

History
of the
U.S. Food and Drug Administration

Interviewee: Nancy Ostrove, Ph.D.

Interviewer: John P. Swann, Ph.D.

Date: June 14, 2013

Place: Silver Spring, MD

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

National Institutes of Health
National Library of Medicine
Bethesda, Maryland 20894

Deed of Gift

Agreement Pertaining to the Oral History Interview of

Dr. Nancy Ostrove

As a conditional gift under Section 231 of the Public Health Service Act, as amended (42 U.S.C. 238), and subject to the terms, conditions and restrictions set forth I, Nancy Ostrove, hereby give, donate and convey to the National Library of Medicine ("NLM"), acting for and on behalf of the United States of America, all of my rights and title to, and interest in, the information and responses provided during the interview conducted at FDA, White Oak on 14 June 2013 and prepared for deposit with the NLM in the form of recording tapes and transcripts. This donation includes, but is not limited to, all copyright interests I now possess in the tapes and transcripts.

Title to the tapes and transcripts shall pass to the NLM upon their delivery and the acceptance of this deed by the Director, NLM. The director, NLM, shall accept by signing below.

The NLM may provide for the preservation, arrangement, repair and rehabilitation, duplication, reproduction, publication, description, exhibition, display and servicing of the tapes and transcripts as may be needed and appropriate.

Copies of the tapes and transcripts, may be deposited in or loaned to institutions other than the NLM, including the U.S. Food and Drug Administration. Use of these copies shall be subject to the same terms, conditions, and restrictions set forth in this agreement.

The NLM may dispose of the tapes and transcripts any time after title passes to the Library.

Date: 6/14/13 Signed: Nancy M Ostrove

I accept this gift on behalf of the United States of America, subject to the terms, conditions and restrictions set forth above.

Date: 6/14/13 Signed: Nancy M Ostrove
Director, National Library of Medicine



CASSETTE NUMBERS: 2

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

DATE: 14 June 2013

PLACE: Silver Spring, MD

LENGTH: 2:21

INTERVIEWEE:

INTERVIEWER(S):

NAME: Nancy Ostrove, Ph. D.

NAME: John Swann, Ph.D.

ADDRESS: Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

FDA SERVICE DATES:

FROM: 1989

TO: 2011

TITLE: Director for Risk Communication, Office of Planning, Office of the Commissioner

INDEX

<u>Tape</u>	<u>Page</u>	<u>Subject</u>
1A	1	Growing up in New York and early education
	3	Graduate and postgraduate education, research on stress management at the Montgomery County, Maryland, Police Department
	5	Washington area social science contract research work, investigations for the Center for Social Research and Policy Analysis in North Carolina
	8	Initial contacts with FDA, tradition of consumer studies at the agency and CFSAN
	11	Arrival at the agency in 1989 to work under Louis Morris in the Drug Labeling, Education, and Research Branch, predecessor of the Division of Drug Marketing (DDMAC)
	13	Early study of Dilantin labeling, work on risk communication in patient labeling of prescription drugs (patient package inserts) and the roles of AMA and the National Council on Patient Information and Education (NCPIE)
	15	Efforts in the branch to study prescriber package inserts/labeling, how labeling is developed and roles of manufacturer and FDA
	17	How communicators in DDMAC and its predecessors interacted with medical officers and others in review offices in the development of product labeling
	21	Research and recommendations in DDMAC study of prescriber labeling for various medical products, cont.
1B	30	The rise of direct-to-consumer advertising (DTC) of prescription drugs from the 1990s forward and FDA oversight, promotion via reminder ads
	41	Drug advertising on broadcast media, fair balance concerns, development of guidance document ca 1997
	48	Problems with enforcing DTC ads, off-label promotion of drugs, change in

		enforcement philosophy
	50	Move to Eli Lilly in 2002 to develop promotional strategies for products, pre-clearance and how FDA interacted with manufacturers on promotional matter
	53	Monitoring ads for possible problems
	54	Challenges of regulating advertising and labeling on products sold via the internet
	56	Return to FDA from Eli Lilly as Director for Risk Communication and the role of Theresa Mullin
2A	58	Integration of risk and benefit communication across the agency in all the ways it communicates, the case of the FDA/EPA notice about methyl mercury in certain fish consumed by pregnant women
	64	The role of social scientific research in decisions on labeling of genetically engineered food content
	68	Formation and role of the Risk Communication Advisory Committee (RCAC) and The strategic plan for risk communication at FDA
	71	On FDA incorporating risk communication (cont.), contributions of the RCAC (cont.)
	74	The FDA Communications Council
	79	Reflections on the role and impact of social scientists in different parts of FDA
	83	Teasing out availability bias in social psychological research
	85	The value of qualitative and quantitative research
	89	End of Interview

Nancy Ostrove

June 14, 2013

TAPE 1, SIDE A

JS: This is an oral history with Dr. Nancy Ostrove. The date is June 14, 2013. I'm John Swann, and this interview is taking place on the FDA campus in Silver Spring, Maryland.

And, Nancy, thanks for joining us. I really appreciate this opportunity to go back over your career and work you've done for the agency.

NO: I'm looking forward to it.

JS: Well, what we try do as we start these is to get some perspective on your own background. Obviously, we're primarily interested in your work here at FDA, but, of course, that didn't exist in a vacuum. You had a rich background before you came to the agency, I think almost a dozen years, 10 or 12 years from the time you got your Ph.D. and you arrived at the agency. So I wondered if we might just start with where you grew up, what your parents did, and how you originally got an interest in the field that you ended up in.

NO: That's a good question. That last one especially is a really good question.

Actually, I grew up in, mostly in New York City, actually in Queens, which some Manhattanites would say is not the city. Also, my husband is from the Bronx. And my parents were middle-class. My mom was a stay-at-home mom, as many were in the '50s, until my brother and I were in school all day long, and then she went to work in retail sales. My dad was a troubleshooter manager for Chock Full of Nuts, which -- my whole family actually was involved in Chock Full of Nuts. One of my uncles was president and co-chair of the board; another one ran the bakery. My grandfather helped build the first store; he was a carpenter. And I worked there one summer. Kids nowadays don't know about Chock Full of Nuts except for the coffee. They didn't realize there was a luncheonette on like every corner in New York, in Manhattan, just all over the place.

Nonetheless, my parents encouraged me to go to college, which I did at a State University, because we really couldn't afford much more than that, and I ended up getting my graduate degree in experimental social psychology from the University of Maryland at College Park. So I actually started living in this area starting around 1972. After getting my degree, I moved out to Ohio and

taught for a few years at a small liberal arts college called Lake Erie College, in Painesville, and discovered that I really didn't belong there. It just wasn't the right place for me. Academia was not the right place.

And my husband, who I'd met in grad school, and I moved back here, and I took a postdoctoral fellowship with the Uniformed Services University of the Health Sciences and was there for about a year and a little bit more, doing research, well, planning research mostly, because it was very difficult to actually get the funding and do it in that short period of time, but working in the area of the consequences and antecedents of stress. So, yeah.

JS: Well, that actually played in quite well to your next position.

NO: Next position, yeah, that's right. I was on some soft money with the Montgomery County Police Department. They were setting up a stress management program, and the woman who they selected, the clinical psychologist, to run that was looking for someone to do some initial research. So I came into that position and I put together what was basically a canvass of the department about antecedents and consequences of stress, surveying both the officers and the civilian population about the stress that they felt and various potential physical consequences of that, basically

how they were feeling and that kind of thing. And the interesting piece of that was that, if you really looked at the results about how people felt physically and psychologically, the people who were under the most stress, despite the fact that the police officers were on this kind of changing around-the-clock schedule, the most stress seemed to be experienced by the civilian employees. They were second-class citizens. So it was really kind of a clear demonstration of job conflict, and it was very interesting, it really was.

JS: It makes complete sense for a place like a municipal police department to do something like this.

NO: Yeah, a quasi-military kind of thing.

JS: So I assume this was not such an unusual thing to bring on someone with a background like yours. But do you know if they took your recommendations and applied them in any way?

NO: No, I really don't. You know, I was there for a fairly short period; I think it was less than a year. The major reason they had wanted that office was to provide psychological counseling for the officers, and they got that from the director of the office. So, once we had done this kind of initial research, I'm not sure that they really did anything more. And I know that the Prince

George's County Police Department also had, again, a clinical or a counseling psychologist who worked with them. So it was a big thing at the time, you know, recognizing the stress that that kind of life and lifestyle has on the officers and trying to make sure that they don't, that it doesn't harm them or the public.

JS: But quite a change in your career after that.

NO: Oh, yeah.

JS: Even though it's a short period, but quite different than working at USUHS or, before that, at a small liberal arts college.

NO: Oh, yeah. I like to say I had a checkered background before I came to FDA. Seriously, I never thought I'd be at FDA more than a few years because I took these short-term positions. After the police department, I started working for a contract research firm downtown, and so we did survey work, we did whatever basically needed to be done. I did that for a while, and the firm is no longer in existence.

Then I had a baby, took a little bit of time. The interesting thing about that is that I was out of work for a while, and my husband took a plane ride and ended up sitting next to one of our colleagues from grad school, who said she was looking for someone to work with her. She was

at Porter Novelli. And Paul said, "Well, Nancy's not doing anything." I mean, I helped write a chapter for a book, but it's true, I was being pregnant and kind of getting unemployment at that point, looking for a job but probably not as hard as I should have been.

So I started working for Porter Novelli in my sixth month of pregnancy, I think, going downtown to Georgetown. Porter Novelli was smaller at that point. And then worked up to the point where I really couldn't just get down there in the summertime. My son was born in October. Actually, I did work all through the summer and took off a couple of weeks before my son was born, and then worked part-time for a while for them.

And my husband -- we basically tried to ensure that we, either one of us had some time with the kids. So, for me, it was our son, and I was home with him and working part-time for the first few years. We moved down to Durham, to North Carolina, because my husband got a job with Duke, with their talent identification program, and I started working with Research Triangle Institute.

JS: This would be the Center for Social Research and Policy Analysis.

NO: Right, that's correct. And they do a -- well, I don't know if they still do it, but at the time they were

doing kind of this yearly survey for the Department of Defense, called YATS for short, Youth Attitude Tracking Survey. It was basically to find out where the youth were, to help in terms of recruitment, retention, that kind of thing, for the Department of Defense. So I basically worked half-time interpreting the data that came back from the YATS survey, incredibly boring work, just writing up tables, and oh my God. But our son went to a little Montessori half-time, and it worked out, because then I could be home with him part of the time, and he could get his social skills and stuff in. And then I got pregnant at the same time we decided we were going to be moving back up to Maryland because we didn't feel we really fit in very well in North Carolina, in Durham, at the time. We probably should have moved to Chapel Hill. It just kind of . . . But we didn't. We were kind of on the outskirts near Research Triangle Park, and we just felt -- it's a very Christian area and people were really, they were praying for our souls. It was . . .

JS: It was nice of them to do that, wasn't it.

NO: It was very nice of them; it's extremely nice of them. But we just didn't fit. Maybe it was coming from New York and having lived in relatively cosmopolitan areas most of our lives.

But, in any case, we came back here two weeks after I had, two or three weeks after my daughter was born.

JS: Was there something you came back to?

NO: My husband was working with the Urban Institute at that point. He left Duke and went to the Urban Institute as a senior scientist. So I had actually been talking with some FDA people in Foods, Jim [Heimbach] -- I can't remember Jim's last name.

JS: Was FDA on your radar before this time?

NO: Not really, no; I really hadn't thought about it very much. And I can't even remember how I ended up talking with Jim about the Foods position. I can't remember his last name.

JS: We'll fill this in.

NO: Yeah. But the Foods Center has always had a group of people in consumer studies, and they've been always very aware of the need to understand consumers to a much greater degree than any of the other centers in the FDA at that point. And they were doing some very interesting stuff.

JS: Certainly there's a consumer consultants program that started in FDA, what now would be the field public affairs specialists.

NO: Yeah.

JS: And this is a very good point you make, because that started in the early 1950s, about 1952 or so, and at that time, if I remember right, they were actually recruiting information from the outside, not the other direction as they do now.

NO: Right, right. That's right.

JS: And their initial interests were in foods products like bread and so on.

NO: Yes. And my belief is it's because of the difference in the statutory requirements and the regulations, because most of the medical product piece of what FDA does is premarket approval. Now it's a lot fuzzier in devices, but in terms of drugs and biologics and even vet med, you know, there's a lot of premarket approval stuff, and you have control over labeling. But when it comes to . . . Well, again, it's a little iffier in terms of devices, but when it comes to foods, everything is post-marketing, almost, except for the color, the additives.

JS: The additives are different.

NO: Yeah. But there's not, that's not the biggest thing. And there's just so much with respect to history, with regard to nutrition, and how, and the nutrition facts panel, that labeling was really, it was, at least a lot of it, an attempt to communicate better about what the foods

that we regulate, so to speak, are giving to the public. And in order to do that, they recognized, which I think is a fantastic thing, that you really need to understand the public. Again, not something that really was in the medical area, where the focus was very different; post-marketing versus premarketing. That's my theory.

JS: So it makes sense for your initial contact.

NO: To be with that group, right. But I don't remember how it actually happened. I may have seen an ad somewhere, but that doesn't seem right. I just don't remember.

JS: This was a time, though, that we're looking at issues. As you said, the food label, and that planning certainly started in the late '80s. Right?

NO: Mm-hmm.

JS: And this is . . .

NO: My daughter was born in '87.

JS: Right. So, 1989 is when you arrived at FDA, but not with Foods.

NO: Not with Foods, no, no. And this I do remember. There was an ad in the *APA Monitor*, the American Psychological Association *Monitor*, you know, this little kind of newsletter that people get, and I was still getting the *Monitor*, and I saw this ad for FDA, so I applied. I

mean, so, usually you don't get jobs through applying from an ad. That's kind of common knowledge. You always get jobs through networking. Well, I got this through replying to an ad in the American Psychological Association *Monitor*, and I spoke with Lou Morris, Louis Morris, who was the Branch Chief for the branch that I ended up in in the Center for Drug Evaluation and Research, and Lou had been doing a lot of work with patient labeling. That was his thing, had been since the early '70s, I think. And we just, we hit it off. It seemed as if my background was consistent. Lou was also a social psychologist by training. So they offered me the job.

The interesting thing was, I had been offered a job with the Foods group a little before that, which I ended up turning down because my husband and I decided we would switch. He had this commute downtown, it was long, he was doing a lot of traveling; we had two young children at home. So we figured give him a break, he would take primary caretaking responsibilities, which in those days was not as common as it is now, and then I would go back to work full-time. But going all the way down to where Foods was at the time, in FOB8, that would have been an even longer commute than the one that he had. So we decided not to take up that particular offer, and instead . . . So I

already knew that FDA was at least doing some of this work, so I guess when I saw the ad in the *Monitor*, it was like, oh, try that.

JS: Did Lou Morris have a reputation in the field that you were aware of?

NO: I don't think I knew Lou before I came here. I mean, he certainly did have a reputation in the field. He had done a lot of work in patient labeling. Lou is an academic at heart, and he's phenomenal. I mean, I can't say enough good things about him really. He's very good. In fact, my husband had worked with him at one point because my husband also was in contract research and had done some work with FDA, and it ended up being with Lou. That was interesting. But we didn't even realize that when I first started talking to FDA about this job.

JS: So you started as a senior staff fellow. Your first position was the Drug Labeling Education and Research Branch, the predecessor of the Division of Drug Marketing, DDMAC.

NO: That branch, plus there was another branch, the Drug Advertising Branch. They together formed the predecessor. So the division was actually the Division of Drug Advertising and Labeling, and that was the branch within it.

JS: So, initially what were you doing?

NO: Looking for research I could do. We actually did a little piece of in-house research, looking at physicians' perceptions of Dilantin. It was one of the first pieces I did, and we had one of our internal people calling physicians and doing interviews over the phone. There was an issue with long-acting versus short-acting and potential problems with physicians perhaps not understanding the switchover from a long-acting to a short-acting form, or maybe it was the opposite direction. I can't remember exactly. But that was one of the first things I did.

I was also looking at risk communication, believe it or not, as it relates to how we were communicating in the - not patient labeling- the patient information. There's a whole history that it would be better to talk with Lou about concerning the evolution of patient labeling for prescription drugs.

I came in in the middle of that, essentially, because at one point there had actually been a regulation that FDA had put out -- I think it was in 1980; that was before my time -- that would have required mandatory patient labeling, as kind of a pilot program, for a set of 10 drugs or drug classes. And then in 1982, that regulation was withdrawn or revoked -- I'm not sure exactly what the

terminology is for it -- with the understanding that the AMA was going to provide patient labeling for their doctors to give out at the point of prescribing, and they had formed NCPIE, the National Council on Patient Information and Education, and I think it was Ciba Geigy at the time had promised, and gave a million dollars to help fund NCPIE, and the whole thing was, let the private sector do it.

JS: This is, of course, kind of playing on this somewhat controversial issue, I suppose, history of patient package inserts.

NO: Patient package inserts, yes.

JS: That, of course, started with an asthma inhaler in the very late 1960s, but, of course, with inserts for oral contraceptives . . .

NO: Oral contraceptives and then estrogen-replacement therapy, yeah, exactly.

JS: You're getting involved from the get-go in some very interesting subjects. I mean, you're studying a 50-year-old anti-epileptic and also getting involved in patient labeling, something that certainly many people have very strong opinions about whether it's the AMA or patient groups.

NO: Or pharmacy groups.

JS: Or pharmacy groups.

NO: Actually, patient labeling, the only groups that really consistently supported patient labeling, at least up until recently, were the patient groups, so that was interesting.

And then the other thing we were doing is Lou and I were looking for money so we could do some more, get some research done. And I said -- I don't remember whether it was me or it was Lou; it was probably Lou -- labeling has never been evaluated -- the value of labeling; not patient labeling itself, but just the package inserts. So we wrote up a little piece for Carl Peck and Gerry Meyer, who were the heads of the Center at that time, and we sent that to them. And Gerry, I think it was Gerry, ended up giving us some money to do an assessment of labeling, of the package insert. So that was the other thing that I got involved with at a very early stage.

JS: And when you say package insert, are you talking about the prescriber insert?

NO: Yes.

JS: And traditionally, for those that aren't familiar with how product labeling, any kind of medical product, that's something that's arrived at maybe in different ways depending on the nature of the commodity that's being

regulated. So, our medical officers, they're having input into that decision, right? Or not?

NO: What happens is the manufacturers draft the labeling. I mean, they do it, and then it comes to FDA, and then it's a negotiation process. So, yes, the medical reviewers have an incredible amount of influence over labeling. The manufacturers do as well. And it's this negotiation process that is a black box to the public. And, in fact, in some of the early work that we did, was we did some focus groups initially to help us design a national survey of physicians about their use and perception of package inserts for prescription drugs. And more than one physician in the focus groups would say, "Oh, I don't pay any attention to the package insert. That's just the manufacturers' promotional deal." If you would tell that to an FDA reviewer, they would probably get red in the face and apoplectic, because they put an incredible amount of work into that. Everything that's in that label, that's supposed to be kind of the state-of-the-art of the knowledge about that particular product, at least at the time that it's approved. After that, you may find out more, it may end up in labeling, it may not. Again, part of it's up to the manufacturer. What happens when it goes generic? Nobody's got the money to research it further,

and there's no profit motive to do it. And, in fact, even for the innovators, there isn't necessarily a very good profit motive for doing a lot of research, which is why you saw the [Best] Pharmaceuticals for Children Act. Give them something; give them extra time on the patent before the drug goes generic so that they'll do some research to see whether in fact this is something that is useful or bad for kids. The profit motive kind of ends up being behind a lot of stuff that goes on.

But getting back to . . . Sorry, I go off on tangents.

JS: That's okay. But I think it would be interesting to find out maybe a little bit more about how this branch interacted with review divisions when it comes to labeling issues. The reason I ask is, we have people that bring very different skill sets to this very important issue that the agency is facing. We have, on one hand we have medical reviewers and others who have their own way of looking at what's important in a product; and, on the other hand, we have other professionals who know a lot about communications and how that can be brought to bear in sharing this very important information with prescribers or with patients. And this is something that, of course, plays out throughout your career here in many different

ways, both in this early stage, the first part of your FDA career, and then in the later one too, when we start talking about risk communications. I don't want to get ahead of the game here, but if there's something you'd like to speak to with respect to your early introduction to FDA, and maybe, did the interactions play out in a way you expected them to when it comes to labeling issues? We'll get to other issues, advertising and so on, later. But I'm just curious how that worked out.

NO: One thing that I learned here is that it's like we always said that the industry is not monolithic. FDA is not monolithic either. When I first came in, it seemed like it was a whole bunch of little turfs, and depending on who was the head of the particular office in terms of the Office of New Drugs, for instance you get very different ways of approaching things.

When I first started, as I said, we had two very small groups. There weren't enough people in either of those small groups, or even in the medical review groups, to make sure that there was sufficient communication between our division and the medical divisions in terms of labeling. I mean, certainly this was something that was recognized by all the people in what eventually became DDMAC. Obviously, the labeling is the crux. It's the basis of all the

judgments that are made about promotional materials. You use the labeling as the basis. Promotional materials need to be consistent with labeling, and they can't be false or misleading.

So, that gets now to more of the regulatory stuff that I got involved with, as opposed to the research. And I did; I got involved in the regulatory stuff, especially when it moved into the patient arena, the consumer arena. But I think that the reviewers in drug advertising and labeling tried their best to give their feedback to the medical reviewers about how labeling could be used to justify promotional material that the reviewers would not want to see. So you have to be very careful about the wording in the labeling. Okay?

But they weren't necessarily, I don't believe that they were necessarily communicators. Most of the people, almost all of them, except, before me, there was Carrie Baum, but beyond that, all of the people in the regulatory groups really were pharmacists; so they're scientists also. They don't necessarily understand how people interpret stuff. So I think there has been that constant kind of tension between the scientists and the communicators.

But the communicators were this little tiny group that we had of social scientists; there were just a few of us in

Lou's group. And then the pharmacists, they'd look at the information and labeling very literally. But even looking at it literally, they often came up with some very good recommendations. For instance, they'd say don't say it this way, because if you say it this way in the labeling, they'll be able to do this in the promotional stuff, and we don't think you want that." Okay?

Now, as time has gone by, that group, which became DDMAC and now it's the Office of Prescription Drug Promotion, got more and more respect, and ability to have a seat at the table with respect to labeling negotiations.

But I do have to say that, when I was involved, it was very difficult for me as a communicator to overrule a medical officer -- to say, "no, they're not going to see it that way." Some of the medical officers really wanted to hear what we had to say, and some of them said, "Hey, I know how people think. I'm a doctor, and I know how the doctors are going to interpret this." You know, just because you're one doesn't mean that you know how everybody else thinks. That's one of the basic tenets that you have to take away from risk communication research -- don't assume you know how your target is going to interpret something. You need to find out, you need to actually ask them, because even the experts make mistakes. So there has

been an evolution, I think, over the years, and it's so much better than it was -- I think it is anyway. By the time I left DDMAC, which was in like 2002, it was better than what it had been when I first started.

JS: Well, when you started, did you and others in your group, the social scientists, were you able to carve out time to do research, to understand how physicians, how patients, how others think about labeling?

NO: Well, that's what Gerry Meyer gave us this money to look into with respect to the physicians, so it gets us back to the previous conversation. We did these focus groups, and then we did a national survey of physicians, which I have to tell you is not an easy thing to do, and don't even get me started on OMB and the kind of hoops you have to jump through in order to do this kind of research in the government, especially within a regulatory agency. But we did manage to do that.

And then the results we got back from that survey; coincidentally, the timing, it's like all the stars came together, because we had the money for the research, and at the same time, I think it was Jane Hennery was Commissioner, she had this real interest. This was after David Kessler was gone, and she had this real interest in labeling, and Mac Lumpkin in CDER did as well, with Janet's

[Woodcock] support, and then Bruce [Burlington] over in Devices. Everybody got interested in labeling. And we, coincidentally, happened to have this survey that was just about to go out, so we got asked to the table, partly because Lucy Rose was our Division Director at that point, and Lucy was married to Mac. So Lucy heard what Mac was doing, and she said, "Well, you ought to have Nancy and Lou come talk to your group about this," because they were interested in revising labeling. We said, "Whoa, whoa, before you start revising stuff, let's see how it's actually being used and what the perceptions of it are." So we got all this support for doing this, and the research actually had an audience that was eager to hear about what it was. And Mac Lumpkin especially was just incredibly supportive of this. He was Janet's deputy at the time.

At that point, DDMAC had become part of the Office of Medical Policy, because of a lot of things, but I suspect partly because it couldn't be under Mac and Janet directly because Lucy was Mac's wife. So, instead, they had this Office of Medical Policy that Bob Temple headed, so we reported to Bob, and then from Bob to Janet. But it wasn't a direct line.

JS: Well, it's not a stretch, though, to put something like this under Policy.

NO: No, it made perfect sense, actually, to do that. And both our group and the Division of Scientific Investigations ended up being under Medical Policy, and the Office of Drug Standards was abolished.

So, where were we?

So, we had this research, this survey, and there was interest in it across all the medical product centers, Biologics and Drugs and Devices, and Vet Med as well. But it was mostly being driven by Drugs, and Drugs is the biggest group, and Devices, as I said, has very interesting issues around the degree of control it has over labeling. But there was a woman, Pat Kingsley over in Devices, who worked with us. We had basically kind of an internal working group. We even had put together a Project Advisory Group of outside people. We wanted to make sure that this was done well and the results would be accepted.

And what we found basically is that physicians use the labeling as a reference. They would go to it when they had questions mostly. They'd go to it when it was new, it was a new product. They'd read it once maybe, and then would consult it if they had a pregnant woman, someone was having a side effect, if that needed to find out whether they had tablets they were scored -- as a reference piece as opposed

to as a real educational piece that you would look at, thinking, well, things change over time.

And given that, and also looking at learning theory and all the stuff that I had been trained in, labeling wasn't laid out right to do that. And it had become so long and unwieldy because of liability concerns and because the state of the art had changed around knowing information about pharmacokinetics and pharmacodynamics. But there was no reason for that information to be all the way at the beginning, which is what the regulations had it as. All the clinical work, the pharmacodynamics, the chemistry, all of that was at the beginning. That's not what the docs were looking for. They rarely looked at that. So we found out how you could improve it, and then we decided to do that.

JS: What did they look for first in the labeling?

NO: How supplied, often, which was in some ways very good. It was at the very back. But if you were looking, for instance, for indications. And dosage; they looked for dosage also. And dosage was an issue because you first had to plow through, you know, page through the entire clinical pharmacology section before you would get to the indications and then the dosage. Right? So we reordered it.

But the other thing was that it was so hard for them to find what they wanted that we found out in the research. They said that there was stuff that they were looking for that wasn't in there, except it was in there: like drug interactions. The drug interactions are in there, but some people said they couldn't find them.

JS: Why? Because they're buried under . . .

NO: Because it was all buried.

Again, if you look at it from the perspective of learning and psychological principles, there's a primacy effect, there's a recency effect, so things you see first you remember better, and things you see last you remember well. But the stuff that's buried in the middle, that tends to kind of harder to find.

So we decided, well, I mean, it made sense to have a highlight section because the physicians told us that it was too long. I won't use the word that they used. It was too long. Mac pulled me out of DDMAC for a couple of weeks because I was not getting to putting together a prototype of a new, of a revised label, which is what we wanted to do based on the research we'd done. So he pulled me out on a detail, put me in an office, and said go and do it now. I had to get away from all the other stuff I was doing, and I just couldn't. At that point I think I was a Branch Chief,

so I was doing management and there was direct-to-consumer advertising, there was all kinds of stuff going on.

So I put together two prototypes. One was about a page long, including a highlights section -- we may have called it a summary of prescribing information -- and then a table of contents. And we didn't call it a table of contents; we called it an index. I put one that was a page-long, and one that was a page and a half. We ran two additional focus groups, and they said the page-long one was okay; the page and a half, they got angry at. And that was just for the summary, I think. It was just the summary that was a page or a page and a half. They actually said the page-long summary was too long, but they got angry when we showed them the page and a half, and said, "Oh, that's not a summary."

So we went back and put together a prototype with a half-a-page summary and half a page of this "table of contents," which reflected the revised order, and then brought that to a public meeting. We presented it to the public and put out basically a request for comments before we even did anything like putting out a Notice of Proposed Rulemaking. And then, after we got those comments back, we put out the Notice of Proposed Rulemaking.

JS: This is fascinating.

NO: It is, isn't it.

JS: One question that occurred to me is, in your research, how was it that that original framework existed the way it was? Why was all of the clinical material and so on front-loaded? That wasn't in the law.

NO: Yeah, it was in the law. No, it was in the regs. It was in the regulations, not the law.

JS: But why?

NO: I can give you a suspicion only, a speculation.

Carl Peck was a clinical pharmacologist, and I believe Carl was kind of at the helm -- I think, I'm not positive; we'd have to check the dates -- when that went through. Basically, people decided this was an educational document. So, how do you do science? You start with the basics. Right? You give everybody the basics, and then you go to the rest of it. Well, the basics is the clinical pharmacology, except it's not the basics for the docs. They don't care about it.

JS: It's the basics, I suppose, if you look at it as that type of document, but that's not the type of document that the receivers were expecting.

NO: Right. It was, that document was trying to fulfill so many different purposes that it didn't fulfill any. Well, it might have fulfilled the liability one, and

certainly for specialists, they were much more likely to like the clinical pharmacology being easily accessible. But they're not everybody, and certainly the general, the primary care practitioners, did not like that being in the front. So now it's toward the back, but it's easy to get to. Because you've got the table of contents at the beginning, you just go to section 18, 19, whatever the section happens to be. You know where it is. And nowadays especially The highlight section and the table of contents were put together with the thought of hyperlinkages, you know, that people will be getting this online more and more often, so you just have to click on something and you take it there. Well, the way that we put it together was kind of the paper-and-pencil analogy of hypertext linkage.

But the question still becomes, are people, are they using labeling?

What we intended to do was a three-part piece of research. It was going to be the focus group exploratory piece, and then the survey, and then we were going to have an evaluation, come up with the prototypes, and then we were going to do an experimental study that would actually bring in physicians and have them look at different formats, using a 2x2 design -- I don't want to get into a lot of details about it, but basically an experimental

study that would expose people to different versions of a potential new labeling format, and then see what they felt would be best for them.

But the money went away. You only have the money for five years, and it just took too long to get to the evaluation part. So we went with what we thought was best, and given all of the public comments that we'd gotten, and then, of course, went to proposed rulemaking. And I was gone from the agency, actually, by the time it was finalized.

JS: But prior to the proposed rule, what was the outcome of the research itself that you did?

NO: The research? Well, we presented it at the public meeting, so there were PowerPoint slides and everything. Lou and I wrote a paper. Okay? I couldn't get it through our system. I could not get it through; I couldn't get it past Bob.

JS: So the paper that you and Lou Morris proposed publishing as a result of this research that would reorient labeling, that didn't make it through the vetting process in the agency.

NO: No, no. At that time it was very difficult to get papers through. And I love our upper-level boss; he's wonderful and smart, incredibly, and an often charming man,

but I just couldn't get it through. It hit a black hole. So, that's that.

JS: But the proposed rule went out. The final rule eventually went out.

NO: Yup.

JS: You had moved on by that time.

NO: I had moved on. Frankly, I was burned out and I needed a sabbatical, and I didn't realize that at the time, but I realized that I was burned out and I couldn't stay, so I left. I was at Eli Lilly in reg affairs for a year and a quarter, and then I came back.

JS: And I don't want to burn you out more over this initial period in the agency, but there's something else I want to discuss about this. And, by the way, if you want to take a break, we can do that if you'd like to.

NO: Is this for me?

JS: That's for you, yes.

NO: Oh, cool. That's water, by the way.

JS: But it's a very interesting time to be in DDMAC and in the precursor to DDMAC, for many reasons, not the least of which is what you've just talked about, but also because this is the rise and the explosion of direct-to-consumer advertising.

NO: Oh, yeah.

JS: Which we'll just say, there had been a moratorium on direct-to-consumer advertising in the early 1980s but those came back on the scene I think around 1985.

NO: '83 to '85, thereabouts.

JS: '83 to '85. And another oral history that we have with Ken Feather talks a little bit about that.

NO: Yes. Oh, yeah. Ken and I might have different perspectives.

JS: Good, excellent. But certainly, direct-to-consumer advertising is absolutely nothing like what we see today. But in the late '80s and in the early 1990s, these start to increase.

NO: Mm-hmm.

JS: But we're also seeing issues when it comes to advertising that prompts some pretty important cases.

The agency gets consent decrees with a couple companies over misleading ads. One is Syntex, with Naproxen ads.

NO: Right. Those weren't DTC, though.

JS: Those weren't, that's right. Those weren't direct-to-consumer ad problems.

TAPE 1, SIDE B

JS: As I was saying, there's more money being poured into this by the industry. At least according to one report, by 1993, 23 cents, almost a quarter of every dollar that that industry was spending on drug development was put into promotions. This is according to one publication. And even the Federal Trade Commission is looking into direct-to-consumer ads, even though FDA, since 1962, has the responsibility for regulating prescription drug advertising. An attorney with FTC at one meeting, in a Drug Information Association meeting, says, "Well, this is something that the Federal Trade Commission is starting to look into." And certainly the American Association of Advertising Agencies was advocating for removing direct-to-consumer advertising from FDA to FTC.

NO: Oh, yes. Okay.

JS: Interesting development.

NO: They'd much rather have FTC do it!

JS: But certainly groups like PhRMA, the Pharmaceutical Research and Manufacturers Association, still feels very much that these ads are empowering patients or so they say. That's why these are so important. They empower patients. But you yourself were quoted around the same time as saying, "Well, we're concerned. The agency is concerned about whether these are

encouraging inappropriate prescribing." And so, among the many things on your plate in this long period, from 1988 to 2002, at which time, by 2002 you're the Deputy Director of DDMAC before you leave, but throughout this time, obviously direct-to-consumer advertising is one of the things on your plate.

NO: Oh, gosh, yes. It was one of the biggest things on my plate; frankly, the biggest thing on my plate.

JS: So, how is it that this advertising came to be as huge as it was, and, I mean, the agency was getting concerns about this from Congress, from others, from consumer organizations, from the industry who were supporting these. How did we deal with this phenomenon of direct-to-consumer advertising for prescription drugs?

NO: Again, some of this is going to be my making statements that I don't necessarily have data for because it would be very difficult to get the data. But here's the thing. The moratorium was voluntary. There was never anything in the law that forbade direct-to-consumer advertising of prescription drugs. But people got nervous, so they asked industry to back off, to give the agency a little bit of time to investigate it. And, in fact, Lou was involved in some audience testing of direct-to-consumer, of kind of mocked-up ads and such. My

recollection of the results of that is that there were three- and four- and five-way interactions that are almost impossible to explain. I'm not sure where we got from that. But, okay. So, there wasn't very much because there was this voluntary moratorium. And, frankly, the industry was never monolithic in terms of their perspectives about DTC advertising. Some of them wanted it, but a lot of them didn't. They saw it as opening up a can of worms that might be really problematic. So there were a lot of companies that said let's stay away from this, but there were others that really wanted to jump into it.

I think that what happened was that the environment changed considerably, and this is what I said in presentations years ago, that the environment moved toward being much more consumer-focused, consumer-empowerment, which is consistent with what some pharma companies may be saying now. But it was basically that people were learning to use 800 numbers to get information about products. It wasn't quite the age of the Internet yet, but we were moving in the direction of people taking, saying, at least, that they wanted to take more responsibility for all kinds of things, including their healthcare. So there was that piece of it.

And then there was managed care, and managed care I think made a huge difference for the industry, because up to that point all of industry's advertising, all their promotion, was directed toward the prescriber. They had this situation where the prescriber just had all this power. So if they could influence the prescriber to use their drug, they were in "fat city."

Well, managed care came in, and all of a sudden the prescribers had less influence, and you had P&T committees, and you had formularies. And the prescribers didn't have as much power. Sometimes they couldn't, especially with new, expensive drugs, they couldn't necessarily just go ahead and say, oh, you should use this new version of whatever it happens to be.

So I think what happened is that the industries thought more and more about using a "pull-through" approach where they started with the patient. They thought they'd have the patient go to the physician, the physician feels pressured, the physician then pressures the formulary committee to get the product on the formulary, so you're kind of pulling it all through the system. So I really believe this but, again, I don't have the data.

But some things change, and you have this combination of factors. As an experimental social psychologist by

training you always want to see "main effects," you always want to see if everybody's going to act the same way if you like expose them to a certain situation. Right? It doesn't work that way. From my perspective, what I've seen is the world is that's it's a mass of interactions. You can expose someone to situation Y, but depending on ABC, they might do three different things, because those factors are going to interact. And so the combination of the self-help consumer-empowerment movement along with the managed-care thing, along with more and more ways to communicate with patients, I think it's that combination that led to manufacturers saying we want to approach the patients.

So they started doing that, but they started doing it in a way that they couldn't be faulted for. They used an exception, an exemption, within the regulations. See, the regulations say that if you advertise a prescription drug product and say what it's for, then you have to give this "brief summary," quote, big quotes, of information about the side effects, contraindications, blah, blah -- basically all the risk information.

But there's an exemption that was put into the regulations for things like product lists. So if you just give the name of the product without telling what it's for or saying anything else that's significant about it, then

you don't have to include all that risk information. These are called reminder ads or reminder labeling, because the intended reason for that was, oh, just let the doc know that this is available, so he doesn't need to know about all the risks. And you can't even do that for products that have a boxed warning because they're deemed to be too dangerous. Even with reminders, if you decide to do that, for a boxed warning drug, you still have to have the risk information associated with it. See, it's very complex.

So, some of the manufacturers decided they would put out these reminder ads, so you saw these ads, blue skies or fields.

JS: For patients.

NO: For patients.

JS: For patients, not for prescribers.

NO: Right. They would do it for patients, exactly.

JS: Reminder ads for products that-- why would the patient even know their purposes.

NO: Even know what it was for -- exactly. So it was this loophole in the regulations because the regulations don't make a distinction between healthcare providers and patients. When the regulations were first put into place in the mid-'60s, nobody was advertising to consumers. It wasn't ethical to advertise. They called them, this is an

ethical industry, pharmaceuticals, I don't remember. So they didn't do it. So the regs don't make that distinction. So some of them used that loophole to advertise to consumers the name of a product without telling them what it was for.

JS: But here's the question. Did we as an agency wonder what did they think they were doing?

NO: Oh, we knew what they were doing.

JS: So this is the question. They had research that they were drawing upon . . .

NO: Most likely.

JS: . . . that told them if you send reminder ads out to the public, even though they're not the ones prescribing these drugs, but this will mean something in terms of your sales of these products.

NO: Well, they tried it, and I'm sure that at least they had some research that showed that they would get a reasonable return on investment, because if they didn't get a reasonable ROI, return on investment, then they would stop doing it. So they were pushing that. So you saw these ads for Claritin and Zocor and a few others. But the issue was, for us, is how could we prove that they were actually making a claim about the product, that it wasn't actually a reminder ad, because we felt constrained by the

regulations? If it's a reminder ad, a legitimate reminder ad, then we can't take any action, even though we think it's bad. And we thought it was bad because it was confusing people. You know, there were women going in and asking their gynecologists about Claritin because they thought it had something to do with women's health because of some of the imagery. And that was the issue. I mean, in order to really make that argument, you would need the data. You would have to show that people were interpreting the imagery in a particular way. This is actually what the FTC does when they get extrinsic evidence. The way that FTC does their work is if it's not clear that there's a claim, if it isn't overt, if it's kind of a covert claim, they get the research done; and then, of course, they'll take them to court, which we don't do. We have very different ways of operating.

And it's interesting. The FTC has always said that FDA has primary responsibility for prescription drug advertising and we have secondary responsibility. But for over-the-counter, it's reversed. We've never said we don't have some kind of oversight function of over-the-counter advertising but we just rarely do any. It would be hard for us to do something. We actually could if we decided that it undermined the labeling, for instance. If we

thought an over-the-counter ad undermined labeling, we would have a reason to go after them.

I'm digressing.

JS: Well, but the Federal Trade Commission, as I mentioned, certainly felt that they had a say in this.

NO: Yeah, and they do, but they, as far as I know, they've never taken action because we're much more sensitive to these things than they are.

There was a period of time when the FDA was not being as aggressive in policing direct-to-consumer ads, or policing ads at all, because of a change in the kind of legal environment in FDA for a couple of years, but that changed when the person who was heading the General Counsel's office left. So, that's where you get into personalities and ideology.

JS: But there were some. Some people might even refer to them as conflicts of interest, depending on where people came from and where our histories were with certain organizations.

NO: Yeah, yeah, that definitely can happen.

So, we saw all of these reminder ads. We didn't like them. We were actually talking with a few manufacturers about how they might be able to do full product claim ads, with the risks, in a reasonable timeframe. Again, going

back to the regulations -- oh, this is so opaque to anybody who hasn't studied this stuff, you shouldn't have to. But, nonetheless, according to the regulations, someone in the '60s did think about TV and advertising on TV -- not advertising toward consumers but advertising on TV. Potentially, they could have been advertising toward physicians, and in fact there was American Medical TV for a while. There were a couple of TV . . .

JS: Advertised drugs had been on radio since the 1920s.

NO: Well, yeah, right

So, in the regs, you could be allowed to do TV, radio, or telephone communications advertisements if you made provision for dissemination of the package insert.

So FDA had actually, for like these AMTV things, had put together kind of a process whereby manufacturers could advertise to healthcare providers on TV. They would have an 800 number that the doctor could call to get the information, the package insert. They would have the page number of the *PDR*, which all doctors get free, that had the package insert, and there may have been a third. I can't remember if there was a third. But just those two. And the doctors could ask to have it faxed to them also. So that would fulfill the provision for adequate

dissemination of the package insert, or maybe it was adequate provision for dissemination of the package insert. But how do you do that for the public? The public has access to the *PDR*, but nobody gets it for free. You've got to pay for it. And, actually, there were a lot of people who were paying for it at COSTCO and various places. Or you could go to the library, but that's kind of out of the way. And people could call 1-800 numbers. So some of the manufacturers had these proposals for, "Well, how can we provide for dissemination of the package insert and therefore have TV ads for the general public?", ignoring totally the fact that the PI is ridiculous as a risk-disclosure document for the general public. It's not designed for the general public. Right? But putting that all aside, because the regulations don't address the general public versus healthcare providers.

We had been talking with some manufacturers about this, and we were waffling back and forth, back and forth. And at one point, actually, we briefed Commissioner Kessler about direct-to-consumer advertising, and we told him what we were doing with the print ads and how we were really being very, very, you know, careful, and we were asking manufacturers voluntarily to submit them before they used them. We looked at them as soon as we saw them. We were

doing a pretty good job keeping things under control with the package insert, making sure, also, that it wasn't just the brief summary that they got with the print ads, that they also got risk information in the body of the ad.

And this goes into another kind of development, because I was involved in providing for the manufacturers advice about how you have fair balance in your print ad, ignoring the brief summary, which, again, is stupid for, it really is, it's dumb for the public, the way it was done then. But you have to ensure that ads are balanced. You have to show a fair balance between the information about risks and the information about benefits, and you can't do that by just slapping all the risk information and technical language on the back. We made that very clear to the manufacturers. So we said, "You have to have communication objectives." What are the major risks that people needed to know about? That has to be in the body of the ad, and it has to be reasonably presented so that it's not just in tiny mouse-print all the way at the bottom. We had given them that advice about print ads.

But then they were moving into the TV arena, and the print regulations are different than those for TV. The regulations for TV say you have to have the "major side effects and contraindications" in the ad itself, so it's

similar to what we said you needed to have in the print ads, and you had to make this adequate provision for dissemination of the package insert for TV. But we never told them how to do it. That's why they were holding back. We never told them how to do it. And they were worried that if they came out with an ad that didn't have, that we deemed as not having adequate provision for dissemination of the package insert, that we would send them a nasty letter and then potentially actually take them to court, and basically cause bad publicity. That's one of the major things, we can make them look bad.

So, one day, after we'd been having these talks with manufacturers, we get a call from one of the manufacturers, and they say, "We're going out with a direct-to-consumer full product claim ad." They gave us warning. They said, "We're going to do this." We told one of our reg counsels that they were going to do this, that we had gotten this call. This is the piece that we don't generally talk about in public. Our reg counsel said, "Oh, we can't let them do that. We're not going to look very good" -- not literally those words, that was paraphrasing, that was, "Oh, no, we can't allow that to happen."

So we called them back and said, "Hey, would you hold off a little while, like six, eight weeks? Give us a

couple of months?" because we decided it would really be better to be at the front of the train than at the back of the train with regard to this TV ad thing. .

I didn't finish the story about presenting all this to Kessler. When we presented where we were before this had happened to Dr. Kessler, he said, "Great job, keep it up. I don't want to see it on TV."

JS: [laughs]

NO: [laughs]

JS: Well . . .

NO: We had a very clear path there. "Great job, keep it up. Don't want to see it on TV." So that was before.

Then, still, they were still pushing, and we were getting more of these reminder ads, and people were getting more confused, and we were getting complaints from pharmacists because people were going to pharmacists and asking them about the stupid reminder ads that had the name of the drug and the flowers in the background and didn't tell you what it was for -- because that was the loophole.

So we had these discussions. And then we had this one manufacturer call us and say, "We're going out with a full product claim ad for our product," blah-blah-blah, "and this is what we're going to do."

JS: About when was this?

NO: Ninety-seven.

We had written a draft guidance. We had one. I mean, practically. It was like in pieces. We had pieces of what we could put out as a guidance. And when our reg counsel said, "No, no, no, we can't let them do that," my bosses basically said, "Well, how long would it take to get a guidance out?" And basically I said, "Well, if people look at it as soon as it hits their desk and it doesn't just sit there, and we really move it through the process, we can probably do it in about six weeks to eight weeks, something like that." And we did. We got that guidance out faster, we got it out really fast. And what the guidance did was essentially say, "Look, this is how you can do a TV ad for a product that tells what it's for, provides fair balance, and gives adequate provision for dissemination of the package insert." That's what the guidance did. Again, it was just something we'd never done. We hadn't made it clear. So we made it clear with that draft guidance, and that opened everything up. And then all of the crap came down.

JS: Did the manufacturer come out with the ad?

NO: The funny thing is, they did, but another one beat them to it. As soon as this other manufacturer saw that guidance, they were out; they were out in a flash.

Yeah, they beat them to it, which was kind of funny. And I think we actually sent them a regulatory letter because we weren't happy with it. [laughs] I'm pretty sure that's what happened. The one that beat them to it, they got a regulatory letter because it wasn't quite right.

JS: But this was obviously, unless you had been thinking of this for a long time -- and obviously you had and the office had . . .

NO: Yeah.

JS: . . . this wouldn't have happened as fast as it did.

NO: No.

JS: We had, as you said, bits and pieces of this put together.

NO: Because we knew that eventually we were going to have to do this. Well, we thought we were eventually going to have to do it. You do try to think ahead, and I think everybody was hoping that the wall would hold, but it clearly wasn't . . . I mean, once somebody actually came out and said, "We're breaching that wall," whether they actually would have done it is another question. They told us they were going to do it.

JS: Well, we'll never know.

NO: I think they would have, by the way. And the floodgates were opened, yes.

JS: This was after, after you had left -- and I want to get to that brief time outside the agency in a moment, but I just want to mention that it was in 2003 that Commissioner McClellan came back, and I think in response to a lot of feedback FDA was getting about this tsunami of DTC ads -- not just that, I mean, but there were also some problem ads out there too. I know that we have taken action against a number of, for example, HIV-AIDS products that were quite misleading. But Commissioner McClellan said he was concerned about the growing number of misleading direct-to-consumer ads and how the agency was responding to those. In other words, were we responding quickly enough to these? The sense being that, well, some people had thought we weren't going after these as quickly as some people on the outside thought we should have been.

NO: Yes. Well, that had to do with a particular individual in the General Counsel's office.

JS: It wasn't just a matter of advertising, direct-to-consumer ads. I don't know to what extent you want to go into this or not, but we also had issues that, of course, eventually resolved in the courts, and in the law to some

extent too. But these involved off-label promotions of prescription drugs.

NO: Yes.

JS: Is there anything you wanted to say about those in particular?

NO: You know, I need to stay out of that area. I really was not, I deliberately stayed out of it even when I was there. There's only so many things that you can take on, and I felt . . . I had like three big things. Between patient labeling, physician labeling, and DTC advertising, I felt I was doing enough.

JS: That's a lot of plates spinning in the air.

NO: Too many, which is, I'm convinced, the reason that I basically burned out. It was just too much.

JS: So, should we continue?

NO: Yes.

JS: Do you want to take a break? Okay.

So, you did move on, for a short time, to Eli Lilly., One of the things that you did there was -- and I want to hear about this -- but among the things, you advised them on promotional strategies for products.

NO: Yes. [laughs]

JS: And that was quite interesting.

NO: Oh, that's what people do when they leave DDMAC.

JS: Did they listen to you?

NO: They listened to some of it, and they didn't listen to other stuff. Yeah. Because, you know, it's all probabilistic in some sense. You can say, "Hey, I think this is how they would look at this." All right? But, you know, the reviewer who gets it might have been more or less critical than me, or may have been involved in something else, and my recollection is that at that time, that was one of the times that . . . I mean, FDA had been kind of pulling back on warning letters. Basically the General Counsel's office was demanding a lot more oversight, and it was getting harder and harder to get out letters without an incredibly detailed legal review that generally did not contribute anything in the long run except delay the process. It was one of the things that contributed to my burnout, definitely. I just got sick and tired of it. It was a ridiculous, ideologically based change in FDA procedures.

JS: We were in the Office of Regulatory Affairs at the time and certainly heard a lot about this.

NO: About that. I'm not surprised. Yeah.

So, getting back to your question, I would give the Lilly people, the Regulatory Affairs people, and the product people, who actually seemed to be, in some ways

more receptive than the Regulatory Affairs people, because that wasn't really my job. That's the other thing. You run into conflicts because somebody else had the position of being like the Reg Affairs person for promotional materials. I was a consultant, and people can get -- I don't know what the right word is; they can get sensitive; they can get sensitive over other people maybe taking on what they perceive as their responsibilities. So, most of the time they paid attention, but in some cases they just said, "No, we want to do this, so thanks for the information, and we'll see how it goes."

And that would happen even if manufacturers sent in stuff to DDMAC. Sometimes they would get opinions back from DDMAC, and when a DDMAC reviewer did a pre-review of an advertisement or a promotional piece in general, they would cite every single thing that they thought was wrong with something. Some of those things were pretty small and, in and of themselves, would not cause a letter to be written, because it was kind of silly. Silly is the wrong word, but they were kind of minor. But if the manufacturer had, say, fixed all the major things and left some of the minor things, they wouldn't have gotten a letter. So the manufacturers choose; they pick and choose. But one of the reasons why manufacturers often, at least for direct-to-

consumer advertising, wanted to get the "yes, we don't find this ad objectionable, this is fine" kind of a pre-clearance, is because it created kind of an insurance policy for the manufacturer.

There's a difference in letters that go out. Advisory letters are private. They're protected by confidentiality, so all of that stuff is not FOIable or it gets redacted. I'm not sure exactly. But it's considered to be trade secret. Notices of violation and warning letters are public, and they get splashed up on the Internet.

If the FDA says to a manufacturer who's submitted an ad for pre-clearance, "Yeah, this is fine; we don't see any problems with it," what that means is that if the agency later changes its opinion, which it occasionally does, rather than getting a notice of violation, the manufacturer will get an advisory letter. The advisory letter, which doesn't go up on the Web, will say, "We've changed our opinion about your ad. Here's the problem with it. You need to change this within 60 days," or 90 days, or whatever it happens to be. Then they manufacturer gets to change it and they don't get any of the bad publicity. So, in that sense, that pre-clearance okay is kind of a little insurance policy against not getting a notice of violation

if the agency later decides to change its mind. And mind changes happen sometimes.

JS: At the agency, how do we do that? There are a lot of ads out there. Do we rely to some extent on people, say competitors, bringing to our attention ads? Certainly the public will; we know that. And we go out . . .

NO: Our own people.

JS: Yes, our own people.

NO: Medical officers. They pay attention, too.

That's one of the things that I actually found to be a great thing. It was releasing, it was relieving that I didn't have to pay attention to TV ads anymore once I left. It was wonderful. It was freeing, because, really, I would make my family crazy. An ad would come on and they'd say, "Pssst, gotta listen." It's ridiculous.

JS: You can't take the agency out of the girl.

NO: You can. You can say, "Okay, it's not my responsibility anymore," you know.

JS: That's true.

NO: I don't like watching TV that much anyway.

JS: But we do have a lot of sources that . . .

NO: Yes, including the competitors, absolutely.

JS: In addition to ourselves that screen these things.

The challenge, of course, is, as the medium changes, it makes things much more difficult, whether it's social media nowadays or the Internet generally, the old days of print ads or TV ads, it's just not . . .

NO: That's Stone Age, maybe Bronze Age.

Yeah, actually, I seem to remember having seen -- I don't remember why I was looking. I was looking some information up on the FDA website for a friend in Sweden because I figured, oh, my God, he'd never be able to find anything. I'll have enough trouble. And I saw that there was a relatively recent conversation, I think, with Tom Abrams on the *FDA Consumer*, whatever that's morphed into on the Web, where the question was asked about social media and how difficult that is. Oh, yeah, there's all kinds of new ways of doing things and you have to try to keep up with it. But it does make it difficult.

FDA actually tried at one point, before I left, to put together a guidance on promotion on the Internet, and we had people from all the medical product centers trying to work collaboratively on this. Jeff Shuren was involved the first time he was here. I mean, it was a big thing. But it was incredibly complex to try to figure out how you make a distinction between labeling and advertising, first of all, because that makes a difference depending on what the

product is. Right? We have the primary responsibility for regulating labeling and advertising only for prescription drugs. We regulate labeling for OTC drugs, while FTC regulates the advertising. It's more complicated in the devices because it depends on the type of device as to whether we regulate the labeling. It's a small, relatively -- used to be anyway -- relatively small segment. And we came up with this relatively convoluted schema for how to do this. We also said if it's on the Net and you can trace it back to the manufacturer, it's labeling, so that we could get OTC drugs involved, because otherwise their advertising would not be regulated under this guidance. So we said if it's on the Internet, it's mostly, as long as it's somehow connected to the manufacturer, labeling.

Well, I think -- and I wouldn't swear to this, really, because my memory is not perfect -- pretty sure it got to the White House, and I'm pretty sure FTC killed it, so we never got that out.

JS: That's interesting, though. That's sort of digitally. You know, traditionally in the agency, of course, if advertising is in a certain proximity to a product, I mean, we certainly took actions against plenty of products. For example, Cordell, back in the 1940s, when

he had displays set up and adjacent testimonials, that wasn't advertising, that was labeling.

NO: That was labeling.

JS: But here we have sort of a digital version of that if it can be traced back to . . .

NO: Yeah, but how many clicks do you have to make That's where it gets convoluted, you know. So, how many clicks do you have to go backwards to trace it back? That whole distinction between labeling and advertising has caused so much aggravation. It really has.

JS: Well, it's all about communications and communicating risk. And I want to use this as kind of a segue into your return to the agency after your year, about a year, at Eli Lilly.

NO: A year and a quarter, I think.

JS: Okay. What brought you back? And, by the way, let me just mention for the record, you did come back as Director for Risk Communication in the Office of Planning.

NO: Yes.

JS: But what did bring you back?

NO: This sounds horrible. I was bored. I had my sabbatical, I wasn't burned out anymore, and I got bored.

JS: It was sort of a sabbatical.

NO: Yeah, it really was a sabbatical, and I enjoyed it for about six to eight months, and then after that, it was like . . . Well, it's never one thing. In this particular instance, Eli Lilly had just lost its patent protection for Prozac, so they had to be careful about their spending. I didn't go out to Indianapolis more than two or three times in the time that I worked for them. I worked in Rockville, basically, not far from FDA. So, communication, and the liaisons, the relationships I formed with the people there, were not, you know, mostly they weren't, so I felt relatively isolated. And at FDA, as much as it did burn me out after 13 years, it was exciting. I had done stuff that I felt had an impact, I felt a good impact -- some people would not agree with that -- on the public, and I really liked having the public health as the bottom line rather than the shareholders' pockets as the bottom line, even though the people at Eli Lilly were very nice people and really tried to do the right thing, absolutely. But, still, the bottom line is a little bit different.

So I started looking to come back, and I talked to a couple people I had worked on and off with over the years because of stuff I had done with Bill Hubbard. So I came and I talked to Bill and told him I was interested in

coming back, and he talked to Theresa Mullin, who reported to him, who was the head of the Office of Planning. Theresa was looking for someone to head, to take this position, Director of Risk Communication, Director for Risk Communication, to increase the visibility of risk communication at the agency and also to increase consistency -- the coordination and integration across the agency, and to ensure that, for planning budgeting and other purposes that risk communication was not ignored.

JS: So, was this a new position or new office?

NO: Mm-hmm, yes, it was. It was a new position at that point. It wasn't an office. So it was me. And she had brought in someone also -- I can't remember what it was -- but she had brought in a couple of people for these areas that she felt were being under-integrated at the agency, that were kind of fragmented across the different centers. I think it was a very foresighted thing to do. And my experience at the agency, it just all kind of came together.

JS: I wonder if you could just say, before we go into this thing more, if you could just say something about risk communications per se. What is it, how is it folded into the agency's regulatory mission? I assume, I guess particularly in the context of how the other product areas

traditionally deal with communicating risk about their products to the consumers, the patients, the prescribers are all involved, because risk communication takes into account all of the people that receive the information.

NO: Right.

JS: So, this concept is not necessarily a new one.

NO: Right.

JS: But how did the agency embrace it?

NO: How did the agency embrace it? I think actually that Theresa kind of forced it on them. First of all, I would say risk communication is a black hole, and it kind of swallows a lot of stuff in that sense, including health literacy and plain language. That's like a tool for risk communication. All these things kind of come together. But really, what FDA does is that it regulates not just the products but all the information about the products.

JS: Oh.

NO: Not in all cases, obviously—not in advertising for some things.

Risk communication is a misnomer. Okay? It's not risk communication. It's called that; I don't know why. It's a historical thing. But it's really about risk and benefit, at least in what we do, what FDA does, it's not just about risk, because why would someone use a product if

they knew nothing about it but its risks? You wouldn't; there's no point.

At least the way CDER always used to look at it, or DDMAC, is, "look, we take care of the risks because the manufacturers take care of the benefits." Well, that doesn't really work well from a psychological perspective because the manufacturers have a different level of credibility than the FDA. So, yeah, they're talking about the benefits, but everybody they're talking to knows they have a vested interest in getting you to use their product. So of course they're going to talk about the benefits, and you're going to take all of that with a grain of salt.

The FDA talks about the risks, and FDA doesn't really have a vested interest in your not using it or using it, so let's pay real close attention to FDA's talking about the risks.

So you get an imbalance, because a lot of these products really do have benefits, and you don't want people to think that the risks outweigh the benefits without considering it for themselves. So risk communication really is about all aspects of what relates to the decision to use something or to do . . .

TAPE 2, SIDE A

NO: One of the first things I did when I came back is got together a group of people from across the agency to come up with a working definition for FDA.

NO: We have it somewhere. I mean I have it. We did; we came up with two, because we put out our own information about products, and we regulate information. So it's not just the information that we regulate; we regulate the labeling, we regulate some of the advertising, but we also put out our own information. And a lot of people just thought that, well, risk communication is just what we put out ourselves, right, so it's just the little risk messages that we'll give to the press and make available on the Web. That's way, way too restrictive a perspective, because risk communication is direct-to-consumer advertising, it's patient labeling, it's physician labeling, it's informed-consent documents, it's all of the stuff that we put out. So it's everything.

It's the Nutrition Facts panel. Why do we have that on there? It's so people can make a decision between different food products and decide which one is best for them. Okay. I'm diabetic; I need to look for sugar content. This one's got five grams; this one's got 19; oops, I surely should be using this. Or I've got high

cholesterol; I need to pay attention to . . . Or saturated fats, you know. Now you also have to have trans fats on there because everybody discovered that trans fats were as bad as, if not worse than, saturated fats. That made a huge difference in the food that was marketed. Now all of a sudden everything is trans fat-free. Now we have a problem with, well, make sure you don't just look at trans fats; you've got to look at saturated fats also. So there's a lot of work that's being done in the consumer studies team over in Foods about how people perceive these labels and how well they understand the relationship between different fatty acids and health conditions. They do these surveys periodically to find out, and they found differences after we made that change to the Nutrition Facts panel. So there's risk there, but there's also benefits, and you've got to get a balance. There has to be some way.

So that's one of the things that I would constantly tell people when FDA was putting out press releases or other kinds of documents warning people about a particular product; "say, you can't just tell them the risks." In our case, we need to give them a little bit about why would they even think about taking this. This is important for women who have osteoporosis. Yeah, there might be risks in

using bisphosphonates, but there's also benefits. You have to figure out a way to do that.

There was a serendipitous finding after FDA and EPA put out this combined public health notice about methyl mercury and the four types of fish that pregnant women should avoid during pregnancy because they're predator fish and they get really big, and they have high levels of methyl mercury. There's king mackerel and tilefish and swordfish. I can't remember what the other one was. Not tuna, surprisingly. There was a big uproar over that. In any case, after the first one came out, there was a study a group of researchers did. They were collecting information from, I think it was pregnant women, about what they were eating, and it's like women stopped eating fish. They would eat shellfish, but they didn't eat fish. You don't want that because you need those omega-3 fatty acids for the developing fetus' neurological system. Right? But what happened is that, from my perspective, this has never been anything that's been published or peer-reviewed, but from my perspective, look at the mental models that people have. Do they really make distinctions between those fish? Or do they just say fish and shellfish? Fish, shellfish, right? So when you say avoid tilefish and avoid this and avoid that, it's, oh my God, fish are bad. Shellfish are

okay, but fish are bad, so I'm not going to eat any of those because I don't want to take any chances. But there was no information about how you still need to get these omega-3 fatty acids for your fetus to develop neurologically appropriately. So I think since then there has been at least one, if not another one, of these public health notices that have come out that have tried to soften . . . And it's not softening the risk message. What it's giving is more of the balance. You should eat fish; you should have two servings of blah-blah every week, but just keep these at a certain level. And I think that's one example that I've used when I've been lecturing about how not understanding people's mental models can lead you into problems, and well, you have to have a little bit of the benefit as well as the risk, even if you're FDA.

JS: We are a public health agency.

NO: We are a public health agency, exactly.

One of the problems, of course, with drugs is that we approve drugs for use for these tiny little sentence-long or maybe two-sentence-long indications. That's it for the benefit. And then you've got, what, 17 pages of risks. It's just that, you know, that's the way, you don't have the same standards for risk as you do for benefits.

JS: And that's why people turn to dietary supplements.

NO: And then they get that stupid thing about this product is not intended to diagnose, mitigate, blah-blah.

JS: But, on the serious side, though, when we make decisions about how to communicate benefits and risks, and when your office was helping develop that kind of communication, obviously you're working closely with all the product areas.

One thing that occurred to me as you were talking about that is, well, what goes on the label? Is there a reason to put it . . . I'm thinking about genetically modified organisms. Now, is there a reason to have that on the label, or isn't there? And . . .

NO: We need the research. We had a meeting. There was a meeting that I got invited to, I think again just as an afterthought. Mostly we were in a, it wasn't really a consultative capacity. It was really more on the larger policy scale, larger policymaking and planning.

Eventually, we started to get brought in. Initially it wasn't that this kind of position, which turned into an office staff, was designed initially to do . . . It was designed to work at a different level, not at the actual

communications level. It was more about developing procedures and policies for communications.

But that being said, I got invited to this meeting about the progeny of cloned animals going into the food supply -- like beef, for instance. I'm not sure -- actually, they were clones; they were clones. And FDA was going to go out with some kind of -- I don't remember exactly the specifics; I should have reviewed this. But they had materials that, from my perspective, didn't address people's needs in terms of what they were telling them. They were just kind of saying, "this is fine, there's no reason to worry about this because scientifically there's no difference between the progeny of these cloned animals and anything else you eat there." And I'm looking and saying, "you can say that, but people aren't going to believe it. You have to give them a little bit more than this. Do you have any idea of the kind of firestorm you potentially could get by going out without being prepared and understanding how people are going to perceive this?"

So, who was the Commissioner at the time, the one who got into trouble?

JS: Lester Crawford.

NO: Yeah, right, exactly.

JS: The vet.

NO: The vet, exactly. And he said, "Hmmm." And so we did some focus groups. We got some money and we did some focus groups, and what that did is it had an impact, I believe it had an impact, on the materials that they put together for the public to try to address these issues.

It was really very interesting because, in the groups talking about it, you'd have like one-third of the groups, and these people would be absolutely adamantly opposed, I mean completely opposed. Nothing you'd say would change their mind. And then there was another group that, they were really for it -- a lot of men, generally - they would say, "Hey, if it tastes good, I'll eat it." And then there was this group in the middle that was so soft on what their perceptions were. They would just go, it was like a tennis match, and they'd go back and forth depending on which one of the others had spoken last. So there was a decent-sized group that was open to listening, and so we had to make sure that we addressed their issues. So that was neat. So we got to do that.

Since then, I don't know what's happening now, but certainly we did get asked on a number of occasions to kind of opine on the communication materials, but we did more of trying to gently push people toward, look, think about what

your issues are going to be in the future, and let's find out how people perceive these and what kind of information they need in order to get to the point you want them to be at where they can make informed choices, because that's really the basis of our definition, it's giving people the information they need to make informed decisions about whether to use or not use the products that FDA regulates.

JS: And this is all pretty much encapsulated in the strategic plan of risk communication that you developed in 2009, a document that's for the public but also for the agency.

NO: For us, yeah.

JS: Right?

NO: Yeah, especially the pieces where, again, this was a big team effort from across the agency. There were people involved from all over, and it was like, okay, what do we need to do to get to the place where we think we should be down the road? What are the actual actions that we can take? So we had, along with the plan and the objectives, the goals and the objectives, we had like 70-plus specific action items, some of which were already underway. We always do that. But others we felt, okay, this is stuff we need to do, and they fell under different goals, basically.

And then the staff that we built up ended up being responsible for coordinating and making sure that these were moving forward. I don't know how things are going now.

JS: But at the time you left the agency in 2011 . . .

NO: And don't forget the Advisory Committee, because that was important, too, from our perspective.

JS: Oh, right, right. Well, this was the Risk Communication Advisory Committee, which started a couple of years before the report came out.

NO: Yes, yes, a couple of years before the report came out. And I think that was significant because that's when the agency kind of went on record as saying, "This is important. We don't necessarily have all of the expertise that we need internally, and so we need to have people who we can consult with to help us become better."

JS: What kind of people did we bring in on the committee? What kind of backgrounds?

NO: We had psychologists, we had communicators, had a couple of marketers, we had medical people, we had pharmacy people but not -- we didn't have . . .

JS: Pharmaceutical clinical sociologists perhaps.

NO: Well, hopefully, yeah. I mean, we, I want to have the charter and the roster in front of me at this

point because . . . But we really were very careful. We wanted to make sure that there were also consumer representatives, that there were representatives not just of consumers, but healthcare providers. And that's the reason we had healthcare providers and consumers, or patients, because we wanted to make sure that this was not just a committee -- ideally it would have been nice to have two -- it wasn't just a committee of academic scientists who didn't have experience and would just be opining as experts about the perceptions of the target audiences. We wanted to be sure that the target audiences were represented as well. So it was an interesting combination of academic expertise and practical expertise-- people who are out there doing communication -- and then the target audience expertise.

JS: This is a standing committee?

NO: Yes, yes. Actually, after we put it together, which was based on a recommendation that we expanded from the Institute of Medicine in their future of drug safety report, the Congress then put it into FDAMA. It's congressionally mandated, so it's not one of those committees that you have to re-charter every three years.

JS: Generally, how does the committee work with the agency? And, particularly, how did they work with your office?

NO: Well, we managed that committee; well, this office manages that committee. And Lee Zwanziger has been -- I'm assuming she still is, and you know Lee -- she's the exec sec, the, what is it, designated federal official, the DFO, of that committee. She works with various people across the agency, in the different centers, to identify the problems and issues that they can bring to the committee, and then the committee works with those people in its meetings to give advice as to how to proceed. And the committee members can also be used as special government employees for individual projects.

JS: I want to go on to a couple other things during this period, but just one more along this line before I do that.

So, by the time that you left FDA, do you feel that the agency really was seriously buying into the importance of communicating risk in the way you've been describing?

NO: When I left, I thought it was, yes, I really did. Obviously, there are always issues around budgets and stuff, but the head of the Office of Planning, Malcolm Bertoni, has been just, was incredibly supportive and

really believed in the importance of risk communication. We had put into place, and I'm hoping it's still used, a kind of internal group for helping FDA informally test messages, using FDA staff as surrogates for the external world, because that way we didn't have to go through OMB clearance. If you have to go through OMB clearance to get approval for research that needs to be done really quickly, it just isn't going to happen. It just doesn't happen that way.

The other thing we had worked on was putting generic clearances into place to try to jump-start that process, but that ends up being dependent on the people at OMB, and if they're still going to sit on it even though they're supposed to give it a two-week review, there's nothing the agency apparently thinks it can do about it. So we had that internal group.

There had been money for using social media. There was a contract for using social media, a group to evaluate how some communications that FDA came out with, how they were playing on social media so that we could actually get some feedback. So there was work that was being done, and there was, of course, the continuing work on the strategic plan for risk communication.

Also, the members and some guests of the Advisory Committee had put out a book, which is on our Website, called *Communicating about Risks and Benefits: A User's Guide*.

JS: Really?

NO: Oh, yeah. It's really quite good. It had chapters on different areas like qualitative research, quantitative research, communicating about numbers, communicating about various . . . It's really good; you ought to take a look at it; it's really quite good.

I had a chapter; you don't need to look at that. But the rest of it's really good.

Our first [RCAC] chair was Baruch Fischhoff, who is internationally known as an expert in risk perception and risk communication, and he's just phenomenal. And the current chair, Ellen Peters, also just -- these are incredible people who understand that there's the theoretical side and then there's the applied side, and you need to figure out how to get those to work together.

Yeah, I think that it was much better. Was there still plenty of room for growth? Oh, yeah. There's still lots that needs to be done. But my feeling was, is that I had left it in a place where other people knew they could take it up.

JS: It sounds like you made tremendous strides, though.

NO: One likes to think so. But on the other hand, I haven't been keeping up with people, so I don't know.

JS: One of the other things you did while you were in this position is you chaired the agency's Communications Council, and I find that interesting, particularly interesting, since our office, the History Office, is now part of the Office of Communications and the Office of External Affairs.

NO: Oh, I didn't know that.

JS: Yes. I didn't appreciate this as much until we moved into our present position in the agency, but there are several communications offices around the agency.

NO: Oh, yeah.

JS: What was your role in this, and what was the Communications Council role in terms of the agency's messaging of responsibilities from the standpoint of the individual product areas and, I guess what the External Affairs office does?

NO: Well, I know that at times before the Communications Council, there had been other attempts to get the different groups within the agency that are

involved in communications to talk to each other and to have cross- . . .

JS: That makes sense.

NO: Yeah. Does the Communications Council still exist?

JS: It does.

NO: Oh, cool; that is very cool, because I co-chaired it with another one of, she was a political appointee who headed External Affairs, and I don't remember her name at this point. I think she left under a cloud, too. It's a hard job; it's a tough position to be in.

And, again, it was an attempt to coordinate better, essentially, to learn from each other and potentially to work together. The Communications Council in some ways was kind of the backbone or became the backbone -- I can't remember which came first, whether it was the strategic plan that came first or the Council; I think it was the Council first, and I think we used a subset of the Council to help put together the strategic plan. But the trouble is that people who are involved in the communications arena -- and I'm not talking in this particular instance about the regulatory arena; I'm talking about FDA's own communications -- it's such a crisis-oriented function that it's like you move from one crisis to the next, which makes

it very difficult to think strategically and to do the work, the research and the understanding that needs to be done up front, before you go out with the messages, and to understand your audience as well as you might think. And what tends to happen in the communications arenas is people use process measures, you know, how many hits did you get or how many publications did this show up in. That's not necessarily a measure of effectiveness.

So, one of the things that we were constantly trying to push is other more solid measures of effectiveness of the communication. And people in the agency, I mean, you get so focused in on your thing that it's all you see, so you see it everywhere. But when you're outside of it, you realize how little people actually pay attention to what FDA is saying and how . . .

JS: But this does speak to the importance of bringing the tools and perspectives of social psychology to decisions in how we communicate, regardless of what product area you're in, or even if your principal responsibility, I suppose, is working with those on the outside who try to capture the FDA for the public. Right? I mean, there's much we can learn from that perspective. But I guess if you're in a mode of moving from crisis to crisis, it's hard to do that, isn't it?

NO: Yeah, yeah. And it's hard on everyone, because the communications people need to get the experts. The experts are the same people who are doing all the reviews. Right? They get pulled away and they look at it as, "oh, my God, another communications crisis. I don't have time for this." And so you have that happening as well, and so once you're finished with the expert, you let him go because they have to go back to their stuff, and you never . . . Are they doing debriefings? Are these things being done to find, okay, what worked, what didn't work, what can we learn from this experience? And how do we convince the experts that sitting with their nose in a review is not really what the public needs? The public really needs them to explain in words that they can understand what the major pieces are that they need to know, the major facts that they need to know given their values and their needs so that they can make an informed choice, they can make informed decisions, or so that they can have informed discussions with their healthcare providers in the case, for instance, of prescription drugs. So it's . . .

JS: But it's challenging to do that with experts in fields like here in the agency, though, isn't it, when your day-to-day routine is to converse in the language that only

your cohorts understand, not the language that people need on the outside might understand.

NO: Oh, right. That's one of the reasons Baruch has this layout of a team that you need. You need a communications team. You need the subject-matter experts. But you also need the decision scientists who can identify what's the most important information that patients or healthcare providers need in order to make a particular decision. And then you need the psychologists to decide, well, how's the best way to communicate that information. And then you need the systems, the communications systems people, to decide, well, what are the best channels. How do you get that out to people? You need all those people working together, and you shouldn't be having the psychologists telling the subject-matter expert what the science is, but you also shouldn't have the subject-matter experts telling the decision scientists and the psychologists that this is what people need to know, because they don't know what people need to know. And then you shouldn't have them saying, "Well, I think you should use the social-media thing," to the systems people, who know when you have this particular target audience, this is what we should be using to get the information out to them. You need these kind of these groups that will work

together, and that's . . . I don't know if we're there yet, if FDA is there yet.

I keep saying "we." I still feel like an FDAer. Two years out, I don't know. You never get the FDA out of the girl.

JS: You never stop, no, you don't.

The last -- and this actually kind of segues into the last thing I wanted to ask you about this period, and that's the social science forum that you chaired, and talk about that per se. But I'm curious what your take is on what role social scientists have played at FDA since you've been here, how social scientists, people with that kind of a background, how they've contributed to the agency's mission, in a general way, or specific, whichever way you'd prefer to look at it. But obviously there are more and more people with very different backgrounds that are at the agency, an agency that's grown to 13, 14,000 people now, which is just hard to believe for those of us who have been around for over 20 years.

NO: Yeah.

JS: But we've brought in a great many people with many different kinds of backgrounds, including many with social science backgrounds.

NO: Not enough. [laughs] I think that was a real problem years ago when I first came in. There were so few of us, seriously. We had the little group in DDMAC; that was Lou Morris, Ellen Tabak, Karen Lechter, myself. And then we brought in Kit -- well, Lou retired, Ellen retired. I think DDMAC now has four or five social scientists, which is pretty good: Kit Aikin and Amie O'Donoghue, and Helen Sullivan, and some new people I don't know.

As I said, the Foods Center has always had the consumer-studies people, which had been a . . . But two people who just retired relatively recently, Alan Levy and Sarah Fein, were very much involved in the nutrition facts panel stuff, very much involved in the work that the group did around health claims. And Steve Bradbard, who I think is doing organizational stuff in Foods and the Office of Foods, both in CFSAN and the Office of Foods. And these people have been, I think had a lot, but not enough influence. They've done a lot of work, they've done a lot of research, and I don't think it's had enough influence, frankly, in areas where the scientists, the nutritionists, for instance, feel that they know, that they have the hotline to the truth, because I think there's a lot that needs to be done around claims, health claims. I think they've been trying, that the social scientists have given

us a lot of insight into, but I'm not sure that it's really being used, frankly. I just don't know.

I do know that CDER has used the social scientists in DDMAC. They've done a lot of research, and they've been involved, well, I was, certainly Lou was, I know Kit is, so CDER has used social scientists. In CBER, I don't think there are any, really, except for the communications people. There are human factors people in CDRH, but I think they're mostly involved in review functions. I may be wrong about that. I think that there's a lot more that could be done with the social scientists there. I don't think there are any social scientists at CVM.

I think tobacco is a real area -- graphic warning labels. But look what happened with the research for that. I mean, you do the research and then you get shut down by the courts. So you can have an impact.

I think social scientists have had an impact over the years, but I don't think that there are enough, and I think that there's always been this sense that social science isn't as good as medical science or clinical science. And I look at it and I say, wait a minute. I was trained as an experimental social psychologist. I did experiments that are just the same as randomized, controlled clinical trials. Yes, sometimes you have to do surveys, and it's

not perfect, but . . . When you set it up such that you basically have this homogeneous populations, and then all of a sudden you let this drug out, or this medical product out, and the whole universe is using it and you've done the research with this homogeneous population, there are some limitations there as well, guys. So, that was always a fight.

JS: But that might be the case, though, even in professional schools, in academia, when you have a confluence of both people that are trained in medical sciences, but then you also have departments of medical sociology or other departments. And my guess is, from the little bit I've heard, they face some of the same kinds of barriers there as well.

NO: Yes, absolutely.

JS: Maybe, whether it comes to tenure issues or turf issues at schools like that . . .

NO: Oh, yeah. It's not unexpected.

JS: No, no, no, no, not at all. But there are things in the agency that we have spent time in looking at them from the standpoint of social psychology, for example, at dietary supplements, products that we know people are using therapeutically, more so than drugs, maybe; I don't know.

NO: We need the data.

JS: Right.

NO: We need the data.

Actually, that was one of the first things I did when I was here. I'd forgotten. We had done, there were data on the use of dietary supplements. It was a survey -- not the Health and Diet Survey, that the Foods people do; it was something that Lou had done, and so I had the database. And what . . .

JS: Was this shortly before or after DSHEA?

NO: This was in 19 -- I came in '89.

JS: Right.

NO: So it was either '89 or '90.

JS: So this was about five years before the Dietary Supplement Act . . .

NO: Yeah. And what we found, what was interesting, at least in terms of self-reports, is that people didn't use dietary supplements as a substitute for medical treatment. They used it as a complement to medical treatment. That's my recollection. I have to go back and see if I can find the paper.

So, sometimes we make assumptions that we don't necessarily have the data on, but we've seen . . . But what you see, there's this availability bias. Kahneman Tversky talked about all these heuristics and biases that

people use in trying to make sense of the world, and one of them is called an availability bias. And basically what it means is that you remember and you give a lot of credence to things that are highly available to you. So that, for instance, even though the number of abductions of children didn't change for years and years and years, people thought that it had increased because they kept seeing it in the papers. So they were convinced that there were so many more than there used to be, and they got more fearful of their children being abducted. So it had real implications for letting your kid play outside with the neighborhood kids or whatever. But it's the availability of the information makes it seem like it's more real even though it may not be. So we think the world is more dangerous than it actually is, or we see . . .

You know, there are lots of things, lots of biases that go into how people perceive risk, for instance. Availability bias is one of them. But there's also, you will perceive a risk as being much worse if it affects children than if it affects an adult. You'll see it as much worse if it affects future generations. You see it as much worse if it's manmade as opposed to natural. And so this affects how, you see it as much worse if it's really, it makes a big splash where a lot of people die in a single

disaster as opposed to many, many more people dying, but in a scattered fashion. So you pay more attention to a plane crash than we do to all the people that die in car crashes over the course of a year. It explains to some extent the underestimation of the deaths caused by cigarette smoking as opposed to things that, you know, as guns.

There's like a whole series of these that you really need to pay attention to when you're trying to figure out how people are going to perceive risk, because if it's manmade, if it affects children or pregnant women, people are going to be much more concerned about it.

And if you think you have control over it, you don't perceive it as much of a risk. So, again, the car thing, you know. People die in car accidents all the time, but they don't think that they're taking their lives into their hands when they step into a car. They've got the wheel. I'm a lot more frightened when I don't have the wheel.

But these are all lessons that can be learned from social psychology, from sociology, from people who have done the work, and talking about the distinction between the social sciences and the medical sciences, geez, I was taught as a graduate student to really look down upon anything that wasn't experimental social psychology. I hated that; that really pissed me off, you know. If

someone was in counseling, oh, that was just not worth anything. And the research they do? Oh, pah, pah. And the same is true, I think, you get all these people, interdisciplinary stuff is often, I mean, people just beginning to bring together all these different areas, because they all touch on them, and there's so much we can learn from each other, but someone who does quantitative work looks at the qualitative work and they say, oh, pah, pah. I think qualitative work can teach us so much more about how people think than a lot of the quantitative work that gets done at this point. Having come from the quantitative background, I'm big into mental models, and you do mental models research through interviews, with a relatively small segment of people, 30 or 40 people in a cohort. And then you validate it with the quantitative work. But you need this combination of methodologies. But everybody, so many people -- and I see that here too -- those who are into the observational methodologies look down on those who are into the really controlled stuff and vice versa. So, what happens? You end up with people who won't talk to each other because they don't respect each other's methodologies. It's kind of short-sighted.

JS: But, again, I think we've made strides from what I've been hearing.

NO: Oh, I think we have; I think we have, and that's positive. And we have to keep moving and pushing in that direction.

I don't mean to end on a downer. I think, I really think that the agency has made tremendous strides, and I hope that it will continue along the direction of keeping the communication going between the different groups. I think that that's absolutely critical, I really do, and there's no reason that it can't be done.

JS: Right. Well, I think among the things you've done here is given me a reminder that I need to pay closer attention to the history of the social sciences and its role in the agency. Certainly when I or someone else writes that history, your role here is going to play a major part in it, so . . .

NO: You know, right place, right time, right people supporting you. That's what you need. I mean, I think that's been the case because you can have a clone of me somewhere where you didn't have the supervisors and the upper-level management who said, "Oh, yeah, we should do that; that's a good thing," and that person could just never get anything done.

JS: Well, that's a good point. It's hard to accomplish much here, whatever background you have,

wherever you are, whoever you are, without somebody higher up who recognizes the contribution it can make. And people that you've worked under, that you've mentioned, certainly have that role.

NO: Absolutely. Without Mac, for instance, the physician labeling thing would have sat in a black hole, and I know exactly what black hole it would have sat in. So, you know, sometimes you've got to work the system, and I think I was fortunate in being put in a position where I could do that, kind of work the system and have people that supported what needed to be done. That's really, that's incredibly positive. I mean, when the people can work together to bring about . . . I'm sorry; this is sounding dumb, but that's really what you need; you need everybody working together.

JS: Well, I want to thank you so much for taking the time to come out here and sit down and talk about your experiences here. I think it's been a fascinating oral history, and I think researchers are going to enjoy going through this and learning more about the agency.

NO: Thanks. I loved being here. This was a great place to be. And I wish I could do more with the agency. It's really a fantastic group of people, for the most part. And everybody is so dedicated to doing the right thing.

Well, again, not everybody; most people, virtually everyone. [laughs]

JS: Good talk. But anyway, I do appreciate your time.

NO: Someone should talk to you sometime about the patient labeling stuff, too. You should talk to Lou about that.

JS: Yes, absolutely.

END OF INTERVIEW