

# History

of the

## U. S. Food and Drug Administration

**Interviewee:** Dr. Jane Henney  
**Interviewer:** Dr. Suzanne White Junod  
Ronald T. Ottes  
**Date:** March 28,29 1994  
**Place:** Rockville, Md.

## INTRODUCTION

This is a transcript of a taped oral history interview, one of a series conducted by the Food and Drug Administrations History Office. The interviews are with persons, whose recollections may serve to augment the written record. It is hoped that these narratives of things past will serve as one source along with written and pictorial source materials, for present and future researchers. The tapes and transcripts are a part of the collection of the National Library of Medicine.

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Food and Drug Administration  
Rockville MD 20857

TAPE INDEX SHEET

CASSETTE NUMBER(S) 1,2,3

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

DATE: March 28,29, 1994 PLACE: Rockville, Md. LENGTH: 146 minutes

INTERVIEWEE

INTERVIEWER

NAME: Dr. Jane Henney NAME: Dr. Suzanne White Junod  
Ronald T. Ottis

ADDRESS: \_\_\_\_\_ ADDRESS: Food and Drug Administration

FDA SERVICE DATES: FROM 1992 TO 1994 RETIRED? \_\_\_\_\_

TITLE: Deputy Commissioner for Operations, FDA  
(If retired, title of last FDA position)

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RO: This is another in a series of interviews on our FDA oral history program. Today we are interviewing Dr. Jane Henney, Deputy Commissioner for Operations, in her office at the Parklawn Building, Rockville, Maryland. The date is March 28, 1994. Present in addition to Dr. Henney is Dr. Suzanne White Junod and Ronald Ottes. This interview will be placed in the Library of Medicine and become a part of FDA's oral history program.

Dr. Henney, to start these interviews, we like a little bit of autobiography. So if you could start with some of your early years, where you were raised and educated and any work experiences that you had prior to coming to FDA.

JH: I'm originally a Hoosier. I came from a very small town in Indiana, Woodburn, Indiana. It's officially the smallest city in Indiana, and at the time I lived there, the population was 512 people. It was incorporated as a city before Indiana passed a law that required to have several thousands residents. It will probably always have some small claim to fame. My father was the principal of the school for many years; then was vice principal for several years. I really lived all my life until I went to college in Woodburn.

I attended Manchester College, a small, private, church-affiliated college in North Manchester, Indiana. There I obtained my degree and a teaching license. I was a secondary education teacher, and I also completed all the requirements that I needed for pre-med. I was accepted to medical school and attended Indiana University. After I obtained my medical degree, I did my internship in Indianapolis at St. Vincent's Hospital. My residency was at Georgia Baptist Hospital in Atlanta.

I went on to complete my fellowship training in medical oncology at the M. D. Anderson Hospital at Houston, Texas. It was during the period between my residency and fellowship that I married Dr. Robert Graham. During my fellowship year, he was recruited to return to federal service in what was then the Bureau of Health Manpower. We decided if I could find a position that I would be challenged by we would move to Washington. Through a series of fortunate circumstances, I

was offered a position at the National Institutes of Health. I was a drug monitor in the Cancer Therapy Evaluation Program at the National Cancer Institute.

It was interesting in terms of the offer, because I carried on the roles of another agency for at least a year. The individual who had been a prior director of the National Cancer Institute was the head of the Health Resources Association, Dr. Ken Endicott. He said, "Of course, we'll float you a position for a year, and the person that technically will be your supervisor will be Dr. Baker." Dr. Baker had been deputy director of the National Cancer Institute. Although I began my career at the Cancer Institute at an entry level position as a drug monitor, I had a reporting relationship to people who once had very prominent places in that institution. They both shared with me their perspective about what was going on at the institute at the time when they were there. It was a wonderful kind of way to come into the government.

RO: What year was that?

JH: It was 1976, the year of the bicentennial.

SJ: A good year to be in Washington.

JH: Well, it was quite hard to get hotel reservations at that point in time. And I remember when we arrived for our interviews that spring every hotel was full. They had lost our reservation. I was scheduled to go on job interviews early the next day. The only place they could put us up was in the dining room of the Holiday Inn Bethesda. So I'm probably one of the few people who have literally slept on the floor of one of the banquet halls in the Holiday Inn Bethesda. And . . . Oh, it was quite a night. I'm not sure I want that captured in anybody's history but my own mind. (Laughter)

(Interruption)

JH: The following year I officially went on the cancer personnel rolls when I became a senior investigator. I had a wonderful experience. I was the project officer for many of the NCI contracts and grant programs developing new therapies for women with breast cancer. I got to be in on all of the action that was going on in the late seventies.

After about a year in that position, I was recruited by Dr. Vincent DeVita, who was then the director for the Division of Cancer Treatment to be his special assistant. He is the individual who developed the therapy for Hodgkin's Disease--MOPP. He was well known as a very strong administrator and an excellent clinical scientist. I thought that if I was going to learn anything about management and administration, it might be a good opportunity.

We had come to Washington planning on staying a couple years and then going back to academia. I had a grant that was funded, and I was going to do research and all of that. What blossomed out of the experience of working with Vince DeVita was an experience that taught me that I enjoyed a wide range of things. I enjoyed taking care of patients all of my clinical career, but I learned that I very much enjoyed and was reasonably good at management and administration. Since most of that management and administration had to do with cutting-edge clinical activities or cancer treatment research, it was just a wonderful experience for me.

After about a year, Vince was recruited, or at least his shoulder was tapped, to become the director of the National Cancer Institute. At that time, there was no deputy for the institute. Guy Newell had been recruited away to take a position at the M. D. Anderson in Houston; the position was vacant; I had served as Vince's special assistant; and he said to me, "Look. I need someone and someone that I'm used to working with, someone I trust. So for a period of time, please come help me." So for a time, I was working two or three jobs. I was still the special assistant



in the Division of Cancer Treatment. There was a division director position vacant, so I became the acting director in the Division of Prevention and Control. It was entitled something else at that particular point. Lastly, I was working upstairs on the eleventh floor, serving as the deputy for the Cancer Institute.

It was a very hectic, very frantic kind of existence, but it was just wonderful. I was able to see the entire breadth of the institute. It was a time when I really expanded my horizons in terms of the issues of importance to cancer, including bench science, clinical science, prevention, and cancer control. It was a terrific experience for me.

In 1984, both Bob and I were recruited by institutions in the Kansas City area. Neither one of those institutions knew that they were recruiting the other partner in this arrangement. They both knew of the other's existence, but it was also interesting at least one of them didn't know that we were married. It was just a very kind of a funny sort of circumstance. Bob was recruited to be the executive vice president of the American Academy of Family Physicians, and I was recruited by the University of Kansas to be the associate vice chancellor.

I stayed at the University of Kansas until David Kessler came out to Kansas City to recruit me. During the time that I was at the University of Kansas, again, I had a wide range of experiences. I was recruited to help establish three centers of excellence: one in cancer, one in aging, and one in environmental and occupational health--to recruit the leadership for those centers, to pull the resources not only from the University but across the state, to garner support for those centers. That's what I was doing and intended to help doing.

I was minding my own business when the dean of the School of Medicine got recruited away to take a similar position at the University of Colorado. A group of faculty, as well as the executive vice chancellor and the chancellor, came to see me and said, "Would you serve as the interim dean for the School of Medicine?" So, not knowing exactly what I was getting myself into, I said, "Sure. I would be delighted." I did it with a certain degree of naivete, because at that point in time, I wasn't a

tenured faculty member. There I was going to be serving as the dean of the school. I had a wonderful year. It was a great experience. There were lots of challenges going on in the institution--malpractice was just out of control in terms of the payment for the rates, a couple of our departments were--in terms of their clinical foundations--in real tough fiscal straits. We had all kinds of issues dealing with faculty and students, promotion and tenure, the whole range of things.

After that stint was completed, I was promoted to vice chancellor for the institution. I was given, in addition to those responsibilities I'd had before, some additional responsibilities that had to do with representing the institution to many, many different outside constituency groups.

It was at that time that my phone rang. Unfortunately, I wasn't there to answer it. Instead I found one of those yellow slips on my desk. What it said was, "Dr. Henney, you've been called by the commissioner of the Food and Drug Administration. Please call ASAP." At that point in time, all I could think of was, Oh, my God! What have we done? You know. Who hasn't filed the right report? How will this spin out in the press? I mean, it was just all of the negatives, because I didn't know David Kessler. I hadn't dealt with the Food and Drug Administration for years, since my experience at the Cancer Institute. I didn't have a clue as to why he was calling.

I called back, and I got Kay Hamric on the phone. I didn't know her then, but have come to know and appreciate her very much since. Her message to me was, "Oh, Dr. Henney. Well, Dr. Kessler isn't here right now, but does he ever want to talk to you." (Laughter)

SJ: Oh no.

JH: Not quite alleviating my anxieties. And so we traded phone calls for three or four days like this. By the time we finally connected, he said, "Dr. Henney, you may not remember me or even know me, but I would like to talk to you about a job."

And so the first thing out of my mouth was, "I've got a job. I'm employed." (Laughter) He said, "I appreciate that. But I would really like to come to Kansas City and talk to you about a position at the Food and Drug Administration."

And I said, "I am extremely flattered that you would want to talk to me. I think you ought to appreciate my particular circumstance. I am very much interested in pursuing a career at this point in academic administration. It's very challenging to me. Bob and I have been very happy here in Kansas City, although we would certainly consider moving to another city if my career path really changed. I loved my time in public service, particularly in the Public Health Service at the Cancer Institute. Bob and I have always talked about maybe someday coming back. It would really be coming back to cap our career rather than . . . at this point in time. I really appreciate your calling, but I think you can understand that I'm interested in something else at this point in my life."

And he said, "Well, I understand what you're saying, but I'd really like to come to Kansas City to talk to you about a job." And we went back and forth about this coming to Kansas City business. And I said . . . I finally said, "All right. If you would like to come to Kansas City, it is a wonderful city. I would be delighted to have you here and to chat with you, but you have to understand that I really know the kind of opportunity you're talking about is probably going to be a real challenge for someone, but I am on a different track at this point. If you would want to come here, that's fine." He said, "Fine. Can I come next Wednesday?" "O.K. Next Wednesday."

He came out for lunch. I found out later that the Kansas City office tried desperately to find out why the commissioner was in Kansas City that day, but they were totally unsuccessful until later. We had lunch, and then we went to my home and we spent six hours with him talking to me about this job. As I took him to the airport, I said, "I can't say for certain, but the kind of institution you're talking about, the breadth of activities in which the agency engages, and what you really want from this individual sounds like I would really enjoy another conversation." I was hooked.

SJ: What do you remember from that conversation? He did say a couple of things to me about how you came to FDA, but it would be interesting to get your perspective. What did you talk about? What kind of vision did he have for the agency at that point?

JH: I remember a number of things that were on my mind at that point. In talking to him about what he was trying to do at the agency, he had sent me a few things. One was his FDLI (Food and Drug Law Institute) speech which happened fairly early in his tenure where I think he really laid out the kind of positioning he wanted to do for the agency. Clearly, he had come in at a time when the agency was being battered around from pillar to post having had to endure the trauma of the generics scandal. One strong hit like that makes you vulnerable for any number of other ones. When there was such a push by many groups--cancer being one of them, but the AIDS groups as well--for looking for ways to expedite the drug approval process.

We talked about several of those kind of things. His interest in the field and in enforcement was quite high. But what I think he had experienced and what he saw . . . He saw the need for the individual that he was trying to recruit to balance the positions. He needed to set the direction, find the opportunities to keep the agency one step ahead and at the cutting edge. One step ahead, in terms of taking strong enforcements, being out front in terms of policies or guidance that related to drug review, being quite strong and forceful in terms of pushing the agency's mission. But he needed--because that takes a tremendous amount of energy to not only identify the finite number of fronts one can push on, and provide outward management for these issues. He really needed someone to come in and add cohesion to the internal workings of the agency.

He was thinking about this organization in terms of a CEO and chief operating officer. We don't have those titles necessarily in the government parlance, but that's what he was thinking.

RO: When we're talking about that, do you see now that you have the deputies-- one for the operations, which you are, policies, external affairs, and management and information--you have a deputy for policy setting, which you have to work with as far as being able to carry out the various product centers' agendas, and also as far as dollars are concerned, you have to work with another operating unit here in order to get the dollars for those operating units that you're over. Have you had any . . . ? It's a lot different than what previous organizations were where each one of those reported directly to the commissioner.

JH: Yes. There are a number of challenges in that kind of management structure.

In the Cancer Institute, there was an executive committee made up of the operating division directors, the deputy which was myself. I served more as the alter ego rather than the chief operating officer. There was the executive officer, really the equivalent to our deputy commissioner for management and systems. It was a very powerful group that met. The meeting of the NCI executive committee provided a forum in which a number of decisions was made, and policy was set by the group. We used this group to make the final decision regarding resource allocations.

Working in a team approach to management decisions was not foreign to me. I think the current FDA management structure has its strong points and it has its weak points. The strong point for creating the multiple deputies is a functional one. When you had all of the associate commissioners and center directors "reporting to the commissioner," there's no commissioner that has been or will be that can have that many direct reports and function well. The span of control was simply too great. Since a structure either allowed or permitted, or whatever kind of word you want to insert there, every individual unit to basically function on its own and fend for themselves. That can be tolerated when resources are not so strained. It is deadly to an organization tight on resources not to have a strong way to pull people together and to make decisions on behalf of an organization. Another problem with the old

structure was that it created a vulnerability in always being picked off by issues. When you have criticism coming at you, then it's easier for other parts of the organization to pull back and say, "That's their problem." When you have a unifying body that looks at organizational needs rather than saying, "That's your problem," everybody knows if they pull together now for someone, then they'll get that kind of support when they need it. While the agency has done that in part in the past, it has become more a way of doing business in the last couple years.

RO: You know, the Gore Committee--and I'm sure they looked at the agency, although I haven't seen any report of it--but as far as levels of reporting within an agency, I've seen where they have been looking very seriously at at least the GS-13, 14 and 15 levels. When they looked at FDA . . .

(Interruption)

RO: I was wondering if they looked at the top hierarchy within FDA.

JH: I don't know that the agency was looked at in specific. I think if they would have, it's not this layer of deputies they were talking about. It's probably one or two or three rungs below this level. This is a very complex agency with a very broad, sweeping mandate. It takes more than senior management to run it. You can't just have reviewers and then the commissioner. It is just not possible. I think even though there are a number of deputies here at the senior level in terms of the role they play, if this organization was scrutinized by someone like the Gore Committee, they would still find value in it. After all, that's what they're really looking for with management is what value does it add to the organization. Much of what they're trying to get at with the reduction in mid-level management is often times people have gotten stacked on top of people on top of people simply to make sure there was

a career path, rather than an added value for the organization. I think that's really the point they're going after.

If I were redesigning the world in terms of this senior level organization, I wouldn't have some aspects of it there are. But is it workable? I would say yes. And probably the change that I would make--and it would sound like a minor modifier to many, but I think that it probably is something that is an important statement in terms of both position and role played--I would have called this particular position the principal deputy or the principal deputy for operations. Ninety percent of the agency's business gets conducted through this office, and this deputy just has a different level of both responsibility and impact within the organization than the other deputies do. That's not to minimize the important role they play, but I think it makes a statement about this office and who needs to make sure that policy, managements and systems, et cetera, are working their issues for the benefit of the organization.

SJ: But do you think that's not been perceived though, whether it's been stated or not?

JH: Oh, yes. I'm such a formidable presence. (Laughter)

SJ: No, no, no. Not at all. You're very . . . You're perceived as very much a team player, a cohesive force. And so I think whether or not it's been stated or not, I think it's still perceived.

JH: I think that's right. But quite honestly, that should be done for the position. It should not necessarily always have to take the force of one's personality or the right click of a personality to make that happen. I think that is the way that I work. Not just in terms of imposing the importance of the position, but I really do believe in turn that institutions have got to pull together, and whether it was my pulling the

center directors together or being a strong participant with the other deputies, that kind of institutional loyalty is something that I really believe in. But this position goes on far past my having it, and it would be something that I think would be important for the future senior or principal deputy. It's just a statement.

RO: How did you find the personnel in FDA compared to personnel in the other positions you had? *They're a little different.*

JH: Oh, very much so. The cultures in the NIH and here are in ways very much the same and in ways night-and-day different, and both are very different from academia. I think the compare and contrast between NIH, the NIH experience, and here has been fascinating for me. I will always be loyal to and a very strong supporter of the NIH. I grew up professionally there, the NIH/NCI gave me more opportunities very early in my career than I probably even deserved. It's been the cornerstone of my career on which I've been able to build and grow. I owe that institution and many individuals at that institution kind of undying loyalty. I was there for nine years. I've been here for two.

I think the institutions are similar in they both have very strong professionals working within the organizations. The scientific underpinnings, you know, are very clear at the NIH, and they are just as clear here. Then the institutions start to part company. NIH, and rightly so, engages in the research of discovery. The romantic side of discovering new things and discovering things for just the sake of discovery. If they impact someday, somewhere, sometime on human health, that's wonderful, but they don't have to now. That is a wonderful mission to have.

But equally strong is this day-to-day importance of science in the here and now that gets driven by the realities and usually the realities of a public health problem. To watch our scientists who are equally intellectually rigorous solve problems because they've got a problem either on the dock or with standards



development is equally stimulating, there is a fervor in and of itself that is just a wonderful process to watch.

NIH is driven by individual accomplishment. There are not too many committees that have ever won the Nobel Prize, and you see that kind of sense down into the inner workings of the NIH, where the individual makes the difference, and it's an individual achievement or accomplishment. The NIH can pull together on certain things. You know, when you have a common enemy, you always . . .

SJ: I was going to say, it's usually defensively though?

JH: Yes. Yes. You always can end up coming together. But at the FDA, that is just not the way it is, and we have many individuals here that on awards day often times are awarded. But more frequently than not, and the way that most FDAers are most comfortable about even receiving any kind of recognition, is in a team, in a group.

SJ: Having solved the problem.

JH: It is the coming together and sharing and grasping that they're doing something for the common good. The number of times that you hear in the hallways, in the conference rooms, in the offices of the agency "for the betterment of the public health," it's unbelievable. It's just how people in this agency think. And it's marvelous to be around a group of individuals who in their own right could have all of the spotlight that they ever wanted, but they don't feel comfortable with that. They also feel what gets them up in the morning every day and takes them home every night satisfied is that they have done something for others. That's a great kind of institution to be associated with.

The thing that makes them rankle more than anything else is to be accused of or confronted with the fact that they may not be seeing eye to eye. We have our

differences. The field sometimes sees things different than the individual policy makers in the center. Or the centers are always upset about whatever it is the fourteenth floor is doing.

RO: How did you find that this is a regulatory agency which is entirely different than the environment you had before this?

SJ: We've understood that the relationship was strained between the Cancer Institute in particular and NIH in general around the late eighties, around the time of generics that the relationship deteriorated rather markedly to the point that it could be detected in policy making and all sorts of things. So I didn't know how much you might have been involved in that or what kind of perspective you might have on it, but . . .

JH: Oh, I was involved. (Laughter) My knowledge of the agency prior to my crossing this threshold was probably limited to that experience of dealing with the oncology drug review process or hearing on the news or reading in the paper such incidents as the Tylenol tampering affair. Beyond that my real working knowledge of the Food and Drug Administration was really quite limited. That experience had not been positive. It was a time in which the NCI, which was then one of the largest developers of oncology drugs, was confronted with all of the restrictions and standard settings and everything else that a regulatory agency has.

I would say the more typical kind of encounter that we always had was one where we were toe-to-toe. Embracing was not the order of the day. It was really a confrontation mentality by both sides. Both sides were very suspicious of one another. One side could offer the olive branch, and the other side would spit on it. It was done by both sides. There was not a good guy or a bad guy in all of this.

What finally got the log jam broken was some very concerted efforts by both the institute and the agency to talk, and to keep talking, and to keep meeting, and

keep figuring out how to get things done until they were done, because the real losers in this confrontation that had grown and was at a very high pitch . . . The real losers were cancer patients. And I think Carl Peck, Greg Burke, Bruce Chabner, Mike Friedman, and Sam Broder had a lot to do with changing this. And Greg Burke coming into the oncology division. They all met around that table and decided, "We've got to get beyond this. We've got to understand each other's workings to figure out ways that we can respect each other's positions and we can do something for the benefit of cancer patients."

I think David Kessler probably took that level up another notch when policies related to expedited review started to come into play. I really think the forerunners of that working relationship, that set, maybe a couple of years before David arrived. The relationship right now couldn't be better.

SJ: Do you think it was a process of each one learning how the other one approached issues? Because the scientists were looking at the great benefits they have for mankind and seeing the regulators as withholding these benefits through bureaucratic detail. The FDA scientists I think were looking at it more along the lines of, "We've had experiences with drugs that started out looking just as good as this, and we had major problems that we didn't detect in the thing." Do you think it was a matter of discussing these things?

JH: Yes. There is a standard here that is set by statute, and it's set by how we see all other drug developers, and there is an equity issue here. I think it was a matter of two perspectives just clashing.

RO: A number of years before that the two agencies had a conflict over the labeling of some of the cereals where the Cancer Institute had said, "Yes . . ."

JH: Oh, I was a part of that as well.

SJ: Were you?

JH: Oh, sure. (Laughter) That's why when I was coming into the agency there were people at the working level of this agency that wondered if David Kessler had totally lost his mind. He had seemed like a smart person to them, but what was he doing? And I remember Carl Peck was giving grand rounds at the University of Kansas. We sat in my office and basically he said, "We wonder what your agenda is going to be, because we know you come from that era of the Cancer Institute." Similarly, Fred Shank worried a lot . . .

SJ: Of course. I had forgotten about that part of it now. Yes.

JH: Oh, yes. When Kellogg promoted fiber . . .

SJ: We just discovered Kellogg's petition over at NLM. Most unusual to have a cereal company preaching to FDA about nutrition. It was quite an amazing document.

JH: Well, yes. We'd never dealt with food labeling. We'd been told that the agency would probably have a position, but we were trying to get a major message out about high fiber and bran. We didn't go into it entirely innocently, but we thought it was a point worth making. And . . .

SJ: You didn't realize how strong the FDA's tradition against health claims on labeling really was. (Laughter)

JH: You know, the FDA reacted with full force, and so, you know, that caused us to come back with full force. Yes, I was there then. (Laughter)

SJ: Do you think that that had anything to do with Kessler's recruiting? I mean, did you all talk about that in your meeting in Kansas City? Were you aware of that?

JH: Not that I remember.

SJ: Do you think he was aware of all that you were bringing?

JH: No. He knew that I had come from the Cancer Institute, and I had been part of an organization that had trouble with the agency over the oncology drugs, but it really wasn't . . . He said, "I bet you don't believe I'm even here talking to you about a job with the Food and Drug Administration." I said, "The only reason why I believe it is because you were so insistent upon coming." (Laughter)

SJ: Dr. Kessler mentioned to me just in passing one day that he had been intentional in his recruitment of women to prominent positions in the agency. And while I'm sure he didn't mention that in his discussion with you, what has been your experience as one of those recruits? Not only was FDA shocked at the multiple deputies, appointed by Kessler, but most especially by the fact that they were mostly women.

JH: Probably the culture shock for me was to work with women. There have been very few times in my life where I had the experience of working with women. At the Cancer Institute, one of our division directors was an Afro American, and me. All of the rest of the division directors were male. Most of the individuals, other than the general counsel of the University and one of my associate deans when I was the interim dean in Kansas, were male. I have grown up at a time where my organizational encounters have been much more typically male than working with other females. What has really surprised me is that when I've established my own office most of the people wanting to work in this office or who were being sent to me for

interview were female. We've had some men in this office who were here on training stints and all like that, and we've tried to be very kind. (Laughter)

It really came home last Saturday. Maria Elliott has been recruited to CDRH to take a position in the new mammography office. Ann Witt hosted a little get together at her house for the five of us who have met every day in our operations staff. There's Carol Crim, who's a secretary and comes from a very traditional background of having raised her family and having come back to work. Linda Suydam, who started out as a social worker and then rose in the ranks at the agency to become executive officer at CDRH and then is now the associate commissioner for operations. Maria Elliott, who has been my special assistant, her background is business and English. And Ann Witt, who's a lawyer.

I didn't say anything as we were having lunch. We were sitting around the table laughing, telling stories about ourselves, and really enjoying one another. We've enjoyed our work together. We see each other as equals. We have a great amount of respect for one another. I think the rap on women working together is that they can't get along, they're too competitive, and it's, you know, it's like the traditional hen house. That has not been my experience. This has been a wonderful and profound experience for me.

Similarly, I have had a satisfying time working with the center directors here--some of them who have been here for a very long time--Ron Chesemore and Fred Shank, Carl Peck and Gere Meyer and Kathy Zoon. We've developed a very strong working relationship. The key to any group is that of respect and trust. You don't always have to agree. In fact, there have been times when we have just disagreed to the high heaven, but everybody around the table or in the room has a very high level of respect and trust in each other. If one can foster that, it doesn't matter if you've got men or women in the room, you can get a lot of work done, and you can have a good time doing it.

(Interruption)

RO: Do you see your role here as the deputy for operations as a semi-filter and a facilitator? Because many times a deputy of an organization is going to filter a lot of the trivia from the boss. How do you envision your role here? Facilitating the issues for the group under you and filtering out some of the . . . ?

JH: I knew when I came to this position it was going to be a bit of a tough row to hoe because of this layering issue. There was going to be nobody who had been here in any of the center directors' positions that was not going to be at the least psychologically hurt by not reporting directly to the commissioner anymore. I knew this was going to be an issue. I did think about it a long time, the right role for this office to play in the agency and for the centers. I do describe my role as an advocate for the centers and for the field.

I do have expectations. I am not just a cheerleader. I won't sell things I don't believe in. For that advocacy, the only price I have ever tried to extract from any of the center directors or the centers as organizational entities is that when we needed to cooperate and come together as a cohesive whole that people didn't try to sit in their corners and not play. I have tried very hard to make sure that my voice spoke on behalf of the centers and the field in this organization, but that there was an expectation that when we needed to come together we could. People were not allowed to go back and say, "I'm not going to play with this one." And I think by and large we've been successful.

SJ: Can you cite any examples of the enforced cooperation?

JH: I think probably the strongest example of some of this is the NCTR (National Center for Toxicological Research). NCTR had a lot of shots taken at it by the Edwards Committee about being too distant from the agency, in isolation scientifically, psychologically, geographically. They had been given some signals before. Working with all of the center directors and with the NCTR, we have entered a

whole new day of how we use the NCTR'S research capacity to undergird all of our centers' scientific decision-making.

(Interruption)

JH: Foods research is another example. This is done in many different sites in the agency. Center for Foods, CVM (Center for Veterinary Medicine), NCTR, and the field. We have developed a governing structure so that the research of foods that we support in any one of these organizations is both identified and endorsed as something that the agency needs. And so that's another example.

The relationship of the field and the different centers is another . . . At the time that I came to the agency, the field and CDRH (Center for Devices and Radiological Health), the field and CBER (Center for Biologics Evaluation and Research) were not enjoying relationships of respect. We may not be there yet. In CDRH, one of the major management initiatives I had them look at was the balance of what they did in terms of compliance/enforcement, utilizing traditional tools versus educational tools. Their bent was to educate the industry into compliance and use few traditional enforcement actions. We've tried to not totally take down that educational form, because it was very strong and in many ways very good, but to bring the use of traditional enforcement up to an equally strong level.

SJ: Don't you think that comes from their background in rad health?

JH: Oh, it comes out of a whole culture.

RO: Of course. Sure.



JH: They had that culture for many years. That was one of the reasons, and only one--why we had such a problem here a couple years ago. It wasn't just rigor of review and rigor of clinical trials. It was also this whole issue of enforcement. The same occurred with blood safety. For years, the field had been concerned about blood safety issues in this country. CBER has grown up in the culture of the NIH, and is rich in research traditions. There is nothing wrong in that. But getting them to see a different way of doing business and the importance for the public health was a real struggle. I think the leadership changes that we made in the centers changed some of this. One of the lines of questioning that weighed heavily in my interviews with candidates for center director positions was, What's your approach to compliance issues? How do you see enforcement? What would you do to build a stronger relationship with the field? It's not that the field is always right, but they cannot be . . .

SJ: Ignored.

JH: . . . ignored. Exactly the right word.

SJ: Is the mammography just--not to interrupt, but is the mammography standards program the first fruit of this, because it's very much going to be an enforcement type of program.

JH: No, I would . . . That's . . .

SJ: A separate initiative?

JH: That's a separate initiative. I would say that our willingness in devices to take on the hard issues like Bard, like dialysis. There have been a number of major enforcement issues over the device center in the past year.

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SJ: Yes. But you're talking about the labeling of dialysis equipment for reuse.

JH: Yes, and others as well. The ITC. That's been a terrifically difficult enforcement issue, but the center has stayed the course. In Biologics, the Red Cross was as tough as any enforcement issue that we have dealt with. We looked at the whole issue comprehensively. What are 483s? What did they look like over the past two or three years? How current is our information? What changes are really being made? With what momentum? The consent decree is a very strong change.

SJ: You were put in charge of that committee.

JH: The steering committee.

SJ: As I understood it, the concern was that the Red Cross might literally fold rather than be able to comply with some of the things that FDA wanted. Now was that close to being correct or was that rumor an exaggeration?

JH: There were a lot of discussions around the table as we were, you know, negotiating the consent decree as to whether the Red Cross was going to--I can't remember the word they used--but in essence, get out of the blood business. It was one of the issues we talked about in terms of our own internal meetings. How do you make sure that you still have a blood supply that is needed, but is safe? How do you make sure there's a confidence level here? One of the issues as we went through those consent negotiations was Red Cross saying, "Well, we may just get out of the blood business. It's very real." That didn't turn out to be the case, but was one of the issues they laid on the table.

RO: It sounds like you really enjoyed getting intimately involved with some of these regulatory issues.

JH: Oh, enjoyment. (Laughter) I have . . . You know, I have a certain curse. I've loved nearly everything I've done, so for me picking things that were the most fun or that I enjoyed the most, it's always hard. I am not afraid to make decisions, and I'm not afraid to make tough decisions. I'm certainly not afraid to make them when I do believe they're right and will benefit the public and the public's health. I wouldn't say it was enjoyable being at the table, but I could speak for those whose safety we were concerned about. I felt I had a responsibility to do that.

The establishment of the steering committee was one of the aspects of that particular negotiation that was amusing in retrospect. It is different than anything we have ever provided any other industry. For a period of time--it probably was hours, but it seemed like a long time--we really were not sure this was a right thing to do in terms of precedent. We decided since this was the last sticking point, okay, we would establish a steering committee.

SJ: That goes back to your fairness issue or your equity issue.

JH: Right. Who would be on the steering committee was the next question. Well . . . And who would chair it was probably the most important. We in FDA decided a chairman in consent decree issue should be the ACRA, Mr. Chesemore. So that's what we said. Well, the Red Cross was not happy with that and wanted it to be someone from the commissioner's office and on and on and on. It was finally decided that I would be the chair of the steering committee. Unfortunately, when the negotiating team of the Red Cross heard that, they wanted Ron Chesemore back in a hurry. (Laughter) I told him he was such a pussycat. (Laughter)

(Interruption)

RO: This is a continuation of an interview in our oral history program with Dr. Jane Henney. The date is March 29, 1994.

Dr. Henney, yesterday we discussed a number of things that you were involved in here. I wonder if something kind of comes out especially as some of the achievements that you've had here at the agency as far as maybe some of Dr. Kessler's initiatives that you have worked on specifically and feel that they were a major accomplishment? Accomplishment probably isn't the right word, but at least . . .

JH: There were a number of what I would call programmatic initiatives on which we worked on that I will look back and feel a special pride at having been involved with Dr. Kessler on those issues. The Red Cross, the BST (Bovine Somatotropin) approval, silicone breast implant controversy. There were a whole variety of those kind of things. But the thing David really brought me to the agency for was to position the agency and ready the agency for its future.

My work in looking at the functional and structural organization of the centers really from top to bottom . . . The Center for Biologics, the Center for Foods, which were reorganized, to try to realign and take perhaps better benefit of melding and marrying the research side of the house with the review side, making sure that we had that right balance that I talked about yesterday in terms of our educational efforts verses our traditional tools of enforcement and compliance and bring that into better alignment. We did with the reorganizations that happened in the Center on Foods and the Center on Biologics. There were also very far-reaching management initiatives that were undertaken in CDRH as well. A functional realignment and recommitment of that center happened there as well. The NCTR realignment. We talked about that yesterday.

SJ: Yes. We might want to go back to that just a moment.

JH: With respect to the field's relationship to many of the centers, strengthening that and making sure that all voices were heard and considered as we went forward with agency action. I came to appreciate there was not only the difference of culture

between field and center, but also between field and headquarters. That was not readily apparent to me when I first came. As I went around to the different district offices, they would talk about what was going on at headquarters. I started to detect there was not always a perfect union there. There was a fair amount of tension between what went on at headquarters and what was happening in the field.

We tried to not discourage the difference or the tension, but to use it as a creative force, so we saw a same problem from many different angles--from the research scientist who might be developing policy within a center, to the field investigator who sees how a lot of things happen in real time, to a headquarters operation of the field that has to be viewing things in a more comprehensive or global fashion. To bring all of those different perspectives to the table, I think, was something we tried to value and be sure nobody felt like their perspective was left out. I'm sure we weren't one hundred percent successful, but that was the kind of tenor we tried to develop.

RO: I think that in any organization like this where you have a headquarters and a field you're always going to have some turf battles.

JH: Oh, yes. It's like the Pentagon and the field operation. The field in the Defense Department never thinks those folks in the Pentagon really know what is going on out here where the action is, and similarly the Pentagon headquarters types always think that they must have a thousand loose cannons out in the field, and don't they understand what the big picture is?

We tried to start developing at a senior level some experiential opportunities. Having a Doug Archer, a deputy director in CFSAN, take Ed McDonnell's place in Boston for a month and having Ed stand in Doug's shoes. It taught them both a tremendous amount about the respect that they should have for each other's position and work. Roger Lowell coming into the Office of Seafood and Tom Billy going out to Seattle to spend a month. Carl Reynolds coming in from Detroit district to run

the Office of Compliance for the Center for Foods. Those kinds of exchanges are critical. They need to be done at a very senior level so that that experience and respect can trickle down. If it happened at a junior level, it's very difficult for that kind of respect to flow upward.

If you're trying to have respect and trust-building happen, everybody in the organization soon knows that Doug Archer understands what happens at the field, and that Ed McDonnell knows what happens in a center. We've similar exchanges in CDRH, and they've been very good for the organization.

Stephanie Gray from the San Juan district has recently been recruited to director of the Office of Compliance for CDER. Jim Simmons, district director in Cincinnati, recruited into the Office of Compliance CBER. Having Carl Reynolds now appointed--although we're still awaiting his SES paperwork--but running the CFSAN Office of Compliance. And those kind of things I think are more than signals regarding the field and center interdependency. These individuals will really permeate how the center thinks about the field and how the field understands and appreciates the center.

SJ: I have a couple of other things that you touched on, but I wanted to talk a little bit about the foods reorganization.

JH: There had been a study going on before I arrived. The center had brought in an outside contractor to work with them to study the organization. It essentially was an organization that had been largely untouched for twenty years. The leadership, Dr. Shank and Dr. Archer, were really feeling the tension of a very under-resourced center in times that had really changed. Changed from a time when the center literally housed all of the strong nutritional researchers, if not in this country, in the world. They were looked to and expected to be doing very active research. They were viewed as the most knowledgeable and the source to go to for any information on food, food additives, et cetera.

The other force really causing the center to introspectively examine itself was there was a new level of interest in nutrition and food by the average American. For many years it was meat, potatoes and milk and not much nutritional teaching in the schools, not much emphasis in the country or a sensitivity or awareness of people paying attention to how nutritionally rich their meals were. It was more proportions and tastiness rather than nutritional content that drove our intake. The last ten years with our fitness and emphasis on health has demanded a different level of effort on the center's part.

SJ: Jerry Mande feels as if his generation of nutritionists were not so much of the school of home economists as they were from the school of biochemistry. And that they weren't getting the answers that they were . . . They weren't getting the research where they wanted it, in one sense.

JH: This study had been going on for maybe six or nine months before I got here. It was in March after I arrived that the center went for what this agency always refers to as "go-aways." We always used to call them retreats, but here they go away. I think it's a nicer way to say that you're not giving up. You know, retreat sounds so . . .

Well, it sounds so, "We can't do it, and so we're retreating." So we went to Annapolis, all of the senior staff of the center. They asked me to say a few things. The only message that I remember giving them was that a structure of an organization needed to be such that it optimized the function internally for people within the center. It needed to make sense to our external constituencies. It needed to communicate what happened within a center. When you have something named the Office of Toxicology, there is no one save the toxicologists of the world that might know what would happen in an organizational unit like that from the outside. And we needed to have an organization so that people could look at it and say, "Oh. I want to know something about special nutritional infant formula or the like. That's

where I should go." Something that would clearly communicate to the outside where you'd find an answer.

As we came back from the retreat, we tried to look at a number of things: identity to the outside constituency groups, be they the public, the Hill, or whomever; making it clear what we're doing; realignment of our review and research so we had our research groups clearly working on things that were important to our review process or to our compliance efforts, and not have the research group sit in isolation from the fundamental workings of the center. It seems like there was another principle tied up in that, but I don't really recall now. There were just two or three fundamental principles that we were trying to strive for as we realigned the center.

The center finally came forward with what they wanted to do, and I had asked them to bring me two or three options. I remember sitting in a room with Dr. Shank and Dr. Archer and them describing, "Well, we could do this much now, then this much, and then this much. Or we could do this much and then this much." And I said, "Absolutely not. We figure out where we want to get for the end, and we do it all at once. You never go through the pain of a reorganization twice. Let's get this over. Let's decide where we want to be in the end, and let's go for the whole thing.

(Interruption)

JH: I remember telling them that the change process is important; it can be a time of renewal for an organization, but you have to be very sensitive to not having the change process run on so long that you tip over into chaos. And stretching something like this out over a long period of time would have absolutely, in my mind, assured chaos. People wouldn't have known what change was coming next. There would have been an ongoing effort to just work at the edges and not get fundamental changes here. So we went for it.



We tried to make sure that information was provided as best we could to the people who were going to be affected. We tried desperately not to have people's grades affected in a negative sense. And I think the only thing that was the real difficulty in doing something this big in the government is that it had to be reviewed at so many different levels, and the sensitivity. It dragged on and on and on. That kind of time lapse in something that is going to affect not only how an organization works, but how people understand where they're going to fit is really deadly. So if there was any negative thing that went on with that whole process, it was really the time we had to await while we went through all of the approval processes.

SJ: What levels are we talking about? That's something I'm totally unfamiliar with.

JH: Oh, through the department.

SJ: But what lay in between that. Personnel here?

JH: By the time we had settled on it, it didn't take the agency long to get the package together. Then it had to be reviewed by PHS; it had to be reviewed by the department. Technically, it didn't have to be, but had we not gone through those steps, I think that we would have experienced a backlash for doing something that big without having all of that level of involvement. Technically, the agency has been given the authority to reorganize within its borders, but this was a major reorganization, just like CBER was. Unfortunately, the CFSAN package went first, then the CBER reorganization got to ride in its wake. All of the slings and arrows of the review process, questioning of this and that came to CFSAN first. There are a few things yet to smooth out, but the reorganization will really position the center very well for its work.

CFSAN is very strapped for resources. We've no real clear end in sight for turning that around. CBER, you know, has enjoyed the development of a different income stream through user fees. This has really boosted its ability to both develop and sustain a momentum. And I think that will be a similar scenario with devices. Foods, even with user fees, if you could get them from things like imports or if you could get them for the food additive petitions, while those would be nice, it would not, in my view, be enough to get them at the level they really need to make them an optimally operational entity.

RO: Well, I'm sure that if you look back over the budgets of twenty years ago, foods was one of the major program budgets as far as the agency was concerned. And year after year it took resources from foods and put it into drugs and some of the other program areas.

JH: Well, it still is a major user of resources insofar as research is concerned, and it was because it was the only entity really in the U.S. where foods research was being done.

SJ: The Division of Pharmacology was one of the foremost scientific groups of its kind in the world at the time.

JH: Yes, but that is where we've had to realign. We drew on those research resources. They probably have been strapped for the reason you mentioned and pulling away of research resources to new initiatives like the food label. or two years, literally no new research projects have been started because all of the people that would have been doing those things were totally directed towards the food label. They are very limited in terms of their resources. I consider this work undone and unaddressed. In the field and the Center for Foods is where we really are desperately strapped.

RO: NCTR is not under your responsibility. Is that right?

JH: Yes. Yes, it is.

RO: It is? Oh. I thought it was under science.

JH: No. No. It is a center albeit a solely research center. I've devoted a lot of time with NCTR. During my first year, I must have gone down to NCTR six times since they were in a transition of leadership. I am also very much committed to this whole notion of having the strong toxicology researchers at NCTR to really undergird the research inherent in all our centers. I mean, we do have toxicology research that goes on in CDER or in CDRH or in CBER, but it can be tremendously complimented and enriched by having the NCTR undergird and complement many of those kind of efforts.

SJ: Have we solved the problem? Are they primarily working for us now?

JH: Oh, yes.

SJ: And we have solved that whole problem.

JH: Yes. Art Norris did a fantastic job during the time he was the interim director down at NCTR. Then we recruited in Bern Schwetz, who had been the director in NIEHS, the national toxicology program. We have a world-class toxicologist manager in Bern Schwetz. One of the tenets as he was recruited was his understanding that the center did not stand in isolation, part of his role and responsibility was linking and tying it to the other centers. We had to make major strides.

RO: I see this organizational chart I have here is in error.

JH: Yes. When David contemplated having a deputy director for science but instead recruited Elkan Blout as a senior science advisor part time, he knew of my own interest in science and science management and made the decision to move several of those offices that had originally been under a deputy director for sciences to me. The National Center for Toxicology Research, the Office of AIDS, the Office of Orphan Drugs, and there was an Office of Biotechnology, all report to the Office of Operations.

We have since taken down the Office of Biotechnology--it was just a small staff office--simply because we now have such tremendous strength in the biotechnology area in both our Center for Biologics and in our Center for Foods. We no longer needed that kind of presence in the Office of the Commissioner. We could simply draw on that strength from the centers.

The Office of Orphan Products remains. When the agency decided to form an office--and I still don't know exactly what the title ended up being, but--for special populations, the base for that operation was the Office of AIDS, and it has moved to External Affairs. There have been additional resources added to that so that they could also deal with the cancer population or the alzheimer's groups, et cetera. The National Center for Toxicology remains with operations. That isn't reflected on all those charts, but it happened early on.

RO: Is there any possibility that the space at NCTR is going to be utilized for other than research use?

JH: We hope so.

SJ: It's in discussion.

JH: We hope so. Ron Chesemore came to me a little over a year ago, and I remember him sitting in that chair next to you, saying, "You're really serious about

this NCTR stuff, aren't you?" And I said something to the effect, "Yes, that is a correct impression you have, Mr. Chesemore." And he said, "Well, a long time ago, the field tried to take a look at the number of labs that it might need and how the field could best be reorganized or organized to meet its laboratory needs." If NCTR could play a role in that, he was interested in beginning an initiative to look at field lab organization and, as one part of that look, determine whether the facilities and the tremendous resource that we had at NCTR could be a part of that:

That has been done. The field has come forward with a plan that would incorporate, not NCTR into the field, but space which could be built out into a field regional laboratory. The field could greatly benefit from the collaborative relationship of the scientists at NCTR. They are very strong in analytical capabilities. The utilization of shared equipment, the possibility of a training facility at a central site . . . There are just a number of things that have tremendous potential for increasing the FDA presence in Arkansas--not expanding NCTR, but increasing the FDA presence that would be a tremendous benefit for the agency. That comes under "work in progress."

Thankfully not "work undone," but "work in progress." We are in discussions right now with the department. Congress will clearly be interested in that sort of thing. The field, to utilize its resources well, really needs to realign itself.

We've too many laboratories that are too old, too outdated, and we've got too many laboratories that have too few people in them. You need a critical mass in today's laboratory. We've some laboratories with less than ten people. They are all hardworking people, but they have to do one thing at a time. One cannot staff up and equip all of the many labs that we have right now with the kind of resources that are available to us. It just no longer makes sense. With today's computers and today's mail service, dividing ourselves into perhaps four or five regional labs and some specialized labs, like the forensics lab, and a few of the other labs that serve special needs for the agency probably is a better plan for the agency than the current

construct. We will have many battles to fight before that gets accepted all the way up the chain.

SJ: They're now talking, too, about contracting in a way that they haven't done before to get certain things accomplished. I mean, there's the problem with continuity of evidence and all that, but do you think that has a role in the future? Or are we more likely to just adequately realign our labs to do the work that these do?

JH: It may take both. Realigning the labs is critical. There has been a second level of question about the contracting out. However, the continuity of evidence is an important one that cannot be dismissed. Contracting out is an easy answer that one goes to, but--as far as I know--there are not many labs doing the quality of work we need for the kind of work we do. It's been suggested, "Well realign yourself with some academic institutions." I've been in academic institutions, and they're not much interested in doing mass screening. That's just not where their fundamental thinking is. It would be like asking the NIH to take on a mass screening project. That's not what their mandate is.

While contracting out is an easy bookkeeping answer, it's not an easy answer in terms of either the legal requirements that we have to make our case, nor our scientific requirements. You just don't find laboratories doing what we do, and we would have to take extraordinary measures to make sure that an accreditation process was in place, i.e., the labs weren't being used by industry for similar purposes. It would take some real hard thinking to seriously consider contracting out our research or analytical laboratory efforts.

There is an illustration where we've developed a successful collaborative relationship--industry, academia and center research--and that's the Moffit Center. We have in place very tight governing structure to oversee those alliances. But taking that to the field, I would have real pause.

RO: We have contracted with state agencies for some of the work, and you could divide or separate out the kind of analytical work--regulatory from your surveillance or information gathering--in which you wouldn't need to have the integrity of the sample carried through. A question though, when you're talking about NCTR, would it be strictly the research in the field that would be done there, or would it be the regulatory work as well.

JH: Right.

RO: The reason I ask I was involved back in 1970 when we first acquired NCTR, and Dr. Edwards was the commissioner. FDA was considering that some of the space at NCTR could be used by the field when suddenly it was decided not to have any regulatory work at NCTR, it was going to be strictly research. So that was the end of the field getting any part of NCTR back in 1970.

JH: Again, I think of it more as a concept of increasing the FDA presence, not necessarily increasing NCTR. I think you can still have the integrity of your different units while you foster appropriate collaborative efforts. If NCTR scientists getting "involved" in regulatory work means coming over and talking about new analytical methods, making their shared equipment available, there's a sharing of resources, but it is not necessarily converting either the regulatory scientist to NCTR or an NCTR scientist to be a field scientist.

SJ: There is a sharing of cultures, which is something that you've been talking about throughout your interview--encouraging sharing of cultures. This is a terrible topic, but I think that we're going to have to deal with this. So can you say a little something about the BST decision. It doesn't seem to go away. It seems to be a sound decision scientifically, but the public's not quite ready to let it go away. Can

you talk a little bit about how you got involved in it and what you've been doing with it?

JH: I have been involved in it more heavily last winter as we started looking at the issues in the GAO report that seemed to be yet unanswered. That's not exactly the case. There were events that preceded last winter's activities. When I first met with Gerry Guest, he said that was going to be a big decision for the center. I clearly knew that. I had met at least a time or two as the center was drawing to a close in terms of their review efforts and their comfort level with the decision that BST was an approvable project. We talked about the labeling issue in some of those discussions, but not nearly with the intensity that came about before the actual decision by the agency was announced.

Last winter, as we once again went through the GAO report to see if all the issues they had raised had been responded to, I was very heavily engaged with the center. It was the time during which Gerry Guest was about ready to transition, and Dick Teske was taking over. First, we had the advisory committee with CVM to look at this whole issue of mastitis, and drug residues, and the milk monitoring program. And then we went to the CFSAN advisory committee, the host committee with the CVM committee there as well when we looked at all of the issues related to labeling. After that meeting, it was clear that we still had some loose ends to tie up, that fundamentally the agency believed it was where it needed to be to make the affirmative decision that BST was approvable. With that, my interaction with the issue lessened as I turned my attention to other issues. Linda Suydam, from my staff, continued to provide continuity from our office and has continued in that regard.

It's unfortunate for biotechnology that BST was the first product through the gate. It is a product that is by and large one that has economic impact, but no apparent beneficial health-related impact, at least for this country. We clearly have populations in this country that go to bed hungry and children who may not be tied into strong WIC programs or the like that could benefit from milk products. These



problems are not going to be solved by BST. They can only be by a different point of action. It is unfortunate that BST was first, and that milk, that product that we associate with such wholesomeness, with some natural kind of goodness was the first biotech food product considered.

SJ: What about the labeling issue? Wouldn't it have been just as easy to decide, you know, go ahead and put it on the label?

JH: I think the precedent for the agency would had to have been very difficult, and the benefits would have been very minimal. It might have been a PR fix. If one realizes that the milk that you bought before BST ever happened has BST in it . . . I mean, that's a PR fix. That's not really a fix that I came to appreciate was there for any other reason.

SJ: Does it enhance the public's understanding of science?

JH: It doesn't enhance somebody's understanding or real choices. There are other situations in which those kind of labeling issues really help a consumer make a choice when there is a choice to be made. But in this case, it's not a choice. And yet, I do understand, at the core, what all the clamor is about--the not wanting your "natural" products messed with. It's something that a girl from a small rural midwestern town does understand. And yet, I don't necessarily know that there was a right or a better answer than how we did it. It's still in that wait-and-see stage as to how all of this is going to play out. Whether there is enough momentum for . . . that will really not have the agency reverse its decision, but having a company basically say, "This isn't worth it." In that case, you might have a reversal. I don't think it will be a reversal of the agency's decision.

RO: Consumers for a long period of time thought milk was one of the foods that was not manipulated. So you can understand why a lot of them are concerned about it.

JH: Yes, there was a tremendous public outcry when they started to pasteurize milk. And God forbid start selling things with words on it like homogenize. What does that mean? The other fallacy in this whole thing is that milk is so pure. Milk is so pure now because we have lots of processes that go into it. But my grandfather farmed and had dairy cows, and I remember going out . . .

(Interruption)

JH: . . . diseases that transmit through milk that came right out of the cow into somebody's mouth. We lose sight of that, and there's . . . That's just human nature. We don't always have very good corporate memories. We have lots of corporate amnesia. (Laughter)

SJ: Another issue I think the agency in the future is going to have to defend is its breast implants decision.

JH: How so?

SJ: Critics argue that the implants were either safe or not safe. They're not safe for cancer victims and unsafe for models. Many feminists, in particular, charged that the agency which traditionally didn't take women's concerns very seriously, had obviously been slapped in the face with them and rolled over and played dead, feeling sorry for one group and judging another group harshly. That's just in the plainest, you know, form that we've seen the criticism take. How would you respond

to something like that, that kind of criticism? Because I know on the inside it looks very different when you were making that decision.

JH: I think that is an easy conclusion to jump to that doesn't show a lot of insight and doesn't show a whole lot of sensitivity to women and their range of needs. I come from the perspective of being an oncologist.

SJ: Exactly, yes.

JH: One of the issues that women fear most in terms of the diagnosis of breast cancer is the whole issue of physical disfigurement, and it was one reason why it . . . It wasn't the pivotal biologic question that drove the studies, but as a byproduct of the studies that looked at mastectomy verses lesser procedure. Breast cancer was postulated to spread at a different time and in a different way than originally thought in the late 1800s. And so all of those clinical trials were set up to weigh that kind of theory. One of the very strong and wonderful outcomes, byproducts from those studies, was that women could have a lesser procedure than a radical mastectomy or even a modified radical mastectomy and maintain their breast. And so women have an option.

When faced with breast cancer, and the decision of lesser procedure versus modified radical, there are groups of women, whose decision I respect, who say I don't want to deal with any of this "bad" breast remaining, even if you say that by partial mastectomy or segmental mastectomy plus radiation you will have provided adequate primary treatment. They say, "I want it off. I want it out, but I also want it back. I don't want to look any differently." And those are legitimate feelings, beliefs, concerns, because it's not necessarily a right medical psychological decision to force everybody into a lesser procedure. For those women who want and desire their physical structure back, I think some accommodation by the agency was probably the reasonable one.

Cancer patients face a different kind of risk/benefit ratio than healthy women who are having breast augmentation. Women once diagnosed with breast cancer never return to the same mortality rate of women who don't have breast cancer. And so seeing them differently, seeing them as not whole, complete, healthy, 100 percent healthy women, has some basis. Potential exposure to an implanted device of some unknown but finite risk, they can weigh, if they are at least told that it is there, with a different level of the understanding and decision making, than a young eighteen year old, twenty-five year old, thirty year old, totally healthy who wants an augmentation. I do believe the populations are different, and therefore deserve a different risk/benefit equation. What the cancer patient needs and deserves is to be knowledgeable and involved in knowing what the risks of that implanted device are, and we didn't know. The agency told the companies to bring forth the data. And boy, when it was brought forth. Whew!

SJ: Just when things got started, yes.

JH: It wasn't there. What was there was the animal data, and then that no clinical studies had ever been done in women just blew everybody away. In my first meeting, I sat with these huge books, and I kept flipping to find the clinical trials. I thought surely they had been done; they'd been done by the plastic surgeons, but I just haven't paid any attention because I'm an oncologist. I was stunned. I mean, I was stunned.

SJ: Are there any . . . ? Let me quickly ask this: Are there any medical procedures for which a mastectomy is indicated now? In other words, not a woman's choice, but it would be done regardless.

JH: Well, there are women who have prophylactic mastectomies, because they're at high risk of breast cancer, but they don't have breast cancer. There are some very

disfiguring congenital diseases where women might desire breast implants. There are women who have traumatic injury, car accidents and the like, where you have tissue necrosis where an implant might be a desirable thing. Those would be the categories that would have perhaps a stronger rationale than the purely cosmetic--"I just want them. I want them because I want them." And yet the women, who came forward and testified, talked about their psychological trauma and whole wide range of issues related to psychological desire/need to have breast augmentation. I'm sure those are legitimate. However, they're very hard for me to put in the same kind of scale and have it come out the same.

RO: We had commented earlier on some of your other awards, and I see you have one here--special investigator. I think you were involved when the agency initially got criminal investigators on the force.

JH: Yes, I was.

RO: And do you think the agency really needed them? Was it just to satisfy Congressman Dingell? Or do you, in your own mind, really think we need them?

JH: I don't think I know the answer to that. I know the answer in retrospect. I don't know prospectively. I simply wasn't here. I don't know what all of the dynamics were that lead to that decision. There was a decision already made on which I needed to act. There was no turning back, in other words. I did get to play a part in Terry Vermillon's recruitment and listening to him talk about the kind of unit he would develop within the agency, the kind of people he wanted to recruit, the blending of the traditional criminal investigators (1811s) with the investigators from the FDA. I was fortunate to be part of that process.

Ron Chesemore couldn't have brought forward a stronger candidate for the position or a more sensitive candidate for the position with a sensitivity to this

agency's tradition, history, and culture. Terry probably wouldn't like himself described as a sensitive individual.

SJ: He's an investigator. (Laughter)

JH: He is extraordinary. He has really taught many of us what it means to have a criminal investigative unit, the kind of complement they can bring to the field force. They have really, I think to a person, been instilled with that, with a complementary role that they play with the FDA investigative staff--that it is a continuum that we have here. It is not a group. The agency now has a continuum of the investigative resources that it needs, and in the criminal investigators, we have recruited extremely talented people. That's thanks in large part to Terry and the kind of key recruits he made, the kind of cases they get here. They have established themselves as a critical force within the agency. Pepsi is probably the most notable, but I don't think it's their best case.

SJ: There are some better cases you're saying?

JH: There were better cases and earlier cases than that. I think the field understood that long before Pepsi ever started.

SJ: Oh, really?

JH: Pepsi was just a big, showy case that will result, you know, in a lot of convictions. The case down in Florida with the woman who essentially poisoned her children. That result was an attempted murder charge and conviction. There are numerous small cases like that. We've been building credibility for the unit all year long. Operation Gold Pill is another example. What I heard from the field was an acceptance of the criminal investigative units long before Pepsi.

RO: You see, Pepsi has been publicized. These others haven't been.

JH: Haven't, but they are well known internally. Internally was the group's toughest sale. I heard it when I would go out to the field. "What are these criminal investigators going to be about? Who needs them? We tried it before. It didn't work. Don't you trust us to do our business?" I was hit with those kinds of questions my first couple months when I would go out to district offices. I barely even knew that we were going to have a criminal investigative unit at that point, but I was getting nailed. No. Pepsi captured it for the external world, but the hearts and minds of the internal FDA field world were believers long before that. I really think so. The field is not ever swayed too much by the big, huge, showy case.

SJ: It's the finesse of the small cases, I guess.

JH: They're swayed by day-to-day hard work. If you can earn your stripes, they're going to punch your ticket. The criminal investigative unit, I believe, has had their tickets punched by their colleagues in the field.

RO: The majority of the people, I think, in the agency don't know about these other cases. The only thing they know about probably is this Pepsi case.

JH: Oh, yes. But see, that's headquarters. (Laughter) That's inside the beltway doesn't know. The field knows. They were the important group that needed to feel like their role was still valued and valuable. The criminal investigative unit could be extremely complementary to their work. I think they've got it.

RO: So you feel right now that the field has really accepted the criminal investigative unit.

(Interruption)

RO: On another note--why are you leaving FDA?

JH: On this week it's hard. (Laughter) It was easier when I said yes. We talked yesterday about where my career was headed when I got the series of phone calls and a visit from David Kessler. Last fall, I got a letter from the University of New Mexico from a chairman of the search committee, Dr. Eaton, telling me that I have been nominated as a candidate for a position that they were creating at the university, the vice president for Health Sciences. The letter described the position and asked if I would be interested in submitting my name in response to this nomination.

I did a lot of hard thinking about that. I have been very satisfied at the agency. I've been happy. I felt like I belonged here from that first day. Sometimes with new jobs you have to go through those periods of wondering, What am I doing here? I never had that. I felt an affinity for what I'd been asked to do and for the people that I was working with from the day that I arrived. And so this job has been easy. It's been challenging, but it's been made easy by those things.

As I looked into the New Mexico position, I realized it was a position that I've wanted in terms of its responsibilities. It's a public university and very progressive in education. The medical school is at the forefront of primary care, rural health and outreach efforts. They have a strong nursing school and pharmacy school, and a whole cadre of hospitals--university hospital, cancer center, rehab hospital, psychiatric hospitals.

It's a university unto itself. It is now part of a system. There's only one medical school and one health sciences center in the state, and it is this one. I decided to apply. In December I interviewed. I met the individual I would be reporting to, the president, whom I enjoyed immensely. My counterpart on the central campus is a woman I desperately tried to recruit to the University of Kansas



when I was there. I knew her and knew our working relationship would be strong. The deanship at the School of Medicine is retiring, so the vice president would have the opportunity to recruit their own dean.

For all of those reasons, I decided that this opportunity might not come my way again. I said, "Yes." It was difficult.

RO: Dr. Eaton was as persuasive as Dr. Kessler.

JH: Yes, he was. (Laughter)

SJ: Well, we wish you much luck.

JH: Sure.

RO: If there's anything you would like to add?

SJ: Do you have any last words of advice? You paved a new road for the FDA in some respects. Would you have any advice to your successor or any words about working with David Kessler?

JH: Words of advice for my successor. Usually successors don't want advice from their predecessors. (Laughter) My only advice would be to trust the people and have fun. The people in this institution are so strong and committed and have so much energy and such a strong work ethic you can't go wrong trusting them to do good things. You can't help but have fun. I mean, you can't help but be challenged. You're working with issues that are so important to people. Everyday you know you can leave this office knowing that you made a difference for somebody. It's a very satisfying and rich experience.

David has been marvelous to work for in many respects, because he has both respected and relied on my abilities. He knew what he wanted to do and what he does best, and for whatever reason, he knew what I do best. I think we were a good team. We're very different people, but I think we both brought our own talents and strengths to the agency. We both share the commitment and loyalty to this agency. Unfortunately, leaders, particularly at David's level, can be selected for a whole variety of other reasons. He is the political appointee, and people can get appointed for a lot of different reasons. I, on the other hand, was the chief career person.

There was a book written a long time ago. I don't even remember the author, but it's called *Dancing With Strangers*. It's about the relationship that the career people have with the political appointees. They come to their jobs with very different orientations. If they can find strength together it's a very powerful alliance. If they can't, it's the worst thing that can ever happen to an organization. You can just watch them being ripped a part. David and I were more in the former category than in the latter. Although, there were a few times when we didn't quite see eye to eye about things. (Laughter)

RO: We want to thank you very much, Dr. Henney.

JH: Oh, it's been a pleasure.