atmosphere.

DR. DAVIS: -- intellectual atmosphere, challenging, that kind --. I think you do have a problem when people can't go to meetings. I think it's excellent, the kind of thing that Susan was talking about training, hooking up with industry, et cetera. Because if you can only send scientists to one meeting a year, and technology is just booming, it's very hard to think that these people can keep up.

DR. SCOLNICK: I would be very complimentary about that program. I think it's one of the most forward going and exciting things I heard. And I don't know the agency well enough, but I think more of those and then making sure that the place that you're recruiting know about those programs will help you recruit better, more better.

DR. LANGER: I think so, too. I think all these kinds of things where you're getting interaction with new types of people, industry, universities I think are very positive in many

ways.

DR. SCHWETZ: You've made some good suggestions on this as well as other things earlier in the day. But I would come back to my statement earlier and ask you to think more about this, and I'd like to come back to it again in another meeting, and that is, if you were charged with hiring the leadership of the FDA 20 years from now, how would you do it?

This information gives you an idea of the recent past practice and where we got people from and what level they were, what kind of people they were.

What Alan is going to talk about later this afternoon is another current practice that's going to put 50 people into the FDA. What I would like to know from you is whether or not you have ideas that are more out of the box and how we can do that to solve some of the problems that we're all concerned about; and things that -- I mean, after you work in the federal government so long you tend to be confined by the thinking of the federal

government. And it sure would be nice to have innovative linking.

DR. LANGER: Well, maybe we should go on.

DR. SCHWETZ: Mary's going to talk about peer review

DR. LANGER: Okay.

[Slide]

MS. BABCOCK: I should have started with our quality of work life effort, because I think I'm leaving you with the wrong impression, that we're not trying to improve -- and I don't know how long ago the CFSAN --

VOICES: No, no, no. We don't believe that. [Simultaneous discussion.]

MS. BABCOCK: Okay. I'm going to talk a little bit about our peer review of our scientists in the agency, and this is really a promotion, how we set pay, and it's really aimed at our higher level employees. People -- I don't know if you're familiar with the government pay system. I did put a pay schedule in your handout so you'll have an

idea.

There are basically 15 levels. The 13 level is what we call our journeyman level. So anyone who goes above the 13 level for the majority positions -- for people in the audience who are in at the 13, I don't want to --. To get above that we have what we call our peer review. Essentially what it is is the people in Human Resources don't have the scientific knowledge or skills to really assess the level of science that's going on in an individual's work, what their publications mean, what kind of science they're doing, what kind of skill levels they have.

So we put together peer review committees for the various occupations. A peer review normally, a supervisor nominates an employee for a promotion. It can be after one year; generally it's between three and five years, and the promotion is a fairly significant bump up; it's at about a six percent increase.

We then have a chief reviewer who does

a lot of work interviewing peers, interviewing the employee themselves, interviewing the supervisors, interviewing experts outside the federal agencies, whatever it takes. And then they present it to a peer review committee which is usually seven to eight scientists who understand the occupation.

The majority of our peer review committees are made up of scientists from all the centers or at least representative of all the centers. We have about 50 or 60 people in FDA who participate in our peer review processes.

I have a list of the various committees here; we have one obviously for reviewers, both premarket and postmarket surveillance scientists; those are the reviewers that are in Center for Biologics and Center for Drugs.

We have one for medical officers, we have one for the consumer safety officers; those really are compliance people in the field. We have one for research scientists.

And all these peer review panels are done a little differently; in the research one for instance, we bring scientists from outside of FDA. We often use people from NIH or the Research Triangle in North Carolina, places like that. And then we have one for our support services, in our field labs.

Essentially the employee goes through the peer review, it's a very exciting, robust process. There often the chief investigator will give a presentation at the peer review, and then it's determined whether the person in fact deserves a promotion or doesn't deserve a promotion.

One of the things I included in the blue folder that I handed out is an actual submission of a peer review. I do have the permission of the employee to share it with you; but it gives you an example, I think it's the last thing in that blue folder, an example of the kind of information we're looking for, the level of publications the person had. It's the one that starts with Roger Williams.

Just to give you an idea of the level of research and responsibility that we look for when we're ready to promote somebody to the next level. We do that for all of our scientific positions. It's generally been working as a good process. If somebody does not get accepted for promotion, the peer review panel gives feedback on where the employee needs to move, what they need to do to reach the level for the next promotion. It's good feedback for the supervisor who put the employee in as to what they are not accomplishing, if in fact they don't achieve the promotion.

So we think it's a process that's working very well in FDA. Something new we've started in a couple of our centers is what we're calling our master reviewer program, where we're bumping them up even one further level: When somebody really understands a review from beginning to end, they understand technology, they can communicate with other people, they have a broader knowledge than just

the narrow scientific field that they're working on.

So our master reviewer program I think will also be good to keep the quality of science at the higher levels, to keep it in check.

That's kind of a quick review. There is more detailed information; we have the peer review that's on our home page that employees have access to.

Just recently we have a new union in FDA -- I don't know if you're aware of that. We have the National Treasury Employee Union, NTEU, a very active federal union. We just negotiated the contract with them, and one of the things that they were very set on is having self-nomination for peer review. In the past only a supervisor could nominate somebody for promotion.

We agreed that employees could self-nominate if they felt, for whatever reason, their supervisor didn't like them, didn't care, didn't appreciate what they were doing. We

now have a process where they can put themselves in for peer review.

We haven't tested that yet, but we're looking forward to our first case of self-nomination.

DR. DAVIS: But you get to pick -- who picks the committee, though, of the reviewer?

MS. BABCOCK: In the self-nomination, they can nominate 3 people, but management has the final say on who is on the peer review committee. Ordinarily, for our other peer review committees, we have a chairperson and members that we can call upon to, when we have cases to present.

Over the last year we did approximately a hundred of these peer reviews, a hundred cases were processed. And I think I have some numbers in there if you're interested, of the number of scientific positions covered by peer review and the number that we processed in the last year.

DR. DAVIS: Of the 100, how many successfully were promoted?

AUDIENCE: 112.

MS. BABCOCK: Oh, those were the ones promoted? Do you have any idea how many cases you did not?

AUDIENCE: Probably about, I remember 10 to 15.

MS. BABCOCK: So 10 percent maybe don't make it through the process?

AUDIENCE: You have cyclical reviews for some of those.

MS. BABCOCK: Yes in some cases, particularly in our research areas, we have a cyclical review, either a three year or five year review, just to make sure scientists are keeping up with what they're supposed to be keeping up with.

DR. SCHWETZ: Well, the real word there is "mandatory."

MS. BABCOCK: Ah, the cyclical --.

DR. SCHWETZ: Cyclical; just be clear, it's mandatory.

DR. SUNDLOF: And in some instances individuals have been demoted, as well, through

that process.

DR. SCHWETZ: So when you have mandatory reviews and a promotion process, you don't get very many promotions in your career, you're going to have a lot of people not being promoted who are undergoing review. Just to be sure that they're keeping up to where they need to be.

DR. DAVIS: But you've had GS-13s, for instance, demoted to a 12? Is that what you mean?

DR. SUNDLOF: We've had GS-15s demoted to 14s.

MS. BABCOCK: That really doesn't happen that often.

DR. SUNDLOF: Not often, but --

MS. BABCOCK: But it's out there, our employees know it's possible, so they try and keep up with where they are.

DR. ANDERS: Do these cyclical reviews mean that a person can go three years without any review? Or is there an annual review.

MS. BABCOCK: No, there is an annual

performance review. This is sort of a separate system from the day-to-day performance issues.

Okay, as far as professional development, we talked a little bit about our training expense and how much time and effort we put into training. Some of the things we're working on, I mentioned the sabbatical program, and that's something that Dr. Henney is very interested in. Whether it's for reward or just for development, I think we'll be seeing more either mini-sabbaticals or long -- what we're thinking about is that people are meeting their PDUFA goals, their drug review goals, and they need to be rewarded, give them four to six weeks to go and do whatever they want to consider professional development, and keep it really broad and loose and let them pick their own avenue of development.

We're also looking into virtual universities where we're talking training anyplace, anytime, web-based training. And we have a couple what we call CRADA -- I don't know if anybody explained that. I heard Peggy

mention that term before, where we're partnering with private sector to try and bring courses that will develop the FDA training module, but then they'll make money by selling it to the industry. So that we'll have some FDA information on the web that then they can go and make some money off the private sector.

We're also trying to increase the attention we have in training the scientific community. In the workforce development plan that we just did, one of the statements they made that, with just a 10 percent increase in the amount of money you spend on training. So if we went from 1.3 to 1.43 percent of the money we spend on training you can get an 11 percent increase in productivity, and that was from the National Employee Survey, National Center on Education, Quality of the Workplace.

So there is some justification to start spending a little more money on our employees. Then the commissioner has a strong interest for FDA employees to go to external training, conferences, universities, to learn

the state of the art of what's going on, so we know there's a commitment to further education right now.

I did want to spend just a couple minutes on quality of work life. An I --?

DR. DAVIS: Just 30 seconds on development? Since it costs a lot of money to send a lot of people out, what about bringing people in? How active are you in internal seminars --

MS. BABCOCK: Actually, I should have mentioned that.

DR. DAVIS: -- bringing in scientists to talk about state of the art stuff.

MS. BABCOCK: We have a lot of activity going on. Almost all of our centers have some sort of staff college where they have speakers, either internal experts on particular --. Our Center for Drugs, for instance, has almost a weekly seminar series that they put on, like on Wednesday afternoons.

Our Center for Drug Evaluation and Devices have what they call grand rounds where

they bring speakers from outside into the center, and then they pipe it out on their web, so everybody can get it on their desktop.

So we're trying some different things with some improvement in technology and what have you. So yes, we do that a lot. We also, not too long ago, put together a package of collaborative efforts

package of collaborative efforts between our centers. Our centers have been accused of sort of being stovepipe organizations; and so in the training and organizational development community we put together a list of efforts that are going on, and it was quite an impressive package, over 150 examples of how we're collaborating within the organization. And I think we'll continue to do more of that.

In the quality of work life, this really was Secretary Shalala's initiative of several years ago where -- I think the theme of it is we really truly trust and believe in our employees, and if we believe in our employees, we're not going to have them signing in and

out, we're not going to threaten them with reductions in force, we're not going to treat them like they're children. We in fact are all going to pretend we're adults and behave that way.

But the truth of the matter is, we have like four cornerstones to the quality of work life effort. The family-friendly with all the flexible work schedules, and we really have pushed that. And I think even though our supervisors haven't embraced what I call the *Any 80* program, they have embraced alternative work schedules and flexible hours in the morning and the afternoon, so that people can balance their family and work life.

We do have a lot of people who take advantage of telecommuting centers and working at home, and we're trying to enhance that as soon as we figure out how to get security on the computer wires. You know, we can let a drug reviewer go home for a month and do drug reviews, but it's the security of the information that we're concerned about.

So a second part of the quality of work life is a learning organization where every employee has an opportunity to learn everything they want to learn. If we're talking about rotating assignments, allowing people to experience new things in their careers, things that don't necessarily cost additional money, but where they can enhance their professional knowledge and development so that they do feel like they're getting new experiences in training. So we're working a lot on that.

Improving communication just within the organization. You know, when you have an organization of 10,000 people, just keeping everybody informed of what's going on is a big job. So we're trying to figure out ways we can improve communicating within FDA, external to FDA, et cetera.

Then the fourth part of it is appreciating diversity, making sure that every employee is -- takes full advantage of what they can do regardless of where they are in the

organization, what their issues are; the more we know about each other, the better we can work together.

So that's really our quality of work life in a real quick nutshell. But we are trying to do some different things.

I think the last slide I have is kind of the cornerstones of our workforce development, which -- our workforce strategic plan? Yes, that one.

[Slide]

If you can see that, like I said, we have contracted with Toffler & Martin. I am really excited about where this project is going, and I think it's going the same direction that you all are talking about, coming up with new and different ways of recruiting and retaining employees, looking at the science base, looking at IT development to enhance our employees' capabilities.

We really need to focus on leadership development. Because we have been so short of resources, most of our money is spent on

training in the science fields as opposed to training leaders in developing the supervisors and managers.

That's sort of a preview of coming attractions. We're just finishing -- it's been about a three month effort now, and we've interviewed the entire top staff of FDA along with people in our industry, people in academia, employees, supervisors. We've been to the field, we've been pretty much everywhere in the organization and I think we're ready to make a final presentation on it. So I'm pretty excited about that.

Thank you very much.

DR. LANGER: Thank you. Comments?

DR. SCHWETZ: One last piece. Bring this down to a real world example. As I mentioned earlier, the Director of the Office of Premarket Approval within the Center for Food Safety and Applied Nutrition has an example that I want to have brought to you. I looked around when we were planning this schedule, of who right now in the agency has

the opportunity to do large hiring activity, to have that brought to you, to lay out for you the agenda, the plan for doing this, and with the prospect that this will come back in November and Alan will be able to tell us how well it has gone. So you'll see it from the front and you'll see it in progress.

We can talk about what things would be nice to do, but this is a real world example, and I'm hoping that it will help all of us.

Alan?

Hiring to support the Science Base of the CFSAN Food Ingredient Safety Program

DR. RULIS: Thank you, Bern. Good afternoon, I'm Alan Rulis, I'm Director of the Office of Premarket Approval in the Center for Food Safety and Applied Nutrition.

OPA is one of the two largest offices in CFSAN, and we do have a research component that does molecular biology research and chemistry research; but our primary goal, our primary responsibility is in the area of premarket approval for new food ingredients.

What I want to talk to you this afternoon about very briefly is what is an almost unique opportunity for us; and that is the ability to hire a substantial number of new employees. So in a sense we'll be focusing or putting sharp focus on some of the things we've had a discussion about earlier this afternoon.

I just have a very few overheads, and the first one is up there now. What I would like to do, this is a summary of what we're going to try to cover; talk a little about the Office of Premarket Approval, what it's like, what it is, what it does. Mention that new targeted appropriations that we have at our disposal, talk a little bit about the current hiring initiative underway, and seek your help, essentially, in getting some ideas about how we can make that work for the long-term benefit of the center and for the agency.

[Overhead]

The Office of Premarket Approval reviews petitions for new food additives, what we call direct food additives, artificial

sweeteners, fat substitutes, anything that you can imagine that might be on the label of a food, a processed food. We also work with color additives; not only color additives used in food but in medical devices and in other settings.

We do premarket notification for food contact substances. The statute defines food additives very broadly, and to include substances that might migrate into food from things that touch food, such as this bottle right here, for example, or a conveyor belt upon which a chicken might ride for a few seconds.

A big program was put into effect in 1997 under FDAMA that created a premarket notification process rather than a petition process, but put an 120 day hammer on the process for FDA to review these applications. In their wisdom, Congress did not effectuate that program without funds. They said there will have to be funds to run this program, and they didn't come up for funds for the first two

years. But last year in October they did; came up with $6 million and said "Okay, run the program." So we are starting that program now.

We also do biotechnology consultations; this is for new plant varieties that are created using recombinant DNA biotechnology techniques; and we do what are called GRAS notifications. There are a lot of ingredients in the food supply that are generally recognized as safe, and they're not food additives in the traditional sense but they do require some interaction with FDA. And they're important components of the food supply and we spend a lot of effort doing those.

[Overhead]

In round figures we have clusters, small, relatively speaking, small clusters of individuals working on these projects. We have the category of people called consumer safety officers. In our office they are more likely than not to be Ph.D. scientists in their own right. Of these 30 or so staff-level people -- this does not include any supervisors or

management, these are the actual workers, people. About 21 or 22 of those 30 there have Ph.D.s in various fields; chemistry, biology, pharmacology.

So they're scientists in their own right, but their real job is to manage the review of new food ingredient evaluations, safety evaluations. So they have to essentially be able to talk with the scientists that are doing the reviews, and make sure, coordinate the review, make sure it's complete and accurate. And then they have to write the regulation that puts that review into effect, and deal with attorneys and create a document essentially for the Federal Register for the public to read.

We have chemistry reviewers whose job it is to ask, What is this additive that's going to go into food? How pure does it have to be? How much of this substance are people going to eat? The toxicology reviewers, of course, are interested in what are the effects of this substance on a biological system. And

in particular human beings, although many of the studies we get are in rodents.

And we have environmental reviewers because under the National Environmental Policy Act, we're required to substantiate that in any action that we take; we have taken care of the environmental aspects of it. That's more important for packaging materials than it is for direct additives, but it is a factor.

A large fraction of our employees are in fact doctorate-level people.

[Slide]

Now this is a slide that shows you what has happened to us since October of 1999. In October of '99, Congress appropriated two, we consider them large sums of money; $6 million to run the premarket notification program for food contact substances, and $5.4 million to enhance, to speed up, to make more efficient, more effective, the review of direct food and color additive petitions.

And under those two programs respectively, we see ourselves hiring about 30

new hires in the PMN area and about 20 new hires in the direct food and color additive area.

This is an enormous opportunity for us; we have not had this happen for 20 years. I am probably the beneficiary of the last large hiring in this area, that took place back in 1977. And I'm getting a little bald and grey, so it's been a while.

[Overhead]

Now what we want to do, Dennis Keefe of my staff is with me, and I've charged Dennis with responsibility to set up a hiring program and to make this happen. It is not a trivial matter. Trying to deal with this kind of money in an instant is a little bit like drinking from a fire hose; you can't deal with it rapidly. But we're trying to set up a program that will bring on these new employees and essentially build for the future, not just fill slots.

So it goes back to our earlier discussion: How do we -- what can we do to

bring on the best possible employees for the future to build and strengthen our organization for the long term.

Dennis will talk to you about what he's putting into place at the moment and then charge you with some questions about how you might be able to help us make this work.

DR. KEEFE: Thank you. First I'd like to say that I think our office views this as a tremendous opportunity. I cannot overemphasize this. This is a once in a career opportunity for us, for me. I've been with FDA for nine years now, and I've never seen anything like this. This is great. I'm very excited about it.

This is going to give us a chance to take a proactive approach to our future, to strategically plan for the future of what we're going to look like for the next 20 years. It's a substantial amount of money, so that we can -- this is a supercritical mass of money that allows us to think creatively, look for the future, and really plan what we're going to do.

It also allows us to think outside of the box. You heard a lot of discussion from Mary what we're doing, you've heard Dr. Suydam talk about things that the agency wants to do with leveraging; this is the nucleus for trying to implement some of these ideas on a grand scale.

[Overhead]

Our goal in recruitment is to recruit scientifically-sound scientists to do regulatory working the area of foods. We want to target our equal employment goals, we want to use this to leverage our scientific expertise with non-FDA resources. And we want to take a long-term approach to this recruiting and hiring.

[Overhead]

Some of the things we've done are the traditional recruiting. We've got the OPM vacancy announcements out on the web page, and these are open until the end of May, and we were going through that sort of effort. We've got the ads in the scientific journals, we're

attending job fairs, we're identifying ones that will have the scientific expertise that we need. We're attending scientific society meetings, we're advertising on employment web pages, we're sending letters to academic departments that are of interest.

Some of you have been involved in recruiting on the industry side, and if you have ideas on how we can expand on these traditional approaches, we would love to hear them from you, if we could implement those.

[Overhead]

We're also trying to think outside the box, using nontraditional strategies. Not only for recruiting but also to retain scientists and also develop interest on the outside in the scientific program, in the academic programs in FDA; make people aware of what we're doing.

Because I can recall when I was an undergraduate, I had no idea what FDA did, and I'm not from this area; there's no reason for me to know what FDA does.

And these are just ideas. We did some

brainstorming. Is there a way we could set up a mentoring program with in-house FDA scientists with current graduate students or undergraduate students? Would it be possible to develop some sort of food safety regulatory academic degree in collaboration with an academic institute? Maybe the University of Maryland, maybe other universities, maybe nationally we could set up some sort of program.

We talked a little bit about sabbatical programs here for FDA scientists. How can we best do that? How can we implement that in a targeted way that develops our scientific expertise in-house and promotes that, helps us retain scientists, but also gets the word out about what we're doing in FDA. So scientists outside of FDA become aware of what we're doing, maybe become interested in becoming part of FDA.

Leveraging, not an FDA resource. You've heard about the JIFSAN program; that's really geared towards research. What we want to

look at is from a regulatory scientist perspective; we can expand there. We heard a little bit about special government employees; that might be one option.

I'm sure there's other ideas, and this is what we're looking for from you to help us think through this thing, through this strategically taking a long-term approach to what our needs are, to try to develop our programs and maintain our scientific expertise. So that's my schpiel.

DR. LANGER: Alan, anything else?

DR. RULIS: No; I'll just turn it over to you. We've been encouraged, in the earlier part of this afternoon, the discussion on some of the ideas that were coming forth about how it is clearly appreciated that we do face enormous challenge in bringing on the best and the brightest for the future in the FDA. I think we're sensitive to that, but we're also appreciative to the sense that you are thinking about ways to solve that for us or give us ideas that may not be the first ones that come

to our minds. We're ready to listen and make the best use of it.

DR. LANGER: Okay. Marion and Bob.

DR. NESTLE: The obvious one that leaps to mind is a traveling road show, where you go and visit the universities that are training large numbers of graduate students and have large numbers of postdocs, and meet with them personally and talk about what the opportunities are.

I know people who'd come to work for FDA. They didn't want to run their own research programs; they wanted to have something where -- where somebody paid their salary and they didn't have to get grants.

That was a big -- and also, to put it another way, they'd be doing something that's really valuable, that has a value system attached to it. I think that's a big selling point. These are important responsibilities that serve the public and serve public health. I would push it to the max. It's true, it's real, there could be lots of people who want to

do that, and go to the best universities.

DR. SCOLNICK: I agree with Marion. I think you can make a program like that, because of the value system behind what you're doing is an important one that I think young people can identify with. And if you put the time and effort into it, I think you can make it work.

DR. LANGER: I'm going to have Bob go next and then Harold; but just -- what companies do; like at M.I.T. they basically just come there for a couple of days and they spend a lot of time, interview people -- some companies actually have real programs with, where we get money obviously you can't do that. But I mean you certainly can come for a day or two to a whole bunch, target a bunch of universities, like Bob was saying before.

I think if you send a couple people there for two or three days and I'm sure that the job placement offices at all these schools, you know, would welcome it. I was amazed, even -- just to pick an example, I was on a review committee for Princeton, how they have all

these people interested in the pharmaceutical industry, but you know a lot of companies don't come there because they're not that big in some of the -- I told this to Dr. Merck.

(Laughter)

DR. MERCK: But I see no reason why FDA should be -- well, only because Merck is -- see it's amazing The reason I actually print that though, Merck is down the street. They're not --

DR. DAVIS: They don't need any help.

(Laughter)

DR. LANGER: But Princeton needed it, so I was trying to help Princeton out. But the point I'm making is that you could have -- you know, you could spend a couple days -- and it was only sending one or two people to these schools.

Anyhow, Bob and then Harold.

DR. NEREM: I actually have some questions before I make a --

DR. LANGER: CalTech, I was going to tell you to do in.

DR. NEREM: As I understand it, FDA normally is going to hire about 500 a year. So because of this extra money, it's going to hire 550. So I guess the significance of this isn't so much the added people as the fact it's in a very focused area.

And yet it's not clear to me that your recruiting strategy ought to be under that focus. That's something that maybe ought to be discussed.

The other question I had was, to what level are you looking? Because I think that has to affect your recruiting strategy. If you're looking at VSMS people, that's one thing. If you're looking at Ph.D.s, that's another thing; and I almost got the impression you were looking for VSMS people since one of the fringe benefits you were running up there was some kind of a degree.

kind of a degree. So.

DR. KEEFE: I guess for the most part as far as the recruiting, we're looking primarily for P.H.Ds and targeting on the new

PH.D. because of the salary structure.

What I was thinking, as far as the B.S.-M.S. program was long-term. If there was an academic program that focuses on a regulatory scientist program, maybe it's not just FDA involvement. Maybe this would involve the other food safety or regulatory agency, maybe; and the drug side of FDA.

If there could be some, maybe a program at a local university, a degree, an M.S. on this; or it could be integrated nationally with an academic program.

DR. NEREM: Well, let me make my comments; and I can only speak on the context of Georgia Tech. And Bob can speak in the context of M.I.T. But at least that Georgia Tech, if you want to recreate at the B.S. level, you ought to be talking to the college placement office. If you want to be recruiting at the Ph.D. level, you ought to be talking to the Research Institute and connecting there, one way to do that is number one, you've got to establish a relationship; offer to come in and

give a seminar -- because that will give you great visibility and as was suggested by Bob, you know, following that seminar you stay around for a couple of days and -- you know, we're always ready to help our graduate students find jobs.

DR. LANGER: Harold, Ed, we'll go down the row.

DR. DAVIS: I keep the critical question is whether the job skills you're looking for these jobs. Are you looking for people with an attrition background; could have Ph.D.s in anything, whatever. I think that helps you to target what schools.

I think in the sabbatical, putting your faculty, your members into certain universities to provide a six month, three month whatever, gives you an opportunity to be in a place for an extended period of time. Three days is greater than recruiting; but if you could pick two or three schools that you really want to be present in, putting people in on a sabbatical.

Another thing I think that works great is internships. If you bring people out of these programs, even if you're looking for Ph.D.s, if you bring people out of these undergraduate programs and want to get Ph.D.s, they start remembering you and thinking about you, et cetera.

I don't know if the FDA or government can use headhunters. Is that taboo? Can you do that? I know companies that have brought headhunters in, not just one at that time, but two or three or four at a time. They have job fairs on your site so that they get to understand what the job is you're recruiting for, et cetera. They get to see the working environment, et cetera, so that they become much more familiar with how you're going to use these people. So they become I think more effective recruiters, instead of just dealing with one headhunter at a time.

DR. LANGER: Ed?

DR. SCOLNICK: Just two specific suggestions; one related to the issue of

potentially a master's program of some kind. You probably know, Temple University, which is down the street from one of our sites, runs a program for basically teaching people about the compliance issues at FDA. And a place like that or other universities like that might be willing to have master's programs to fill some of the master's level needs that you have. And I think getting in touch with the Temple School of Pharmacy that runs, gets a program on compliance, might give you some ideas on how to construct that kind of program.

The second point, in terms of your going to universities and giving seminars. Within whatever limits you're legally allowed to do this, the way to engage students is to talk to them about science. And you do have these public meetings that are open information through FOI on drugs, and if somebody within a rational way can put a talk together that says, "Here's what we do. Here's the science we reviewed. Here are the issues we faced. Here's how we resolved it scientifically." So

you give them a flavor scientifically of what it is the job is all about, and get them excited about that, you'll engage the students.

If you go and tell them about government service, it's too dry. Even though it is a nice thing to talk about, you won't attract them with that kind of approach, is the primary approach.

DR. ROSENBERG: I have a slightly different perspective. Given that you have a focused program and you're talking about as many as 50 people, that provides a unique opportunity, actually, for attracting first a couple of people who were actually known or with some name recognition. You've got a big enough program to actually -- it's not a one-off, it's not "Come here because I've got eight jobs to fill" and therefore you can't give them structure or actually provide them additional resources as you can when you start talking about having a reporting structure of maybe eight, ten people under somebody who you can now attract to a program.

This gives you a chance to kind of use the advantage of going and picking a couple of key people with name recognition who would add to the whole presence of your organization, and they will end up being your recruiting capability. They do the job because of their name recognition. It only happens when you have enough resources to be able to attract a couple of people with that stature. Now if that can be done in this area, I think there's a great opportunity for you to use that kind of strategy.

DR. SCOLNICK: I think it's a great idea.

DR. LANGER: Excellent. Mike?

DR. DOYLE: This isn't a short term approach that you need, but long-term, I once had a student from Health Canada who was on their hook; they paid all the tuition and everything else for her to work with me for, I guess it was three or four years. And she then had to work back two years for every year she was with me, with Health Canada. But, you

know, it's the opportunity for the agency to pick their best at the undergraduate level, send them on to graduate school and have them for a longer time.

DR. LANGER: Other suggestions or comments?

Well, thank you. Anything else on this topic?

Then I guess we'll go to the final topic, which is concluding discussion, further direction for the Board. We discussed some of this over lunch and I thought maybe what we could do was actually have Bern summarize some of the action items and see if anybody wants to add anything.

DR. SCHWETZ: This is being constructed on the fly so it will take a second to think about it, and be sure I'm saying what I think happened.

DR. LANGER: People can correct it.

Concluding Discussion: Further Direction for the Board

DR. SCHWETZ: In the context of the

response by CFSAN, to the report of the review of CFSAN, Dr. Scolnick mentioned the benefit of having information on what's going on in the center related specifically to c.v.s for new recruits, information on publications and other documents that would have come out from the center staff, and examples or complete list of impacts that have come out of the work that's being done. And if the board wants to expand that so that it's more than Dr. Scolnick's thoughts and adopt this as recommendation, it appeared to me that Joe and Bob were prepared to do that. And I would like to see that happen as a model.

DR. LANGER: I think that everybody seemed to think it was a good idea.

DR. SCOLNICK: Yes, with a balanced view of what Harold said, there would have to be publications.

DR. DAVIS: Just impact work. What have they been doing.

DR. LANGER: Yes.

DR. NEREM: Measures of impact.

DR. LANGER: So that will be a formal recommendation. Good.

DR. SCHWETZ: One of the things that we talked about at noon, and we've got the specifics. But the discussion on future directions in the Science Board and items that we could talk about where we would bring you particular issues or information for your response. And we will include that list of topics from that discussion this noon.

To capture your thoughts about the need for the agency to bring focus and priorities on the bigger picture of all that goes on. And to use that as a basis then to overlay on priorities at the center level. We tend to have priorities and plans at the center level, but we haven't very often captured those in a whole set of plans for the agency.

One specific was that you accepted the peer review report of the review of CFSAN, and another specific of that was that Dr. Fennema and I were to talk about guidelines for future reviews. Owen has already come up with a draft

of that, which I will look at and give some more thought to and get back to you

DR. FENNEMA: It needs some more work on it yet.

DR. SCHWETZ: You did well in the short time that you had. So we'll continue to work on that.

There was a recommendation that there could be a position paper written by members of the Science Board on something as specific as GMO foods, and that Joe Levitt and I and Marion and Rita Colwell would get together by telephone and talk about what that might look like, and discuss the possibility that there would be a position paper that would come out on a topic that specific. So we'll talk about that.

DR. FENNEMA: So we didn't talk about what would be done with that, once it was prepared.

DR. LANGER: I think we weren't even at that stage. At this stage I think we want to just sort of map out a plan. You know, get

their advice on --

DR. FENNEMA: Before you do something, you ought to figure out how you're going to use it.

DR. LANGER: I think that would be part of what they would come back with as a recommendation; that's what I meant.

DR. FENNEMA: All right.

DR. LANGER: I mean I agree with you, and I think -- but that would be part of what they would do.

DR. FENNEMA: Very good.

DR. SCOLNICK: One thought on that. I really don't know whether anything has been done by now, but you might consider engaging the IOM in that activity because they're always -- there are views of an independent organization, and it's the kind of thing they like to do.

So I don't know whether they've ever done on engineered foods or not, but just another thought.

DR. NEREM: May be another part of the

National Research Council besides IOM that may be better equipped --.

DR. SCOLNICK: Yes.

VOICE: The NAS just did --

DR. NEREM: Yes, I don't know who --

DR. LANGER: It's a good suggestion and that's part of what could be incorporated into when they talk.

DR. NEREM: Yes.

DR. SCHWETZ: With regard to the Office of Women's Health presentation, the suggestion or the request of the volunteer was made that they will pull together information on the successes of their grant program, and primarily in the context of which of these have been a stepstone for larger projects that continued to get that kind of information, and use it as a basis for guidance for how they would provide support in the future.

And that they would, it be helpful if they spent some effort to define the border areas between the Office of Women's Health here and the Office of Women's Health in NIH, and

the kinds of activities that they support.

DR. NEREM: I think the whole issue of one to two year grants versus longer projects needs to be addressed.

DR. SCHWETZ: Long-term commitment to fewer areas of effort.

DR. NEREM: Right. With periodic peer review.

DR. SCHWETZ: Yes. Those were these two that were here. To maintain objectivity in the peer review process and develop longer-term plans.

DR. LANGER: And focus.

DR. SCHWETZ: And focus, yes.

One of the things we will get back to you before the next meeting is some additional information -- Mary, you bailed us out on an organizational chart, but there must be other information that we can provide to you that will give you a little more background information on the agency, and we'll give some thought to how we could present information to you at the next Science Board meeting that

would give you a better profile of what's going on in the agency.

I would say though, that when we did this for the Science Board earlier on, we may have given too much information, because they had the feeling that we had a lot of dog and pony shows and no issues. And we will keep it brief and targeted so that this doesn't go on for meeting after meeting after meeting and just get details of what's going on.

DR. LANGER: I think part of the issue, too, was not just the organizational chart, but understanding how the different centers maybe interact with each other. I think that was one of the things that came up.

DR. SCHWETZ: That would be part of it; but also if we can get you to understand what the issues are of a center, and in that context understand what the center is about, that's much better than simply telling you what the center does. So we'll try to keep it issue-oriented.

We do have recorded that Dr. Scolnick

will make a presentation next time on global information gathering, and how that could be done in the context of the future for the agency. Is that --?

DR. SCOLNICK: Well, in terms of the review process.

DR. SCHWETZ: Yes.

DR. SCOLNICK: A global review process or concept.

DR. SCHWETZ: The idea of pursuing a public education for GMOs is something that we will look at as well.

And then some specifics about this recruitment and retention discussion this afternoon, to get you to continue to think about how you would do this if you were charged with what the employment list of the agency would look like in twenty years, to give us some additional thoughts from you on how you might do that; for us to get more involved in university programs, to have a larger presence in targeted university programs through sabbaticals and time spent there, in addition

to more time spent recruiting on site. To get our face in front of more potential employees.

And Harold, your point is well taken that we will continue to look for historically black colleges and universities and to focus as much as we can there. There's a very limited number of people who are available, and any help that we can get in knowing where else to go to keep turning over more stones to find good people, we would sure welcome that kind of help.

Your note about talking science to the students and get them to understand the science as opposed to the 1906 law, I agree with that thought.

DR. NEREM: At the graduate level, those of us that have NIH training grants, we are continually responsible to NIH for showing how we're reaching out to produce a more diverse scientific community. So generally those programs will have a reasonable number of underrepresented minorities in the graduate programs.

DR. SCOLNICK: I don't know how we would do this, but it's just a spontaneous thought, but you might be able to work out some rational way of doing it: About two years ago, Merck gave a substantial sum to UNCF to try to foster fellowships for minorities; a variety of schools, both small schools and large schools. And we have a fairly organized program now that involves doing that and recruiting from that talent pool. There's no way we will attract those people nor are there enough jobs. If there were some way we could plug you into that program -- I don't think there would be any real conflict of interest there. I don't know how we would do it logistically, but if you want me to look into it and then I guess you'd be the contact?

MS. BABCOCK: Yes.

DR. SCOLNICK: I'll have somebody get in touch with you. Maybe there's something we can do to be helpful.

MS. BABCOCK: Okay.

DR. NEREM: Are people with those

fellowships, is that public knowledge?

DR. SCOLNICK: Right. Oh, yes, it's public knowledge. Yes, it's a completely public program. There's nothing here that's a conflict of interest in any way, shape or manner.

And we could make sure if there was some -- you know, we can take care of whatever issues there are.

DR. SCHWETZ: There were some additional recommendations in this context of being more involved with universities, internship programs, things of that kind. Trying to focus more on job contentment and what it's like to be a government employee, to work in public service.

There's a former consultant to ours who is helping you with various meetings and things who is writing a book and has interviewed many of us in the FDA, and asking us "why did you continue to work for the FDA as long as you did?" To try to capture what there is among long-term happy government employees

that might be the kind of message we would want to give in a recruitment activity about -- you know, everybody doesn't work for the government just for a few days and get out.

So I think there are some things to be said for why there are a lot of good people who do work for the government for a long time and are happy about it.

So that, Bob, captures I think a lot of what --.

DR. LANGER: The other one that I had -- something to the effect that in the dietary supplements strategy plan, I think there were some concerns about it being, certain things maybe being a little vague and maybe trying to focus in on that. I don't know if we took anything down to -- [Remark to Mrs. Bond]

Okay. Is there anything else anybody would want to add for other things we might do in the future?

Maybe I'll just make a couple of closing comments. I just wanted to say, just from my standpoint as chair, I thought that the

thought FDA presentations were terrific, right to the point, very provocative, and having sat through a number of science boards and been on a number of different science boards, this is by far the best one I've been on. You guys all, the women all did a fantastic job. Lots of great questions, lots of great comments. I really appreciate it, and I think hopefully it will augur well for the future.

So I guess -- do we have a motion to adjourn, or do you want to say anything else?

DR. SCHWETZ: I would like to reinforce that we're looking forward to good leadership. If this is the beginning of a new plane, this is wonderful. This has clearly been a very useful meeting for us and we really appreciate the level of interaction that you've provided for us. Thank you very much.

DR. LANGER: So we have a motion to adjourn?

(Laughter)

DR. LANGER: Okay. I think that will pass pretty quickly.

[Whereupon, at 2:40 p.m., the meeting adjourned.]
