brought it up, you know the possibility of something like this ending up with NIH funding, was that an --

DR. MILLER: A real life example.?

DR. NEREM: Was that an FDA person?

DR. ANDERS: NCTR staff person.

DR. NEREM: I guess my bias about NIH would suggest that the kind of things that NIH would ultimately be interested in in fact would not be the kind of things that we're talking about, maybe this program ought to be targeted.

DR. SCOLNICK: Well, no, it's -- it's too short a time to understand it all, but I'm not convinced of that at all. I mean, if you talk about issues of pharmacokinetics and drug metabolism, things like that, there's so much basic science going on in that world outside of the FDA that -- I'm not at all convinced that that's not already going on; all the FDA has to do is take advantage of that body of information and what they have to fund separately.

DR. NEREM: Oh, I agree.

DR. SCOLNICK: So I don't really have a good sense for the distinctions here and what really should the FDA's purview -- I can tell you that I echo Harold's comments.

DR. MILLER: Right, but we'll look at that, we'll look at this, how is this going to impact our regulatory decision-making processes. How will this influence our label-writing, how will this influence our --?

DR. NEREM: I would be more interested in that than I would be whether it had the potential for NIH funding.

DR. MILLER: But as you notice, I've had three goals, and one was fill gaps. The second was new directions; and actually Jill James fell under new directions of research. That was something we would put a little bit of money in, see if it leads anywhere, has a potential.

DR. SCOLNICK: It really relates to what Marty Rosenberg said. If you're going to be funding research into womens health without the kind of infrastructure of peer review with

investigator-initiated best ideas for womens health that NIH has, then I think it's really like it's a very different process. And it really needs to be scrutinized.

DR. LANGER: Let me, as we close the session, make two comments that might be good to go over at a future session that I heard.

One is to try to put together some statements that make, I guess the lines less blurry. And the second I think this issue of peer review; I agree. I'm concerned that when I hear this, Bob's comment about asking your friend -- in other words, the question is how do you maximize this objectivity? And I think that maybe needs to be given some thought.

So what I might suggest is if you at a future meeting, those two issues I think highlight a number of important points that people make.

DR. MILLER: So how do we focus in on FDA issues only.

DR. LANGER: Well, I don't think it has to be worded like that. I think --

DR. NEREM: On FDA's needs.

DR. MILLER: On FDA's needs.

DR. LANGER: Yes. And the second thing is, I think a greater way of ensuring peer review and objectivity -- I mean really his point about, you know, how do we really make sure you get the best things done?

DR. MILLER: Great. Thank you very much for your attention.

DR. LANGER: Thank you.

So what we'll do now is I guess we'll take a lunch break, and I'd like to meet back at 1. And we can do some more work over lunch.

[Whereupon, at 12:20 p.m., the meeting recessed for lunch.]

AFTERNOON SESSION

[1:08 p.m.]

**Joint FDA and Industry Training**

DR. SCHWETZ: This example is an effort that involves training and outreach. One of the things that we struggle with as an agency is the rapid pace of changing technology, and this example of training programs that actually take place out with the industry, joint meetings between the industry and FDA scientists and others, is meant to move us up on the learning curve faster, so that we learn about technology before the submission actually comes to us, and we maximize the interaction between us and industry early on.

Susan?

[Slide]

DR. FITZPATRICK: As we heard earlier today, one of Dr. Henney's chief initiatives is to increase the science base at FDA. So she asked us to begin this project about ten months ago to look at joint FDA-Industry technology training as one way of not only leveraging our

resources but helping to increase the science base at FDA.

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The specific objectives of this training were, as most people -- this is for our review scientists that are reviewing the petitions that are coming in from the industry or our field investigators that are out in the field, actually going on inspections.

They need a way or a mechanism of staying up to date with the fast-paced change in technology, and recognizing that most of the technology that we -- new technologies that we deal with are developed in industry rather than in some other setting.

We decided to try to see if we could set up a program that would have the industry help us train our FDA review scientists and field investigators in some of the new technologies before they see those technologies in some type of petition or in a field inspection setting.

So the specific objectives were to

have the industry talked about the technologies. For FDA to talk in general terms about what types, for those technologies, what types of assurances they would need to make sure it was well-controlled and adequately validated. And also, we thought this would be a good way for FDA scientists and lab analysts, field investigators and the industry scientists to be able to discuss technologies, the technology and the science apart from the regulatory arena.

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Most of the time when we're dealing in meetings with industry, it's probably over a regulated product. Those aren't always the most collegial meetings, and this was a way to be able to talk about science without the regulatory aspects of a particular product.

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I think one of the important things that we envisioned in this program was, we wouldn't just be talking about it; we would be going out and actually observing it. And when

I talk about the specific courses that we've done, I think it will become a little bit more apparent.

Now only do we have people talk to us about the technologies, but we've actually gone to the laboratories or the manufacturing facilities of the industry and viewed the technology firsthand and had a chance to really talk to their scientists, but questions that come up as we actually view what's going on.

[Slide]

Our anticipated outcomes in this type of training, we thought, you know to give our scientists and our field investigators a more in-depth knowledge of the technology may help facilitate more expedient scientific reviews and more expedient field inspections. A lot of what goes on in the review process is back and forth, trying to understand what's in a submission; and if we can give our scientists a heads up on some of the new things that are coming in, that might make the whole process more timely. And in addition, it might help

these technologies enter the marketplace sooner.

I think the other thing that's important is that FDA and industry will gain new perspectives on each other's concerns, especially in the area of new technologies.

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We just started this program last June and we had several training mechanisms that we used to implement the program. The first was because originally this program focused on the field investigators, and then we brought the center scientists into it, we had to choose -- we chose the topics and new technologies based upon a technology interest survey that we did of our senior field investigators.

We went out to all the district offices as well as headquarters and asked our senior investigators what technologies they thought that they might need training on. We wanted the training to cover a wide variety of scientific issues in the different centers and we wanted the training to take place in

different geographical regions of the country.

And of course we needed some way of making an agreement with industry in order to be able to do this type of training, which was a new endeavor, a new way of thinking for the Food and Drug Administration. So we used what's called a cosponsorship agreement as a mechanism for developing or making an agreement with industry to do joint training; and in that agreement we talk about the responsibilities of FDA, we talk about industry responsibilities. There's no money that exchanges hands between the two parties.

We make a specific point that we're talking about science, and we're not talking about specific regulated products. In other words, if we go in from the industry, this isn't sort of their way of having a private meeting with the FDA to discuss products that they might have pending; we really want to keep it to the science. I must say that the industry has been really wonderful about just keeping to the scientific issues.

We have our cosponsorship agreement looked at by our ethics department as well as our general counsel, and of course the industry has their lawyers look at it; and the information that they give us, the confidential information that they give us is treated as if it was a submission given to the FDA under any other circumstances; it's not public knowledge, it's kept confidential; we're bound by 2061 which is our confidential and trade secret agreement. That binds us in these courses and in any material that they might give to us.

We have been putting that into the cosponsorship agreement so that it's made clear that if they're talking about confidential things, that they're not going to have to worry about those getting out to the public.

And for our own sake, so to speak, we also, in addition to making a cosponsorship agreement, we look at the regulatory history of the place that we're going to train. If we're in the middle of a regulatory disagreement, so to speak, with that firm we probably wouldn't

go there to train on some new technology at this point. So that's an additional safeguard that we look at when we're developing these programs.

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Our first course took place last September, and it was cosponsored by the Food and Drug Administration and Merck. And it took place September 29th in West Point, Pennsylvania.

One of the things that a lot of our field investigators wanted to find out was about the new technique of barrier isolation technology. It's a new sterilization technology, and we knew that Merck had a new, state of the art barrier isolator that was just coming on line in their West Point facility.

So we jointly put together the agenda with the Merck scientists, with the Office of Science, the CDER, CBER and CVM sterilization experts; these were our senior scientists put the agenda together with our senior ORA field investigators, and we went up there on

September 29th.

Not only did we listen to them talk about the scientific aspects of the barrier isolator, we talked about our validation concerns; but we actually spent three hours in the barrier isolator itself, and I don't think that there's anything that you can do -- not inside. But in the room -- you have to really see it; it's a $40 million piece of equipment that takes three or four rooms, and 600 vials go through in a minute, and I think by actually seeing this type of technology stimulates a lot more questions in your mind if you're an investigator or if you're a scientist reviewing the nationally -- reading about it on the paper.

They actually got to see it and we had an interactive-type session; and then after that we came back, we talked about, some more questions. One thing that we did prior to having this course is that we exchanged a list of questions. Merck gave us some questions that they were interested in having us answer,

and FDA, the different parts of the FDA that attended the course gave Merck some questions that they like covered as sort of a starting point.

If anyone has been to an FDA meeting, and you comment and hit people cold, it's often not the best way to get answers from the FDA. So this was one way of exchanging questions in advance that we'll be able to know and think about what we wanted them to talk about.

So I think that was very successful. We took about 25 FDA people up there, then we had a lot of industry people go, too; and I must say Merck was really wonderful in hosting this activity.

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Our next course that happened this past January was how the application of ELISA rapid screening methods to the FDA field investigations. Now, ELISA rapid screening methods probably doesn't look like a new technology to anybody here, but it is a new technology in FDA field investigations. And

this course was cosponsored by the FDA, the National Center for Food Safety and Technology, which is our Moffett Center; and the Grocery Manufacturers of America, and it took place in Minneapolis, Minnesota and General Mills. Our participants were CFSAN and CVM scientists from headquarters, the ORA headquarters and field investigators include several of our import investigators.

We had the NIST scientists and we had the Minnesota Department of Agriculture scientists also attended the course, and really what it was was not only did we learn about the theory of ELISA rapid screening methods, or they talked to the investigators about it; but we actually went into the General Mills labs -- they ran them themselves.

They ran microbiological assays and they ran chemical assays, and they got a chance to interact with some of the General Mills and the Pillsbury scientists about the pros and cons and pitfalls and questions, and got a good sense of what, if they had to either evaluate

these out in the field or use them out in the field, what kinds of things that they would run into that -- that you might not get from just reading about it on a paper. Anyone that has tried to duplicate someone else's technique has to almost go into that lab and learn it, because they don't write down all the little nuances that you need to be able to do some of these things successfully, without going over and over and over again.

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Our next course is coming up in a couple of weeks. This is a course on Microarray Technology. It's cosponsored by FDA and the Bay Area Bioscience Center. It's May 16 through 18 in the year 2000, and it's going to take place in San Francisco, California.

The Bay Area Bioscience Center is a biotech association located in the San Francisco Bay Area. They have pulled in -- and with it, we have -- what's more, Dr. Schwetz, who comes to all of these and actually, there's great support and it's really appreciated. I

think by all of our field folks and scientists for endorsing this type of training and showing the importance of it.

But we have our, some of our people that are really knowledgeable in the area of microarray technology, from CDER, CBER, CDRH and NCTR attending, as well as our San Francisco and San Diego field compliance officers and investigators.

And the course agenda, it looks really interesting. It's going to take place the first day at Stanford. We have five different companies from the San Francisco area that are to present their technology. We're going to have three companies that are not developers of microwave technology, but they're users of the technology talk about what they've seen, and then the next day, we're going to -- two of the developers of the company; I think it's Heisic and Insite (ph), to look at their actual microarray systems and talk to them about quality control issues.

Then we're going to go to Roche, who

is an end user, and look at the way they're using these technologies, their applications of it; and then the following day we're going to go to Afametrics (ph), because they just built a new manufacturing facility and we want to view that and really talk about quality control issues, but talk about them with just that one firm so that they can feel a little more free to talk about those issues.

In addition, NCTR is going to present to San Francisco some of the research that we're doing in the microarrays.

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So I think this is going to be a really exciting course; and then the following week, May 22nd, we have a course on Nucleic Acid Amplification testing. This is a new way of screening blood that many of our field investigators as well as our center scientists wanted to learn more about.

Before, it's actually required in all of our blood banks. And we're cosponsoring this with these five companies which are

actually developers of the technology. They're not the ones that are going to be doing the screening in the blood banks, but they have developed -- four of them have developed different NAT testing procedures and instrumentation; and that's Gene Probe, Roche Molecular, Chiron/Bayer Diagnostics, Organon Teknika, and then the National Genetics Lab actually has not developed the technology, but it has -- it uses a lot to be doing screening, samples are sent in and they screen them.

So they are actually, they're going to be here in Rockville for May 22-25, and each of these four companies are bringing in their instrumentation and their technology and they're setting them up in one of the CBER labs, and all of the labs are -- we're providing four different laboratories; they're all secure facilities so that we're treating their instrumentation and technology as if we would treat a submission; we're to our best effort making it as confidential as possible.

One of these companies, I can't

remember which one, has some giant robots they might be bringing in, too, as part of their system; so that will be interesting to see. The participants are, once more Dr. Schwetz, and we have CBER and CDRH scientists and our national blood experts are going to be coming to this course.

CBER and CDRH, the scientists who are actually doing the reviews, are going to be talking to each other about their different perspectives on this technology, because one thing that we've learned in this endeavor, we've picked topics that are sort of crosscutting; they affect more than one center. And it's a way of, and a stimulus for our different -- center scientists from our different centers, to actually be talking about and sort of agreeing on common approaches to these -- and common thoughts and perspectives on new technologies.

So they'll be talking to our field investigators; then we're breaking them down into groups of eight or nine, and they'll spend

a half a day at each one of these laboratories.

Actually, I don't know if running or seeing run or actually viewing firsthand all the different ways to do the NAA testing in anticipation of actually having to either go and be an investigator in a blood bank, looking at the technology; or in anticipation of having to review this technology.

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And the last course that we're working on for this year is called, New Trends in Sterilization Technology. And this is going to be cosponsored by the FDA and Johnson & Johnson, and it's scheduled right now for September 5th through 8th of this year, and it's going to take place in New Brunswick, New Jersey.

The course -- we're going to take up to New Brunswick are probably, our senior sterilization experts from CDRH, CVM, CDER and CBER and our ORA field investigators. But we are also going to try to broadcast the lecture part of the series out to our district offices,

and then we're going to go to the different labs, either Johnson & Johnson or some of their other manufacturing people in the New Brunswick area and actually view some of these new technologies in the laboratories and have a chance to talk to them about it. That part, I don't think that we're going to film because I don't know technically. If we can, we may. If we can't, we can't.

But then we're going to follow up with a lecture series for more of the beginning reviewer on just general principles of sterilization. We're going to try something where we broadcast it; the person may be there in one of our -- here in the headquarters, but we're also going to try to broadcast that to the district and maybe have that as a follow-up every week for a few months after that.

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That's really what we put together in last ten months. I might say that this program has been met with just very positive enthusiasm, not only from all of the centers

have given us great support in running this program, been really cooperative in developing the agenda and helping us design the courses. But I think it's been met with very positive enthusiasm from the industry. I think Dr. Henney has been really applauded for her foresight in being willing to support something like this; and we're hoping that we'll be able to continue it in the following years.

We feel like, for one thing we've been able to train a lot of scientists. Really, the cost to FDA is getting our scientists there. And I know for example on the barrier isolater course, I saw an announcement for one of the trade associations giving a course. It was an all-theoretical, it had a very hefty price tag, and I don't think you can match what Merck did for us in actually letting us go in and viewing the instrumentation right up front.

That was just so much more valuable than sitting there and listening to it for two days, about the theory of it; actually seeing it and watching it run and stop, and seeing all

the things you might have to think about if you were trying to decide if it was actually doing what it was supposed to do.

So in anticipation of additional funding for our program next year -- and it's nice to see Dr. Suydam here listening to this as we talk about that part of it -- I have a couple questions for the Science Board.

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One of the questions that we're talking about is what were the other mechanisms to select new topics or technologies for this program? I told you earlier that we did a survey of our senior field investigators, because that was the emphasis at first with Dr. Henney, was to get our field investigators really competent in all these new technologies are on board.

And actually, we have expected our field investigators to have the same level of scientific rigor in taking these courses as are center scientists.

What would be other ways -- because

not every technology we're going to find from the field and if we continue, we want to have maybe less of an ad hoc way of selecting topics.

Then, what recommendations do you have for improving the program? Every time I give one of these courses, I try to analyze what I can do better on the next one. What ways can I get people to talk more, can I get people to interact more. What are some follow-up activities that might come of the training instead of having just a one-time deal. For example, for our ELISA test, the investigator said "Maybe we can have a checklist to go in to, when we go in to, on an inspection, a checklist of what we should be thinking about if we're evaluating this kind of study." And that's one of the reasons we've had this follow-up lecture series on sterilization.

How can we train all of our scientists and have as broad an impact as possible? And work with industry on that type of program.

So with that, I'll turn it over to the

Science Board and the audience for questions.

DR. LANGER: So, comments or answers to the questions?

DR. DAVIS: One point. When it says that industry scientists were present, like at the merck one and also the General Mills, does that mean people, scientists outside of Merck got invited, or just Merck people? What does that mean.

DR. FITZPATRICK: At the Merck facility, only Merck scientists were there.

DR. DAVIS: Okay.

DR. FITZPATRICK: Because of the location and because of the --. But we felt that we weren't really giving an undue advantage to Merck because by training our scientists in this technology, we're really anybody, any manufacturer who's bringing this technology in to the FDA. Because they'll all benefit for a reviewer or a field investigator that really understands the technology better.

DR. DAVIS: No argument; I just wasn't sure --

DR. FITZPATRICK: But at General Mills, there were scientists from about nine companies.

DR. DAVIS: The reason I asked that--

DR. FITZPATRICK: There was Hormel and Frito and Pillsbury --

DR. DAVIS: The reason I asked is the -- that's in the Bay Area?

DR. FITZPATRICK: Yes.

DR. DAVIS: -- I'm assuming, because that's a host of companies --

DR. FITZPATRICK: Right.

DR. DAVIS: -- but there will be a host of companies represented.

DR. FITZPATRICK: Right.

DR. DAVIS: And actually, we went on the web at my company just the other day under Biocom to see if we could find something out about the meeting. And there was nothing there.

And that's why I was a little confused whether that was going to be open or not open, or -- do you know what --

DR. FITZPATRICK: Well, they're not generally open to the public. They're not public meetings and we don't -- they're really training sessions. We haven't done a Federal Register notice or anything like that, opening it up to -- because we're dealing with people's scientific -- it will be open, I think, for those firms that are interested going through -- we've left it up to the Bay Area Bioscience Center, as we left it up to Merck, to decide whether they -- who was going to represent them at the industry.

DR. DAVIS: So it's not unusual to you that it's not on your web page?

DR. FITZPATRICK: No. No.

DR. ANDERS: I think Ed provided a partial answer to new topics in your comment this morning when you're evaluating staff; what's the most exciting new findings or new technologies in the field? And that can certainly be, guide you in selecting topics for this program.

DR. LANGER: Yes.

DR. ROSENBERG: One way you may do that is through Pharmala or Bio. You can use the trade associations; that way you can get access to all the pharmaceutical companies. I'm sure there might be things that, each of the companies that would be of interest to you. Those kinds of things.

The other comment, though, is also that -- make sure that for some of these things, for example what you're doing now with array technology, that's such a new technology, and not yet firmly established. You're going to have to make sure that you reassess as you go along that you don't kind of do this as a one-off and think you know or understand the technology. I think there's an incredible amount of development.

And my sense, and I'm just getting into my own personal opinion, is that when you get four biotech companies, you'll get four info-commercials about their technology. And therefore, you'll need to follow up with end users even moreso on a new emerging technology

to make sure that you're really seeing the problems, the caveats, the upsides and downsides of these technologies, and so on and so forth. So that was just a general comment about circumstances.

DR. LANGER: Good point.

DR. FITZPATRICK: I almost sound like a broken record when I'm in these planning meetings because I say continuously, "Now we really don't want a commercial on your product. You know, we're talking about science and technology there, and I understand that any company that comes before a large body of FDA may want the tendency to do it," but we kind of build that into our cosponsorship agreement. That we're not talking about your products --

DR. ROSENBERG: No, it isn't that; it's just that any scientist will always present the positive side, and tends to limit some of the negatives and caveats, particularly if it's their technology. And it's sometimes the end user who is trying to use it, who figures out all the problems with it.

It seems to me some of the things you're looking at are more established technology, some of them are earlier technology.

DR. FITZPATRICK: Yes. And we did ask that we didn't want any presentations on the microarray systems from any company that's more than a year away from having a product, an end product.

But we do have three end users on that are going to talk to us about how they view EoS - Roche and one other; they're going to be talking about -- they've used a lot of the different microarray systems.

DR. LANGER: Michael and then --

DR. DOYLE: Marty just addressed my point.

DR. LANGER: Okay. Harold?

DR. DAVIS: I think that as an end user myself, one of the things that concerns us in industry, if I can speak somewhat more globally, is that when FDA sees these new techniques, they get convinced that they are

ready to be applied. And then the question comes back to us when we're standing there with a dossier is "Why don't you use this technique to answer a question" et cetera, because these new biotech companies will convince you that this is ready, that it's validated and it will answer all the questions.

We are fearful that we will run up against the FDA, saying "Well, why didn't you do X, or you need to do Y." So I think one has to be careful that every new thing that comes down the pike will, over time, prove to be a very useful tool, doesn't become a regulated tool necessarily so quickly.

DR. SCOLNICK: I also think you ought to reach out to universities for this program.

DR. FITZPATRICK: The problem with going to universities is that under the cosponsorship -- and actually, they are going to have some university scientists speaking from Stanford at this. The FDA cannot pay for university people under the cosponsorship agreement mechanism.

The only thing we can pay for is FDA employees traveling to that facility. We can't even pay for a special government employee coming to that.

DR. SCOLNICK: No, but I know --

DR. FITZPATRICK: So the industry has to be willing to fund that.

DR. SCOLNICK: But you can try to gather information from the leading science departments in the leading universities as to what technologies they think are interesting, and then go to someplace like Pharma and try to get them to sponsor it.

DR. FITZPATRICK: Right.

DR. SCOLNICK: The course, what visits -- you know. Because all this stuff starts in a university somewhere.

DR. FITZPATRICK: Right.

DR. SCOLNICK: And it's just keeping you up.

DR. LANGER: And the FDA can have courses here. I remember doing that myself a number of years ago in drug delivery. So I

think that Ed's point is good; you know, you could probably expand it -- bring people here. It's not the same thing as seeing it; it's just a complimentary.

Other comments or questions?

Okay. Well, thank you.

Now we have a session for open public comment. Are there any people from the public that would like to speak?

[No response.]

DR. LANGER: Okay, that's I think what we anticipated.

So now I'm going to turn this over to Bern for really essentially the rest of the meeting, whereof he's going to lead a discussion on strategies for maintaining quality of science at the FDA.

**Strategies for Maintaining Quality of Science at FDA**

DR. SCHWETZ: One of those measures that we have been working on to help to strengthen our science base to reach out and gain access to people who could help us with

mechanisms other than hiring them, this whole topic of leveraging and how we manage that, what the directions are.

Linda Suydam has provided leadership and focus on this, as you've all in the last couple of years, and Linda is going to lead us through some thoughts on where it is currently.

Linda is the Senior Associate Commissioner.

**Leveraging Resources**

DR. SUYDAM: Thank you. I am very pleased to have this opportunity to talk to you about leveraging, one of our major priorities in terms of mechanisms for being able to get FDA's job done.

There are a couple of points that I'd like to make about why leveraging, what is leveraging, why now, and what we're hoping to accomplish.

Let me start out by saying that the FDA budget at the present time is clearly not enough to meet all of the competing needs that we have for our resources. And the other

limiting factor on that budget is that about 70 percent of it is tied up in salaries and benefits for the people in the organization.

So we have very limited resources to go outside of the agency to do things, but we felt very strongly that we needed to focus more on, how can we expand with others mechanisms of getting our job done?

So we took on a leveraging initiative. Starting last fall I chaired a working group that was across the agency, and I think we've had tremendous successes. Now leveraging is not new, leveraging is something that we've been doing for a long time; but what we're doing is changing the emphasis.

So let me start by saying what is leveraging? Leveraging is the creation of relationships and/or formal agreements with others outside of the FDA that will ultimately enhance our ability to be able to meet and to do our public health mission.

Leveraging amplifies that public health impact, it emphasizes a proven way of

doing business. We have a number of successes in this area, including our Moffett Center out in Chicago, and a number of programs like our *Take Time to Care, Use Medicines Wisely* program that was operated out of our Office of Womens Health.

It also capitalizes on existing assets that we have, both intellectual and structural, and it values the capability of others in supporting our common goals. And we want it to be a primary strategy.

I think one of the reasons that FDA has not focused on this is that we've tended to be in the past a relatively insular agency that has believed that we can do it all. And unfortunately, we can't do it all, and that doesn't say that people aren't doing their jobs or they're not doing their -- they're giving 120 percent. It just means that in order to be most effective we have to use resources that are outside of the agency.

And why now? Well, it's very clear to us that the expertise and ideas and solutions

no longer reside in either one person, one organization, or at any moment in time. We think that the value of what we do is determined to a greater extent by the stakeholders to go outside of the agency and the FDA Modernization Act of 1997 actually called for it; it said consult with outside experts.

We also believe that effective responses to public health threats require an involvement of a diverse group of key players. So we can't do it within FDA alone.

Then finally, science, technology, global economics and communicating information and public expectations for safety all demand a leveraging type of professional alliance.

As I mentioned, we have a number of examples of very successful leveraging projects. The Moffett Center, which was established more than ten years ago in Chicago in order to look at the safety of food technology. The Mammography Quality Assistance Program which is run out of our Center for

Devices is another good example of how you can use FDA resources to get things done through other bodies.

Recently we've established our Product Quality Research Institute within the Center for Drug Evaluation and Research, which is a consortium of lots of people outside through the American Association of Pharmaceutical Scientists, who are putting money into a centralized project. And that project with its Board of Directors then decides which projects are going to be funded for research that is common to all of the people in the pharmaceutical industry.

Our Joint Institute for Food Safety and Applied Nutrition at the University of Maryland is another example; and I mentioned briefly our *Take Time to Care, Use Medicines Wisely* program, which is run out of our Office of Womens Health, which has been an incredibly successful program using the National Association of Chain Drug Stores to distribute the materials that we developed, and to use a

variety of other organizations to partner with us to get the messages out.

In doing this, we're really talking about changing a culture at FDA; and when you change a culture, you need to provide people with the tools that they need to change that culture; and as a result we have put together a whole variety of mechanisms that we think will be helpful to people in the future.

So we've developed a leveraging action plan, we worked on the priorities in that action plan. We developed a vision statement and guiding principles. We have a leveraging handbook, which is available for all FDA employees on line. We have an FDA Internet website. We have a compendium of leveraging examples.

We've recently held two stakeholder engagement meetings on leveraging, one out at Stanford at the end of March and one at Duke, just last week -- I think it was just last week; it seems like it. It must have been last week.

Both of those were incredibly successful meetings in terms of people coming forward with ideas about how FDA can work with a variety of partners to help get our public health mission completed.

Then in addition to that, we're building the infrastructure within the agency so that we have center contacts, we have a leveraging task force group that will be working as a consultant panel; so that if you have a leveraging idea as an agency employee, you go to the consultant panel and they will give you advice on how in fact you can get that done.

Then we're finally building leveraging into our performance plans, both individual and organizational, and also building it into our budget.

I think the handout you have shows a couple of different figures of how FDA's supports are leveraging initiatives, and we really believe that the circle of innovation that we're trying to accomplish can start

either with FDA scientists, it can start with people outside. It can start with any of our partners, professional organizations, universities, industry, consultants, consumer groups, state, local or federal government, are all partners and people that we can work with to leverage the resources we have.

I think we're very enthusiastic about this project, and we really are hoping that it will help to build relationships and also expand the intellectual capital that's available to the FDA in order to get our job done. And leadership is needed because right now sometimes the ideas are ill-defined. Our partners are also not always very organized. The power and resources may not be even and so we have to have the kind of principles that we have. Problems can be scientifically or technologically complex. Sometimes different perspectives can also breed adversity, but we think we can work through all of these things.

So we think that leveraging can be a variety of things, and want people to know

that. It can be formal or informal, it can have short-term results or long-term results, it can be a project where we have high control or where we have little or no control, a project where we have great oversight or where we have little oversight; it can be a project where we work with one organization or with many organizations. It can be a project where we're working with partners that we've known for a long time that we've worked with in the past like our state counterparts within all of the state governments, or it can be a project that will be with new partners, people that we have not yet worked with.

And then it can also be something that is a proven approach somewhere where we already have a model in place, or it can be a totally innovative effort. And I think the project that Suzy talked about just previous to this presentation certainly points out that this is a way FDA is in fact leveraging its resources, by using these types of training programs that we're working with industry on.

We've asked our senior staff to be incredibly supportive of this program; we've asked them to be champions for it; we've asked them to help build the infrastructure; to promote it as an option early on. So not to think when they're presenting new ideas or new programs that it means we need more people to get the job done. It's a project that we want them to think of, how can we leverage resources by taking some dollars and applying it outside the organization?

We expect our senior staff to monitor and track progress at the projects, to reward and recognize efforts and to report the progress periodically to the commissioner.

So at the Science Forum last year, Dr. Henney said "We leverage so that we can bring a wider range of scientific thinking to bear on public health issues. It's a smart way for us to do our business." And I think that's the message we're trying to get across about this project.

I'll be happy to take any of your

questions.

DR. DAVIS: In the material in the book, and several times mentioned this morning, you mentioned Moffett.

DR. SUYDAM: Yes.

DR. DAVIS: And also there is JIFSAN, two different leveraging programs. Is it the same thing just on different places, or two totally different programs? Could you explain the difference, if they are different?

DR. SUYDAM: I think I can explain, the initial Moffett Center was started out in Chicago in 1989, and it was focused on, primarily on food packaging, as I understand it, you know? And processing. Packaging and processing.

JIFSAN's focus is much broader in terms of food safety, and I think those are the differences, although Bern may have a better--

DR. DAVIS: So is Moffett still in processing and packaging, or has it broadened itself?

DR. SUYDAM: No.

DR. SCHWETZ: But they're also, I gave the example this morning of, the research that's going on there to figure out how to do a pasteurization of products without destroying them; cold pasteurization, other -- there may be other people in CFSAN who could say a lot.

DR. SCHWETZ: Sam, you can help me.

Work of that kind that has a direct problem associated with it for health, that we know there is a problem with contaminated juices; and the work can go on there to try to figure out exactly how to do it; the work that Joe mentioned on sprouts, to make sprouts safer.

Sam Page is the director of JIFSAN.

DR. PAGE: I think another major difference is that JIFSAN is a virtual organization. We have a very limited amount of staff involvement with a liaison between FDA and the University of Maryland and private sector. Whereas there's actually a major branch of the Food and Drug Administration that is part of the Moffett Center in Chicago, in

our Office of Plant and Dairy Foods and Beverages.

The other part of that in fact that JIFSAN is one of the major if not the major initiative is in the integration of FDA research components with the university. We have a new building under construction at College Park adjacent to the University of Maryland that we're quite excited about.

We are also integrating our major analytical instrumentation; our NMR group is already there, for example. We will have an unveiling of a new electron microscopy suite which is at the University of Maryland which incorporates both FDA and University of Maryland staff actually working there at the university. We're starting to design a mass spectrometry facility.

We're quite excited about the Center for Drug Evaluation move, a new lab that will be under construction shortly at White Oak, which is the other side of the campus from the Center for Food Safety. So we're starting to

explore options there with the joint utilization of equipment.

But what we're looking for in the long term is a substantial integration with the university system in both training, training programs, continuing education program as well as in the research efforts. But certainly there will be much more integration with the regulatory and research programs through the Joint Institute at Maryland because of the close proximity with the centers.

DR. SCHWETZ: Sam, the clearinghouse is also a big difference between JIFSAN and the Moffett Center.

DR. PAGE: Yes. As brought up by Bern and Joe, one of the major points of emphasis here is risk analysis, including risk communication and part of the president's Food Safety Initiative, put the Risk Analysis Clearinghouse in JIFSAN at the university; and this is a consortium among all of the federal agencies involved in risk assessment. This database will be available for people doing

risk assessments, both in the public and private sector.

DR. DOYLE: Linda, one of the examples you use is a public education campaign using, addressing safe drug use.

DR. SUYDAM: Yes.

DR. DOYLE: And I know FDA and U.S.D.A. and the industry has also been involved in a similar campaign with *Fight Back* and food safety. GMOs is a major issue right now where we need a public education campaign.

Has the FDA thought about some sort of a collaboration with industry, U.S.D.A., others, to do a similar thing?

DR. SUYDAM: We have thought about it, and in fact we do believe that there is a major public education component to the issue of GMOs, but we have to build that into our overall strategy and how we're going to deal with genetically modified organisms in food. And I think it's just not right here at this moment that we're ready to do it.

VOICE: The L word.

DR. DAVIS: The L word?

VOICE: Labeling.

DR. SUYDAM: We thought the L word was leverage.

DR. DOYLE: I'm talking about just a general education of the public so they know what GMOs are and basic principles. Not getting into those types of issues.

DR. SUYDAM: Good suggestion.

DR. LANGER: Yes, that's good.

Other comments?

DR. DOYLE: What's happened to *Fight Back*? You don't see much about it or hear much about it.

DR. SUYDAM: It's still being used extensively in public schools, and has received excellent evaluations.

DR. DOYLE: Great concept. Novel.

DR. SCHWETZ: What we would like to do from the standpoint of interaction with the Board is to continue to have dialogue with you on where we're going with leveraging, what the successes are, what problems we've encountered,

and to get your reflections, your advice, your help, on how we can do this bigger and better and get more of an impact from it.

So you will be hearing more about this as we go along.

The next topic is one that I know is going to be brought back to you from time to time; because while the mission of the agency is, and we've talked about it in terms of safety and efficacy of products and protection of public health, the most important part of the agency in being able to do that is the people we have, obviously. It isn't the laws, it isn't the other things, it isn't the brick and mortar; it's the people we have.

One of the things we realize in the agency, and Mary may be talking about this some more, is that because of major hiring practices in the agency and earlier years, we have a bulge of people coming forward right now who are ready for retirement. And on the one hand that represents a major concern of ours, because there's a huge amount of institutional

memory in this bulge of people whom we will lose, but on the other hand it represents an opportunity for us to structure the agency of the future.

I think a lot of hiring activities, especially in -- well, in good times, too; not just tight times -- we tend to think of replacing people one at a time. And at least I guess I would admit that I haven't thought, in the past when I have had the opportunity to hire people, that I'm hiring the leadership of the agency in twenty years, or the leadership of NCTR or NIEHS or whatever it was I was involved in.

I think in reality we need to look at the hiring activities that are in front of us in the next few years as nothing short of the expectation that we need to hire these people so that they are in fact the best leaders that the agency could have in 20 years and not just that we're filling vacancies.

And as a result, I wanted to have you get a feel for what is the profile of

scientists in the agency today? In a lot of different ways, not just expertise but other characteristics; and Mary Babcock is going to present some of that information. She is the Director of our Office of Human Resources and Management Services.

So you've got a lot of information in the packet that you received earlier and additional today, and it isn't our intent to have a one-time pass-through of all this detail and never come back to it. What we hope is that we open the door for some questions today as opposed to put things to rest, because this is so important that we want to talk about recruitment and retention on an ongoing basis, and have you help us with those things that in effect will determine more what the agency is like in 20 years than guidances that we write today or products that we approve individually or whatever else.

So this is something that we think is of major importance. Mary, will you lead us through this?

MS. BABCOCK: Yes. Thank you very much.

**Retention and recruitment of scientists**

**Flexibility of the profile of scientists**

**Training, retraining of scientists**

**Peer Review of Scientists**

[Slide]

MS. BABCOCK: I hope it's all right with you if I sit down; I have a lot of paper to shuffle, and I was afraid it would fall of the podium and embarrass me.

Well, we're going to sort of shift gears from science to our scientists, and I have a lot of detailed information in your notebook that you might want to look at while I'm talking. I've just put some highlights on the slides for the people in the audience.

I also, in the blue packet I just handed out, I put an organizational chart of the Food and Drug Administration. I'm not sure what kind of an orientation you had before you came here about what the organization looks like.

And I know in FDA -- I'm sort of considered a newcomer -- that we throw a lot of acronyms around, and you might be sitting there saying, "Now what is CVM, or CFSAN?" So hopefully with the organizational chart, it's going to be easier to follow along.

One other thing I'd like to offer, if anyone's interested, and it might help in some of your quality reviews of our organizations is, we have further organizational charts that go down to every single organizational layer; it's a package that's about a half an inch thick. But if anyone's interested, I certainly can provide that at some later date.

The part of my organization that says management services is the organizational piece of FDA.

[Slide]

The first handout in your package, and the next slide that I have is the overall onboard strength of FDA science. And I've tried to highlight on the board here the major occupations that we work with in FDA. In your

first handout in your notebook you'll see down to the detail of every last individual scientific position we have.

So this only highlights the major occupations. I think you'll notice, the consumer safety officer is our biggest occupation; that's really the field investigators, for the most part. We have consumer safety officers in every organization, but the bulk of those 1800 positions are the ones that are located in our field organizations.

The require there, it's not necessarily a degree in science although we prefer a degree in science, they have to have at least 30 hours of science to qualify for that position. All of our other scientific positions require a degree. The majority of our scientists have a master's or Ph.D. degree.

If you look in your notebook, you'll find any number of sorts of detail. I wasn't going to bore you with all that, unless you have any questions on -- I've sorted it by

center and by occupation.

You'll notice, at the bottom of first chart there's a percentage for each one of our centers. The total percent of FDA, 78 percent of our positions that we have are in fact scientific positions. They're scientists or support positions for scientists, which only leaves 22 percent administrative staff.

[Slide]

The next major group of charts there is our attrition rates. We have some issues with attrition. We have high turnover in several of our scientific positions; one that's really critical to us is pharmacokinetist. We basically can only keep a pharmacokinetist three years and they're out. So we lose one third of that every year. That's a problem in our recruitment and retention.

For the most part, though, our attrition rate is fairly normal, typical government attrition rate. Every year we recruit about 500 people to backfill the 500 people that we lose. Unfortunately what we

thought the board could help us with is identifying new and different places to recruit employees.

Now, we've compared our attrition rate to the whole Department of Health and Human Services and also to NIH and CDC; and actually, FDA's attrition rate at least today is lower than the other organizations. So we're doing as well as can be expected, I think in that area.

One chart I did put together is the, kind of looking at the attrition within one of our centers. The Center for Drug Evaluation and Research, this is 1999 they took a look at it, -- and those numbers might be hard to read I'm sorry, that was the best --.

The majority of the people we lose in the Center for Drug Evaluation go to private sector. What we're finding, they come into FDA, they learn our business, they learn how to do drug reviews, and then they become very valuable to industry, and they can command huge salaries.

So we're sort of learning to live with that and just -- we're trying to change our culture a little to, instead of bringing people in and trying to keep them 30 years, we're trying to figure out how to take advantage of new, young people coming in with some technical knowledge, keeping them for five years, and then bringing a new group in behind them. So it's sort of a change in the way we've been doing business.

It kind of matches the way the younger generation is coming into the work force; they're not prepared to stay 30 years in a career any longer, they'll be moving around.

[Slide]

As far as projected hiring, in addition to the 500 positions that we normally hire in a year, that's just our normal attrition. We're doing some projection for the year 2001. In the year 2001, we've put together some budget strategy that we're going forward to Congress with to hopefully get some new money in FDA, and right along with the

budget strategy we've tried to identify what kind of people and how many we would be hiring if in fact we're successful with Congress.

So this just gives you highlights of the new positions we would be hiring. Altogether, we're projecting another 450 to 500 positions if we get the increases we're asking for. So next year we might be looking at hiring 1,000 people.

So just to pique your interest, if you know people who are going to be looking for jobs out of the universities.

[Slide]

I thought maybe I'd talk a little bit about our hiring authorities. I don't want to bore you with the federal issues but FDA is lucky in a way, as a federal agency we have a lot of flexibility other government agencies don't have.

Normal federal government hiring is done under what we call Title 5, which is the laws, rules, regulations that govern hiring. It's a very tedious process, it takes a long

time. If we started a vacancy announcement, it might be six months or more before somebody walks in the door using the normal federal hiring process.

I know it's long, but it's just the way it goes; we also deal with veteran's preference laws and things like that.

FDA has the advantage of having two other laws that govern hiring. One is our Title 38, which is for medical doctors. Title 38 is really for the Veterans Administration, for their hospitals hiring doctors, but they've expanded it to the Food and Drug Administration.

So we're able to hire medical doctors without going through a whole lot of competition and paperwork, and we also are able to pay them much higher salaries than the normal government employee would be hired.

So our retention with medical doctors under this new Title 38 authority has been much better. In the past we were losing one doctor for every one we hired, so we never got ahead

with the number of doctors we had on board. We'd hire one and one would leave, so we were always like a hundred underneath.

With this new pay and hiring authority, with Title 38, we've been able to add 100 doctors just this year. So the medical doctor is really key to our drug reviews, in particular; they're kind of the final reviewer, so it's important for us to have them on board and have them trained in the drug review process.

The Center for Drug Evaluation is really where most of our medical doctors are located.

We also have the advantage of the Public Health Service Act, the Title 42, we're calling it, where we can really go out, identify good people, and bring them on board immediately. We don't have to go through much of any process.

Title 42 gives us authority to pay up to $2 00,000, which is the current cap on the federal government. That's what the

president's salary is, so we can't go beyond $200,000 at this point. We are not authorized to pay that much, but at least we have this authority to expand some of our current salaries.

So that's pretty exciting that we have this kind of flexibility; so that if we can target our recruitment, if we can find the right schools or the right places to go, we can in fact offer jobs a lot faster than the normal federal process.

We also have several what I call contract authorities. This is where we can pay stipends to bring students on board, or faculty from academia or other places where we can train them, we can bring them on board to work in our lab; we have over 50 labs across the country where there's a lot of education and sharing we can do, bringing postdocs or just professional documents on board to work in our labs and work with our employees, and learn our business, and we can learn from them in the state of the art.

We used that, particularly in the NCTR, we use the ORISE program, where it's the Oak Ridge Institute for Science and Education, where we partner with the University of Arkansas.

One thing we've put together for you, and I hope at some point between the next meeting you'll have a chance to look at, we actually went through every single person we hired, every scientist we hired last year in FDA -- and I believe it's the last handout in your notebook. And we did a profile that includes the grade level, and I'll give you a chart with the grade levels. The degree, the school they came from, prior experience and any honors and associations that the person had.

What I think we'd like to ask the Science Board, and I think this is what Bern had in mind is, to just quickly look through it and see, are we targeting the right schools? Are we getting the right quality of science in the organization? Should we be doing something different. To me it looks pretty impressive

that the level of people we get, the quality of the person we attract into FDA; but I don't know all the scientific -- I don't know if hiring a medical officer from certain schools is a good thing, or may be a mediocre thing.

So I think what we'd like to do is have some kind of a response back from the Science Board saying, "You're really hiring A quality students or B quality students" type feedback.

Do you all see that in the back of your notebook? Okay.

The other couple things I've done, as far as recruitment of scientists; this is our brochure that we use when we go to college campuses or job fairs or other kinds of recruitment at the entry level. It's just information about FDA; it's got our web site, it's got our offices listed, tells a little bit about the organization, and we have inserts about individual occupations that we have.

So you can take that or leave it, whatever. One of the things we have found is,

with the jobs that we've advertised over the last year, we now put them up on the Internet through the Office of Personnel Management, which covers the whole federal government.

And the response to our announcements has been maybe triple-fold over what we used to get, as far as people we see. Unfortunately, even though last year we looked at 12,000 applications, we only selected 250 people. So we're doing a lot of work; we're reviewing a lot of applications but we're not necessarily reaching the people that perhaps we need to reach.

So that's just the recruitment material we use. The other thing I put in the blue folder, and I apologize, I didn't get this into the book before it was time. Just some examples of the kind of vacancy announcements we use. There's one for a medical officer, and it talks about all the medical specialties and how people apply for a position, if you're interested in looking at something like that.

One of the things we've talked about

for a long time is how to simplify the process to get into the federal system. So any suggestions you might have on that would be appreciated.

Are there any questions about recruitment before I go -- I thought I'd talk a little bit about our peer review process.

DR. NEREM: Just a couple comments. As far as whether you're hiring from the right schools, one of the things you might do is talk to some of the bigger companies that bring products before you, and find out where they're recruiting from. Because in some sense, you ought to be recruiting from the same places.

The other thing I was going to comment on, if you add up all the engineers you have, I think it's 179. I'm actually surprised you might not have more. But one of the emerging things in education is the obvious attractiveness of young people to the bio-world. A lot of those people are going into either biomedical engineering or bioengineering, and it's not clear to me that

there's in fact enough jobs in industry to take care of them, all these bright young people, and that might be a good area to recruit in because these people are coming with a combination of biological background and a more engineering product-oriented background, and that might be a good match for FDA.

DR. LANGER: Go ahead.

DR. DAVIS: As I thumb through the sheet here looking at the schools, what's strikingly obvious to me is that you're not doing a great job of recruiting from historical black colleges. Now whether it's that you aren't giving them or they aren't showing up -- but as I just look through here, the only school I see you consistently getting people is Howard, which is located right here in the area, and that sort of makes sense.

I know when Dr. Sullivan, past head of HHS was here, that was a program he started down at Moorehouse Med School, I think it was called EMS, that he was involved in. There's a consortium of historical black colleges who

have medical programs of some persuasion; med schools, dental schools, veterinary schools, pharmacy schools, et cetera. And I know he has gone back to Moorehouse, and his brother's there, and they're still very active in that, and I've been involved. I would say if you're going to find people from sources you don't routinely recruit from, you're going to have to go get them, and that would be a good place to look.

MS. BABCOCK: Actually, we have quite an active program for reaching out, for diversity. Right now we have a major effort going on in the Hispanic area. We are seriously underrepresented in the Hispanic community, so we've been working with partnering with the universities, University of Puerto Rico, University of New Mexico, and a university in Texas that has a high Hispanic population.

We do routinely go to the historically black colleges and universities to do recruitment.

DR. DAVIS: Well, that's actually an organization, so even just a one-off --

MS. BABCOCK: Right. We have a list of them; I think there are 150.

DR. DAVIS: -- that's a great way -- they normally bring about 8,000 college students together for a medical forum every year, so it's sort of a one-time sort of everybody's there.

The other point I'd make is you made the comment that you're going to lose one-third of your force due to just people going out because of age. And that it sounded like you were saying that you were sort of acquiescing that that was just going to happen, but you were going to try to -- you're changing the mode of operation that, we're going to try to get people in and keep them for a few years, knowing they're going to go away. We're just going to lose a lot of these young people.

That scares me as a person who brings an application for it, because it sounds like there's always going to be people sitting there

fairly new. You know, that these reviewers, at least that I see, are going to be people with two years, three years' experience. Just keep turning over all the time. And that's sort of frightening.

MS. BABCOCK: One of the things we've talked about is, if we identify somebody who's really on a fast track, who is really an excellent reviewer, figuring out ways to pay them more money to keep them in FDA longer.

We figure it takes two to three years to train somebody to be a really good reviewer, to follow drug from the beginning to the end. So it hurts us when we lose people that quickly. So we're trying to come up with incentive programs where we can keep people longer.

Unfortunately I think part of our problem is that industry is able to pay so well for some of these people that we can't compete within this federal system.

Now my comment was more that 30 years ago people started a career and expected to

stay when placed for 30 years. It was kind of a lifelong career and we've had a lot people in FDA who have been here 30-35 years. And now that's not the model anymore; at least all the data shows that people are more inclined to have seven or eight or nine careers throughout their 30 years.

So I think it's just a matter that we have to kind of rethink how we treat our people, and try and keep the best ones as long as we can, but just face the fact that that's going to happen.

DR. DAVIS: We have the same problem in industry, and when I first came in there were a glut of people who were on that site who might have been there 30 years. But now people move from company to company to company, so industry fights the same battle, "How do we keep our good people without throwing up our hands?"

MS. BABCOCK: We've also talked about, how can we attract people who have had their career in industry, at the end of, when they

retire bring them back into FDA? One of our issues is, the ethics issue of a lot of private sector people's retirement is in stock holdings that they have, and of course we have very significant rules that govern how much -- you really can't hold any stock in regulated industry.

So we have a couple issues there that we've been talking about. You know, is there anything we could do if we wanted to attract somebody who retires from an industry after 30 years and bring them onto FDA? So we're trying to be creative as we can with some of these issues.

DR. LANGER: Ed?

DR. SCOLNICK: It looks like you're getting Ph.D.s from local schools. And you're not getting a wide variety of schools represented. So the question is, you know I've found over the years in recruiting that the best recruiters are not -- don't take this wrong -- they're not the HR people, they're the scientists.

So what is your program where people who run your divisions and run your centers, the scientists that lead your organization, in an organization you want to be more science-based, what are they doing to help bring in talent, given your restraints, and your pay scale, which is difficult?

MS. BABCOCK: Actually, when we have big recruitment programs, and I think Alan Rulis will be talking about this a little bit this afternoon, but when we have big numbers of people that we're going to try and recruit for one center or something, they actually are the ones who go out and do either college recruitment or --

DR. SCOLNICK: No, but you have a constant need for people. Recruiting is not filling a job, recruiting is a lifelong process of establishing relationships with science departments, constantly making your presence known, getting your people known, getting the young people to know you exist, comfortable with you and constantly applying to fill your

turnover as well as your big boluses.

And if you're really serious about upgrading the scientific staff of FDA, I think you really need to look at how you recruit. Because if I take you at face value about the losses that Harold talked about and look at where you're getting your scientists, I think you have a major problem, and you really want to upgrade the science in the FDA with what you're doing, you have a big problem. You have an enormous problem.

You'll never fill the jobs that you need with the quality of people you need, and if this is the best that can be done, you need to rethink the whole structure of how regulatory reviews are done for products that affect the health of people. You'll never improve.

DR. NEREM: I don't know how Merck and Amgen and SmithKline do it, but I know some of the major medical device companies that basically target seven, eight universities. And those are the ones that they're

establishing specific relationships with.

DR. DAVIS: That's what everybody does.

DR. SCOLNICK: That's what everybody does. That is the mode for all the industry recruiting, whether it's law firms or pharmaceutical firms or whatever.

DR. DAVIS: That's sort of what I meant by historical black colleges. Just as an example, you can't show up once and try to recruit. People look for relationships.

In our company, we actually -- this is public knowledge -- we actually pay members of our scientific staff for recruiting people. Because we recognize that we're in competition with other people. Now, I'm not sure that the government can do that, but we have an ongoing -- it's been going the last five years, an internal thing where if you recruit a scientist and the more top-notch that scientist is, the higher level, the more you get paid.

Now directors and above don't get to participate in that so it doesn't count for me,

but for more junior faculty, it's a way of getting the scientists themselves involved in their alma maters or in their trade associations or whatever, to help find these people.

DR. SUNDLOF: Well, the way the NCTR does it --

[Simultaneous discussion]

DR. LANGER: Is there any type of -- it's really a good point because I just think about my students, my graduate students and undergraduates. If they have a relationship by knowing people at the company, the chances of them going there just go up tremendously.

So the question that people are raising is, are there any -- and it's actually very consistent; the schools that are closest to here are the ones that you're getting. So if there are ways to try to have people speak or join research programs or something like that at universities, in other words as an investment for your future, I think it's -- trying to come up with a creative strategy -- I

mean, Ed is absolutely right.

DR. SUYDAM: I think that's actually one of outcomes that we pulled from the leveraging initiative as well. Because if you start building partnerships with institutions across the country, then hopefully those partnerships will yield you people that will want to come to work at the FDA.

DR. SCOLNICK: If you reach out for your review process and your information process more widely, you'll build the kind of research partnerships -- I mean, I agree with you. I'm actually quite worried, looking at this background information.

DR. LANGER: And I think what you're saying is good, but I don't know if it goes far enough. In other words, the question is, how do you get really the students exposed? Like if you want to get good young people, how do they get exposed to what you're doing?

DR. SUYDAM: Yes. I understand what you're saying, but it could also be that FDA scientists would be out working within the

university.

DR. LANGER: Right.

DR. SUYDAM: Hoping to give lectures and --

DR. LANGER: Exactly

DR. SUYDAM: -- being part of an ongoing curriculum. And in fact I know we do have some Center for Drug employees who are actually in a curriculum program at Duke, in the Duke clinical research system, which gives them exposure to the medical students at Duke.

So those are the kinds of programs we have to build on.

DR. LANGER: I'm also -- go ahead.

DR. NESTLE: I just want to point out that the CFSAN report had a number of suggestions along those lines about postdocs and internships and people taking positions at universities and adjuncting and all of those were in there, for just exactly this purpose.

DR. FENNEMA: Another approach, particularly at the master of science level, which is incredibly effective, is a program of

internships, summer internships for undergraduate students to come into your laboratories.

I know from our experiences in Wisconsin that that is a very, very effective employment tool, and is one you might think about.

MS. BABCOCK: We have those mechanisms; it's just that we haven't been using them as much as we probably should.

DR. NESTLE: Every student in our department at every level does an internship, and they, I would say 60 percent get jobs in the places where they do their internship. I mean some astonishing percentage. It may even be higher.

DR. SCOLNICK: I think you have a crisis, and I don't want to overstate it, but I really believe it, and Harold and I share the same view.

DR. DAVIS: It's just if you look at regrettably the salary structure, you know, which is not your doing, it's the government's

doing, what industry is paying them, if you look at - you see 30 percent of your people, senior people could walk at any time, and if you look at where you're getting people from, primarily just the local schools, there's no way the local schools can make up the differences for all the head count that you have, and then you factor on top of that the inequality of salary that can be offered. It just seems frightening.

DR. NESTLE: And the ten days vacation. That was one that made my heart sink.

DR. DAVIS: We don't take a vacation anyway --

DR. NESTLE: It doesn't matter; it's the principle of the thing.

MS. BABCOCK: Some of these new hiring authorities do give it some flexibility in the salary schedule. So that's going to help, I think somewhat. We've hired a consultant firm, Toffler & Martin, to help us put together kind of a future vision of where we want to go in

the organization, how to get there? It's really aimed at work force planning and a lot of the ideas we're talking about that you're suggesting in fact are in there.

The senior staff of FDA has really bought in to trying to do something a different way. So I think we're going in the right direction.

DR. ROSENBERG: Given how serious the problem is, and I agree with you on the seriousness, the point you made earlier about trying to at least in a temporary mode use industry retirees I think is an excellent idea. It will help supplement that.

But you've got to find a way to allow those people to participate; just because they have stock in the company they worked for all their lives --.

DR. SCOLNICK: Or more university reviewers, or really enlist, or really go to the universities and -- it's a contentious issue that I know has been around for a long time, that is, the use of people in

universities to supplement your reviewers in a really much more significant way.

I really think we cannot understate the level of seriousness of this problem. It's the single biggest problem I've heard today.

DR. DAVIS: Have you looked at the former pay scales in terms of what they guesstimate people in industry make? Because the question I have is, are you holding your own or losing ground over time? If you looked at it over the last five years, in terms of trying to look at a GS-somebody versus an RS-somebody in industry, comparable positions, would you say you're losing ground or --?

MS. BABCOCK: I would say, until we were able to have this new flexibility, we were losing ground.

Now one of the things we've tried to do in the past, we have what we call recruitment and retention bonuses where we can pay up to 25 percent additional salary. One of the requirements that the government put on us is that the employee wanted to give a retention

bonus had to have a legitimate job offer in their hand, or at least a potential job offer in their hand.

Every time we'd send somebody off to get a job offer, they took the job.

(Laughter)

So it was kind of a Catch-22.

DR. DAVIS: That's a program that worked.

And again, SGE programs, or how do politicians who get elected, who hold stock? Again there are perhaps not nearly as many of them; but they don't sell their stock, they -- don't they put it in trust or something?

DR. LANGER: Varmus had a blind trust or something like that.

MS. BABCOCK: There is such a thing as a blind trust. The problem with FDA is, we have a published list of stocks you cannot hold. And so anybody who is being considered for the job would know up front what stocks. So it's hard to have a blind trust when you already know you can't hold that stock. It's

been a little Catch-22 we've been dealing with, but --.

I think every commissioner that's come in to FDA has in fact had to sell.

DR. NESTLE: Exactly.

MS. BABCOCK: Yes, even the political.

DR. SCOLNICK: I don't want to give you a specific solution to that, but the kind of thing -- and it really depends on cooperation. In theory the government could contract with a big company that runs mutual funds and work out transition position for people where for the time they were there, their stocks were managed in a different way by an outside company where they would give up what is called beneficial control for the time they were in the agency, for the time they were in the government. And they would have to do that. Yet they wouldn't lose financially, because it would be being managed presumably in some kind of significant professional way.

DR. LANGER: Maybe even better.

DR. SCOLNICK: Maybe better. Probably

better.

(Laughter)

DR. SCOLNICK: But I mean you could just think out of the box about to do that in order to enhance your ability to attract talent.

DR. FENNEMA: Well, there's another aspect to this. This isn't always a matter of salary alone. If it were, you wouldn't have anybody left in the universities.

So the other major aspect of this is job contentment, and there's a lot of facets to this particular problem and many of them which I think you can work on, and should work on. Professional development is one of those. You know, the pleasantness of their environment is another one. And you can go on and on with all these kinds of things.

But that is incredibly important; somebody who really likes their job, they're not going to be tempted away by another $10,000 a year.

DR. NEREM: Bern said it earlier; the

people you recruit in the next few years is going to be the leadership 20 years from now, and you've got to have a strategy for recruiting and for professional growth that's going to produce those leaders 20 years from now.

DR. DAVIS: And assuming 50 percent of those people are going to be gone in ten years, sort of in my opinion, it's not a good strategy for looking at who potential leaders are. Because you're saying half the people we bring in, or something, are going to be gone in ten years.

DR. SCHWETZ: Harold, I would pose an alternate way of looking at that, changing it from a problem maybe to an opportunity. When you have a high turnover in some categories like certain of the reviewers, we have a training program going on, but we're not calling it that. And we're always hired under the level it takes to get that job done. It would seem as though it would make more sense, but it may not to you, as a company submitting

work, that we actually call this a training program.

And what we want to do is, eventually after three years, be able to hire the best and the brightest of the people who are in the training program; then you do like you do with postdocs: you bring a bunch of them in and you say "There's no promise of long-term employment, but this is a wonderful training opportunity for you wherever you go. And we're going to take on twice as many or three times as many as we would ever want knowing that we're going to very selectively just pick out a few that become who we want around 20 years from now."

We have a training program, we just don't call it that. They just keep disappearing. Call it a training program and overhire, and pick the best out of it.

DR. DAVIS: Well, if you can afford to hire twice as many as you're going to need three-four years from now, that's a different story. I guess I'm under the impression that

the hiring quotas are so tight that the FTEs you've got are basically what you need, and so you're always playing catch-up.

And oftentimes the people who are leaving, other people who are frustrated by whatever they're frustrated by, low salaries, poor working conditions, don't get to go to enough meetings -- whatever the reason that oftentimes we find it's the best and brightest who are going other places because they have the opportunity to go other places.

If you're losing bad people, you don't really care, but it's the good people that you really worry about, and the good people always have an opportunity to go somewhere else.

DR. SCHWETZ: But there are training programs for epidemiologists and other groups that are run that way.

DR. LANGER: This really seems like there are two issues -- I mean it's more than two issues, but two ways of looking at it are first there's the recruitment of young people -- and I think some of the points that are being

made about trying to get it to the universities are very important -- then the other thing is, that concerned me when I listened to this is the large percentage of people -- maybe it happens other places, too -- but the large percentage of people that leave so quickly. And how do you incent them to stay?

One question I had is, I don't have enough of a sense of, like if somebody does a great job do they get some great title or some great honor? Or what happens? Do they just get like a promotion of like $10,000?

DR. SCHWETZ: We give them more work.

MS. BABCOCK: Yes, we give them more work.

(Laughter)

DR. LANGER: That's the reward, basically.

MS. BABCOCK: We do have a reward and recognition program, but not the kind of money you're talking about.

DR. LANGER: No, I'm not even necessarily talking about money. Like what

universities do, say take Bob, he's a professor at Georgia Tech, stuff like that. Do you do things like -- a lot of people have chairs. In other words, there's ways of giving people some kind of recognizes that I think enhance -- that make them feel better.

MS. BABCOCK: One thing we're talking about now, and I think we're starting to do it in Center for Veterinary Medicine, is reward people who have done an extraordinary job with sabbaticals. We have not used the sabbatical concept too much in FDA, but whether it be a mini-sabbatical or a yearlong --

DR. LANGER: Well, I think that's a good thing anyhow, for other reasons we talked about.

MS. BABCOCK: Well, yes, but with the resource issues we have, we haven't done that a lot. Dr. Henney is very interested, though, in starting to roll that kind of a program out.

DR. NESTLE: I hate to get down and dirty, but it's late in the afternoon --

DR. LANGER: That's okay, you go

ahead.

DR. NESTLE: One of the things that was just very, very evident in the CFSAN review, was how demoralized the staff was. And the issues were very apparent, they just didn't feel like they had any control over their work.

Every study that I've ever seen on job satisfaction lists control right at the top. You know, controlling your time, controlling what you're working on, controlling when you come and go, what other activities you're involved in.

Having been a federal employee myself, I fled back to the university. I couldn't stand it. It was just awful. And some of that has to be beyond what the federal rules are.

MS. BABCOCK: Well, actually, I think we have created and rolled out some of the most flexible and creative programs to address those under our quality of work life issue. One of the problems my staff and I have been having is to get our supervisors to accept it.

For instance, we created a program

that we call *Any 80*. The normal two week work period is 80 hours. And the government requirement is that you have core hours that every individual has to be there during core hours. In this program we said your core hours are Wednesday from 11 to 12. So it's the program where you have to come to lunch on Wednesday.

And other than that, you can flex from midnight on Sunday night to midnight Saturday, within a two week period, as long as you put 80 hours in. So the vision was, you know, you could work 12 hours one day, 3 hours the next, don't come to work the next, and fit your family around the work schedule.

And believe me, this is the first in the federal government; no other agency has this *Any 80* policy. Right now I would guess that maybe 10 percent of our employees can take advantage of it, because our supervisors haven't been able to let go of the control, and they're afraid that they won't be there for industry, so the core hours now -- I mean,

managers still set core hours, so they've set core hours Monday through Friday from 9 to 3, so you can flex a little bit around that, but it hasn't really worked as well as I would have liked to have seen it.

But we're trying to come up with some new creative ideas for our employees, and I'm sure the staff will say that -- we've been pretty out there with some, the quality of work life initiatives, we just --

DR. NESTLE: The things that drove me -- he wants to know what my --

DR. DAVIS: No; I'm just being facetious.

DR. NESTLE: You're being facetious. You want to know what it was like?

MS. BABCOCK: We also have telecommuting, working at home. We're trying to push that program right now. About 4 percent of our employees are able to work at home at least one day a pay period. We'd like to see that.

One of the proposals that I have in my

workforce plan is to make it mandatory for supervisors to work at home at least one day a month so that they get an idea that you're not just there goofing off, that you're actually doing something productive at home.

But we have issues with security and computers and things like that.

DR. NEREM: I thought maybe you wanted the supervisors to stay home to minimize their damage to FDA --

(Laughter)

MS. BABCOCK: But we are trying to work with some of those family-friendly programs.

DR. SUYDAM: I think Mary and her staff have worked very hard to try to and improve the quality of work life within FDA. I think that there are other things that have worked in just the opposite direction. And some of those other things are clearly the limitations of our budget, in that we can't afford to send people to professional meetings as much as they should be going to professional

meetings.

We can't afford to do very many sabbaticals. I mean, there's just a very limited number of those, because we don't have the staff to fill behind them. And then when you're operating under the deadlines that we have in a lot of our programs, where you have statutory obligations to review products. In the prescription drug user fee area where we have performance goals and performance measures, if you don't have staff on board and if they're not there, you can't meet those performance goals.

So those are all the forces that are forcing in this direction while we are trying to improve the quality of life in the other direction as well.

DR. NEREM: On a per capita basis, what is the travel budget for a professional at FDA annually to go to professional meetings?

MS. BABCOCK: I can tell you what we spend on training and development is 1.3 percent of our total budget. Now I understand

in industry, in the pharmaceutical companies, it's about 2.5 percent.

DR. NEREM: If I was an employee --

MS. BABCOCK: It's about $1400 per employee.

DR. SUYDAM: In terms of travel, I think it's even less.

MS. BABCOCK: I'm talking training and development. So the cost of attending a conference plus the travel to get there and whatever else. The average employee gets 4.4 days of training a year. That's rolled up in an average.

DR. SCOLNICK: So here you're looking at probably one meeting.

DR. SUYDAM: One meeting. And that's unusual. That's not 100 percent.

DR. NESTLE: I don't understand. The very wealthy university that I work for has a salary scale that's just like FDA's, it has a budget for meetings that's just like FDA's, and it has happy campers who work 80 and 100 hours a week and are there all day, all night, doing

the work because they choose, they control their own work flow.

DR. SUYDAM: Well, and I think that perhaps you're getting the wrong impression if you think that most FDA employees are not happy campers. I think we've done the quality of work life survey, and the morale survey shows that FDA's morale is among the highest in federal agencies.

DR. NESTLE: Then why are they leaving?

DR. SUYDAM: Our attrition rate is only 5.8 percent That is not a high attrition rate. That's much lower than the average government-wide.

DR. NESTLE: Then why are you worried about it?

MS. BABCOCK: I'm just projecting --

DR. SUYDAM: She's talking about retirements.

DR. SCOLNICK: No, but I don't think that's the only problem. The problem is in who you can attract.

DR. LANGER: Right. That is the problem. I think that, as I look at it, is the key problem. The problem is the recruiting at the early stage, the young people.

DR. DAVIS: They don't have the luxury of working on whether they want to work on it. They're not writing specific grants to pick their areas, et cetera. They're spending taxpayer dollars on things that someone else has decided is important.

I can understand that; I don't think you have the luxury, necessarily in a government lab to say "I will do whatever I want to do" as a major part of what you do. So that's not going to be where you're going to be able to make people happy. That's the real world.

But it's those other things, I think, in terms of who you get to attract. People feel good about coming to work because the relationship with their colleagues, supervisors, the kind of place they work --

DR. SCOLNICK: Intellectual