And I think -- and that actually came up when we started Food Labeling because I remember we rote the advanced notice of proposed rule-making in our office, and that’s when that problem came up. And I thought that when our achievements, then, was, if you were restoring leadership of the FDA, food-labeling issues should be in CFSAN. That was my time with Jim Benson.

David Kessler. David Kessler, I worked with personally the least of all the commissioners, and I went with Jim Benson over to Medical Devices. But I remember the day he came, he said that -- again, he followed the, he was the next person as commissioner after the generic-drug scandal, and he wanted to raise the visibility and credibility of FDA in the public eye, and he did that. And how many people are able to do what they said they were going to do when they walked in the door? Not very many, I’ll tell you. And he achieved that. And while he probably will always be best known for the tobacco initiative, what I always felt was, the fact that he was able to take on the

tobacco industry was indicative of where he brought FDA, because he couldn't have done that his first week here. So it was important work to be done, but was able to do it.

He also taught me to try to learn something from every one of them. There's nothing like focus and preparation. This man could focus like you'd never believe

It used to be, for the commissioner, for a congressional hearing, you could get, you'd get an hour. A major, major hearing, maybe you could get two one-hour sessions. The generic-drug scandal broke, and I remember Frank Young, we locked him up for an entire day. David Kessler, if you said a congressional hearing, three weeks. He does nothing for three weeks but prepare for that hearing. Unimaginable! Unimaginable! The ability to focus. So he'd take a certain number of things . . . Remember when _____ breast-implant thing? He moved into our office. He moved in! He didn't visit. He moved in. That was his level of focus, and it was extraordinary.

Michael Friedman. Michael Friedman, I remember was, as Dr. Kessler put in _____ a whole row of deputy commissioners, and they were all parallel, and so when he left _____, they didn't name Michael Friedman the acting commissioner, like that's so wonderful. He was the lead deputy commissioner. You know, the acting commissioner is in a weak enough position to work from, even _____ lead deputy commissioner, which actually worked. It actually worked because it resulted in camaraderie among them. And Michael Friedman was just always upbeat and positive. There wasn't anything that _____ that would get him down. What I remember him more is he appointed me my job, and I remember he called me over and he said he wanted to see me. I said, "About what?" He says, "You'll find when you get here." That didn't sound good. But he said

there was going to be a change in the food center director's job, and they wanted me to do it, and so obviously I owe a lot to him.

Jane Henney. Jane Henney, I had worked with before when she was deputy commissioner of operations. In fact, her first day of work was the day David Kessler filed for the removal on silicone implants. I had worked with her on that there. But I had just a marvelous relationship with her when she was commissioner. And I always say that she brought out the best in me or allowed the best in me to come out. She believed and she picked on two major issues, and she expected her senior people to take care of their work, and to be very much in-line management, a line-management person, without question.

She also was a commissioner with the most values of the permanent commissioners, the idea of building the capacity to deal of the organization, the Jim Benson issue that I talked about before, and always talked about strengthening the scientific base of FDA. Every day you heard from Jane Henney, "You've got to strengthen the sciences", and that's what she meant. What she meant was you've got to have the infrastructure – that is a terrible word till post-9/11 -- the infrastructure of the agency, strong, professional, scientific, and that's where the credibility comes from. And she believed in that completely, and we tried to do that.

She also had two marvelous sayings. One she copied, one she cast on from somebody else, which was, in the world of public health, always see faces, never see numbers. She told me that my last day when she was here the first time. I reminded her first thing when she came back the second time. The other was something you don't expect a commissioner to say but its worth to remember. As she was leaving, she told a

story about -- I'll see if I can remember correctly -- about when you're given -- I guess when you get to be a grownup, you're given five balls. Four of them are glass, and one of them is rubber. And the four ones that are glass are your health, your family, your friends, and your integrity, and the rubber ball is your job. And while there's all the focus on the job, if you drop one of those other balls, they'll shatter, and it's awfully hard getting them back together. If you drop the rubber ball down, eh, it'll bounce back. Very unusual thing you expect a commissioner to say. But, again, it goes back to a belief in the deeper, underlying things that make people run, that make organizations run: your health, your family, your friends, your integrity. That's what works for people, what works for individuals.

Bern Schwetz. Bern Schwetz. Let's see. We had the lead deputy. He was the principal deputy commissioner. When the administration changed, there's some rule about you can only be an acting head under some law for 120 days, and then . . . So they name all the acting deputies, principal deputies and an _____ FDA everywhere else.

SWJ: Okay. I didn't know how the "lead" designation came about.

JL: And so Bern Schwetz became the principal deputy commissioner, again, not a position of great strength. But he was the commissioner. He was the acting during 9/11. I remember when he began, even before that, the worries about Bovine Spongiform Encephalopathy (BSE) flared up right when he was brand new. They put a lot of effort into that.

But I'm sure he will always remember, like I remember the anthrax episode, he'll

remember being commissioner on 9/11. And I remember, I never made it all the way downtown, came back to the Parklawn Building. He was in Baltimore, and he came back. And we were -- there was a small, by then maybe only 15 of us maybe in the ORA conference room, and people like Ellen Morrison were there, I would guess. I remember Mac Lumpkin was there. We were trying to figure out what to do next.

And then afterwards I followed Bern up to his office, and somebody had talked before about the Parklawn Building being a potential target, and we said, "Oh, come on," you know. I mean, in Rockville, a target, but to over there? And target the Parklawn Building? So I'm sitting in his office, and all of a sudden a plane flies overhead. There was utter silence, because the feeling of, wait a minute, they shut down all of the airports. What are you talking about targets? We realized they were probably surveillance planes they sent around. But again, Bern did the very best under difficult circumstances, and he helped us with the anthrax in the building episode, and he went to the department, and he was a good man.

SWJ: And a good e-mail correspondent.

JL: Oh, he _____ e-mails because he likes e-mails. He likes . . . Some people, you know, each person -- I should go through this again, but I won't -- communicates in a different way, and you get used to one, and the other one does it differently.

I remember when Carl Peck became head of head of drugs; he wanted to talk to me. He'd send me an e-mail. And Bern Schwetz was the same way.

So it does much better to think deeply and he'll fire back an e-mail. But we learned to communicate more that way.

Lester Crawford came. Let's see. The principal deputy commissioner, was the deputy commissioner, who was to function as the acting commissioner but not be the acting commissioner, whatever that meant. But he was a political appointee _____, and I know him from before and he joked when I was five years old. I guess that's how old I looked when I worked in the commissioner's office back then.

And Les Crawford very much moved out and took charge and it was clear that he had the secretary's confidence, and that was important to us. And he was very involved with food issues and knew them very well. And I worked with him very closely, and we just kind of, you know, kept proceeding like we didn't miss a beat.

Mark McClellan came, I guess it was November. Does that sound right?

RO: Yes.

JL: I think it was November. We then had a little -- _____ actually had a party at his house and introduced him to everyone. Mark McClellan got me on the Blackberry.

And Mark McClellan probably -- you know, they're all energetic. I mean, how can you say which commissioner is more energetic? Because they all go nonstop, but, boy, he gives new meaning to nonstop. And the number of different issues that he is able to deal with at once is extraordinary. Just in foods, he must be involved in 50 different issues, and that's just foods. There's drugs, there's biologics, devices, and on and on. He has an extraordinary capacity to, for different things.

You know, he came in November. He testified before Congress Appropriations in February or so, and usually all the technical questions are referred to staff. He

answered every question himself. That was the first year. You wonder what will happen the second year. So his capacities were incredible _____. He's very balanced in his decision-making, and he likes explosions. He likes things to happen. He's also one of the ones who really foresaw the visibility _____ and really one of the first _____ catalyzed the revitalization of our _____. He fought very hard for resources for food security and was able to get the \$5 million we had for research last summer and brought me into the communications age. Everybody did get Blackberrys, and I learned if I want to talk in real time, I'd better learn how to do it, too. _____ fate of the legal pads.

SWJ: How does the fact that he has a degree in economics benefit the agency? We were wondering how that might influence his view of medical and health issues. Given his intelligence and special interests, not to mention is White House connections.

JL: I think it's -- anybody with an M.D. and a Ph.D., especially in diverse fields, I think that more reflects his diversity of thinking. Some things . . . We haven't really seen it very much in the food area so much, but certainly in looking at moving things over to drugs, understanding cost containment, understanding the whole drug reimportation issue both from an economic standpoint, so I think that's part of, I think that's part of him. But he is a physician, and he's a man of goodwill, and he wants the best for the FDA, and that is the most important.

RO: Thank you, Joe. We've exceeded your one o'clock. Thank you very much.

SWJ: _____.

JL: _____ so I wrote that as many places as I could, and at Health and Human Services (HHS), Health, Education and Welfare (HEW) at the time, Food and Drug was first _____. So everybody thought that was my first choice, and that's how I got vetted to the FDA.

RO: That was in 1978.

JL: That was in 1978. Actually I got hired in the fall of 1977 because they did the hiring ahead of time because of law school came right around Labor Day of 1978.

Richard Cooper was general counsel. And the general counsel hired each year about four or five people right out of school, the class of each year. They also hired people with a certain amount of experience. But I came right out of school. At the time, we all started on litigation, which I thought was good, notwithstanding whether I enjoyed it or not.

RO: I didn't realize you were a litigator.

JL: Yeah. We're all litigators for the first several years. But the importance of being a litigator is twofold. Number one is you don't think of yourself as a drug or a food or device person; you think of yourself as an FDA person. And number two is you get to work with the field, and the field is such a . . . But the field is one of the main core of FDA, and at headquarters, a lot of times it's hard to get to know the field. Headquarters is so dominated by _____ that getting on the ground floor and knowing the field is

critically important. And I had, like other lawyers, I had different seizures and injunctions and criminal cases.

Probably the one case that I was most involved in that has historical significance is a case _____ involving public health _____. This grew out of the bioresearch monitoring initiative from the '70s. As historians, you'll know. And I wasn't here, I was in college or law school or somewhere.

But Kennedy held a whole series of hearings, and there were three major testing laboratories. There was IBT, there was G.D. Searle Company. They're both two big companies from the Midwest. And there was one small company from New Jersey named Biometric Assessments, and all of them dealt with fraudulent animal-testing practices of one kind or another. And this was a case where they actually never bought the rats to do the studies. The FDA came up to do an inspection, and the guy goes, "Oh, can't come today. Come back next week." And while we were gone, he went and moved rats around and assembled the study and got through the inspection.

When they submitted the study to FDA, they just wrote down that no animals got tumors of any kind, and the reviewers looked at it how could this be. Every group of rats. That's why you have the control group to find if the test group got more because the control group was _____. And this was, I mean, not only whether it's honest. They were stupid.

And so by the time I got involved, it was just; it was about six months before it went to trial. It was going to a grand jury and then trial. Eventually there was an animal facility, and the people associated with that where the study was done. The actual lab director, we had to get out of jail to interview him and prepare him for trial, because he

was convicted of car theft in a car theft ring.

So there was no question that the company had submitted false statements. The question then became, how high in the company did they know? And it essentially ended up that the people associated with the laboratory all either pled guilty _____, and the higher-ups were acquitted in the trial. The company was convicted.

But what that really did for me, again, I spent probably the better part of a year up in New Jersey, worked very closely. Tony Panzica was a compliance officer, and he really trained me as much as anybody else in the FDA; and a guy named Chuck Walsh, who was the assistant U.S. attorney at the time, in charge of the fraud division. You know, we worked very closely together for almost a year. I went up there every week, and wrote briefs in the summer, and we had a five-week trial. It went on and on and on. But I think that it gave me a very, a different understanding of how the field operates, the importance of collecting evidence, the importance of doing a good job, and also that you don't always win. You know, it's a bitter pill to go through all that and have people that we had indicted be . . .

END OF INTERVIEW