U.S. FOOD & DRUG ADMINISTRATION

Oral History Interview with
Kathleen Uhl, M.D.
Assistant Commissioner of Women's Health
2006-2009
Director of the Office of Medical Policy
2010-2013
Director of the Office of Generic Drugs
2013-2019

FDA Oral History Program
Final Edited Transcript
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Oral History Abstract

Kathleen "Cook" Uhl, MD, came to the FDA in 1998 as an officer in the Public Health Service and initially worked as a medical reviewer in the Office of Clinical Pharmacology. From 2006 to 2010 she served as the Assistant Commissioner for Women's Health and the Director of FDA's Office of Women's Health, where she oversaw the expansion of both the office's research program and stakeholder engagement efforts. In 2010 she was appointed Deputy Director of the Office of Medical Policy and from 2013 to 2019 she served as the Acting and then permanent Director of the Office of Generic Drugs, implementing organizational, staffing and workplanning changes mandated by the Generic Drug User Fee Amendement and its reauthorization.

Keywords

women's health; generic drugs; clinical pharmacology; user fees; biosimilars

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Interviewer Biographies

John Swann, Ph.D. is an Historian at the U.S. Food and Drug Administration. He is a subject matter expert in the history of the FDA, with a specialization in the history of pharmaceutical and biologics regulation. He joined the FDA in 1989, after earning his doctorate in the History of Science and Pharmacy from the University of Wisconsin, Madison, and researching a centennial history of the University of Texas Medical Branch at Galveston. He is the author of *Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth-Century America*, as well as numerous articles on this history of therapeutic products published in scholarly journals and edited compilations.

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

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Interview Transcript

JS: My name is John Swann. I'm with the FDA History Office. The date is August 26th, 2019. And I'm here conducting an interview over the telephone with Dr. Kathleen Uhl, former director of the Office of Women's Health, who left the agency in 2019 as the director of the Office of Generic Drugs. So Dr. Uhl, if I may, I'd like to start this off by just going back, if you don't mind. If you could just discuss a few aspects of your early life, and this is part of the pre-FDA story. Where you were born, where you had your higher education, your postgraduate education, and the influences that were impactful on early decisions you made in terms of the schools you attended, your majors, and your professional direction.

KU: Sure. There are multiple questions that you had there, John, so if I don't cover them in my answer can you please do a follow-up question?

JS: Happy to do that.

KU: Because I think I heard about five or six questions. I was born in Philadelphia and I did all my education in the Philadelphia area or in Philadelphia itself. I grew up in a suburb outside of Philadelphia. I went to Temple University for my undergraduate degree, and I majored in chemistry. Then I went to the Medical College of Pennsylvania, which is now part of the Drexel University system. I went there for medical school.

I went to medical school under a military scholarship called the Health Professions Scholarship Program, so I left the Philadelphia area after I graduated from medical school, and went to Fort Benning, Georgia, for my scholarship was with the army. And I did a residency in family medicine, and I served down there at Fort Benning in an outpatient troop clinic and an outpatient family medicine clinic for about two years.

When I was an undergrad, I did a fair amount of research. I did a lot of lab-based research, and I wanted to get back to some more research-based professional activities versus just cranking out patients. In the military health care system, especially as a primary care provider, you were just cranking them out. So I then went to Walter Reed Army Institute of Research (WRAIR) up in Washington, DC, and I did a one-year medical research fellowship. I followed that with a two-year clinical pharmacology fellowship, and I did work on drug metabolism while I was doing my fellowship.

And then I had a couple more years of army payback, and during that time and during my fellowship I had the opportunity for lots of interactions with FDA. The program at the time was housed out of USUHS, the Uniformed Services University of the Health Sciences, in Bethesda, and there were some pretty substantial and phenomenal interactions between the university and the staff at FDA, particularly CDER, during my fellowship training.

So I met people at FDA and I had several people really try to entice me to come and work at FDA. They were very encouraging that it would be a good opportunity for me and that there was-- especially in CDER - the need for physicians with clinical pharmacology experience. So I finished up my army payback time and I subsequently did what's called an interservice transfer,

so I went from the army on a Friday to the Public Health Service on a Monday and started working at FDA.

That might sound really easy, but it probably took about nine months for all of the bureaucratic paperwork to go through. Plus I think somebody lost my paperwork twice. But I came to FDA. I want to say it was 1998.

JS: It was, yeah.

KU: And I came as a clinical pharmacology reviewer in the Office of Clinical Pharmacology at CDER.

JS: Yeah. I know, having done one of these oral histories with him, that Carl Peck I believe stood up the program in clinical pharmacology at USUHS. This was obviously back in the 1980s.

KU: I believe that is true. And Carl Peck was the CDER center director at a time, and I think he went from his position in USUHS to being the CDER center director as well. So his time at USUHS and FDA predates my time at both, but I have had the opportunity to interact with Carl professionally over the years. As a matter of fact even him reaching out to me in my retirement time or even before retirement to see if I would be interested in working for his consulting

company. Which I haven't done. I'm only retired six months, and so the idea of work or I guess the fear of -- starting to do consulting on a part-time basis as I've been told evolves or devolves into full-time rather rapidly. So I'm taking things pretty slow, intentionally and purposefully.

JS: Of course. Before we move on to the FDA years, just a quick question. Did anything in particular prompt your interest in clinical pharmacology?

KU: The research program, or research project, that I did when I was doing that medical research fellowship was creating a malaria-infected model for drug metabolism. So there were some concerns about people who get malaria and its treatment -- obviously a very military concern. They either focus on infectious disease or they focus on battlefield trauma. But things that are very specific to the military is what the military does its research in.

And so you had the opportunity to go around to a variety of different laboratories at Walter Reed Institute of Research, otherwise called WRAIR, and it just intrigued me that that was the work that they were doing. They had some case reports of people who didn't respond as well to the medication traditionally used to treat malaria and they were trying to better understand why that was. And so one of the hypotheses was either there was a drug-drug interaction causing a problem, or there was the fact that you had a high parasitic load because of the malaria and that maybe that was impacting the ability for the liver to metabolize those medications.

That was pretty interesting to me, so I was like, "Yeah, that's great." So I started doing that project, and that project was in a place called Experimental Therapeutics at WRAIR, and that's where they housed the clinical pharmacology fellowship. So I worked with people who were current fellows. I learned more about the program. Learning more, I was like, "Well, that's really interesting." And then they needed a fellow to fill in a year, and they asked if I wanted to stay and do that fellowship. So it was serendipity, to tell you the truth.

JS: OK. One other thing too I wanted to ask about, because this bears very much on your experience at FDA as well. Once you arrived at the agency you continued to have a very regular involvement in clinical practice, primarily at Walter Reed, but of course as a member of the Commissioned Corps of the Public Health Service. And as far as I could tell, you kept this up pretty much almost until the time you left the agency. I guess what I'm wondering is that level of involvement, and I know you had both teaching and clinical appointments outside of the agency. But was that kind of involvement typical of a full-time medical officer at FDA? And did that have the full support of whoever the leadership was at the time?

KU: One of the interesting things about the Public Health Service, when I transferred from the Army. In the Army there are certain bonus pays that you're eligible to receive certainly as a physician. And there might be similar in other types of circumstances. Whether you're board-certified in something or specialty-trained, things of that sort.

When I transferred from the army to the Public Health Service, the way that the Public Health Service had it at that time was in order to qualify for those particular bonuses you had to

do, I don't remember the exact number, I'm going to say about 120 hours per year of clinical work. So one, there was a financial incentive to do that. But two is my thinking -- and I think it was very well received, because there were people already in CDER doing clinical time outside of the FDA, but I think you're better at your work at the agency if you understand what's going on in the world of medicine. Making policy decisions on how you might for example implement some kind of REMS (Risk Evaluation and Mitigation Strategies) program or something without really understanding the practice of medicine is really difficult.

So it was important to me that I still understood how the practice of medicine was going, how things were being diagnosed, how it was treated, etc. So I did about four hours a week of that type of activity at Walter Reed in the Internal Medicine Clinic. And it was good. As I advanced in my career at FDA it was much more difficult to get that time outside of the office in order to do that type of work, and so I had to dial back and dial back. By the time I was in the Office of Generic Drugs I was not doing any clinical practice outside of the agency. Although I did keep my faculty appointments at USUHS, and I still did teaching, coordinated with some medical students, some small group activities every once in a while I think with the clinical pharmacology program, but also with the ethics course.

So is that common? I think there's a fair number of physicians who do that. But it's challenging. You spend four hours or five hours at clinic in an afternoon, your FDA work still has to be done. So you typically end up going home and logging on and trying to close out your day. Probably less of an issue as a primary reviewer and more challenging when you start taking on management positions or team leader positions, where people are working for you or reporting to you.

JS: Of course. But I think it's extraordinary though that you were able to maintain that as deep into your career here as you did, considering you did have --

KU: I really thought it was important to have your finger on the pulse of what's going on. And I would say while you might be impressed with that, I still think that whatever amount of time I did, it was less than adequate to really have your finger on the pulse. To the degree right now I would feel very uncomfortable working in an outpatient clinic seeing patients full-time. I would really have to buff up on a lot of stuff.

But again it was a good way to keep current. Part of my philosophy too is try to learn something new every single day. And when you teach, you learn, because the people you're teaching ask questions, and they challenge your beliefs and hypotheses and assumptions and things like that. So it was a two-way street. I was giving but I was always receiving something in return.

JS: That's very helpful. Thank you. So once you arrived at the agency, that must have been an interesting transition though, becoming a medical officer, and spending a good chunk of your time reviewing INDs and NDAs. Quite a change from what you'd done before. What was that experience like?

KU: I think it's probably the same for most clinicians too who come to the agency. I was essentially full-time in a research laboratory, and so it is very different coming to the agency, and having to review just like you said, review INDs, or review an NDA, or review certain kinds of reports that come in and such. The thing I found most challenging was when you're in a lab, you're on your feet. You're on your feet, you're going back and forth, you're doing all kinds of stuff like that. A lot of the work at the FDA is very sedentary. You're sitting, you're looking at a computer screen, or you're in meetings most of the day.

And so that change in just physical activity was such a huge change for me. And I think the same is true for people who come to the agency who as physicians were in full-time clinical practice. Seeing patients all the time. And then it's a pretty substantial change in what you're doing on a day-to-day basis.

And so I think having managed that with those fortunately tons and tons and tons of training for new reviewers, especially in CDER, so you learn, there's a lot of OJT, you learn while you're doing the job, but there's lots of training to help you learn. And in the process of doing that you're meeting a whole bunch of people who are kind of in the exact same boat as you are. So you create your own support group by that. People that you run across in future classes or future meetings. I'm having this challenge, are you experiencing the same thing? How are you dealing with it? Any suggestions? That type of thing.

JS: In that position you also got involved in some professional development activities, like you directed a lecture series. And one of those I wanted to ask you about was the questions-

based review. That was I gather something that promoted good review practices at the agency. Can you tell me a little bit about what that was like?

KU: Whew, that was a long time ago.

JS: That's OK.

KU: Yeah, that was something that if I recall correctly Larry Lesko, who was the director of the Office of Clinical Pharmacology at the time, that was something that he was trying to institute with his reviewers in clinical pharmacology. Kind of along the same lines as what you're saying. For good review practices, and consistency among and across reviewers and the review activities and such.

It was I also think partly -- I guess I wasn't the first medical officer to ever go to work in the Office of Clinical Pharmacology, but one of the very first. And I think they wanted to do some outside-the-box activities with the new medical officer too. What different can I bring to the table than a brand-new clinical pharmacology reviewer? So there was opportunity. It wasn't just lectures like that, but we would bring in some clinical lecturers to help. So that's what my memory is from 20 years ago.

JS: Yeah. As you said, there's so many training opportunities for medical officers and others. And I guess that's pretty important.

KU: Yeah, when I first came to the agency I told people there's so much training, certainly at CDER. There's so much training that you could basically be in training full-time. That's how much training opportunities there were, which of course you can't do that obviously, because you have a job to do.

And that's not just for medical officers, it's across the board for people of all kinds of disciplines.

JS: Right. It wasn't too terribly long before you moved into your next position, which I gather is probably your first supervisory position in the agency, in the Division of Drug Risk Evaluation. That was around 2000, I think.

Obviously this office is very much involved in postmarketing safety, drug usage, and so on, risk assessment. We know the way drug safety was organized and operated changed in general a few years later with some major safety issues that came, like Vioxx for example. But at the time though how did the work in that division intersect --

[00:20:00]

-- with the review divisions in the center? I understand your team helped provide regulatory insight and editing to review documents, right?

KU: Yeah. Again it was very much a postmarketing realm. I think the interesting part, when I was in what was then called OPDRA --Office of Postmarketing Drug Risk Assessment. Peter Honig was the director of that, and then he left and went to work in industry. And he has since been in industry his whole career. But Peter had a remarkable influence on my career. He was one of the people who had encouraged me to come to FDA, and then he encouraged me to come to postmarketing, again with my clinical pharmacology background and I think a larger generalist picture of drug development, drug review, and things of that sort.

But interestingly, this was the time when there was no PDUFA (Prescription Drug User Fee Act) money for postmarket activities. And so I would say a fair amount of the postmarketing activities, they were all done out of the budget base. And I do believe it was because of, just as you mentioned, some exceptionally high-profile safety issues that put postmarket safety in the limelight with one of -- I don't remember which PDUFA negotiation it was, maybe it was PDUFA III, that then opened the door for PDUFA funding for postmarket activities and such.

So I would say one, I was only there for about a year and a half before I moved on to my next position. I think it was a bit of a challenge integrating the postmarket activities into premarket review activities. And trying to establish good working relationships with the Office of New Drugs and all of those premarket activities. But those things have expanded so much over the last couple PDUFA cycles and with Gerald Dal Pan's leadership in that office. The new drug review and the postmarket review activities, there's almost seamless management of those

activities now. It was a little more challenging back in the day when I was in that postmarket office.

JS: I gathered so much.

KU: And Vioxx happened after I left that office. There probably were dozens of safety issues that we dealt with when I was there. But one, I probably can't necessarily talk about them, if this becomes something public. And two, I'm not sure my memory is good enough to remember which specific drugs and things of that sort.

JS: This is FDA, we always have experiences of some kind or another along the way. I should ask. How was the transition to -- I gather this was your first supervisory position in the agency, is that right?

KU: It was in the agency. But I had been in the military before. Public Health Service is quite different from active duty military. And I had had supervisory experience prior. I think the difference is really understanding more of the civilian type rules and regulations and the union.

But again, lots and lots of training for that type of activity. And I also think being a supervisor at FDA, and probably being a supervisor anywhere, no matter what you read in the

books or in the classes, the rubber doesn't meet the road until you have to utilize that experience and have some real-world experiences as well as a lot of on-the-job training.

JS: Right. You were there until 2001, which leads us to your move to the pregnancy labeling team. And that would appear to be the beginnings of a greater role involved in what of course led eventually to your position in the Office of Women's Health. So just a couple questions about that experience if I may. First of all, how long had the team been around? Did this precede your joining it in 2001?

KU: I don't know exactly. But I would say a couple of years. There was a small team in the Office of New Drugs that was working on the regulation to change pregnancy labeling. So to move pregnancy labeling from the letter categories, which are not very descriptive or informative, to something that would be much more useful for clinical decision making. Because patients who get pregnant need to take medications. They get sick. And patients who are taking medications get pregnant. But just the strict ordinal scale of a single letter was not very helpful on a clinical basis.

So there were two people. There was a medical officer. And boy, I'm picturing her face but I can't remember her name. And then there was a pharmacist, Dee Kennedy, and they were located in the Office of Drug Evaluation IV in the Office of New Drugs. When OND reorganized, it moved to the OND Immediate Office. But it was always under the direction of Sandy Kweder, who was the Deputy Office Director of ODE IV, and later the Deputy Director of OND.

And then that medical officer left and went to NIH, so they were recruiting for a medical officer to fill in with that team. So it was a very small team, at one time I think we had up to four people. And after I left and moved to Office of Women's Health there were some major reorganizational changes in OND (Office of New Drgus), and there continue to be. And that team is now I think even a division within one of the offices in CDER now.

JS: OK. Can you just characterize the kind of work you did there? For example I know you were involved in a pregnancy registry while you were there. Is that right?

KU: There's certain pregnancy registries, they're pretty much very drug-specific, or disease-specific. So what we did as a group, one, was a lot of regulatory work. Writing up proposed rules for both pregnancy and lactation labeling. Writing numerous guidance documents related to pregnancy and lactation, one of which was a document on pregnancy exposure registries. And as well working closely with the review divisions in CDER when there were questions related to pregnancy or lactation. And as well engagement with the external community, the scientific community, and even industry, and groups that are very involved in the use of medications during pregnancy and how to get better information about that.

So a lot of outreach activities, also some interactions with NIH, who had -- I can't remember the name of the group there but they had a group that was doing some things as well.

JS: OK. Did your team have occasion to interact much with the Office of Women's Health?

KU: We did, because OWH would work with CDER and OND related to trying to get some studies done, looking at drug pharmacokinetics in pregnant women and pregnancy exposure registries as well. They had some money. We had some ideas. And it was a nice marriage between the two offices. And there was -- how do I say this -- challenges I would say in getting these type of studies approved by IRBs and by FDA's IRB, which I don't know what it's called right now but it used to be called the RIHS Committee. Research Involving Human Subjects.

So there was a pretty lot of interaction between the two offices. And to get some buy-in across the women's health groups and women's advocacy groups, CDER leveraged the contacts and such that OWH had at the time, when we were trying to explain stuff related to the regulation on pregnancy and lactation labeling and any of the guidance documents we were trying to do. So it was a natural partnership.

JS: OK. So speaking to the OWH, I notice you'd been a grant reviewer for them since almost the time you joined the agency. So you obviously were very familiar with their work when you arrived here, right?

KU: When I arrived at OWH?

JS: No. When you arrived at the agency. You'd been certainly one of the grant reviewers that they had drawn upon within the agency, right?

KU: Yeah, I don't remember how many years I reviewed stuff for them, but I kind of got adopted by that group to do some activities, before I even knew anything about that office.

I think part of it was they were, again, doing work in conjunction with CDER, and a lot of those studies were clinical pharmacology type studies. So who's a clinical pharmacologist who they could have as part of their review panel and such? So I don't even remember how it came to me. Like hey, there's this activity. Would you be interested in doing this? And I was like, "Yeah, sure." It's a great way to learn something else.

JS: It's a good match of interests and skills, it seems. As you've characterized, there were a number of intersections between what you were doing and what the OWH's interests were well before 2005.

KU: That's correct.

JS: So 2005. That's an interesting time. At that time, as is fairly well known, the person who preceded you in that position as director of OWH, Susan Wood, had resigned her position over the issue of expanded access to Plan B emergency contraceptive. So when you were offered this position, did this come up? And was there any expression of a direction that the office should take on this issue, or any other policy issue for that matter? I guess what I'm asking is did Dr. von Eschenbach, our acting commissioner at the time, did he have a vision for

the office. Not only the issue of Plan B, but was any of this communicated to you when the offer of the directorship came up?

KU: In short the answer to that would be yes. I was not looking for another position. I was very happy with the work I was doing with pregnancy labeling. And you're correct. Susan Wood's resignation from the agency is what precipitated me going over to the Office of Women's Health.

Terry Toigo was acting for several months in the interim. As you're probably very well aware, Susan's resignation was very public and very widely broadcast. She was even on *60 Minutes* afterwards. I think this was about Plan B not even necessarily expanded access. I think this was just the approval of the first Plan B medication, if I remember correctly.

JS: You're correct. I was mistaken.

KU: No, that's OK, because there have been issues about expanded access over time, but I believe this was the first Plan B even prescription medication. So the agency did not approve it and Susan, as you're well aware, very public, that was the reason for her resignation and her reasons are very well articulated in her resignation e-mail as well as publicly on interviews and such.

JS: Let me just jump in if I may. Of all the transitions you've made in the agency, this was a little unusual, this one. With something that's going on as you say so publicly. But you understood that, and yet you accepted the position.

KU: Well, you wear a uniform, and I think you make decisions in a way that might be very different than I think straightforward civilian. It's about the mission. It's about public health. There are jobs that you would take, not necessarily that you want them, but it's the right thing to do at the time. We can circle back to this with Office of Generic Drugs if we have time.

Dr. Woodcock was also the deputy commissioner at the time of all of this, and she interviewed me for this position, and then so did the chief of staff for Dr. von Eschenbach. Again I can picture this gentleman's face but I can't remember his name. He interviewed me. And I'm not necessarily sure I was interviewed by von Eschenbach or not.

But it was very clear to me that what needed to happen was that the external groups -- again back to these women's health groups, women's advocacy groups, and such -- these groups were absolutely outraged by the lack of FDA's approval of Plan B. And so part of my task was, and it was very clear that we needed, to figure out how to communicate with these groups and how to calm the waters so to speak because of that.

And so part of that is as well a communication strategy that best explains, or explains, what's the role of the office, both internally and externally. Because I think internally there were a lot of interactions between OWH and some of the centers, and I think this very public resignation compromised some of those internal interactions as well. Because you're inside the FDA fire wall and you're privy to a lot of predecisional information, and there was I would say

some concerns about how that information was dealt with and how best to share information and partner.

So first was meeting with some of these external groups and listening to them and understanding what their concerns were, and then also explaining what the role of the office is. And part of that was an understanding that the office did not have a regulatory review role or regulatory decision-making role. And I think there was some misunderstanding about what the role of the office is or was at the time, and still is, because it does not have a regulatory review role and is not involved in regulatory decision making.

And then secondly the other part was I think the remit to me was really to up the ante on the science and the basis of the science that the office is doing. So you mentioned grants and things of that sort. How could the office improve how it's using the money for the grants and really creating a robust scientific program around women's health?

And so the first, the outreach activities and the external groups, that was a big stretch for me. I'd spent a lot of time talking with patients and a fair amount of time giving public presentations, but I did not have experience with groups external to the agency.

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Somewhat from my experience with the pregnancy labeling group, those were more scientific professional groups that we worked with, less advocacy groups. So that was a stretch and an opportunity. And I learned a lot by doing that.

The scientific part was a great opportunity to learn more about what happens across the other centers in FDA, and I thought I could easily leverage my scientific foundation in order to do that. So I'm hoping that that answers your question, John.

JS: Well, it does. It does prompt other questions of course, one of which is where these outside groups -- as you mentioned, you clarified what role the office has in the agency. But was there some kind of expectation that the office should somehow be exerting an influence on those other agency offices that have authority when it comes to regulatory and approval decisions?

KU: Well, I think there's always expectations of external groups on FDA that for those who are inside the agency recognize that they go counter to what the agency can legally do or things of that sort. And I've seen this my whole career at FDA. FDA should do this. Whatever that this might be, we legally could not do that.

And I just think that there was a basic misunderstanding about what the role of the office was, and that's something that I had experienced even earlier in my career. This office should do thus and such. Thank you for your suggestion. That's a very interesting idea. We can take back that suggestion. And let's just explain a little bit about how certain things are set up, or how the laws are written, to demonstrate what the FDA can or cannot do. So I would say I think there were definitely some external groups who really thought the role of the office was that it gave a thumbs-up or a thumbs-down on whether certain products that impacted women should be approved or not. And while the office could certainly advocate in one way or the other, it did not have the pen for decision making.

JS: So this also, it must have pointed out a need for as you said greater connection perhaps, a need for greater connection between the office and the centers and their work and the work that they do that has an impact on women's health. And I understand you formed a committee to help facilitate that. Is that correct? The Women's Health Advisory Council.

KU: Yeah, we did set that up. It was, how would I say, there was the intent to have that function in that regard. Did it do everything I wanted it to do? Probably not. But that was really a by-product of the need to build and bridge relationships between OWH and the centers, and for each group to better understand what are the roles and responsibilities of the other group.

One of these great articles, it was actually later in my career, but it's called "Who Owns the D?" Quote, unquote D. It's actually from a *Harvard Business Review* I believe. And the D is decision making. So who owns the D? A lot of times when there's clarity around that then people can better align on -- they might not agree with what the decision is, but they can better align on what the decision is because they understand that they don't have – or who does have decision rights and who doesn't have decision rights. And that was part of the function of that council, to better understand what things might be coming up, how could the office help, and if there was a need to engage with these external groups in advance of any kind of an approval or certain types of decision making.

JS: So this had representation, I gather, from all the centers.

KU: It did, yeah. And then a natural segue I think from that was how do you build a more robust scientific program by the office. And the way of doing that is to really understand what are some of the gaps in knowledge that the centers are dealing with when it relates to products that are specific to women's health.

So then we could leverage and say, "Ah. So we better understand your needs, might we be able to use some of the funds that the office has to do some kind of contract or grant to help answer some of those knowledge gaps?"

JS: I wanted to ask about a couple of those studies. Before I do, you did mention -- this is essential to what the office is doing, particularly because so much of its funding goes to sponsoring important studies that help fill in gaps in the agency. But another obviously very public thing that came up early in your tenure in the office was the issue of the proposal to reduce funding for the office fairly substantially. Can you tell me where that came from and how it was resolved?

KU: I think that just came about in the typical annual cycle of budget. And I think that there's always stuff that comes down from the department to the agency. You have to do this or you have to do that. And sometimes some of those budget exercises are you have to reduce your budget by 10%. There's all these activities every year multiple times a year.

There was a proposal on the table. It was not on the table by the Office of Women's Health, but there was a proposal on the table I think by the agency, one of the ways to meet those specific requests would be just to cut the budget for the office.

As it was, it would have been to cut the budget for multiple offices. And the women's health community heard about that, and they were a bit outraged, and they lobbied strongly to be sure that the office had a set budget and a relatively safe budget. And in one of the pieces of legislation that funded FDA kind of as a fallout of this is that there was a line item within that budget that specified how much money the Office of Women's Health would get. And I think it was $6 million at that time, and I don't know what the office's budget is now.

JS: OK. The numbers I had seen when I was looking into this was a budget of about $4 million that would be trimmed to a little bit less than $3 million. But anyway it was as you said part of the natural flow of cycles in the federal government, particularly for a regulatory agency, right?

KU: That's my remembrance of that.

JS: OK. Well, you mentioned some of the so many important studies. In fact it's quite remarkable when one goes through how many studies came out with the support of the office. I wanted to mention a couple. But one there seemed to be a number of grants funded while you were there that focused on gender differences in outcomes associated with cardiovascular

devices. Particularly involving drug-eluting stents. And I was just curious from the work that had been done on this subject. Did we see any impact on regulatory policies or otherwise ways that devices were used that came as a result of this research that your office supported?

KU: Well, there was always the assumption that women were underrepresented in clinical studies. And especially that became more obvious so to speak when looking into what was the extent of the participation of women in clinical studies. So that was one thing that the office funded, and funded a lot, that type of work. And what became apparent looking at that was in some areas women are actually overrepresented in clinical studies. For example in some of the dermatologic diseases and probably some neurologic as well or psychiatric. And there's not necessarily a real clear understanding for why that would be.

But what else we saw was a pretty substantial underrepresentation of women in clinical studies for cardiac disease. And in that regard in those coordination and communications with the different centers, CDRH was having some issues related to the drug-eluting stents. There were some safety issues that they were seeing. There were questions potentially about do these work as well in men as they do in women. And I think that was the genesis for why the office started doing some activities in the drug-eluting stent area.

And then that kind of blossomed into a bunch of other things. Again in the cardiovascular area there was some collaborations with Duke on EKGs and EKG monitoring. Again that's a device-related activity. And the other part is -- I think I just said this, but -- there was a pretty intense interest in this area from the center. So if the center has an issue and an interest, and they don't necessarily have the money to do certain types of research studies, and

that it was some more natural collaboration between a center with certain scientific issues or regulatory issues they need to understand and the office.

JS: This points out something perhaps worth bringing up, which is in FDA how many entities within FDA have as a regular part of its program to go out and fund studies to the extent like you have. Certainly in terms of the proportion of your budget, most of that presumably went towards support of these studies to support particularly the questions that come up in the centers. Right? So how unusual was this in the FDA to have a program that does this?

KU: Well, so one, I'd say the Office of Women's Health budget was split between the regulatory science, regulatory research activities and outreach activities. I don't remember the exact split between the two. But there was probably close to equal distribution. So that's one.

Then the other part would be how common would that be. So most of the centers, the biggest part of their budget is to do review activities, and not to conduct independent science. That certainly changed over the tenure that I had at FDA. And I don't know necessarily across the other centers, but I do know in CDER that there has been a variety of different scientific activities that increased independent of the straightforward review activities. I think they've come about over time with some either congressional interest because of a particular safety issue or the PDUFA reauthorizations and such.

There's a lot of information. CDER has a regulatory research program that is managed by ShaAvhree Buckman's group. But also within many of the suboffices within CDER there has definitely been a growing research program and such within them.

JS: What's your sense, if you can recall? The office funded both intramural and extramural projects. I gather most of the funding was dedicated toward intramural work, right? Is that fair to say? Or was there a substantial amount of extramural funding going on as well?

KU: There was both. I can't actually recall the breakdown in my mind between what percentage was intramural and what was extramural. Sorry.

JS: That's OK, just curious. Another of the activities that seemed interesting that came up, I guess this was in collaboration with the NIH Office of Research on Women's Health. But you developed a collaborative online course for clinicians and researchers and others on the science of sex and gender and human health. How did this course come about? And how long did it continue? Just curious.

KU: You're digging into some deep recesses of my memory here. That's one I totally forgot about.

JS: Given the important interests that the office had in explaining and publicizing the importance of gender differences in clinical trials, it sounded like this was actually geared for again people outside of the government who conduct these trials.

KU: Again this is digging into my memory. And so I think that the Office of Research on Women's Health at NIH was very interested in doing something like this and had tried over a couple of years to get something going. And I think as we partnered with them, between the two of us, I think let's set a timeline. Let's set dedicated individuals to work to develop this kind of thing and get this out on the Internet. So I don't know how long the course was there. I don't know if it's still there or if it's been updated or not.

It was not an easy thing to do if I recall correctly. Especially because you had to get clearance from two federal agencies. But there was definitely an interest in getting the course complete and getting it up online. And I don't know when that finalized. But probably towards the latter part of my tenure there at OWH.

JS: Well, the office had so much going on in terms of its outreach programs and all the wide variety of research projects you were involved in. And then forming the ties, the connections within the agency, which I understand was a pretty important thing to do. So I think before moving on to your next stage, as you look back, are there other things that stand out in your mind that are particularly noteworthy about activities that the office was involved in during the time you were director?

KU: Well, I think another thing that we did related to --

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-- the scientific program was to be able to summarize all those activities and catalog them and explain the benefit of having a research program and what the impact was to the agency and to regulatory decision making and such.

And a lot of the activities really helped with the clarifications to some of the guidance documents that were being worked on. It's great to have a program. But sometimes if you can't explain what the program has done and why it did it and what the impact was it's just research for the sake of research. And I believe that that office continues to partner with the centers to better understand the impact of the research that it's conducting.

The other thing I would say is the outreach program really -- it's hard to say that it blossomed. But it really exploded with I think being in the right place at the right time with certain external groups. And even with HRSA for example and third-party payors who gave information about what kinds of materials would be beneficial to consumers. And then we were able to develop certain types of materials that then were distributed by these other organizations. And so I think the ability to penetrate more communities and more deeply down to the consumer or patient level was a real tribute to the program and the effort that was led by Marsha Henderson at the time.

JS: Right. I know Marsha had been in that position, leading that outreach program, for many years.

KU: Absolutely.

JS: I think when you started you brought Marsha on as a deputy. Is that correct?

KU: Yeah, that's right, but she was already in the office. She had been the outreach director for a number of years. Right. She was the deputy for me for a couple of years that I was there, yeah.

JS: Well, that's very helpful and it gives a very important context to what the office does and it's important. As you said it's not research for research's sake in terms of that program. It has to have a bearing. And sounds like it did in many ways, for example the way guidances were constructed, and relying on that important research.

In 2010 you changed positions, and you went to the Office of Medical Policy in CDER, where you were deputy director. What prompted your decision to move on?

KU: I really wanted to get back to more of my scientific roots in clinical pharmacology and drug development and drug regulation. The position in OWH was very interesting. I think I learned a tremendous amount and I would say it was a much more political position than I really wanted to have. I really wanted to be closer to the science.

And I think that what I was tasked to do at the office when I took over five years before, I think that that had been accomplished. So I really wanted to get back to drugs. I looked at CDER and looked around at what kind of opportunities were there. And the Office of Medical Policy in CDER used to be a relatively small group that resided within the Office of New Drugs. Dr. Woodcock's vision was to really create a stand-alone Office of Medical Policy that did a lot of the policy work for the whole center as it relates more to writing guidances that were more general across the whole center. Not the same kind of policy work that the Office of Regulatory Policy did, but more of the product developmental type work. But not very product-specific, which is more guidance work that gets done in the Office of New Drugs.

And so that office was looking to expand, and major reorganizations, major growth in hiring, and that kind of stuff. And I had done those types of activities in the Office of Women's Health, albeit not on that same scale as what was required for OMP, but I did have a lot of experience doing that kind of stuff. There was certainly a lot of regulatory work being done in OMP that I was not familiar with. So it gave me opportunities for learning a bit more.

It was just kind of a nice opportunity and the right place at the right time, that type of deal.

JS: An office with this sort of a mission must have had some particularly interesting challenging issues that came up while you were there. And I'm guessing certainly there must have been a wide variety of policy implications that accompanied various laws that came along as part of user fee reauthorizations or whatever. Are there any that stand out in your mind as you look back on this period?

KU: I'm going to get the timing of this wrong. But in exceptionally close proximity to when I started in the Office of Medical Policy was one of the PDUFA reauthorizations that put forward the biosimilar stuff.

The Office of Medical Policy did a lot of the coordination of biosimilar not necessarily review, but getting the policies straight. Even what kind of products are going to be regulated as a biosimilar or as a biologic, versus as a drug. And OMP pretty much led all those efforts. So to say this in simplistic terms, what I thought the job was going to be was very different than what the job was, considering that that legislation was just passed. So I was drinking from a fire hose with biosimilars for a long period of time, in addition to a lot of the administrative work of standing up a new superoffice, a big reorganization package, and hiring a large number of employees, probably 50 employees or something within a year or two.

JS: Sounds like a whole variety of HR headaches to me.

KU: Yeah. Well.

JS: Comes with the territory, right?

KU: I think it comes with the territory. And so that whole biosimilar stuff was very fascinating, but it was critical that the agency get some of the policies really clear so that industry could figure out then how best to develop the products and get applications submitted, or at least even get INDs and things of that sort to the agency. That would be probably one of the biggest things that happened during my time in OMP that wasn't necessarily as expected.

But there were a number of activities that they had at the office that was related to drug labeling, a variety of guidances and rules related to the drug labeling.

JS: But it strikes me as challenging in and of itself that this is an office that has coverage across the entire range of the center's interests. That must been almost overwhelming.

KU: Where there are things that are very specialized, those types of regulatory work were pretty much done out of the specific areas and offices within CDER. This was I think more the policy-related activities that were broader in scope. Here we go. Things like human subject protection. That was a large activity for the Office of Medical Policy, where there's not a natural break for where that activity resides within any of the other offices within CDER.

JS: Right. I was just thinking that perhaps things come up that might originate in one area but have a policy implication broadly, though of course I can't think of one at hand. But biosimilars, that's particularly interesting, a whole new category of products. How do you deal with that? How do you deal with that in a policy sense?

KU: Unbeknownst to me, there were years' worth of conversations related to biosimilars and how to get biosimilar products because of the way that the law for the Food, Drug, and Cosmetic Act for drugs differed from the law for biologics. The law for biologics didn't allow for quote, unquote generic versions. And I don't want to use generic in terms of biosimilars, because they are different, because they're regulated by entirely different laws. But there were a large number of people who had been working on this area for a number of years.

So fortunately there were. So those types of people were brought together in order to put pen to paper and create some of these policies. So that was good. There was a lot of learning as we went along, trying to implement certain policies and such. But there were experts already in the center and in the agency in the world of biosimilars.

JS: By the time you left the office in 2013, how many biosimilars had the agency actually approved? Do you know?

KU: I don't know the answer to that. But I would venture a guess that probably none. That's probably very searchable in the FDA Web site, when was the first biosimilar product approved.

But I think there needed to be clarity for industry on how to develop these products first, and that's what had to happen. And that kind of clarity is guidance writing, regulation writing, things of those sorts. In the last several years there have been more and more applications submitted to the agency for biosimilars, and there's been a couple more biosimilars approved.

It's not surprising that there wouldn't have been a biosimilar approved right away, because the industry wouldn't even have submitted their application. A lot of work, a tremendous amount of money on the industry's part to develop these products, because they wouldn't want to waste their time and then put something together and submit it to the agency and it's not what the agency wants. Yeah. But there have been some biosimilars approved so far. I don't know the exact number, and that surely is probably changing on a month-by-month basis now as more and more companies are getting into it.

JS: And even with approval, it does still take time to actually bring the product to market too, right?

KU: That's true, yeah.

JS: This leads us to your final position, where you spent most of your time in the agency, at least longer than any other, and that was in the Office of Generic Drugs, where of course you were director. Can you talk a bit about what led to that transition?

KU: Interestingly, probably two years before I took the position the center was recruiting for a director of the Office of Generic Drugs. And I was encouraged by a colleague to apply who said, "You would be great at this. Your knowledge of drugs and clinical pharmacology and your work externally would really be very helpful."

So I interviewed for the position, and at the time just seeing this huge deer in headlights and said, "Oh my, I don't want to do this." There were conversations between FDA and industry to develop a generic drug user fee and so it just would have been a tremendous amount of start-up. And I had just done all that start-up work with OMP. I just was like, "Wow. I'm not sure this is what I want to jump into right now."

I interviewed with several people, even talked to the center director, and just landed on this is not the right thing for me at that point in my career. The center eventually did hire a person to come in as the new director of the Office of Generic Drugs for the sole -- not the sole purpose. But the purpose was really to get the program in line so that it could meet these generic drug user fee commitments, because I want to say it was PDUFA V when that was passed, so the first GDUFA (Generic Drug User Fee Act) was passed. So they hired this gentleman and he came in. And it was like OK. I end up talking to him, and like, "I have a lot of experience with CDER, I have a lot of experience with the agency. I can help you to do this if you're interested in some assistance."

So I went over to OGD as a senior adviser or some such title like that. And then for reasons that I'm not fully aware of it didn't really work out with him. And he left the agency very abruptly. And Dr. Woodcock turned to me and she says, "Cook, we need some help here. Can you help?" It's like that's what you do in public service. You take on roles and

responsibilities that you might not otherwise want to. Like OK, sure. And it's going to be hard work. This is not a job I want. But I'll do what needs to be done.

JS: Before you go on, can you speak to the state of affairs in generic drugs at FDA at this point in time? For example the backlog of generic applications.

KU: I would say that the program was kind of a victim of its own success over years. When Hatch-Waxman was passed in '84 there were very few generic applications approved, and not necessarily so many generic applications submitted. When Hatch-Waxman got approved and there's plenty of data on this to show that the number of applications increased and increased and increased and increased. And as well at the same time the utilization of generic drugs, largely driven by financial decision making by third-party payors, insurance companies, things of that sort, the utilization of generic drugs continued to increase.

So you have the supply-demand, increasing use, increasing applications. All of that happened while the workforce doing generic drug review activities was pretty stagnant. There was not a requisite increase in the number of resources and the number of staff to keep up with the program. And so naturally what happened was there would be what was called this backlog. Applications came in. There was no assigned due date for review activities. And so when GDUFA was passed, I think, and I don't have the right number in my head, but there were 2,500 or 2,600 or so generic drug applications that had been submitted and hadn't been acted on.

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And then there was as well a large backlog of what are called prior approval supplements that had been submitted and industry hadn't heard from FDA on them. So that was part of what you're alluding to about the backlog.

JS: And the level of staff at the time that you arrived at OGD?

KU: I think the office was maybe about 300. Again I'm not 100% sure on the exact number. But that included multiple divisions of chemists, division of microbiologists, some labeling reviewers and reviewers that did filing assessment. Three hundred kind of sticks in my mind of what it might have been.

But what GDUFA required was almost 1,000 new hires with the first three years of GDUFA. And it was split up that 25% were to come in on the first year, 50% were to come in on the second year, and 25% to come in on the third year. So that's 1,000 new hires in a three-year time span. So I would say probably a hiring activity that was unprecedented at the agency.

JS: Presumably staffing is where most of the fees went to. As I understand it over the five-year course of the law before it was reauthorized -- we'll talk about that too -- but there was a provision for up to about $1.5 billion. Does that sound right?

KU: Yeah. That was what was negotiated by FDA and industry for GDUFA I. So industry paid, I think it was $1.5 billion. But they don't pay per staff. The way it's broken down is there's a fee. There was a backlog fee that they paid. There was a facility fee that they paid. Maybe they didn't have a facility fee in GDUFA I but they have it GDUFA II. And an application fee.

And so then that's what industry pays. How those moneys are spent is determined internally by FDA. But there was a provision in GDUFA I that there were this many hires that the agency had to bring on. Not necessarily a provision that said how much money of that $1.5 billion had to go to staffing.

JS: In exchange for that, what were the performance requirements of the office?

KU: Well, there were review goals that implemented in year three. So the first two years, there were no performance goals except for hiring goals. That's again if I remember correctly. But then there were review performance goals that implemented October 1 of year three of that first GDUFA cycle. And that meant the new ANDA or abbreviated new drug application or generic drug application came in. A certain percentage of those had to be reviewed by, in response to industry, and then there was a set goal on that, say 15 months.

And then year four it changed to a higher percentage of applications had to have a response by 15 months. And then by year five again if I'm remembering correctly it was 90% of applications had to receive a review by 10 months.

So that was just for original applications. There were review goals for prior approval supplements. There's a whole bunch of presentations that are out there and on CDER's intranet and internet and such that delineate all of the different requirements. And there were a lot of requirements in GDUFA I.

It's kind of like a fee-for-service. Industry paid and the expectation was that FDA would deliver a certain response within a specified time period.

JS: And so how did the agency do?

KU: The agency met or exceeded every single GDUFA I commitment. Yeah. So a pretty amazing performance story, I would say.

JS: It really is. And when you think about it, as you alluded to earlier, the level of the staffing increase and the speed at which so many people came on board, that in itself must have been just an incredible challenge. Just to bring so many people on board.

KU: Yeah.

JS: Just finding space for people if nothing else.

KU: That's correct. And so what I called it was pretty much like a perfect storm. We had to hire a large number of people. I say we collectively. This was not an Office of Generic Drugs activity, this was an activity for the whole agency. From inspectors in ORA to lawyers in OCC to reviewers in OGD and in other offices across CDER, it was a collective agency effort in order to make the implementation of this program a success.

So there was a large number of hires. There was basically changing every single review activity so that it would meet those performance objectives. Because basically you have to change all your processes. If your processes aren't meeting that then the process isn't working. You have to change your process. You have to document your processes and train on them.

And in addition to that we had a major reorg that we had to do. All of the chemists were being moved -- chemists and microbiologists -- moved from OGD to the Office of Pharmaceutical Quality, a new office that CDER stood up. And then make OGD its own superoffice on par with the other superoffices in CDER.

And OGD at the time was in multiple buildings scattered across Rockville. And so we moved OGD from those offices to the White Oak campus. All of that was successfully done and the program was implemented. And like I said, the agency met or exceeded all of the GDUFA commitments.

JS: And before you know it, it was time to start renegotiating into GDUFA II, right?

KU: That's true because you're usually starting about two years in advance of when a user fee ends. The agency is starting to renegotiate with industry. So the GDUFA II reauthorization was led by Keith Flanagan, who was a lawyer in OGD who set up an Office of Generic Drug Policy in OGD, and Mary Beth Clarke, who runs the Office of Executive Programs in CDER. So the two of them co-led the GDUFA II reauthorization negotiations with industry.

JS: I know obviously GDUFA I took place before you joined the office. But you had more of an insight into how this worked with GDUFA II, right?

KU: I was not part of the negotiations for GDUFA II. I was not part of the negotiation team. I was informed about what was going on and could provide some input to the FDA negotiating group, but I was not part of that. Which actually worked fine because there were still a large number of GDUFA I implementation activities still underway in the midst of GDUFA II negotiations.

JS: How did what happened under GDUFA I affect the terms of GDUFA II though? Clearly the agency has done an incredible job meeting all of those goals that came up. Were fees set separately, goals set quite differently? How do the two differ?

KU: Well, I think the co-leads for GDUFA II, their intent was to streamline the program and make it easier to be able to implement a new or a reauthorized user fee.

The number of commitments and such in GDUFA I was pretty astronomical. And the more commitments you have, the more things you have to track and have to report on. So it was critical to kind of let's streamline this, and be able to then have people investing their time and effort doing the review work and such versus monitoring all the work that's being done.

If you look at what the review goals and commitments were for GDUFA I, you basically had a large table that sequentially implemented numerous activities over five years. Very difficult, very challenging. And as well, trying to negotiate a reauthorization even before the agency is implementing for example the toughest requirements is really difficult. So they're in the midst of negotiation on a new user fee. But it's not even year five yet. So the agency is not even doing year five yet. So more of a simplified implementation for anything new that the agency would be asked to do.

And there's a couple other key talking points on GDUFA II reauthorization. And I have to admit they're just not in my head right now.

JS: We can always supplement the record if you would care to do that. That's certainly fine too. I'd like to wind this up with a question. You left the agency, retired, in February, right, 2019?

KU: I retired March 2nd of 2019.

JS: March, OK, forgive me. You've seen a lot of the agency, you've been involved, no doubt about it, particularly when you were at OWH. But clearly you have a perspective on CDER, the Center for Drugs, probably more than any other part of the agency. And so I guess what I wanted to ask you about, maybe a comparison a bit. Since you've seen other centers. You've spent more time in CDER though. But looking at how the center has done different things over the years.

For example how it has responded organizationally to either statutory needs or other public health needs, how the agency's communications have been between the senior leaders and the medical officers and other professional staff. We'll go over these again.

I'm interested in hearing about how differences in scientific and policy opinion are addressed in the center. And that's come up from time to time. And then I guess, finally, you've already spoken a bit about this, the way the center has addressed training needs and opportunities for advancement within the staff.

The Center for Drugs has always struck me as just an organizationally complex center. You've mentioned several times superoffices, which is always a great term. But it speaks to how complex the organization is. Has this served the center well as you look back on it?

KU: I think you're right. CDER is a very complex organization. Most of my career at FDA was in CDER. Five years in the Office of the Commissioner. I never worked in any of the other centers except the Office of the Commissioner, which technically is not a center. So it's hard for me to compare how other centers do what they do.

I would say that you're right, CDER has changed. Certainly it's changed a lot between when I joined and when I retired. The one thing that I would say that FDA does really well is it knows how to respond to a crisis. That's exactly why the agency was created in the first place. So the agency is just great at dealing with public health crises and addressing them and putting as many resources together to tackle a problem.

I think it's more difficult to be long term strategic because of that, and I think the agency gets hit on an annual -- not even annual -- a very frequent basis. There's some other crisis or some political hot spot or something like that. I would say that most of my time in CDER the center director was Dr. Woodcock. When she was in the Office of the Commissioner as the deputy commissioner there was someone else who was the center director. But most of my time in CDER has been under Dr. Woodcock's leadership. So she is exceptionally strategic, very big picture, and very inspirational and such.

To your point about how certain things have -- how responded organizationally and such, in my experience there's almost always some reorganization happening in CDER at any point in time. And I think it's the opportunity to realign priorities and realign strategies and have the form of the office or the center -- kind of form follows function. What's the function? Therefore what should the format of that be? Those types of things are difficult. Anybody in federal government knows that making change in the federal system is slow and sometimes purposefully slow. But that doesn't mean that change doesn't happen because there's a tremendous amount of change in certainly my tenure when I was at CDER.

Another part of your question was related to communications and senior leadership. Under Dr. Woodcock, again, under her tenure, she tried very hard to institute executive

leadership across CDER. But that's really difficult when the people in those positions still have day jobs to do, meaning running their relevant superoffice.

And I think the way that our industry counterparts would be staffed is quite different for what there is in a regulatory and government type organization. And I think that there's been efforts to try and communicate that kind of information to staff. Probably most of the time at the very staff staff level, people are so busy, there's just so much work to be done, that sometimes you can't even worry about that kind of stuff or be engaged in that, because as a reviewer your workload is just -- it's never going away. You're constantly staying busy.

The people in the senior leadership positions are very dedicated to the staff and they're very dedicated to the organization and they're very conscientious about sharing information and communicating information especially across that senior leadership group.

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JS: It seems to me the Office of Communications in the center is a very vibrant one that accomplishes a lot of this too.

KU: They do, as well as the Office of Executive Programs. That group has more of a function across the senior leadership of the center. The Office of Communications is very very busy, always, because there's a lot of activity happening at the center. Under Dr. Gottlieb when he was the agency commissioner, he took communications to another stratosphere. And so that office was exceptionally busy dealing with a lot of the communication that was coming out of the commissioner's office at the time.

And there continued a need to expand what communication venues the centers engage with. It's like changing technology. If you think about it, years ago no one would have even known what a tweet is. Now to see the agency on Twitter and other types of social media, that has to be responsive to the times.

JS: That's right. You already mentioned how, if you wanted to, in the center you could spend your full time taking training on any variety of activities, so it seems that that responsibility of the center is more than adequately attended to, no doubt about it, right?

KU: Yeah, there's always training gaps because there's new staff coming in, because the staff turnover is pretty -- I guess it's about 10% to 15% at CDER. But when you have -- I forget what CDER's FTE count is but I'm going to say probably in the range of about 4,000, so that's a pretty substantial number of people that turn over on any annual basis. And there's new requirements that the center has to implement, so every time there's that there needs to be additional training. And there's -- how would I want to say -- kind of overarching training that's required by everybody universally across. So there's centrally run training. But then there's very specialized training within a particular review discipline and such. And that stuff can really only be organized and orchestrated by those specific areas. So I would say that there's lots of training opportunities. But learning is a continuous activity.

JS: Yes, it is. So we've covered a lot of territory here. You've had a pretty interesting career at FDA. But I know we haven't covered everything. And I guess this is a chance for the glaring omissions that I've left here. What haven't we covered that we really should?

KU: I can't think of anything off the top of my head. But I will agree to let you know if there is something especially after I read the transcript. If there's something that just says, "Oh man," either we missed the boat on this or we absolutely missed something, I'll flag it to you and we'll decide how to address that.

JS: That sounds like a good plan. But I do want to thank you so much for sharing so much about all of the positions you've held here, all the activities you've been involved in. You've had really quite a rich career here at FDA and affected so many aspects of what it is the agency does. And so I appreciate particularly your perspectives of the Office of Women's Health, which really initiated this oral history. So that's been very educational for me. I appreciate that and appreciate your time.

KU: I'm happy to help. And if there's anything else you need, John, just give me a shout.

JS: Thanks.

END OF INTERVIEW