them a year later and they are still working on it. So be careful in how that is interpreted.

DR. PARKINSON: When they are post-post-docs, right?

DR. McNEIL: So yes, Rhona. And then Cathy.

DR. APPLEBAUM: Just a couple questions. And, again, the focus on unnecessary redundancies. So I am assuming then that when this was done internally, that was looked at in terms of eliminating the unnecessary redundancies. Obviously you always want a check and balance so that is number one.

The other one is in terms of being able to integrate synergies across, if that was done.

And number three, this is an excellent report but there is always a challenge, as we have in industry, as it relates to external third party review. And

obviously this is one external third party review but I was just wondering if this had been reviewed by any other groups.

Again, it just adds more, you know with all due respect, we have to face this all the time, but it just adds to the integrity and the credibility as it relates to you guys got it right and you weren't looking through, you know, a lens that was only based on ORA.

DR. GLAVIN: Was the question to me?

DR. PARKINSON: Were you referring to the -- I think it wasn't clear to me either. Were you referring to Revitalizing ORA Report?

DR. APPLEBAUM: Pardon?

DR. PARKINSON: The one that has not been examined by external --

DR. APPLEBAUM: Right.

DR. PARKINSON: Oh.

DR. APPLEBAUM: Yes. Right. I mean obviously you -- we have or, you know,

prior you all, the subcommittee has reviewed it. But again the three questions are redundancies, leveraging synergies across, and in a perfect world, you would be able to leverage synergies across agencies. But I know we are not there yet. And then third, the review, the additional reviews that were done on this.

DR. McNEIL: Reviews of -- just to be clear, reviews of what?

DR. APPLEBAUM: Of the report.

DR. McNEIL: This report?

DR. APPLEBAUM: Of the ORA Report.

DR. McNEIL: The Revitalization Report?

DR. APPLEBAUM: Yes, I'm sorry.

DR. McNEIL: Just to be clear.

DR. APPLEBAUM: ORA's report of itself.

DR. GLAVIN: We have not had another review of it. We did have, within the group that developed, membership from the

various centers and also membership from two of the state organizations, the Food and the Feed Organization had membership on it. So we had some outside look going on but we have not had it reviewed.

In terms of integrating synergies across, it seems to me that some of the recommendations that the subcommittee is making would, you know, as I am listening to them, would lead to my going to the centers and, you know, as we need additional expertise or as we need to develop some things, are there ways that that could be done without ORA developing a lab to do X.

Can we partner better with the centers on some of those things? The centers all have laboratory capacity. It is a little bit different than -- used for a little bit different purpose than we use ours but is there some way that we could develop some synergies there. So I think that is going to be real important to us.

I'm not sure if you were talking about other synergies also. That was the one that came to my mind when you asked the question.

DR. APPLEBAUM: Yes, you know, so you are leveraging, if you will, the resources across the entire FDA.

DR. GLAVIN: I'm not saying I'm doing it. I am saying I need to do it.

DR. APPLEBAUM: Okay. And then the last one was redundancies. So you have checked out all the unnecessary redundancies because there is always a situation where, especially in this complex environment that we are all struggling in, is what should you continue, what should you start, and what should you stop.

And I know that is a big challenge because your plate is always full and you can't stop anything. But it sometimes helps if there are redundancies maybe you shouldn't even be doing that to that point or maybe if

other groups are doing it as good as ORA, maybe you can then assign resources other places.

DR. GLAVIN: Yes, real honestly, that was not a real focus of what we looked at. So I'm not sure we paid as much attention to it as you are suggesting we should.

DR. McNEIL: Cathy and then a final quick question from Gail.

DR. WOTEKI: Great. First of all, I wanted to compliment you, Maggie, and the hundred other people that contributed to this self study.

I've read a lot of similar documents prepared by other government organizations or universities' departments and this one obviously reflects an enormous amount of self reflection, incorporation of critiques that you have heard from many different sources and ends up, I think, with a very good blueprint for the future.

And my reading of the committee's

report is essentially an endorsement of that blueprint that has been laid out.

I just wanted to kind of underscore a couple of things that are in the committee's report and raise then two comments at the end. I also very much endorse the phased-based approach towards implementation.

The Commissioner referred to that in his opening comments. The committee report refers to that approach as well. So I think that that is obviously the direction that has to be taken.

With respect to the whole issue of the subcommittee on page 20, identifying the important of unambiguous FDA leadership support for ORA change, in the second paragraph under that, the committee makes the observation that the Office of Regulatory Affairs planning not be fragmented or separate from the larger FDA effort. I think that is am important point also just to underscore.

And then directly below that, the

support for the discipline of regulatory science, certainly it is in this area in particular, although you can see applications throughout all the centers, of this whole concept that there really is a body of regulatory science. And here is where it is actually implemented.

So I agree very much with the subcommittee's findings there. My only concern, and this is the first of my concerns, is that the dilemma is, again, the leveraging of the resources to actually get the attention towards the development of that regulatory science.

Clearly the scientists at the Food and Drug Administration have a leadership role to play in that. And the leadership of the organization, though, has a responsibility with respect to actually getting that leveraging done. So that's concern number one.

And concern number two, Lonnie

addressed somewhat. But I was not familiar with the term capacity index systems. So the concept that you described sounds good. It was just one that was unfamiliar to me.

So I put a question mark there as to whether that is, indeed, a recommendation or is it a -- with a big R, is it a recommendation with a little r?

DR. PARKINSON: It's a recommendation with an LK for Larry King.

(Laughter.)

DR. KING: It is implicit in the others.

DR. WOTEKI: Great. So with that distinction, that is the end of my comments.

DR. McNEIL: A quick comment or question, Gail?

DR. CASSELL: Yes, very quick. Just in defense of that post-doc, they were just given a two million dollar start-up package at Stanford. And they have turned down three other offers from prestigious

institutions. So this is a very bright post-doc.

But seriously --

DR. McNEIL: Well, you didn't say where the other packages were from.

(Laughter.)

DR. CASSELL: Well, you know one of them but there were just a couple of things. And that is that I wondered, Maggie, has there ever been another external review of ORA as an entire entity? We couldn't find one or the report of one in the past.

DR. GLAVIN: I am not aware of one. We did, as was referred to in this report, we did a less intensive effort about a year ago. And it was not a successful one. So this was a follow on. But I am not aware of a comprehensive --

DR. CASSELL: I don't think so.

Well, the last thing, Barbara, I wanted to do is to say Cathy, you laid the groundwork for my sharing something with the

Science Board. And that is that I share your concern about the leveraging of resources and the need for science based and more research obviously.

And as you may know, on January the 29th, there was a hearing by the Energy and Commerce Committee, the oversight committee based on our report. And one of the individuals who testified was Donna Porter from the Congressional Research Service who talked about resources.

And I brought a copy of her testimony for you because Figure 4 actually shows allocation for research at the agency over the past two decades or more. And I think you will find it as disturbing as I did and as others have.

So I think we need to keep this foremost in our mind in terms of what all we need to do to try to get those resources so we can get the latest methods and the best --

DR. McNEIL: Thank you very much,

Gail.

Carlos just reminded me, this will be posted on the web so --

DR. PEÑA: As part of the meeting --

DR. McNEIL: As part of the meeting --

DR. PEÑA: -- proceedings.

DR. McNEIL: -- proceedings.

DR. CASSELL: Well, I didn't realize that but that would be great, especially if you could enlarge Figure 4.

DR. PEÑA: We will see what we can do, Gail.

DR. McNEIL: Oh, yes. Enlarge Figure 4.

DR. CASSELL: And if you go to the original, they are in color which makes it even more dramatic.

DR. McNEIL: Well, let's see. It is getting a little bit late and we are running over our time for this session.

Are there any burning questions or comments?

(No response.)

DR. McNEIL: If not, what I would like to do is have a motion to accept, revise, or reject this report. Gail?

DR. CASSELL: I recommend that we enthusiastically accept the report.

DR. McNEIL: Do I have a second?

DR. WOTEKI: Second.

DR. McNEIL: All those in favor?

Okay. So the vote is unanimous to accept this report.

Thank you very much David, Lonnie, et al.

As a result of the enthusiastic and unanimous acceptance of this report, it will be -- or I guess it has been now officially transmitted to the agency.

So we will break for lunch. And we are due back here -- let's make it at five past one. And we will start promptly with

public comments.

(Whereupon, the foregoing matter went off the record at 12:11 p.m. to be reconvened in the afternoon.)

A F T E R N O O N S E S S I O N

1:11 p.m.

DR. McNEIL: So we have one member of the public who would like to make a statement I understand. Is that individual here? I was asking if the person who signed up to make a statement from the public --

If there is nobody in person, I just want to mention the fact that we received in writing a statement from Sherry Ward, who is President of BioTrend Solutions in New Market, Maryland.

And she has written a number of comments regarding our Science Report. And the letter is a bit too long to read but it will be posted on the web as part of the proceedings of this meeting. So you can look for the letter from Sherry Ward.

Okay, so it is now two o'clock, according to the agenda. And we should move on to hear about -- we thought that it would be a good idea to hear from each of the center Directors about how they thought that the Science Board could be most helpful to them.

The worst thing in the world is to have a group of very competent Directors get bugged or micro managed or in some ways intruded upon by a Board like us, like ours that meets twice and now four times a year.

Everybody wants to be constructive and I thought when I was talking to Carlos and Norris and the Commissioner and Frank that it would be good to hear from the various Directors about how they thought that we could be most helpful to them.

So there are a lot of them. There are six or seven here. And we have an hour for this. So we have asked each one of them to talk for no more than about five minutes or so, to be really crisp. And then open it up for discussion.

So what we will do is crisp presentations and then we will hold questions. Otherwise, Maggie will never get to talk because she'll be the last one. And we don't want that to happen.

So let's see, Jesse, are you first?

DR. GOODMAN: Okay. Well, Barbara, with your goal, you may not have wanted to call on me first.

(Laughter.)

DR. GOODMAN: But I will try my best.

DR. McNEIL: Just try your best.

DR. GOODMAN: I've actually put down a few notes of things I wanted to share.

First of all, we really at CBER appreciate the input of the Science Board, both your prior report and the continuing input and the framework that Frank and Andy have put forward. And we really actually look forward to that. And appreciate your comments.

We also appreciate that you noted that we do have a process in our center for getting regular input from external parties. We bring our scientific program annually to our different program area advisory committees

and put together a set of priorities and plans based on that input and that of our own scientists.

But your input is special. It is big picture. And it cuts across the FDA so we will look forward to that.

I think that the areas where it can be particularly helpful to us are the kinds of things you were talking about when you were talking about innovation.

These are sort of the forward-looking areas that the Science Board identified in their report. We have identified some others where I think there are opportunities to either build or strengthen capacity and collaboration. And in those areas, we would really appreciate an ongoing relationship and input.

And I have listed just some of them. One, for example, is our engagement in building capacity and collaboration in analytic tools for dealing with large

datasets, particularly healthcare data, et cetera. And particularly for some of our unique products like vaccines and blood transfusion medicine, human tissues.

And we are very engaged with the other centers in the Commissioner's Office, for example, in the Sentinel Initiative. And some of our scientists' work, for example, with CMS on influenza vaccine safety, have really provided, I think, some tools that will enable that. So that is one example.

It also ties to Dr. Applebaum's comment. I think that we envision science as including both laboratory and population-based science. And think that is very important.

Another area where we have recognized opportunity and need is in the genomics of biologics. The genomics of pharmaceuticals is pretty clearly there.

We have seen, you know, for example, in the guidance FDA issued and some of the drug labeling around testing, some real

progress that has enabled us to begin to either target therapies or avoid adverse events. We've seen much less of that in biologics.

And we have actually a strong laboratory group that has done work on biomarkers, done some very interesting work on quality of biologics based on gene expression, for example, of cell substrates in which biologics or vaccines might be made.

But we also, I think, in part in response to some of your comments and also to our recognition of the need, I want to see the biologics and things like vaccines positioned to take advantage of the fact that I think in ten years we will have everybody's genomic profiles.

So how do we be sure in the studies we are doing we are getting the right kind of data that we can then build on that? So that is another example of an area.

And actually there, rather than

investing more in the laboratory right now given our very constrained resources, we are investing in trying to develop review expertise and statistical expertise in looking at genomic and other omic data.

Other examples, tissues, as you noted in the Science Board Report, as Gail noted in her question to me, this is a dramatically increasing area, one and a half million tissue transplants plus a year in the United States.

And yet modern microbiology and manufacturing technologies are only beginning to be applied. So we are making a small investment in trying to recruit to build essentially a tissue microbiology and quality program.

It is an area that other than individual companies, it is a classic area no one will do. But the rewards are potentially tremendous.

And in that area we certainly want

to collaborate, for example, with people out there. And we already have a collaboration with our colleagues in clinical microbiology at NIH on this area.

Another area is an example of an area where it gets to Lonnie's question, regulatory science. Nobody is going to kind of do this.

There is a public health need for pathogen identification, pathogen inactivation in a number of products, for example blood and tissues. This could be from naturally occurring agents or from bioterrorism agents.

Again, the science there -- and there are new tools, for example, to treat blood to kill even unknown pathogens.

But these have a number -- you can imagine blood is a complex -- these are complex red cells or platelets and there is a lot of concern about functional characteristics. So again, we are uniquely positioned to work with the developers of

these tools to help assess them and define the pathways.

The Board mentioned regenerative medicine. I think, again without resources, we have worked with colleagues in CDRH, including Larry in some innovative ways to try to address this. We have a joint review team which, as far as I know, is probably the only one.

But we can do much, much more. This is a field that needs standards and pathways established. The Board has some individuals who are experts in this and we could work with them on trying to do that. That is an example.

And another one that I happened to list here that we decided to, again, start a very small program now that our resources have at least stabilized somewhat is in the preservation and quality of blood cells.

Another area where, again, there is not going to be a lot of commercial interest

yet we are called upon to evaluate new products.

And as many of you may have seen in the New England Journal within the last couple months a publication raising questions about how well aging red cells function. And so this is critically important for our medical care system. And we thought it was worth investing in it.

And then finally, one other things I was going to mention, it is not in your report and I'm not even sure we identified it to our subcommittee but it is of concern to me.

We serve as a global -- we are a WHO collaborating center for biologic standards and serve as a global resource for product testing and quality, particularly for vaccines and blood products.

And we are doing that. I think we are trying to modernize our capacity to do that. We are involved in about 70 standards

activities in these areas a year, you know, what is the standard going to be for factor 8 or pertussis vaccine yet we have been doing that in, generously speaking, 1950s or 1960s facilities and tools.

And fortunately, pandemic supplemental appropriation has given us the opportunity to begin to modernize that. And it is a critical role we play.

And we want to move -- we want to maintain being a gold standard on a global basis there. That is important so we can be confident in product quality that American's get the products but also it is important globally.

And those are the main things that I was going to mention. The more general things that we may want to bring to you from time to time, we share the concern you have identified, Frank has identified, how do we nurture our own scientific capacity.

And I'd like to mention one thing

there which is that I brought in that to include, for example, our clinical reviewers. And again, our statistical and population scientists.

It's not just having lab people who know how to use genomics. It is having our clinical people who evaluate applications be up to date and engaged. And the fellowship program may help us by enriching that.

And the other is a specific thing for CBER. You know we are the last in the queue to move to the White Oak campus. Our subcommittee recognized both challenges and opportunities in that. And we see them, too.

A big challenge is that probably almost the majority of our work is in collaboration with colleagues at NIH in several institutes. And we receive substantial funding through interagency agreements. How do we keep that up?

The advantages are, obviously, that we going to bring all of our people together

in one place. And we are going to be together with our colleagues in the other centers.

But we want to design and carry out that project in a way that is visionary and has an opportunity to actually improve things and bring everybody together.

And so those are the major things. And I think we want to make -- I think we have an exciting place to be but you all have heard and identified many of the challenges.

I think for all of us a really critical thing is going to be not only supporting our own people but getting them to help build the next generation.

And, again, I think the fellowship is a step in that. But it is going to take a lot of work on the part of our existing staff who are already quite busy to do that.

DR. McNEIL: We are going to have to move on, Jesse. That is great.

DR. GOODMAN: No, I'm finished.

DR. McNEIL: Thank you. I want you

to just, since we are going to have a question period, think for the question period about some very specific examples of how the Board would help.

DR. GOODMAN: Yes.

DR. McNEIL: Many of the things that you mentioned involved collaboration. And try to be a little bit more specific when we come back for the Q&A later.

DR. GOODMAN: Sure.

DR. McNEIL: So, Janet, CDER. Thank you for coming.

DR. WOODCOCK: Thank you. Good afternoon. I'm Janet Woodcock for those of you who haven't met me. I'm the head of the Center for Drugs at FDA.

I'm going to talk about some things somewhat different than what Jesse and maybe some of the other folks have talked about because my interactions with the Board have been a different realm, okay, than looking at research or something like that.

As science develops and moves into new types of regulated products or we can develop new tools to evaluate existing or new products, we have to evolve the way we do regulation. And so we have to do regulatory innovation to match scientific innovation.

And I have been engaged in a process of doing that for the last five years. And the Board has been actually extremely helpful in allowing us to move that forward.

Whenever you try to do regulatory innovation, a lot of people, including Larry, become worried, okay, about what you might be doing. And it is very useful, in fact, to have a neutral scientific body that you can present this information to and get input.

So I want to go through the types of things we have done with the Board. Most of you weren't on the Board during all this time and so you won't know.

The first one we did was the --

DR. McNEIL: Janet, could I just

interrupt for one second?

DR. WOODCOCK: Yes.

DR. McNEIL: It will be most important that we think about going ahead. Is that what is going to be in your remarks?

DR. CASSELL: I think it would be really helpful to know the types of things in the past that have been helpful, not really having --

DR. McNEIL: I think that is great as long as we know about the future as well. I'm just worried about time.

DR. WOODCOCK: I'm not going to take more than five minutes.

The first one was the Product Quality for the 21st Century, our manufacturing initiative that has actually caused a major change in manufacturing. This was such a change from pharmaceutical manufacturing around the world really and is now a very robust initiative. This actually was a very radical idea at the time we

proposed it.

We brought it to the Board. Actually, I believe people were fired as a result -- not in the agency but externally for participating in these presentations. It was really a very radical approach that we put forth.

The Board was extremely helpful. Agreed that we should move forward this initiative. We did so. We have implemented these changes both internally and externally. And it has made a tremendous difference.

As far as pharmaceutical quality since we have had like the heparin incident, people realize how important pharmaceutical quality actually is. And it has had a tremendous effect on quality going forward.

The second one was our pharmacogenomics initiative. If you recall, I presented to the Board along with my colleagues a proposal to have a safe harbor. And we would have a voluntary genomic data

submission to the agency.

At the time, people were appalled by this. They were terrified. Other people didn't like the safe harbor aspect.

The Board considered this very carefully, advised us on some small changes to the program and the way to move forward, agreed, voted, agreed that this was a proper way to innovate in regulation.

We implemented this program. We have had a huge number of voluntary genomic data submissions to the agency. Some of them have moved into regular product submissions and are supporting products in development.

The third one was the Critical Path Initiative. And I won't talk about that. I think most people are aware of that.

The fourth one was just last year, the BIMO Initiative to try to change the way we regulate clinical trials. We were just launching that. We may be coming back with some proposals at some point.

And then another one for the future, again, we have just proposed, I think last week or the week before, the Sentinel Program, a new science. Gail is on the Drug Forum at the Institute of Medicine. We have been working about the emerging science of safety. We have put on some workshops with the IOM at the FDA on the emerging science of safety.

And this Sentinel Initiative is actually a reflection of a new and scientific way to do safety evaluations for marketed productions. And I think at some point we probably will want to come to the Board and talk about how we are setting that up. And get your input.

It provides a public forum for us discuss our regulatory innovations, something that really doesn't fit any given subspecialty advisory committee.

DR. McNEIL: Any thoughts going forward about other areas? Or just an

expansion of what you already mentioned?

DR. WOODCOCK: Well, I think the next one is Sentinel. We have proposed something extremely different and radical: public/private partnership between the FDA and other parties in the healthcare system to provide surveillance, safety surveillance in a new way using electronic healthcare records, transactional data, and so forth.

We are currently working that up. And I believe at some point in the next year, we will bring this to the Board as far as what our concept of operations of that might be to get your input.

DR. McNEIL: Sounds great. Thank you.

Larry?

DR. KESSLER: Good afternoon. Thanks for the opportunity to ask us how you can help us.

I'm going to talk about three things and I'm going to take less than five

minutes. I'm going to talk about fellowship issues, students, and workshops.

So the first thing is to mention the Center's Medical Device Fellowship Program. For the last four years, the Center for Devices has generated a Medical Device Fellowship Program which brings in between 20 and 30 fellows into our program.

And it has been very useful. One of the major uses of it is to identify very specific scientific expertise to actually help us with some of our regulatory problems.

There are certain classes of scientific professional that are very hard to hire in the device world in a permanent way because they can make an enormous amount of money elsewhere. We can't compete.

But there are individuals who are willing to spend part time working on some of our problems. And they give us both regulatory as well as scientific advice. It has really been a great program.

And anything you can do to continue to support and expand it would be helpful. And identify academic collaborators in the areas that involve devices so can continue to find those people and expand and work collaboratively with some of our academic colleagues.

Second, we want you to help us work on enhancing mechanisms and increasing the numbers of students brought into our laboratories. As Jack Linehan will tell you, having seen the Office of Science and Engineering Labs that have just been built last year, we have the opportunity to bring in a large number of students who, similar to the fellowship program that Frank and Dr. von Eschenbach have been talking about, could not only help us do the kind of scientific work that can enhance the things that we need to do in our various divisions but populate academic environments and later industry with knowledge about the regulatory and scientific problems

we face in the Science and Engineering Labs in the Center for Devices.

The third thing -- wait, I'll come back to that.

We have targeted the universities in the area here, Maryland, Hopkins, GW, because those students have to pay extra for lodging, transportation. They are here already. And those have been very fruitful collaborations.

It is somewhat harder to bring in people from Northwestern or Marquette or Stanford but we would like to be able to expand and then you have some logistics problems. But I think there is a great opportunity to do so.

Last thing. In the Science Board Report about the Center for Devices, you recognized that we had a two-tier review system for the laboratory work that we do in terms of setting priorities and establishing collaborations and coordinations both within

the agency as well as outside. And you recommended participation of the Science Board on those review committees.

Well, we have worked with the folks who deal with the committee management and unfortunately the Federal Advisory Committee Act prevents us from having a group review our work that is both Science Board and members of the staff of the Center for Devices or federal agencies. You can't mix them.

So we tried to figure out how can we get your input, you know, in a similar way. And what we have launched on is we'd like you to support the concept of at least one, but preferably two workshops a year, held at a fairly high level, externally driven, to cover areas that are very specific to the anticipatory research that we need to do.

And the reason I emphasize that is because the advice we tend to get from the agency tends to follow what is on their plate today, as you would expect. We are all under

the gun about some particular product.

And being able to do the kind of research that we need to do that anticipates projects we are going to see in three to five years is harder. And your advice would be particularly important.

The areas we cover in my office are physics, imaging and applied mathematics, electrical and software engineering, mechanics, material science, and the biological effects of devices. Those are the six divisions. And we would probably divide them up into a couple of workshops a year.

We think it could be very helpful. It is helping us set research directions.

In addition, it is very difficult for us to bring industry in to help us think about that. There are conflict of interest stuff. Those workshops would be terrific places for you to help us bring in industry input.

We'd like to use that complementary

to the program that we conduct every few years, and Jack participated in this in this past year, the technology forecast that we do specifically to try and think through the technologies that we are going to be seeing in five years and that helps us drive recruiting and our science.

And so if you can help us support the idea of workshops to give us your ideas of what are the technologies we are going to be seeing. And what are the critical research questions that belong at FDA and what are those that belong elsewhere that could be done in academia.

And a final comment about that, in general, most of the research, not only the applied research but even the developmental research related to devices is not well supported by NIH. The funds for that tend to be where they applicable in the National Science Foundation and the Department of Defense. That is where you find them.

NIH doesn't like our very applied device stuff. It is just not too sexy. But you could help us help them understand what are the directions and move ahead.

Thank you.

DR. SUNDLOF: Thank you. And I would also like to thank the Science Board for giving CFSAN the opportunity to talk about some of its needs.

Let me just start out with a simple one and that is that we would hope that you would continue to serve as an external review body for the various centers' research and science programs. That has been very helpful to us in the past.

At CFSAN, we have taken very seriously the recommendations of the Science Board's Report. We are trying to implement some of those changes now. And once we do and we've got that underway, then I think we'd like to ask for another review from this committee. So that would be very helpful to

us.

Initially that is what this Board was intended to primarily do is to review the different programs. And I think that function is as needed today as it was when we first developed the Science Board.

Another area that we think is important is at least in the foods area, there is a lot of basic clinical research that we can't really do in the FDA but it would give us a lot of information that would help us do our job.

And an example of that is allergenicity. A few years ago, a law was passed that said that FDA has to require companies that have allergens in their food, things like, you know, eggs or shellfish or milk or wheat even and others, that they have to be labeled because certain individuals have allergic reactions to those.

But it didn't really set any levels. And the problem is that through cross

contamination and such, a lot of food companies are actually labeling their products as may contain allergens even though they may be below some threshold which would cause an allergic response in even the most sensitive individuals.

What we think would be a rational approach to resolving some of these issues is to have NIH or others do some kind of clinical trials where they actually identify what those thresholds are for the individual allergens so that we could set some levels under which we wouldn't have any concerns. And that would help everybody.

But we're not an organization that can really run human clinical trials. We would hope that the Board and whatever influence they would have, something Larry just mentioned, that these are not the kinds of studies that are high up NIH's list of priorities. And we think that there are some very important issues that they could address.

Another one that we are dealing with is biomarkers for what we call good health. All of these nutrient claims and all of the claims that are out there are virtually unsubstantiated.

And we don't have good biomarkers. I think in very few cases do we have good biomarkers that would say that people who consume this nutrient at this level will actually have some positive health effect.

We need some -- and I think there is a real role for NIH and others to help us develop those biomarkers so that we can look at the effect of various nutrients on those health food biomarkers. Rather than looking for biomarkers for disease, let's try looking for biomarkers of health.

So those are just some of the examples that we think we need real basic research in order to advance our cause.

We also would like to see this Board take an active role in helping us bridge

the gap between academia and industry. And I think you have heard this before.

The Center for Foods has done this but we are not at the point where we want to be. So we have the National Center for Food Safety and Technology that is associated with the Illinois Institute of Technology, that they accept grants from industry but also a yearly funding from FDA.

And this allows us to evaluate all kinds of new food processing technologies. And new food processing technologies are coming about all the time. But we don't know.

So if you irradiate a package of spinach, what about the chemicals in that packaging that may get into the food. We have thousands of questions like this.

That particular center is coming to a point now where it is getting more of its revenues from industry than from the government. And we think that is the model that we would like to see.

We have other what we call centers of excellence like the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland which hasn't really gotten that far along yet. But we think that that is an area where they could be of tremendous benefit.

And a lot of things they are doing is looking at issues such as acrylamide in foods. They are doing outreach to other countries to make sure that the foods that they are producing and exporting to the United States meet our standards.

So there is a lot of capacity building. And would rely on those kinds of centers for excellence to continue to do those.

The most recent one is at the University of California -- Davis, where we are looking at good agricultural practices, especially in the Salinas Valley where we have had problems with spinach.

And we don't have a lot of good answers as to why that occurred. How did E. coli 15787 get from the environment into the spinach. Lots of questions about that.

So we would hope that the Board would help us advance those kinds of programs.

Another area that we would like to have information that probably already exists but is not in the public domain, the food industry has lots of information we are aware of that pertains to how they are in manufacturing, and where they found problems in the past. And what they have done to remedy those problems.

And we would like to find some way o accessing that information in a way that is blinded so that it wouldn't be in the public domain. It wouldn't be attributed to any particular company. But it would give us the kind of information that we would like to have in order to start setting some standards as we go to a more preventative approach to food

safety.

I'm glad that Rhona mentioned the social sciences. This is an area that, you know, until a few months ago, I had no idea why social sciences was in FDA but now I get it. And the issues are -- all of the food labeling, we have a nutrition labeling panel that has a lot of good information n it.

We don't have a good sense of how many people are actually using that. If they are making healthier choices because of that food panel, is it conveying the kind of information that they would find useful, we don't have good consumer research on that.

Other things that are coming up faster than we can react to them is front-of-package labeling so that helpful symbols are being included on the front of packages.

We know that those products sell better than products that don't have that labeling on it. But we don't know how that impacts the impact of the public.

We would really like to have better information on that and we have minimal capacity to do these kinds of consumer research. In addition, we have to -- it is a very laborious process because we have to go through the Office of Management and Budget every time we try and survey the public.

The food industry has millions and probably billions of dollars spent in market research that understands how people's behavior changes as the result of certain messaging. And we would really like to have better input from the industry because you folks know this stuff much, much better than we do.

We are talking right now about revising the food label to give more meaningful information but we don't know how that is actually going to be interpreted and used in terms of public health. So that is a big issue for us.

And then the last thing I will talk

about is sustainability of the science program in FDA. All of the centers that have user fees have a somewhat stable budget for those areas that benefit from the user fees.

But research is not one of those generally. And so in good times, research benefits. And in lean times, it virtually collapses in the FDA.

It experiences the biggest swings of any part of the program. And if there was some way that we can come up with that would give us a kind of a stable floor on that so that we are not subject to these huge swings in budget every year, I think that would be something that I certainly would be interested in and I'm sure probably the rest of the centers would be as well.

Thank you.

DR. DUNHAM: Yes, good afternoon. And once again, thank you all very much for being able to participate in this Science Board commentary. And I do want to

specifically thank Dr. Woteki and Dr. Jim Riviere for their wonderful review of CVM and all the help that you provided us. So thank you.

I've got four small examples of where we hope we can continue to interact. One is one that we've talked earlier, the support for education and training initiatives in the emerging sciences. And some of the examples we have already discussed be it genomics, nanotechnology, combination products, just to mention a few.

We have a very nice opportunity with our staff college to interact and bring guest speakers in, to be able to work with industry. And we have also just recently set up with one of our universities nearby an opportunity for our folks to be able to get an M.P.H. and do the distant learning program.

So opportunities like that are easy right here. But we could network further and have our folks have an opportunity to maybe go

to some of your facilities or facilities in industry that you can identify would be incredibly helpful.

And I think that gives that breath of fresh air that we want for our folks as well. And a good exchange of information. And allowing us to pick up the state-of-the-art techniques.

Number two is another big area and that is risk assessment and risk management and how do you get those tools. One area could be a focus for us with the animal feed safety system. We saw what happened with melamine. It has opened everybody's eyes as to how embrace prevention, intervention, and response.

And this also knocked home the globalization of everything we are facing with where the ingredients are coming from, the processing, and delivery of that product all the way to consumption in the case of food animals, which then glean another food product

for us.

So how could we do that would be very, very helpful because the folks that are specialists in risk assessment and risk profiling are rare. And we need to perpetuate that group of scientists.

And you may have access to those for us. And we'd like to team tag that wherever we could. And that would also help us because I think the bottom line that you are hearing is we can longer continue to inspect everything.

We really do need to think smart and be able to take advantage of these tools. And almost like a way to incorporate how to address the good companies, the ones that need more help, and enhance the transparency both domestically as well as globally.

Number three would be support in crafting an improved NARMS. This is our National Antimicrobial Resistance Monitoring System which, again, I thank you all for the

review that we've had. It was very, very much appreciated.

We need to expand that. We need to harmonize it. And this is now linking the whole area of antimicrobial resistance monitoring that is not only domestic but globally.

This is where we could continue to receive advice from you on some of the scientific issues that are impacting this, support for interactions again with the scientists from industry, academia, and other government agencies on this whole program.

I think it would help us to identify some of the new technological capacities that we could share and help NARMS expand.

And then the biggest challenge is communicating all of this with the public. How do we enhance their understanding of the hazards with regards to antimicrobial be used for human medicine, be it used for veterinary

animal health? And how do we further modify our technology for the various bacterial pathogens we are trying to follow through.

And then finally, I think because we are involved with WHO for the salmonella program, other capacities like that internationally that can bring us together would be very, very helpful.

And finally, as you've heard, fostering research and research collaborations in the technology for detection of tools for food safety. This again brings us all together and helps us with the expertise that we need to identify and also I think can get us into the global market a little bit more.

So those are the four that I wanted to address that I think there is great opportunity for us liaison with you. And doors that you can open for us that we appreciate.

And, as you heard earlier, with the Reagan-Udall Foundation, that is another way

for us to continue any one of these four examples to bring in folks, work with them, and maybe they will going back to your locations, maybe they will going back to industry.

But the more we can enhance and communication, I think it is going to be a win-win for us and it helps us to be able to really show what you know, how fantastic our folks are, all the work that we are doing here. So those would be much appreciated.

Thank you.

DR. SLIKKER: Yes, thank you, Barbara.

You know just the fact that science has been reviewed within the agency is a big help to the NCTR and to the whole agency as a whole. And I really appreciate the fact that now you are going to be meeting four times a year which gives us even more opportunity for these exchanges. And I think focusing on science is what is going to help us move

forward.

I want to just mention that not only does NCTR develop data that can be used for decision-making in the regulatory environment for FDA-regulated products, but it also is developing and perfecting new assessment approaches and strategies.

And along that line, you have identified in your report earlier some of the concepts or approaches that advance science within FDA.

One of those is the area of nanotechnology. And that has been spoken about a lot today already but I think this is really a critical one for NCTR's contribution to all of FDA.

We have done this through interactions with not only the other FDA centers but also with other government agencies, including NIST, NIEHS, and NCI. And with academic centers as well.

And the idea is to develop tools

that can be useful for safety assessment of materials that contain nano particles. This is really critical because there is a tremendous amount of resources going into nanotechnology in general but not nearly enough going into safety assessment. And so that is one area that we think that FDA and NCTR can work together to do that.

The other area is bio imaging. And we feel this is an area that has really been a tremendous workhorse for clinical care. But I think that it has real opportunities within the area of safety assessment and especially for preclinical assessments.

And we are working on this in conjunction with various universities as well as other centers of the FDA to try to develop bio imaging approaches that can be useful to safety assessment and the application to develop information in a noninvasive way.

And another area that you identified earlier on was, of course, the

Omics technologies and bioinformatics. And these areas are ones in which NCTR has been working for some time.

In fact, there are some 230 publications that are done in conjunction with NCTR staff and staff from other centers and other universities as well as industry to pull this area forward.

In fact, it is providing the tools that are available now to help lead into personalized nutrition and medicine. And just as Catherine and I were talking over lunch, this whole area of applying Omics technologies to nutrition in one in which I think has a tremendous future and opportunity because it allows you to look at things in a more systems biology type approach.

So those are some of the areas that we have been working on. But we really also need your help on is to really look at advancing science within the FDA and identifying other areas in which there are

crosscutting themes that can be exploited.

And your help in trying to pull together groups of individuals for FDA to work with, I think would be key. This could be developing partnerships with us and other government agencies, with academic forces, as well as with industry.

And I think there are some examples where NCTR has been able to provide leadership in this kind of approach before. If you look at the microarray quality control projects number one and two, you can sort of see a nice history of the application of resources to solve important problems.

Microarray quality control Study One really looked at the technical performance of microarray approaches. And that one resulted in several publications in Nature Biotech and several other outstanding journals.

And it was done in conjunction with 130 different participants from 50 different

organizations including industry, other government agencies, as well as centers within the FDA. This kind of outcome is the kind of integrative approach we are looking for.

And the Macq2 is looking more at signal extraction from Omics data. And this process is ongoing now and will be completed in 2008. So I think these are examples of things that have worked in the past.

We'd like to find ways to get your help to identify additional themes that could be exploited in this way. And provide the leadership within the regulatory community for application to FDA-regulated products.

Thank you.

DR. GLAVIN: Well, first of all I want you to forget everything the other people have said and listen to what I have to say.

DR. McNEIL: They gave you enough time.

DR. GLAVIN: Okay, thank you.

The subcommittee report very

generously pointed out ORA has been thinking a lot about what we need to do to position ourselves to meet the challenges not only of today but of the future.

And so it is in that vein that I am laying out some things that would really, really help us if you could help us with them.

You know we talked about -- or the subcommittee identified the challenges, the increasing globalization of our work, the increasing complexity of the products and processes. And the fact that there seems to be an increase in opportunities for and unfortunately the incidence of counterfeiting of regulated products for a variety of reasons.

So with that in mind, one of the things that -- we are obviously going to have to retool our regulatory labs and re-staff them in coming years. And so what are the areas of expertise that you see, analytical needs, and areas of expertise that you see as

the primary ones we ought to start investing in.

You know Bill and I have been chatting for some time about a collaboration in the area of nanotechnology but there are many, many, many others that we simply have no expertise in.

And also if there are some areas that we have expertise in now but that, and particularly if the subcommittee saw some weaknesses in those areas, that we have lost expertise or we don't have enough of it, that would be useful.

On a parallel track, the same kind of thing for our inspection staff. We are hiring for the first time in a long time. And what should we be looking for? What kinds of expertise do we not have?

And as I said, we have traditionally hired entry level people and trained them up. We are also an aging workforce and have a huge percentage of our

workforce coming close to retirement or already eligible to retire. So we're going to have a big gap in those higher skill set areas.

And we are going to have to start doing some hiring at higher levels than we have traditionally done. So what should we be looking for there in areas of expertise?

And then two other ones that are somewhat related, one is methods development and validation. What kinds of collaborations? Where could we collaborate on some of those things?

As was pointed out in the report, we have to have validated methods because we have to -- if we are going to take a regulatory action based on a finding, it had better be solid and we better be able to prove it is solid.

And those kinds of validations are really enhanced by collaboration. We often collaborate with academia. Can we collaborate

with the regulated industry also on those things?

And then tied to that is rapid test kits are something we are very much in need of. They are wonderful ways to expand how much we can do at a relatively low cost by screening out products, particularly at ports of entry. To use rapid test kits would be extremely useful.

They are not easy to develop. And we don't have the expertise. We do some of it just because we have people who like to tinker but it is really not an area. So where can we look for that kind of expertise for rapid test kit development?

DR. McNEIL: Wow. That is a huge amount. Oh, my God. I think Andy said he needed to. And he was going to increase the Board by a factor of two and a half or something like that? Two? Is it two? That's not enough. I mean, God, you need to increase your staff by a lot you are doing so much.

Well, let's' figure out how to proceed on this before we go to the questions of the Board to the speakers. Let's try to think about framing what we want to get out of the questions in this discussion because we really want to do a couple of things.

One is we have to think very pragmatically about those things that we want to do for the October meeting and then the meetings in `09. Just concrete things, reviews, training, whatever. Those are probably on a parallel path with some of the things that you have been talking about.

So what I would like to do if we could, and I'm talking live here and I may not be right, is let's ask for clarifying questions. And then let's figure out how we can -- and you, together, can think about those areas as a result of these questions and your discussion that we could really be most helpful in and what steps we could take to do it.

Because we have talked about collaboration and we are all interested in that. But how might we do it? Just taking it as an example.

Said differently, how can we make it a little bit more specific about some of the terrific comments that you have already made about suggestions and going forward because what I don't want to do is have this nice list that gets incorporated somewhere that we all look at and then say now what? I'd like to take it a little bit farther than that.

And you all have so much more experience in this than certainly I do and most of the rest of the Board. But I want to think a little pragmatically.

But first questions. Anybody, I guess, would be the way to go. Cathy?

DR. WOTEKI: I know that we post this originally as FDA-oriented questions. And that this Board is constituted to provide

advice to FDA. But one of the things that struck me is that all these issues -- or many of these issues actually are ones that are facing other regulatory agencies in other countries.

So to what extent could we also consider posing some of these questions again from the global perspective, not just what this Board can do in helping FDA but can we also think of other forums, other places where we can help to leverage these questions in an international context?

So to this question of methods development and validation, yes, there are ones specific to FDA's concerns but your sister agencies in other countries have got that same issue. So is it just an FDA issue that we are talking about or should we also be considering how we can be helpful, perhaps, in that global leveraging.

DR. McNEIL: Maggie?

DR. GLAVIN: Absolutely it is not

just an FDA issue. And I'm not going to answer your question but you triggered an example in my mind which is that, as you know, FDA has had, for years, retail food standards. And, you know, they are the law of the land. And states adopt them, et cetera.

And we have recently put out manufacturing food standards. This is CFSAN and ORA work. And in the China MOA, the basis that the Chinese food agency is using is the manufacturing food standards. And, in fact, they have translated it and that is their requirement.

So it is a good example of -- but it went in the other direction. I'd like some to come in our direction.

DR. KESSLER: I can answer your question for Devices because we are a little bit unusual. So I know there will be three answers to it.

The first answer is that I Chair the Global Harmonization Task Force which is

the organization that is trying to harmonize device regulations around the world. And the scientific questions, you are right, are very similar to all the other agencies whether it is Health Canada, or Therapeutic Goods Administration in Australia.

We try to identify emerging technologies, combination products, medical device software, and others where we can work on what are the key regulatory/scientific questions. And we have been doing that.

So having international input is a good idea. We are trying to get some of it. We could use more. It is difficult because of the logistics. But it is a good idea.

The way we do this most in the device world is by working collaboratively with the international standards organizations. The Center for Devices and Radiological Health has 250 people who populate 450 international standards organizations committees, ISO, IEC, ASTM,

AMEE, et cetera.

And that is the way we identify collaborative issues in the science base that need to be worked on either in our laboratories, the development of test methods. And that is one of the best ways we get industry input. So that is working pretty well.

But the third thing in terms of identifying scientific issues we can work on with other agencies, in the device world, and I can't speak for the other guys, there is no organization in the world that has a lab that looks anything like us. They have all been closed down.

So the U.K. used to have a fairly substantial device presence. They are now one laboratory doing prosthetics and wheelchairs, full stop.

They don't look at drug-eluting stents. They don't look at heart valves. They don't look at anything because the

regulatory model for devices outside the U.S. is to outsource all the work. They make industry pay for evaluations, pay for laboratory testing, pay for everything.

So we don't have colleagues to do that. The regulatory agencies have the questions. But the way they get the answers is by making industry pay for them. Different model.

DR. GOODMAN: You know, just to add a similar comment to that, you know, in some of the subject areas I mentioned, we are almost continually engaged with other global organizations in leveraging exactly like you said. For instance, almost all of our standards activities for vaccines, blood, cell, and tissue, et cetera, we leverage with WHO.

We have maybe four or five sister organizations that are biologic regulators that we frequently engage in collaborative studies with them. But to second Larry's

point, one of the things we all are trying to protect here is as concerned as we are and as on the edge science at FDA is, and as under resource, we are still looked to for the science underpinning those standards.

And that is good for global quality. It is good for innovation in the U.S. but it is right on the edge. So hundreds of times a year we sent people to WHO to participate in activities that advance global public health and standards. And we need to be able to do that, you know, even better.

The other thing we are doing more and more is regulatory cooperation with other agencies. And we have a number of agreements and we work together, especially we just had a recent discussion with EMEA to inform the EMEA about working together in what they are considering as advanced therapies.

And, again, they look to us for what should we do with cell therapies? What shall we do with regenerative medicine?

The flip side is they intellectual capital and innovation themselves. And it it critical that we learn from them. So these are very important relationships. And they are another example of something that -- there is no budget line for working globally in knowledge and innovation.

DR. CASSELL: I was just going to answer Cathy, too, that the CDER working group last year asked for a comparison internationally in terms of research to back up the regulatory decisions. And what it was like in the other agencies.

So Mack Lumpkin spent about well an hour and a half with us summarizing and comparing what was going on. And it is much like we just heard about devices. And that was that everybody really looks to the U.S. and depends on science that comes out of FDA.

And so if we don't provide it, then my suspicion is that it wouldn't weigh in nearly as much as it does today. And even if

we lag behind, then we end up following somebody else's standards, which I don't think is a good idea either.

DR. LINEHAN: In listening to some of the interests in getting help for scientific questions or technological questions, I have been thinking about the comments this morning about cross-agency types of interactions.

And by example, I remember X number of years ago before people could spell biomedical engineering, NIH, for some reason, couldn't fund anything that had the word engineering associated with it.

So as a result of this, there was a political pressure -- not to get into all the details but a cross-agency organization called BEACON, a bioengineering consortium was formed that brought together a lot of agencies, including NIH, NSF, NIST, DOE. But as far as I know, not FDA.

Now I don't know if that agency

exists anymore but there should be something like that for the issues that we are talking about because there are plenty of folks in this fine country thinking about devices as we speak.

There is a meeting going on in California now bringing together a lot of the physician inventors who have a lot to say about and have done things in the cardiovascular area.

So it would seem to me that we could take advantage -- and I talked about that a little bit this morning with regard to the CTSA -- but take advantage broadly with all the agencies. When you talk about nano, there is lots of money being spent in lots of academic institutions on nano research.

This is not something that I think we need to have -- what was it called -- reducing redundancies. I don't think we need to have redundant approaches to it. We need to take advantage of what we already have.

I think Larry's point about workshops is an excellent point of view. We can find out what is on the mind of people if we get the right people together. OSEL had -- one workshop he mentioned was to look at the future of the technologies, what they would be seeing five and ten years down the road, which was very difficult.

But, you know, there is one community that really thinks hard about this and this is the venture capitalists at least in the medical device industry. I was amazed to find out that about a third of the venture capital money last year went into biotech and medical devices.

And for medical devices, I tell the undergraduate students when I'm giving talks, this is good news -- 3.9 billion last year was invested in medical devices. Now these folks are not playing roulette. They are putting the money where they think there is going to be something significant.

So if we want to find out what is the future, that would be a source of inspiration for us I suppose. Now I don't know about conflict of interest. I suppose there is that problem.

DR. McNEIL: Can I just ask a procedural question? And then Gail.

Several of you mentioned workshops in some form or other. And the issue of venture capital or industry or potential other stakeholders who might be perceived as having a conflict of interest that might arise.

Are there guidelines that are available to indicate who could sponsor? Janet, you probably know the answer to this better than anybody. Who could sponsor or put money behind workshops that would fit the bill that several of you mentioned?

DR. WOODCOCK: Yes, what we might do, we have a range of options, we can just get somebody else to sponsor the workshop and invite us. That works, okay?

We can cosponsor a workshop with other parties. We frequently do that. There are some rules on that but we can just about have anybody cosponsor a workshop with us if we follow the rules.

Or we could work with other bodies such the NIH or the Institute of Medicine or others to do workshops. Or we can hold workshops ourselves.

So we have a very wide range of options. And I think with Reagan-Udall, we will probably have additional options for getting money together to hold workshops in that regard.

DR. McNEIL: Could I just pursue this one more second?

Gail, just to be very specific, suppose -- I can't remember who said which workshop but suppose we wanted to have a -- some one of you wanted to have a workshop in September or October, very soon, on I don't know, name me something -- nanotechnology in

September so that we don't have a lot of time to get Reagan-Udall money in there.

And we don't have a lot of time to do a lot of paperwork that might be required if the FDA was sponsoring it itself, what would be the mechanism of saying okay, the FDA is going to cosponsor a workshop or be invited because functionally they could be essential identical --

DR. LINEHAN: If I might just point out, I just ran such a workshop April 30th here in D.C. for the Center for Devices. And it was sponsored by inHealth, which is the Institute for Healthcare Technology Studies, which is a nonprofit.

So they provided the wherewith all to bring in the speakers. It was on how medical devices are developed.

It even went so far as to split the issue such that -- I don't understand this thing -- we went to lunch in one room and the FDA had box lunches sitting in another room or

something.

It really towed the line as far as conflict of interest went. But there was a tremendous FDA presence and industry presence and venture capital presence all in the same room for one day.

DR. McNEIL: Is that something, Janet, you know, is that something --

DR. WOODCOCK: Certainly, all these things can be done. They are mainly limited perhaps by our staff time, okay, our ability to work with people to put these on.

There are a wide variety of either nonprofits or professional organizations that also -- in my world, the Drug Information Association is a gigantic organization that is a nonprofit that we often have workshops with.

And there is the International Society of Pharmaceutical Engineers, for example, they could put on -- say we had some burning issue in nanotechnology, we have different partners we could probably get a

workshop together in the fall on if we really needed to get that done. We have many ways to do that.

But we are limited by the amount of our staff and we do it a lot, yes.

DR. McNEIL: Just to clarify, you are limited by the number of staff who can help plan it or who are available to attend?

DR. GOODMAN: Both.

DR. McNEIL: Both.

DR. GOODMAN: So we choose, we do do a lot of workshops and especially in emerging technology areas. We just had one on hemoglobin-based oxygen carriers. For example, when we wanted to develop guidance, we got the academics, the American Society of Gene Therapy, and cosponsored a workshop on long-term follow ups.

So we do a lot of this but we -- given some of the resource issues you've had, we have to say where are the important issues that need to be dealt with, where are the

important forward-looking opportunities.

So you can help us, perhaps, by identifying some of those. But we are always trying to do that. We have one coming up we are cosponsoring with, in this case, people that include blood transfusions centers on software used in the blood transfusion centers.

DR. McNEIL: Okay. Gail?

DR. CASSELL: I was just trying to think of a mechanism where we could try to accomplish a lot. And one of the things that was the recurring theme that we have again heard today was the collaborations with academic institutions.

And I wonder shortly after the second Emerging Infectious Disease Plan was released by CDC, we brought together the groups, where scientific counselors worked with the CDC to bring together stakeholders. And amongst those stakeholders were not only academicians but foundations that would be

potential funders, some industry.

And I'm thinking why couldn't there be such a meeting? And we could either do it through IOM or maybe through the Science Board at the October meeting but where we would invite the deans from the medical schools or their designee.

We would invite several of the university presidents that would be relevant or open it to all of the university presidents that are doing relevant research. I'm thinking of the Purdues of the world that might have interest in the food safety and engineering challenges that we have heard about this morning, the CSTA directors.

And to share with them, number one, what has come out of the Science Board Report in terms of the recommendations as well as hearing the response now from FDA that this is a real need. Now how can we do this together?

And we would need to make it clear at the outset we don't have a lot of money to

give you but we need to leverage all of our collective expertise and dollars.

But it seems to me that that would be one of the very quick ways to maybe get some ideas and mechanisms where things could begin to gel.

And it would probably be better to have a bigger group and a mixture that to, you know, kind of take it individual subjects or topics at a time is what I am thinking. It may be a bad idea, I don't know. But that would be one suggestion that I have.

DR. McNEIL: All right.

DR. CASSELL: And if could just, along those lines, have two other questions related. One is like the Illinois program for food, is that on a competitive peer review basis?

So when you are going to renew the program, do you broadly advertise it? And get proposals from a wide range of institutions so that you are confident, you know, you are kind

of getting the best. And how well is it advertised that FDA is looking for academic partners?

DR. SUNDLOF: Well, the answer to your question is no, it is earmarked in our budgets. A lot of times there is interest in the state to support that program. And so we find it as an earmark in our budget.

We do work with these organizations quite extensively. And I don't want to make that sound like we don't think we are getting the most for our money because we really do benefit from them.

But we ask, you know, UC Davis was our latest partner in the Centers for Excellence.

And we did quite a lot of work with them because we knew that they were going to be going to The Hill and asking for funds to be appropriated for that program. So we did a lot of groundwork with them, knowing that they were going to do that to make sure that the

program fit our needs.

But in terms of overall review and competitive process, that does not happen.

DR. McNEIL: Lonnie?

DR. KING: So, Barbara, one of my concerns about it is that our list of challenges grows.

DR. McNEIL: It's kind of good that --

DR. KING: It is good problem definition but, you know, they have asked us how we can help. So, you know, if we are going to meet is it four times a year now? So rather than just adding to the list of problems, you know, maybe we ought to think about devoting one or two of those meetings to really specific workshops.

And maybe the workshops ought to be held in Centers of Excellence at universities. This is part of the vision of the science moving on in collaborative ways. Put the onus on them to help design that and put it

together.

And certainly the Board could do that. And just listening to you for the first time across the way, I'd say, you know, here's some topics that are kind of cross cutting. One is this technology forecasting and anticipatory research. I think that is really critical.

You know what are you going to be doing in five years or longer. You need to get ready now for that. I think that would be a great workshop topic and it fits into our report as well.

Public/private partnership models of collaboration, you are doing some of those. I am interested in Janet's idea about the Sentinel Program. You know what have we learned, what are those prototypes, and can we bring those together and make them more broad?

Defining regulatory science, I'm still very much taken with that idea. It is part of doing science in the agency. That

would be a great workshop at a university. You know what is the curriculum for regulatory science, you know, how do we do that? And how do you drive that?

Messaging and marketing, Steve, you talked about that. And certainly at CDC, you know, we are putting huge resources into trying to modify behavior through different marketing strategies. It is not typical marketing.

You can put anything on the label you want but if it doesn't change people's behavior, it doesn't help much. So I think that is a good area.

Risk communication, you have all talked about that. I think that is a science in itself. Or at least a growing science.

And the last one is networking systems not only for internal but external. This governing by network is a whole phenomenon that is moving on that I think is part of re-engineering FDA.

So I mean those are some things that I heard kind of cross cutting that could be workshops in very specific areas to walk out specific ideas that could be helpful. So it is just a way of kind of managing these and prioritizing.

DR. McNEIL: You know I can imagine that for some of these, if you took the anticipatory research, I would hate to see funding get in the way of holding some of these workshops.

But if we took the area of anticipatory research, I would have thought -- I guess it is Jack who brought this up -- that we could identify a couple of venture capital crowds -- groups that might like to throw in not a lot of money, this would not be a lot of money, to bring together the pertinent people from each of the relevant groups at the FDA plus some leading thinkers in each of the areas for an invited-only meeting.

It would not be open to the world

because then there is really not an opportunity for much interaction. Would something like that ever be possible?

I mean that is one where I can imagine the funder would stand to gain a lot and, therefore, they might be willing to fork over the money much more so than -- I know for a fact if I went back to Harvard and said let's fund, let's Harvard fund a meeting of this, I know I would get nowhere, absolutely nowhere.

DR. WOODCOCK: This is Janet. I think the Advisory Committee can't participate in this -

DR. McNEIL: The Advisory Committee, what? I'm sorry.

DR. WOODCOCK: Could not participate in such a thing as an advisory group. You know you couldn't -- you probably could attend as individuals. Carlos would have some theories on that. But, you know, you are bound by a lot more strictures than

the FDA is.

DR. McNEIL: So we could go as individuals? If they happened to invite all of us it would be okay?

DR. WOODCOCK: Well, I'll have to defer to Carlos on that.

DR. PEÑA: Yes, we would have to check that the regulations that would allow for you all to participate as our advisory members and these additional activities.

DR. McNEIL: Well, it may not -- it's more important than you attend that we all attend.

Yes, Jesse?

DR. GOODMAN: I was just going to say I think generally we try to have open meetings and public participation.

DR. McNEIL: So right. I understand. But if you really wanted to grill a few people about what was really coming down the pike and what infrastructure you should be building up, or what lead scientist you should

be recruiting, do you do that better when there are, you know, a hundred other VCs in the backroom dying to ask the same questions for their own selfish interest? Or do you do it better when you have been invited as individuals?

It's just a question. I understand the concept of open meetings. And I am totally for them. But if it is really to get information that is going to help you in whatever way possible, is there a chance that you can get outnumbered by the 500 VCs that are in the audience who are going to just grab the microphone faster than you can.

Larry?

DR. KESSLER: We had the National Venture Capital Association staff come and visit us about two years ago and spend a couple of days with us.

And you get different things from different meetings. So from that, you get them to see what we are doing. They are

generally fairly tight lipped about the technology that they are developing for obvious reasons.

So you are only going to get a glimmer of what they are interested in. It is more productive if you are going to have anticipatory research from people who are actually inventors and/or academicians who are working in relevant scientific disciplines.

And then the meeting being open is not a problem. But the VC folks themselves, where they are putting money --

DR. McNEIL: Oh, I was thinking they would fund it. And you would invite the academics to talk. Oh, no. I wouldn't -- no, you don't want them to talk.

DR. KESSLER: Right.

DR. McNEIL: You just want their money. Cold hard cash.

Let's see, Larry and then Martin.

DR. SASICH: As new products are being developed and applications are

submitted, depending on how long the development program takes and where you guys, the regulators, become involved, don't you have a fair idea about new technology that is going to be used say for the manufacture and the use of these products really early in the process?

Well, not really -- I don't know how early in the process. But can you use that as a key to help drive the direction of research?

DR. WOODCOCK: Well, I think it, you know, very different for each center. Like Gail gave me some presentation from this morning. You see that the Center for Drugs doesn't really have a research budget.

So to get people in to help us to direct our research budget isn't very helpful because we don't really have one. And so -- and, to your point, yes, the situation with pharmaceuticals and pharmaceutical development, including the biological

therapeutics, is that we have a pretty good understanding. They have to get into clinical trials. It takes them about five to seven years.

So the issues for pharmaceuticals are not around specific products or "technologies" as much as they are around what are the endpoints, what are the statistical designs and manufacturing, new control strategies, new types of toxicity, the whole issue of the emerging science of safety that we talked about, which is everything from genomics and proteomics and so forth. Those all cut across. They aren't related to specific products.

So I know it is very different for devices because they have this whole let a thousand candles be lighted or whatever of different kinds of products. And they really do have to know. And they have a shorter development cycle.

So I think it is real different

each area. Personally my reaction to lumping those together would be somewhat negative because I don't know whether I would get a lot out of a general discussion.

DR. SASICH: I guess I don't see lumping you all together but, for example, if you see a new pharmaceutical and the manufacturing of that pharmaceutical that is part of the MDA, is that an opportunity for you to collaborate with ORA and say, you know, better start looking at this because there is going to be a need for new validation tests, new GMPs, those types of things.

I mean there is no way that since things cut across different centers, there is no way to kind of tell, on your own, or at least have an idea, on your own, what direction industry is going and what you might need to do in terms of regulatory science.

DR. WOODCOCK: I'm saying for drugs we very well know. I'm agreeing with you. I think for others, they may not know so well.

But for drugs, we very well know.

We have the whole IND phase where we are seeing the products while they are clinical trials. So we know how they are manufactured and so forth and so on.

DR. GOODMAN: Yes, and we have a spectrum of products and they are different places, all of them, but I think a lot of us are engaged in some of these forward-looking exercises. So I think it is more helpful to be specific.

You know, for example, the idea of regenerative medicine and tissue engineering, we have worked together with CDRH but to follow up on a comment over there I guess John made, there now is -- we participated in what is called the Multi-Agency Tissue Engineering something or other -- Science or MATS Initiative that issued a report on the state of that field.

But then we, together with our friends at CDRH, NIH, et cetera, actually put

on a workshop where the innovators and companies and all these people came about a very specific scientific area there. And we used that to help learn what are the standards we need in that area, what are our scientific needs.

So where I could get help or we could get help going forward, for example, in that area is we are thinking about examining internally what are our current practices, where do we think standards are needed, where might guidance be needed, et cetera.

And that might be one where, for example, the couple of experts on the committee could just work with us to have a process that is successful in doing that. So we've done the workshop.

Then internally as part of my asking my offices to develop their research plans, I ask them what are the INDs you have now and what do you see as on the horizon in the next five to seven years. And we actually

ask our advisory committees that same thing. And those advisory committees should be experts in those fields and know about innovation.

So I think there are ways to get this innovation information. But what is important is then we build that into our practice and we act on it. So these are some of the next steps that I think you could help us in.

DR. McNEIL: Bernadette, Bill, and then I'm going to ask us to think about how we want to proceed on this because we really need some concrete steps. And we can go back and forth. Oh, okay.

Bernadette, Bill, and then Martin.

DR. DUNHAM: Thank you. Just wanted to mention for the Center of Veterinary