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EBERLIN REPORTING SERVICE
576 Hooker Drive
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P R O C E E D I N G S

OPENING REMARKS, AGENDA OVERVIEW AND MEETING MINUTES APPROVAL

Norman R. Augustine, Chair, Scientific Management Review Board

CHAIRMAN AUGUSTINE: Good morning, everybody.

I'm Norm Augustine and it's my privilege to chair this group.

Let me welcome all the board members, new board members as I'll come back to, those of you on the phone, our invited guests, we appreciate your time and we look forward to your comments, and a special thanks to our visitors who have joined us from the public either to listen or to make comments or both.

We last met in person several months ago. As you know, we had a teleconference in May and we had a chance to talk some about the status of the follow-up to some of our prior recommendations and also to talk about the working group that we'll focus on today, which is the NIH Small Business Innovation Research and Small Business Technology Transfer Programs, referred to as SBIR and STTR, which is probably the nomenclature we'll use today.

We have a full agenda as you can see and I won't go through it even though, I guess, the agenda calls for me to do that but you can read it quicker than I can talk through it. Basically what it comes down to is Sol is going to lead much of the meeting because it will concern the group that he is leading.

Also we have several new members of the board that we want to welcome this morning. We have an administrative situation where their presence today is an ad hoc capacity and the reason for that is that they have not yet completed the rather onerous, if I may, editorialized process to become a member of this select group.

We thought with the SBIR/STTR consultation and the delivery of Dr. Collins' new challenge to our board, new charge to our board, it would be good if they could participate and, indeed, we thank them for doing so.

So I'd like to welcome Dr. Garry Neil, who's the Corporate Vice President of the Office of Science and Technology at Johnson & Johnson.

We're pleased to have you here and thank you for joining us.

Dr. Gilbert Omenn, who is a professor of

internal medicine at the University of Michigan, and he is on the telephone from Seattle.

Could we ask that you de-mute your telephone so that we can be sure you really are there? Are you there?

DR. SNYDER: It's 5:15 in the morning.

CHAIRMAN AUGUSTINE: It's 5:15. We will look forward to you joining us at a more respectable time.

(Laughter.)

And Dr. Yancy, who is Chief of the Division of Cardiology at the Northwestern University Feinberg School of Medicine, who is also joining us on the telephone.

And I won't put you on the spot but feel free, all of you, to chime in whenever you wish with questions or comments. We do thank you for joining us.

One of our other incoming members is not able to join us today but will be participating in our future meetings, and that's Mr. Steve Burrill, who is the CEO of Burrill & Company.

Before we begin the meeting, as has been our tradition to help the visitors who are here, it's probably a good time to go around the room

and each of us introduce ourselves in terms of what we do in life.

And why don't we start, Sol, with you?

DR. SNYDER: I'm Sol Snyder from Johns Hopkins, the Neuroscience Department, and I've been involved in neuropharmacology and interested in the drug industry.

DR. SHURIN: I'm Susan Shurin. I'm Acting Director of the National Heart, Lung, and Blood Institute.

DR. ROPER: I'm Bill Roper, Dean of the Med School and CEO of the Health System at the University of North Carolina.

DR. BRIGGS: I'm Josie Briggs. I'm the Director of the National Center for Complementary and Alternative Medicine here at the NIH.

DR. NEIL: Garry Neil, and I head up Science and Technology for the Corporation of Johnson & Johnson.

DR. COLLINS: Francis Collins, Director of the National Institutes of Health.

DR. CASSELL: Gail Cassell, Visiting Professor in the Department of Global Health and Social Medicine at Harvard and retired Eli Lilly Vice President for Scientific Affairs.

DR. RODGERS: Griffin Rodgers, Director of the National Institute of Diabetes, Digestive and Kidney Diseases.

DR. GOLDIN: Daniel Goldin, Chairman of the Intellisis Corporation and former NASA administrator.

CHAIRMAN AUGUSTINE: Okay.

DR. BRODY: Norm?

CHAIRMAN AUGUSTINE: Yes, Bill?

DR. BRODY: Yes, Bill Brody on the phone from Salk Institute.

CHAIRMAN AUGUSTINE: Are you at the Institute right now?

DR. BRODY: Yes, can you hear me?

CHAIRMAN AUGUSTINE: Yes, we can and your dedication in terms of the hour of the day is wonderful.

DR. BRODY: Oh, I do like to get up so early in the morning.

CHAIRMAN AUGUSTINE: Great to have you here, Bill.

DR. BRODY: Thank you.

CHAIRMAN AUGUSTINE: Amy?

DR. PATTERSON: Amy Patterson, NIH.

Thank you.

CHAIRMAN AUGUSTINE: Okay. I already introduced myself.

The focus of today's meeting will be two stakeholder fora related to the SBIR/STTR Working Group. These activities that we will hear about will include updates from the chairman of that group, which has been hard at it, and also from the SBIR/STTR Program Manager, Dr. Portnoy. And then we will have panels that will deal with specific aspects, each with a specific aspect of the issues, and in a moment I'll let Sol talk a bit more the specifics in that regard.

And at the end of the day we're going to discuss the new charge that Francis would like our group to address and we will look forward to hearing that.

Francis, before we go ahead, we always like to give you a chance to say whatever you'd like to say.

DR. COLLINS: Thank you. That's most kind, Norm.

I do want to thank all of you for being here for what I think is going to be a very interesting day in terms of the materials and discussion that has been planned. We do think the

SMRB has an opportunity here to give us some really good advice as you have done so ably in the past, and in this case about our SBIR/STTR programs and how to make them even more muscular than they have been.

Certainly we continue to live in a paradoxical time where the science and biomedical research has never been more exhilarating. I spent last weekend in Colorado at the national retreat of the MD/PhD students that we support through many of our MSTP training programs and it was a remarkable environment to be put into the middle of in terms of the talent, the energy, the creativity, the vision that these physician scientists to be demonstrated and, yet, they are deeply anxious about the direction that they see biomedical research going and looking for reassurance that somehow there is going to be a stable trajectory for them to live out their dreams.

I wish I could be more reassuring in the current climate.

I certainly can assure them and assure all of you that the scientific opportunities in terms of making new discoveries that are going to transform our understanding of life and create new

opportunities for medical benefits are going to be there if we have the resources to support that remarkable engine of discovery but we do see this paradoxical situation where people have been at NIH a long time--and I guess I'm now one of them, approaching now 20 years of being here, I have never seen a time of more uncertainty and instability with now having lost 20 percent of our purchasing power for medical research since 2003 and facing what could be an absolutely devastating downturn if the sequesters are to kick in on January 2nd, which would cause us to lose in one fell swoop about eight percent of our budget and maybe more.

So it is an anxious time to be sure and certainly that's all the more reason why we have to figure out how to do even more with what we have to be smarter, to be seeking in every way opportunities for collaborations and partnerships across public and private sector opportunities and hence the discussion about SBIR as an important part of what we're doing is even more timely and important than ever.

So again I just want to thank all of you for your willingness to put your time into this. You've done a great service to NIH, this board has

already, in many ways. You have helped us in other debates and discussions to chart a course forward, including the founding of the National Center for Advancing Translational Sciences, which is now going terrifically well just six months after it stood and got started.

We're in the midst of figuring out the details of this new institute devoted to addiction and that is also, I think, coming along quite well and your advice there was extremely helpful. So it has been a real benefit to us to have this board put into place by statute as a wonderful venue to deliberate on important issues and today will be just one more wonderful example of that opportunity.

I'm going to be here all day and I'm looking forward very much to the discussion and learning what I can about the expertise that you have put together to advise us and we expect to do something exciting and different with our SBIR/STTR program as a result of this discussion.

So thank you.

And, Norm, especially let me thank you as our longstanding and very devoted chair who has been such a wonderful source of advice to NIH in general and to me personally.

So thank you.

CHAIRMAN AUGUSTINE: Francis, thank you.

I would just say I'm sure my colleges share it's really a privilege to be able to devote our time to something that's worthwhile and to work with you and such an extraordinary group of people as you've collected here. It really is a--it's a privilege.

Having said that, let's move ahead with a couple of important administrative items and then we'll get into the substance of the meeting here.

The first is that we always afford an opportunity for the public to make remarks and we have a comment period that will take place later in the day. There's a signup sheet at the desk in the lobby. If members of the public would like to sign up to speak, please do so. We like to hear from you. We do ask that you hold your remarks to five minutes so that everybody will have a chance to speak that wishes to do so. And if those who are not in the room and are listening or those in the room would like to submit written statements, we welcome those. We post them on our website so each of the members will have an opportunity to read them and we and the folks at the NIH do take them very

seriously.

Another administrative item is that I'm told that the--we have a push to talk system here at the table and that if more than three of us try to talk at one time the thing explodes.

(Laughter.)

And so I'm not sure that I got that right technically but it's something like that. So when you're talking it should be red and when you're not talking it should not be red, and I think that's the key.

And then let's see.

The minutes for the meeting we held on May 29th were completed and we need to thank Drs. Pettigrew and Rubenstein for reviewing those and attesting as best they can to the accuracy of them. And I would welcome a motion to approve those minutes.

DR. RODGERS : So moved.

DR. SHURIN : Second.

CHAIRMAN AUGUSTINE: Thank you.

Is there discussion?

Those in favor please say aye?

(Chorus of aye.)

Opposed?

All right.

As we always do at each meeting and are required to do is to go through again the NIH Conflict of Interest Policies so that we don't ever create a problem in that area. Dr. Patterson is going to do that for us.

REVIEW OF NIH CONFLICT OF INTEREST POLICY

Amy P. Patterson, M.D., Executive Secretary, Scientific Management Review Board

DR. PATTERSON: All right.

I'd like to think that this is the most exciting part of the meeting but I know that's not true.

(Laughter.)

All right.

So as members of this committee, you are a special government employee and, therefore, you're subject to the rules of conduct that apply to government employees. These rules and regulations are explained in the report entitled *Standards of Ethical Conduct for Employees of the Executive Branch* and you may recall that each of you received a copy of this document when you were appointed to the committee.

But at every meeting, in addition to you

having memorized that booklet, we also like to take a chance to formally read into the record and to remind you about the importance of following the ethics rules. I'm going to review the steps we take and ask you to take to ensure that any conflicts of interest between your public responsibilities and your private interest and activities are both identified and addressed.

And, as you know, before every meeting you provide us with a lot of information about your personal, professional and financial interests. We use this information as the basis for assessing whether you have any real, potential or even apparent conflicts of interest that could compromise your ability to be objective in giving advice. And if such conflicts are identified we either issue a waiver to recuse you entirely from that particular portion of the meeting or we may waive a conflict of interest for general matters because we believe that your ability to be objective will not be affected by your interest in such matters.

And we rely a great degree on you to be attentive on an ongoing basis throughout the meeting to the possibility that an issue might crop up during the course of the discussions that could

affect or at least appear to affect your interest in a specific way and, if that happens, we ask that you recuse yourself from the discussion.

And, as always, if have you any questions about the rules we would be happy to try to address those.

CHAIRMAN AUGUSTINE: Thank you, Amy.

At this point we'll go over the discussion of the SBIR/STTR.

And, Sol, I turn the chair to you.

OVERVIEW OF SMRB SBIR/STTR WORKING GROUP PROCESS

Solomon H. Snyder, M.D.

Chair, SMRB SBIR/STTR Working Group

DR. SNYDER: Okay.

(Slide.)

I'd like to--a group of us have been working on this for a number of months and this is an interim report today, which is going to consume a good bit of the day. Much of the day will be devoted to panel discussions of individual institutes and how they have handled the SBIR and other agencies and how to handle things.

Preceding the panel discussion, we'll have some presentations to give you some of the meat of what's involved in the SBIR program for NIH, as well

as for other government agencies.

So let me begin.

I'll give an initial presentation for what we've been doing up till now and then Matt Portnoy, who handles SBIR/STTR for NIH, will give a presentation.

(Slide.)

So we've been working on this for a while. Our charge was to review what has been done up till now and figure out what's going on and where we're going in the future.

The question is why are we doing this?

A very good reason is that the SBIR in the Reauthorization Act has--the proportion of funds going to it is increasing and it's actually pretty significant. So it's pushing a billion dollars a year at the NIH. One interesting issue is the NIH's role is to just acquire knowledge about health that might be relevant to disease situations and how that fits in with the issue of commercialization.

It may be different for the NIH compared to other government agencies, especially the Department of Defense, which would have the largest SBIR program. NIH's SBIR/STTR program is probably the second biggest.

(Slide.)

Here's a depiction of one of the key issues in the Reauthorization Act. Namely, right now the SBIR is 2.6 percent of budgets for federal agencies but I think it's federal agencies that give out more than a $100 million a year in funding.

DR. COLLINS: By the way, SMRB members, if you're looking for the hard copies of these slides, they are under Tab 4 just in case you haven't discovered them yet.

DR. SNYDER: Oh, good. Thank you. I forgot to point that out.

(Slide.)

And the STTR, as you can see, is a little more than ten percent of SBIR appropriation. Anyhow, the increase will be Phased in over about five years to go from 2.6 to 3.2 percent for SBIR and from .35 to .45 to STTR. So that in itself is pretty important.

(Slide.)

So our charge is to figure out how we can handle this optimally--to basically evaluate how it has been going and figure out what we can do better.

(Slide.)

We're trying to address the issues of how

we can make this work better and how we can get-- how best to get the small business community to do the things that are important for the NIH. And what will come up again and again is the extent to which we handle it like the NIH handles R01s, that is investigator-initiated programs versus, our being proactive and saying for each institute what do we really want done and how are we going to get small businesses to do it for us. And every institute addresses this somewhat differently.

(Slide.)

The working group that has been dealing with this are indicated here and we've had a series of meetings, a whole bunch of teleconferences, and we're reporting to you now.

(Slide.)

The framework for how we're addressing this uses the same framework that we set up through our task force that Bill Brody led some time ago, which is to figure out what the need is, how you're going to about doing it and just going about it and just proceeding to do it.

(Slide.)

You might ask why are we meeting at all to deal with this business considering that the

SBIR/STTR programs have been evaluated previously. And so this goes back to a GAO report about six years ago and in 2009 the National Research Council had to report and the NIH itself reviewed it and the General Accounting Office reviewed it again. And, indeed, when I was asked to do this I raised the question not whether or not I'm willing to chair it but whether or not we should be doing it at all.

And I was persuaded that this is--that there are important--that it's worth addressing and that it's actually a good program that has been evaluated and has been found to be good, and that tweaks could be induced to it but that basically there are still some important questions that should be addressed and we're addressing them.

(Slide.)

What's depicted on this slide is the ways in which we're approaching handling all of this, which has to do with the simple steps in SBIR grants that are addressed. And each of them is important. The first one is how do you promulgate the notion that there is a need for applications. And the two models are you just have a call for applications and people just send in whatever they want to send it, sort of like NIH investigator-initiated grants, and

the other is that each institute decides what they think is important and sort of very proactively goes out and finds people to do it for them. And in our discussions and our interviews with IC Directors we found that different institutes handle this in dramatically different ways, and whether that should be coordinated, whether the way it's going on presently is the best way, we'll see.

(Slide.)

So here are some of the preliminary findings and the title of the slide is from "Good to Great." And that deals with the issue that we actually think the SBIR program at the NIH has been quite useful and has accomplished a good bit for the amount of money put into it. And our goal is to try and make it better.

So, basically, it has been working. One important element has been the flexibility that I already alluded to, namely that there hasn't been any top down directives saying every institute has to do A, B, C, D, E, F, G but rather each institute could do what they feel is appropriate. And that flexibility has been pretty darn good. And the institutes vary a great deal in the size of the programs and that also has relevance to the size of

the grants. There are guidelines for how many dollars can go to phase 1, how many dollars can go to phase 2 of an SBIR, and those are just guidelines.

And so some institutes, we found in our interviews, say, no, it takes a lot more money to develop a drug, if that's what the particular project is, and we'll just give a lot more money to this particular program because we think it's really promising and we recognize that there will be less money left over for other things but maybe it's better to do a few things well than to do many things sloppily. And those are some of the issues that we have to consider.

(Slide.)

Some of the concerns about the future of the program have to do with metrics and that, of course, comes up with all research. Namely, how do you know that you did a good job or did a bad job and how do you measure the output? And in this case it is sort of tricky since we're talking about commercialization and are we trying to just say we gave a grant and a guy started a company and he sold four trillion widgets and made a lot of money, therefore it was a success. Or are we saying our

mission, the NIH's mission, isn't to make money for anybody anyhow. Our mission is find causes and cures for disease and maybe we should have a metric that takes that into account even if we fund a program that didn't bring in a lot of money subsequently.

One of the issues is how to encourage applications because in a business community they are not--people in universities know all about the NIH and they know exactly how to go get grants and they know the game.

And in small companies people are pretty ignorant so there's a need for some handholding and educating the applicants to do a better job. And how much energy can we afford to put into that kind of program?

Then the peer review is another issue. Peer review is so well worked out for grants to investigators at universities, we've been doing this for 60-70 years, but for this program it's sort of tricky because the standard NIH model has to do with academics saying how carefully you did your experiment and how many placebos and how controlled and artifacts and things like that. And they very frequently just don't--don't have a clue--

academics don't have a clue to what the real needs are for developing a product in the business world and, therefore, a grant could be dinged when it really is a very good grant from the SBIR perspective.

And then tracking success, we already alluded to, is an interesting challenge.

(Slide.)

So here are the panels that we'll be having today:

The first panel will be dealing with how different components of the NIH have addressed all of this and the second panel will deal with how other agencies have handled it.

(Slide.)

And after lunch we'll also--we'll have a couple of regular presentations and then we'll have the third panel which deals with figuring out what the metrics should be, how do you judge whether something works or doesn't work.

(Slide.)

In October there will be a meeting of stakeholders to tell us what they think and I've already had interaction with the business community and a lot of people there have a lot of ideas and

are eager to let us know what they think.

And at this point that's enough background and we're already running a little late so Matthew Portnoy who heads the SBIR/STTR program for NIH will tell us how we do things.

DR. COLLINS: The rest of the presentations you're going to find under Tab 5 all separated with purple sheets which I think are in the order of presentation, as well as the biographies of our speakers.

DR. SNYDER: Thank you.

SBIR/STTR REAUTHORIZATION UPDATE

Matthew E. Portnoy, Ph.D.

Manager, NIH SBIR/STTR Programs

DR. PORTNOY: Good morning.

(Slide.)

Thank you, Dr. Snyder and Dr. Augustine, Dr. Collins and the SMRB for inviting me here today to give a brief update on what the status of the reauthorization is that's kind of driving many of the things we're doing today.

(Slide.)

And so as was briefly mentioned at the last meeting in October, the reauthorization was not quite a done deal and now it is. So the SBIR

reauthorization was formally signed at the end of December and is part of the Defense Reauthorization Act.

Thank you very much.

As a part of that and so the reauthorization is--it reauthorizes the program for a period of six years through fiscal year 2017. And the reauthorization is complex, lengthy and is the most substantial change to the programs since their inception 20 and 30 years ago. And so I just want to give you an update of where things are in the development of the policy and the implementation.

(Slide.)

And so there are two parts of the reauthorization that are moving pieces. One are the eligibility criteria for companies and these are put together from the SBA, the Small Business Administration. They are called size rules. This addresses the 51 percent U.S. owned and operated. This addresses the new venture capital provision. All of those are under size rules and SBA had 120 days from the signing to issue the size rule in draft form for public comment and I'll talk about those in a minute.

Separately, there's all of the rest of the

rules of the program, the phasing of the program, the guidelines, the set asides. All of those things are part of what are called policy directives and SBA had 180 days to issue those.

And so the size rules were issued. The eligible rules were issued by SBA on May 15th and they are currently open for public comment. The public comment period closes in a few days on July 16th. This is the chance for everyone in this room, everyone who happens to be on the video cast or on the phone to provide comment to the SBA on what they think about the size rules. This addresses, as I said, the venture provision. It address when companies need to be eligible. It addresses everything with affiliation, how companies who have other companies working with them are counted.

There are two places where one can provide public comment and it's important, if anyone feels strongly about it, to do so. Both in the *Federal Register* and at regulations.gov. And I should say that for those federal officials in the room, federal officials can provide public comment if they do so as a private citizen on their own time after hours using their home computer, et cetera, as long as they're not representing in any

way that they are part of the government.

The NIH, as an agency, did have an opportunity to work back and forth with the SBA, as did all of the SBIR agencies in the winter and spring on the drafts of all these documents prior to them going out for public comment. So the timing is very short now on the size rules for public comment.

(Slide.)

The other items are the policy directives. These are rather lengthy documents. Two, one for the SBIR program and one for the STTR program. And, as I said, these address all of the other rules besides eligibility. These are not quite yet out for public comment. We are expecting them any day, any week to go out for public comment. They will be open for a 60 day public comment period at the same two sites that were shown and we will be able to provide the links to the community once they become available from the SBA.

An important note I should mention is that the size regulations addressing the venture capital provisions specifically will not be effective and in effect until SBA issues the final rule after the public comment period, which is expected at the end of the calendar year in December. So the venture

capital provision and all of the revised size rules are not in effect. And so until then we have business as usual. We have open solicitations. All of the old size rules or essentially the current size rules are still in effect.

(Slide.)

The policy directives, SBA tells us, will go into effect when they are issued for public comment. So this is a little backwards from the standard way policy is issued. So in a few days or so when the policy directives are issued they will be effective. However, most of them will not be able to be implemented depending on the timing and also awaiting the size rules.

(Slide.)

So what I wanted to do in the next few minutes is blow through many of the key provisions in the reauthorization so that the panel is kind of up to speed on some things that we will be dealing with and will have to implement across NIH and, of course, all federal agencies. This goes for everyone.

(Slide.)

I won't belabor this point. This is what Dr. Snyder mentioned first. It is that the set-

asides will be statutory increased each and every year for the next five or six years.

(Slide.)

Second, the guidelines for the awards sizes will be altered slightly. The STTR, as you can see over here, have lagged behind the SBIR and now they will both be the same, 150,000 for Phase 1, one million for Phase 2, over all years of the project.

A new provision in the bill is that there are now hard limits or hard caps on the award size. These are set to 50 percent over the guidelines. I should also say per the statute the guidelines will be adjusted each year by the SBA for inflation annually and so they may be 155 next year, et cetera, and they'll be going up every year per SBA.

The hard caps are essentially 50 percent over these guidelines and for--and would now be 225,000 for Phase 1, 1.5 million for Phase 2, and these are hard caps, cannot exceed, cannot make an award over that amount.

However, in the reauthorization, there is a provision allowing an agency to request a waiver to exceed those caps on a specific topic basis. It does not allow a blanket waiver for an agency which

is what we had prior. We had flexible spending over the guidelines. However, we will have to, as an agency, request SBA approval to waive the hard limits per solicitation, per award, et cetera, on a topic basis.

And this was one of the key provisions that concerned us the most in the reauthorization.

(Slide.)

As I mentioned before, there is a venture capital provision to allow companies that are majority owned by multiple venture capital operating firms, hedge funds and private equity firms to be awarded up to 25 percent of NIH, Department of Energy's and National Science Foundation's SBIR funds. The other eight agencies in the program are allowed to use up to 15 percent of their budget for venture capital backed companies. A key provision here is that the word is multiple. A company must be or have ownership by multiple of these types of firms. In the case where there's a small business that has a majority ownership by one venture capital operating firm that company would still not be eligible for the program per the reauthorization.

(Slide.)

The reauthorization also allows us to increase our technical assistance programs to small businesses. You heard briefly, I believe, by Dr. Rockey at the meeting in October that we have two technical assistance programs. A Niche Assessment Program for phase 1 and a Commercialization Assistance Program for phase 2. You'll hear a bit more about that this afternoon from Dr. Rockey. That had previously been SBIR companies only. That reauthorization now allows us to expand that to the STTR companies and allows us to spend a little bit more money per company on technical assistance from the set aside.

(Slide.)

The reauthorization requires all agencies to continue to work with the National Academies on continued study of the programs and initiate a new study on the STTR program which to date has not been formally studied. And agencies are now currently in talks with the National Academies to coordinate those studies.

(Slide.)

One of the most attractive and interesting provisions in the reauthorization is to allow all agencies access to up to three percent of SBIR funds

from the set aside for administrative purposes to allow us to manage the program, make improvements, increase outreach and, quite frankly, allow us to actually comply with all the requirements of the statute that's going to take quite a bit of resources and personnel beyond what we have now just to do what we're required to do. And we'll be discussing this shortly at NIH on how we might use this provision.

(Slide.)

Some of the--kind of the nuts and bolts provisions: A small business can receive a phase 2 from a different agency than its phase 1. This is written into the statute. However, we've already been using this on a case by case basis at the NIH.

For instance, we have accepted a phase 2 application from a company that has a phase 1 from NSF and vice versa. That is already allowed but we continue to do that.

(Slide.)

This is an interesting provision here that was previously forbidden. It is that a company can now switch mechanisms at phase 2. So if they receive a phase 1 STTR they can now apply for a phase 2 SBIR and vice versa. That was previously

not allowed by the former reauthorization and this is a new flexibility. This obviously will bring in some tracking issues, which program do you attribute the award to, success metrics and also tracking centrally.

Another provision is to eliminate phase 2 invitations. This is mainly important for contracts whereby typically in a contract a phase 1 SBIR contract you can invite the ones you would like to compete for phase 2. This requires all agencies to invite all phase 1 contract awardees to compete in a fair and open competition for phase 2.

(Slide.)

The next provision allows the NIH, Department of Defense, and Department of Education to make direct phase 2 awards. So previously there is--there was no possibility for a company to apply directly for phase 2. They had to apply for phase 1 and then a phase 2 or at the NIH they could apply for a fast track grant, which is a combination of phase 1/phase 2 but, regardless, there was no way to get directly to phase 2.

This provision allows these three agencies the authority to issue direct phase 2 awards provided the applicant has demonstrated

they have done the equivalent phase 1 work in their application. NIH plans to pilot this on a limited basis once we get going on this. We think this may have some merit but we have a fast track program. We have review criteria and want to tread carefully into a direct phase 2 because, as can you imagine, this would obligate larger awards without necessarily a phase 1.

Another provision is to allow civilian agencies, including the NIH, to develop a Commercial Readiness pilot program called a CRP where we can spend up to 10 percent of our SBIR or STTR funds on--to make awards to small businesses to further them along commercialization, provide technical assistance, et cetera. This was a program that was more or less in its current form piloted by the Department of Defense and now their pilot program is a regular program and all the other agencies are now able to pilot this type of assistance.

(Slide.)

There are provisions in the reauthorization for agencies to make awards quickly and more quickly and reduce the time line. The NIH along with NSF has been given one year from close up solicitation, essentially a receipt date, to

notification of intent to fund. So the language in the upcoming policy directive does not say receipt to award. It now says notification of intent to fund. Small businesses have told us and told the Congress that they need to know sooner rather than later yes or no. It's fine if it's no but they really need to know sooner than later. And so the other agencies besides NSF and NIH have 90 days to make a decision and they can get a 90 day extension. NIH and NSF received a one year time period. As you can imagine, and as you all know, NIH has additional requirements that are unique to this agency in terms of second level peer review by council, et cetera. All of that takes additional time. We also use an outside peer review system which takes more time than an internal peer review system.

(Slide.)

There are new benchmarks for commercialization. The reauthorization is designed to essentially prevent companies who receive multiple grants who don't do anything with them from continuing to participate in the program. We will have to develop benchmarks for the phase 1 to phase 2 conversion rate and the phase 1 or 2 to

commercialization rate, all of which are defined in statute.

It also provides for increased outreach to women-owned small businesses, socially disadvantaged small businesses and outreach to states with historically low application and award rates. Tied into that is a requirement for agencies with either an EP score or an IDeA program and NIH has the IDeA program, the Institutional Development Award, to coordinate with those programs in order to improve outreach and improve quality and number of applications. And those talks are underway already.

(Slide.)

There's an entire part of the provision related to fraud, waste and abuse for agencies to coordinate more with their Inspector General offices and provide information to all applicants and awardees about fraud, waste and abuse and where they can report fraud, waste and abuse, and we'll be working with the Inspector General on that.

(Slide.)

And just the last few points. There is a new OSTP level committee called the Interagency Policy Committee that's set in the statute to

provide advice to agencies and this involves representatives from OSTP, SBA and agencies.

There is an exceptional amount of new reporting required in the reauthorization. There are new databases that are talked about that SBA has to--is responsible for and has to build and they are listed here. We already have some of these. An award and solicitation database are built and the rest will have to be built and rolled out. And we will be required--applicants and agencies are required to provide information in all of these databases.

Some of these are open to the public. For instance, the award database and solicitation.

These databases are closed to the public and available only to government.

And, of course, they have to build a commercialization database. One of the continued--new requirements is to track commercialization across the board more carefully for each and every single awardee. That has been a challenge for many agencies due to a lack of resources required to do those type of things and we should be able to do that much better with the administrative funds.

There are many other reporting

requirements in the reauthorization on this and that to the SBA, to Congress, on the pilot programs, the venture capital provision, the phase flexibility, coordination, et cetera, and so there's quite a number of reports that were required to provide annually, biannually, et cetera.

(Slide.)

And where we are with this is we're going to begin phased implementation of the policy directives when they're issued. However, much of the implementation will have to wait until the final eligibility rules are issued because all of the program goes off of what the rules are for participation and so I don't really anticipate us getting into the hard core implementation until 2013 and beyond. As can you imagine, all of these new requirements requires us to adjust our forms, to collect new information, adjust our databases to collect and track the information, and all of that requires various levels of coordination and approval.

We have already begun and will be continuing to coordinate with NIH institutes on different parts of the reauthorization and, in fact, we have a meeting tomorrow to continue that

conversation and we are coordinating with SBA and other sister agencies also in developing implementation. In fact, there's a phone call later today with the agencies and SBA.

(Slide.)

So with that--I know that we're already running a little bit behind but I'm happy to take questions or we can move on.

DR. SNYDER: Super. People can ask questions now.

Yes, Gail?

DR. CASSELL: Could you just clarify two points for me, please?

DR. PORTNOY: Yes.

DR. CASSELL: One, I am aware that when the SBIR program was initially introduced it was required, I believe, that a small company had to have a university partner and maybe I'm wrong about that but could you just verify one way or the other whether that was true and also when it changed because I don't think that came out as a requirement?

DR. PORTNOY: So when--you are saying that the SBIR program--

DR. CASSELL: Was initially introduced.

DR. PORTNOY: Yes, that there was a requirement to have a university partner.

DR. CASSELL: Yes.

DR. PORTNOY: So I wasn't aware of that provision and there is no requirement for it. There is a requirement in, of course, STTR for a not-for-profit research partner, which is typically university but not necessarily but there is no requirement of any type of partner. The SBIR, the company can do all of the work if they wish.

DR. CASSELL: And in relationship to Francis's comment about leveraging dollars today, I wonder are there any ground rules that would preclude a joint solicitation between--with two agencies pooling their dollars but for specific, you know, initiatives?

DR. PORTNOY: So we have--

DR. CASSELL: Maybe CDC and NIH who have a lot of common goals.

DR. PORTNOY: Well, CDC--so within HHS is NIH, the CDC, the FDA and the ACF, Administration of Children and Families, all have SBIR programs and they are all on a joint omnibus solicitation. So we already coordinate with the HHS agencies and CDC on the contract solicitation. There's no reason we

can't issue joint solicitations.

We've also issued the joint solicitation between agencies and so we had a robotics SBIR program announcement two years ago with NIH and five other agencies. Because of all of the peer review regulations that are involved NIH led that and everybody had to conform to NIH peer review and at the end they got the application to be able to fund them at their own discretion, but the issue of joint agency solicitations has come up before.

And, in fact, there's discussions now on an education gains SBIR initiative, which is going to be out of the Department of Education, that will be a contract solicitation. But the challenge is in any joint agency solicitation is that all of the rules at each of the agencies need to be followed in order for them to properly issue awards and NIH, quite frankly, likely has more regulations than most other agencies in this regard.

DR. CASSELL: Thank you and just one last quick question.

DR. PORTNOY: Yes.

DR. CASSELL: Are there ground rules that would preclude collaboration with other countries that have similar programs in place? And the

reason--well, I could elaborate on the reason for asking the question but I just wondered if there are ground rules that would preclude it.

DR. PORTNOY: Basically there are. The Program, as designed by Congress, is for domestic U.S. businesses. All of the work must be done in the U.S. by U.S. companies. There is a small ability if there's a unique population or a unique resource that can only be found abroad, they can collaborate with a foreign company or foreign entity but they cannot be the applicant or the prime awardee, and it's limited. And so there are essentially statutory prohibitions on that.

Yes?

HON. GOLDIN: I notice that there was a $5,000 research technical support--

DR. PORTNOY: Yes.

HON. GOLDIN: --which is a pretty small number. The problem that small companies, especially start-ups, have are facilities and equipment. And is there a provision that will allow them to, if you will, partner and draw on resources from the NIH where they may have some significant instruments, facilities or other resources to help them along because it's a small amount of money and

that $5,000 is a very confusing number.

DR. PORTNOY: Right.

HON. GOLDIN: It goes away very fast.

DR. PORTNOY: Well, the technical assistance dollars up until recently--that money is not given to the company. The NIH pools that money and provides services via vendors to the companies which we have been able to buy in bulk and one is a technical market report and one is a business training program.

In terms of your question about what can they use to provide capital equipment or upgrades, typically obviously with the size of the awards that's not really possible in phase 1. They could buy those type of things in phase 2 if it was necessary for the project but there are other programs at NIH that small businesses are eligible for to leverage medical instrumentation programs. They are eligible to apply for those.

HON. GOLDIN: I wasn't asking to give it to them but sometimes you could make some quick measurements. Are any of the facilities or resources at the NIH available to them that could take them over the top and help them do a little bit of the feasibility work?

DR. PORTNOY: And so that's something we could look into. There are--many of the facilities could be available and they can partner with them and that's something we could look into.

Yes, Dr. Collins?

DR. COLLINS: Could you just say a little bit more about the Commercial Readiness pilot because it sounds like that might be a useful opportunity and I don't think most of us know a whole lot about what that would look like and how we could use it?

DR. PORTNOY: Sure. So I don’t have the--the language from the statute is relatively concise and I didn't paste it in here because you wouldn't be able to read it. But what it does--and it allows the agencies to spend 10 percent of SBIR or roughly $63 million at the NIH, across the agency, for awards to small businesses that allows them to move further along the commercialization path. A key provision in there, it allows us to make these awards under the Commercialization Readiness pilot up to three times the guidelines without the need for a waiver from SBA. So the guideline is $1 million, anything above $1.5 million we need a waiver. This allows us to make $3 million awards

without the need for a waiver. So we've been thinking about this particular provision as a way to fund our Phase 2b program, which is high dollar follow on research to phase 2 for technology, very specific to go to FDA or drug clinical trials, et cetera. It's a way we could fund that program without going through the administrative burden of getting a waiver but we are open to ideas on other ways we can possibly use that pilot. We also have to get approval from SBA to use that pilot.

We also have to get approval from SBA and Congress to use the venture provision. There's a requirement that we provide--yes, so we have got the ability to use it and in there is that we have to now make a case for us to use it.

DR. SNYDER: Garry?

DR. NEIL: With respect to the venture provision and the other elements of this new program, what about collaboration of large companies? I mean many of us, if not all of us, have venture capital.

DR. PORTNOY: Sure.

DR. NEIL: And so, would large corporate venture capital qualify as a source of venture capital and, secondly, what about large company

collaborations, matching grants or--you know, something that we've done a lot of is grants which are convertible to equity at the milestone but there's no rights up until that time. So can you talk a little bit about that?

DR. PORTNOY: Sure. So the SBA is setting the rules and the guidelines for the venture capital provision, what constitutes a venture capital firm in terms of being able to own a portion of the company and that company still be eligible. Companies can collaborate now with anybody they wish, whether be it a small or large business, university, within the guidelines of the program. And an SBIR program up to one-third of the phase 1 and half of the phase 2 can be subcontracted to any party, including a large business and including a large pharma company, et cetera. And the guidelines are slightly different for the STTR program. But I think it's something that we could look--you know we can investigate further on how this might work in the new regime.

DR. NEIL: Maybe in the discussion we can talk a little bit about that, about how we can enhance--

DR. PORTNOY: Mm-hum.

DR. SNYDER: (Not at microphone.)

PANEL PRESNETATIONS

INNOVATION WITHIN THE SBIR/STTR PROGRAMS

PANEL PRESENTATION I - PILOT INITIATIVES ACROSS NIH

Moderators: Josephine P. Briggs, M.D., SMRB Member and Solomon H. Snyder, M.D., SMRB Member

DR. SNYDER: Okay. Now we can initiate the panel presentation. It will be moderated by Josephine and I.

Since I've been doing a lot of work maybe you could do most of the moderating.

(Laughter.)

But I have a feeling that the panelists can sort of take care of themselves and the panelists are largely going to be sitting up here.

So maybe we could commence with the panelists introducing themselves and then making their presentations and deciding amongst themselves who goes first.

DR. BRIGGS: Jodi, can you start and can we get introductions from our panel, please?

DR. BLACK: Yes. I'm Jodi Black and I'm from the National Heart, Lung and Blood Institute.

Michael is going to go first. He is already up there.

DR. KOUSTOVA: I am Elena Koustova and I lead SBIR program at the National Institute on Drug Abuse.

DR. WUJEK: Jerome Wujek from the National Eye Institute and I am the sole program officer at the National Eye Institute running the SBIR/STTR program. NEI is a small to medium sized institute.

DR. BRIGGS: And Michael?

MR. WEINGARTEN: Yes. I am Michael Weingarten from the National Cancer Institute.

DR. BRIGGS: So, for everyone, in Tab 5 you have both bios of the people who are going to be presenting and their power points.

So, please, Dr. Weingarten.

Michael Weingarten, National Cancer Institute

MR. WEINGARTEN: Okay. Thank you.

(Slide.)

So thank you very much for inviting us to speak today. I think this will be a good opportunity for you to seek some of the different strategies, the different types of ICs that the NIH has developed for the SBIR programs, all the way from the large institutes to the small institutes.

(Slide.)

We've actually been working at making some

enhancements to our program since 2007. We took a look at the program overall back about five years ago and thought there were some opportunities to improve the overall impact that we were getting out of SBIR. So I'm going to review a series of those changes, including how we manage the program. We've actually set up a center for managing all of our SBIR awards. We call it the SBIR Development Center. Sol mentioned that a number of the ICs have moved towards more targeted solicitations as a way of seeding the development of promising technologies. I'll talk a little bit about that.

I'll also mention a new program that we have launched. We call it our SBIR Phase 2 Bridge Award and this is really to help deal with the whole valley of death type question.

Garry, you had some questions about partnering with pharmas and how can we do that. I think that's a really good model for how we can do that.

And then also discuss our SBIR Investor Forum which we use to try to help connect our best small companies with investors and also with strategic partners like pharma.

And then I'll close with some suggestions

on issues for the SMRB to consider.

(Slide.)

So why do we care about the SBIR program at the NCI? We really use this as a resource, really as our primary resource for helping enable the commercialization of some of the promising technologies, many of which come out of a lot of our other programs at the NCI. So we actually use SBIR to support technology development, small molecules and biologics, diagnostics imaging technologies, as well as electronic health and education tools. So essentially the program is there to support many of the technology areas that are already being supported at a basic research level by the RO1 community, as well as by the small business community.

In terms of dollar size, it's a $115 million program at the NCI.

(Slide.)

Probably--I think the most significant change we made going back about four or five years ago was if you looked at the way the program was being managed before, the program was really split up across our institute. We had over 50 different program directors, each who spent maybe five or ten

percent of their time on SBIR as a whole. So it was really a very small part of their jobs overall. And a few of these program directors really had any sort of industry or commercial type backgrounds.

So one of the major recommendations we made, which our director endorsed, was to actually set up a center for managing the program and this is actually a ten member management team that is exclusively focused on managing SBIR on a daily base. We spend 100 percent of our time on SBIR and we spent about two years actually going out and recruiting the right talent, many of whom are from industry, to actually come in manage the program.

And what we're able to do because we spend 100 percent of our time on SBIR is we can work really closely with our other NCI divisions and integrate all of our small business initiatives with some of their major priorities. I'll give some examples of how we do that in just a second.

And we can also launch some new initiatives to help the small business community as a whole.

(Slide.)

So this just gives you a picture of just what our team looks like. We were able to actually

recruit some talent from companies like Johnson & Johnson, also from Pfizer, some folks from small business and biotech experience, and also some individuals from the medical device community.

(Slide.)

And in terms of responsibility because we have a dedicated team we're able to be fairly aggressive in getting out and conducting outreach events and actually getting out and going to the key places where small businesses are operating, places in Boston, in San Francisco and San Diego as examples, and we are really putting on seminars to really educate the small business community on the program and really advise them on how they can develop stronger applications because getting through the NIH peer review process for a small business is often a difficult proposition that if they haven't done it before. So we really try to hold companies' hands and really educate them on how the whole process works.

Once awards are made we're also very actively involved in coaching applicants on actually throughout their development process and providing rigorous oversight and active management of the projects.

And we can--as they're coming to a conclusion of their projects we can also help facilitate matchmaking with potential investors, too.

(Slide.)

I mentioned a minute ago that we also are moving towards more targeted solicitation. So when we took the program over, about 95 percent of the budget was based on investigator initiated research. We thought that there was an opportunity, and really a few targeted areas was to catalyze the small business community to apply in areas that we wanted to see the development of, areas like companion diagnostics and novel cancer imaging agents. And these are really areas that we see as emerging and as opportunities where the market growth is there. And if we come out with a targeted solicitation we can encourage small businesses to actually apply in those areas.

The other benefit to a targeted solicitation is that the review is conducted by our NCI Division of Extramural Activities and we're able to work very closely with them in terms of recommending reviewers to actually serve on the peer review. And as a result of that, industry

representatives now make up about 50 percent of the review panel. So you have a very balanced representation between the academics, the scientists, as well as the industry representation.

And we can make sure that they get a very nice balanced review and that they're looking at the strength of the commercialization strategy as well as the strength of the science.

We also have started actively using the contracts mechanism at the NCI and what that does is it allows us to make awards that are milestone based with defined activities and deliverables and really are a very effective tool at managing the project and ensuring that it's accomplishing its goals and that it's moving towards commercialization.

(Slide.)

And how do we pick these targeted areas? We actually convene what we call our own internal technology advisory group. We work with all the different NCI divisions at the NCI. People typically will propose topics that maybe came out of a NIH or NCI workshop that we had with industry. And what we do is we look for that opportunity where you have a strong scientific need but you also have a strong commercial opportunity. We select

those topics that really have--you know, match both of those areas.

(Slide.)

I'd like to just briefly talk about our new program that we launched four years ago now. We call it our SBIR Phase 2 Bridge Award.

(Slide.)

And Matt gave you an overview--Matt and Sol both gave you an overview of how SBIR is set up. SBIR phase 1 is a feasibility study. That's followed by the full research and development of the technology, which is a phase 2 development on the technology. And then typically companies have to then move on into phase 3, which is commercialization. But we all know particularly in the biotech area that there's a huge gap between when a company typically finishes its phase 2 award and the actual commercialization. A lot of companies run into this valley of death issue. So what did was we launched what we call the Bridge Award to help facilitate companies creating relationships and partnerships with big pharma, with strategic partners, but also with investors.

(Slide.)

The reason that we did that is because of

the large costs involved, for example, in developing new drugs. This article recently came out in *Forbes* and it talks about how the average cost of the developing a new drug is at least $4 billion but it can be as much as $11 billion. So with those costs and small business obviously needing to raise a lot of resources in order to get over that huge valley, the bridge is a good step to help move them forward.

(Slide.)

So how does the Bridge Award work?

Well, what we do is we tell companies that they can apply. As they are finishing their Phase 2 award they can apply for up to $1 million per year for up to three years. So a total of $3 million in additional funds.

But what we do is we use the NCI money to help the small business attract other dollars from other investors or from other strategic partners. The way that we do that is we give competitive preference and funding priority to applicants that are able to raise matching dollars. So that's a key part of the review of all these proposals. We expect that companies that are going to come in and are going to request an additional $3 million in funding, that they have formed these partnerships,

they have formed these collaborations and that they've actually raised additional funds. So we don't want to just give them additional funds. We want to help seed the development of a technology through them creating these relationships that move the technology forward.

(Slide.)

The benefits to the NCI are that we have the opportunity to leverage millions of dollars in external resources but we also get valuable input from the third party investor that's involved on the project. So before a strategic partner like pharma is going to engage and invest in a project, they are going to do their own commercialization due diligence on the award and on the project itself. And they will also be able to provide a lot more commercialization guidance during the award. And the goal is that that their partner is not going to be involved just on the first $3 million of a project but they are actually going to be in there for the long-term.

The benefit to the third party investor is that they have the opportunity to partner with small businesses that have already been through the NIH peer review process and that have been vetted a

total of three times because by the time they get their Bridge Award they will have been through NIH peer review at least three times.

And there's also--the additional benefit is that substantial proof of concept data already exists on this project and they have the opportunity to share in the early stage investment risk with the NCI.

(Slide.)

The review for these projects have to be done differently because they are a lot more advanced. So we ensure that the reviewers are not only academics but we also have clinicians and industry professionals, as well as venture capitalists as part of the review of all of our bridge award programs.

And the review criteria is also a bit different in that we--we emphasize the importance of the commercialization strategy, as well as consideration such as intellectual property and their strategy for gaining FDA approval in the long-term.

In terms of the third party fund raising plan, that is another critical part of the review. They don't actually have to have the money in the

bank when they apply but they have to have a good plan for how they are going to raise the money and we need to see who those partners are going to be. So in terms of what they can raise and what they can bring as part of the fundraising plan, we will accept cash, liquid assets or convertible debt. And the sources of the funds can be another company. They can be a venture capital firm. They can also be angel investors or foundations.

(Slide.)

So I mentioned that we had started this program back in 2009. We have made a total of 12 Bridge Awards to date. Those cut across therapeutics. Three therapeutic projects, six imaging technology projects and three molecular diagnostics projects.

(Slide.)

And that just gives you the funding levels and also just some of the titles of the work.

(Slide.)

And in terms of the leverage that we have been able to achieve from the program, the NCI is investing a total of about $31 million in all 12 projects and, in turn, the companies have been able to go out and raise over $72 million in private

sector funds. So the NCI is getting greater than a 2:1 leverage for the money that we're putting into these projects.

And we really--what we're finding--we created the opportunity but the companies are all finding different ways to go out and raise capital. So a third of the capital is coming from the venture capital community. A third of it is coming from strategic partners, like pharma. And then a third of it is actually coming from the angel investment community.

(Slide.)

Another key initiative that we launched back in 2009 we called our SBIR Investor Forum and what we do on an annual basis is we'll go through our portfolio of companies that we're funding and we actually pull together an external panel of industry people to help us identify what are the top small businesses that we're actually funding in the portfolio. And we put on an investor forum to showcase those companies to the investment community, as well as to the strategic partner community.

So we actually--just back in April we had our last event. We showcased a total of 18 top SBIR

funded companies. We were able--we held it in the Bay area so we were able to get 200 life science investigators and leaders to attend. And as a result of that meeting, the companies are participating and we were able to have one--over 150 one on one meetings with potential investors. So our goal is--you know, we set up programs like the bridge but we also have an event like the Investor Forum to create the relationships so that we can help them raise the funds that they're going to need ultimately to be successful.

(Slide.)

The last event that we held prior to this year was back in 2010 also in the Bay area. We had a total of 14 presenting companies. And as a result of this event, six out of the 14 were able to close deals valued at over $230 million.

(Slide.)

This just gives you a listing of four of the companies. Our biggest success story is a company out of San Diego called a company Zacharon. It's a company that is focused on developing therapeutics for rare diseases and cancer. They finalized a partnership with Pfizer that's worth up to $200 million if the company achieves all of its

milestones.

In addition to that project--and that again is focused on the rare disease areas and also I know that NCATS is actually looking potentially at working with this company.

Lpath is another company in the therapeutics area. They were able to close a $4.9 million equity financing round to fund the continued development of two cancer drugs that they're developing.

A company called MagArray out of the Bay area closed a strategic partnership worth $10 million to continue development of its cancer diagnostic platform.

And a device company called ImaginAb was able to raise $12.5 million in a Series A round to engineer antibodies and *in vivo* PET imaging agents for targeted molecular diagnostics.

(Slide.)

Some issues for the SMRB to consider.

And I think, Sol, you mentioned this in your presentation, too.

I highlighted three different areas but really, I think, the most important thing is to tailor the peer review process to the needs

of the small business community. The review criteria currently are the same for R01s as they are for SBIRs. I think we should consider whether we should potentially change the review criteria to adjust for the commercial realities that small businesses need to face.

The other thing is to consider increasing participation by industry professionals on study sections. Again, I mentioned with our targeted solicitations we're able to get about a 50 percent representation by industry in those reviews and I think those reviews benefit greatly from that.

And the other thing is exploring strategies for how do we shorten the timeline between application and selection. Matt mentioned that we have to be able to actually award these projects within a year of the solicitation coming out. So we need to think up some strategies for how to speed up the process.

The other most important thing, I think, is establishing a comprehensive metrics program for collecting metrics and analyzing those data. And as part of that I think it's important to be able to track companies not just when they complete the award but because it takes five years or more for

most of these companies to actually reach commercialization, we have to be able to track those companies post award. So coming up with incentives to actually get the companies to report how successful they are in terms of sales that they have achieved and in terms of job creation and in terms of other metrics that are really important.

And also to put that information in a database so that all the institutes and all the people that are working on a program have the ability to access it and analyze the raw data on individual awardees across the NIH so that we can really track how successful the program is.

And the third point is the need to maintain program flexibility on award sizes. Again one of the things I think that makes the NIH program special is that we're able to exceed the awards limits currently. You need to be able to do that in order to get these projects to a key inflection point so that you'll be able to pull potential investors or potential strategic partners in on these projects to invest jointly with the NIH.

That's--those are some of our suggestions. I would be happy to take any questions that you have.

DR. BRIGGS: Thank you very much. This was terrific.

Comments or questions for Dr. Weingarten?

Dan?

HON. GOLDIN: Some of the other institutes in our discussions seem to have more of a conflict of interest problem in bringing in industry peer review. You seem to have been able to get around it what did you do differently?

MR. WEINGARTEN: Well, I mean, conflict of interest is an issue on the academic side, too.

HON. GOLDIN: But specifically there are a lot of concerns raised about how you could get people in that could do peer review that could do it without creating problems downstream--

MR. WEINGARTEN: Right.

HON. GOLDIN: --with subsequent lawsuits and other such problems.

MR. WEINGARTEN: Well, so I think the way companies are able to deal with that is if they are working with a company that's undergoing reviews they simply leave the room during that discussion but it really has not prevented us from being able to bring both investors as well as partners as part of the review.

HON. GOLDIN: I would say that this is a subject that this committee ought to take a look at because I heard this from numerous institutes and we could certainly have some help from industry because this does not allow--you know, it's a lot of science focused but SBIR is to do commercialization. So helping us get over that hurdle I think will take us a step forward with that. It's a huge issue. Things like intellectual property, contamination and competitive issues, all of that.

DR. BRIGGS: Gail?

DR. CASSELL: I hate to keep bringing this up. By the way, very impressive programs. I like the Bridge Award. With respect to the Bridge Award, can the matching funds be from outside the U.S.?

MR. WEINGARTEN: Yes, they can.

DR. CASSELL: From outside the U.S.?

MR. WEINGARTEN: Yes. We don't--the matches is a requirement but we don't actually manage--the NCI doesn't manage how they actually spend those funds. So they can come from any source. But, no, that's actually a good source of funds.

DR. BRIGGS: Francis?

DR. COLLINS: So many times I hear from small businesses that the thing they find most vexing about our program is just how darn long it takes to get an award and they are often in a circumstance where every week is burning the capital that they've got and waiting a year to get started makes it just not very attractive.

Have you done any experiments at NCI in terms of trying to shorten the timetable for doing review and making awards because it does seem like our process doesn't fit this particular circumstance very well.

MR. WEINGARTEN: Yes. So for the targeted solicitation announcement, for example, with our Bridge program, we're able to actually get those through the process much quicker. The numbers of applications are also a lot smaller, which is one of the ways that we're able to handle that.

So for targeted areas I think you can do that. For the areas like the omnibus that--for the NCI we have probably 1,500 applications that come in every year and that's a bigger challenge. And, you know, we would really need to explore some new ways of doing things in order to tackle things like the omnibus.

DR. COLLINS: How do you do the Bridge Awards in terms of the second level of review because some people are just stymied by the council cycles. Do you do those electronically?

MR. WEINGARTEN: Actually those are presented to the board at the end. At the end of the process. So typically--I'll give you an example--we had two receipt dates for our Bridge Award this year. Our last receipt date I believe was in March and we are going to have all those projects awarded by September this year. So that's, you know, a six or seven month turnaround.

DR. BRIGGS: I think all of us are impressed with the Bridge program. Is that going to be jeopardized by the new potential targets maximums?

MR. WEINGARTEN: Yes. So if we can't get a waiver for that program then it would be because the caps that the SBA is talking about are $1.5 million on the total awards size. You know, Bridge Awards go up to $3 million. So that could potentially ruin what I consider to be probably our biggest jewel in the entire program.

So we're hoping that--you know, Matt mentioned that, you know, we're going--there is the

opportunity to seek waivers. We'll need to work very closely with the Small Business Administration to make sure that programs like the Bridge but other programs--you know, we want to be able to do these larger sized awards to get these companies far enough along that they can actually accomplish something. So that's a key concern.

DR. NEIL: I mean so--and perhaps we'll have a chance to talk about how NIH can help here but so often these very, very, promising programs don't die just because of a lack of funding but they die because of their missteps of a management team which doesn't really understand how to do this. It may be some of the advice that they're getting from big pharma partners or burdening these things with cost and--I use the term advisably--quality standards which might be used in big pharma that aren't necessarily helpful to the program to a naivety about the regulatory path which needs to be followed.

So a lot of these are issues of management. Venture capital partners, good ones, spend an enormous amount of their time after they've made an investment making sure they have the right management team in place and making sure they are

getting the right advice and spending time with that team and training them how to do this. And I think there's--there's some soft elements to this which could be enhanced in some way. I don't have specific suggestions right now but maybe we can come back to that.

MR. WEINGARTEN: Yes, absolutely.

I think, Dan, you asked the question, too, about being able to tie into other resources that would benefit the small business. So NCI runs programs like our NExT program which provide resources primarily to the academic community to help with the preclinical development of a drug to drive that drug to an IND stage so that it eventually can go into clinical trials. We work closely with that program. We try to steer companies that we think would be good candidates into that program so they can have access to the same types of capabilities and that's just one example of a resource that the NCI has. Other institutes have very similar resources that really try to make that same resource available to our small companies.

DR. BRIGGS: So we've got Norm.

CHAIRMAN AUGUSTINE: I have a question but

before I do I'm advised that Dr. Omenn is on the phone now.

We had a chance to welcome you formerly before.

Also, I just want to say for you and Bill and others who are on the phone, feel free to interrupt at any time if you have a question that you'd like to ask.

I just want to reinforce what Francis said about the timing of these grants. The small start-up companies I work with, a year is--you start a company and it will grow three times in a year. And I'm familiar with programs at DARPA some years ago where they could make a grant in ten days. And that's--I don't think they can do that anymore but that ought to be the kind of time we're looking for.

And I had another question about intellectual property but I'll save that for later.

DR. BRIGGS: I think we do have to keep going and, in fact, we're going to have to make the subsequent presentations a bit briefer.

NCI obviously has put superb resources--and Mike is to be really congratulated on the team he has developed. So I think it's also important to look at some of the challenges of running these

kinds of programs where the resources and team is, by necessity, smaller.

So, Jerry, I think you're next.

Jerome Wujek, Ph.D., National Eye Institute

DR. WUJEK: All right.

(Slide.)

Can everybody hear me okay?

Okay. I'll take that as a yes.

So I'm Jerry Wujek. I'm from the National Eye Institute. I'll be giving a different perspective, a perspective from a smaller institute and the Eye is a small to medium sized institute; whereas, Michael has a department, the NEI has me. So we are a smaller institute.

(Slide.)

So very quickly I'd like to tell you about the mission of the NEI, how we've managed our SBIR/STTR program, a new initiative that we have for navigating the FDA regulatory pathway and some of the issues and challenges that we have faced, which I think many other ICs are facing also.

(Slide.)

So very briefly, the NEI, the National Eye Institute, we're about vision and preserving vision health. So we conduct and support research

into vision and blinding eye diseases, research into mechanisms of vision and pathophysiology of eye diseases, diagnosis and prevention, and also rehabilitation and assistive mechanisms for people living with blindness and low vision. So that's a very important thing because so far we--there are still many diseases we have no effective treatments and certainly no cures so we have to deal with people and help people who are dealing with these issues in their everyday life. And, lastly but not least, of course, is training new vision researchers, both scientists and clinician scientists.

(Slide.)

So NEI is, similar to NCI, clinically-oriented. When I say clinically-oriented, although we strive to understand the basic mechanisms of vision and vision health, we are really driven in large part by eye disease and visual disorders. We're trying to find cures and treatments for these and in the interim also working to create new devices, assistive devices, abilities just to navigate the internet for somebody who is blind is huge. Okay. So those are things that really drive us. We are committed to investigator-

initiated research. So what this means--again, in this case, rather than top down model, it's the scientists and clinicians, the people who are working in the clinics, in the labs who are really close to the patients, close to the discoveries and the technologies. It's through their grant applications, their foresight, they are coming to us with their ideas which derive in a large part, not entirely but in a large part the research direction of NEI funded research projects.

And then lastly we have a crosscutting management.

(Slide.)

So simply put, of course, you can take--this is the Division of Extramural Research at NEI. So we have portfolios to fund the research--the vision research throughout the country. You can divide it up simply by anatomy and disease, and that's one simple way to do it but, of course, life is complex and as you dig deeper you realize it's not that simple.

So we have created crosscutting portfolios such as genetics, immunology, collaborative clinical research of course cuts across everything. So we have a crosscutting style of management to take

advantage and manage those areas of science which cut across the simple anatomical and disease boundaries. So trying to prevent anything from falling into the cracks and to try to keep silos from being formed.

(Slide.)

Management of our SBIR/STTR program has been in a similar vein. So like the NCI, originally we had managed our SBIR/STTR programs across many program areas. Many program officers were managing them. So for each individual program officer, small business was a small subset of what they did on a daily basis. They had the research expertise that they were managing in their portfolio. They knew the retina. They knew genetics. But, again, very little industry experience. So the NEI has consolidated under one program officer, because we are a smaller institute the numbers can be managed by one person. So for me, small business is the primary focus. I've had eight years working in the biotech industry so I come with that background.

Over the years I have gained knowledge of the small business NIH regulations and policies and, as you can see from Matt's presentation, those are

changing. It's always fun to play a game where the rules are changing as you play the game itself. And, lastly, I bring in the experience with small business because what's out there in the real world, in the business world, that affects how we should be dealing with the small businesses and our SBIR/STTR programs.

(Slide.)

And some of these things I won't belabor because Michael has talked about them and I'm sure you'll be discussing these in greater detail. Issues and challenges facing us as a small to medium size institute:

Tracking commercialization success. Of course, that's a major one. There really is no systematic way, a quantitative way to follow the grant applications, the projects and the companies that we fund.

A long timeframe as Michael alluded to between first phase 1 to when you finally commercialize something to a particular drug or a therapeutic.

Acquisitions and partnerships. I've had the experience of one of my companies, one of our grantees, a small business with Lily bought out by a

larger company to get at its technology. Now that project is off our radar screen. I'm not going to know how well that one did. I weighed it as a commercial success because some large company put a crowbar to their wallet and bought the company. So in one sense somebody thought it's a great technology.

One problem that the NEI has and it's sort of the problem most people would like to have is we have an abundance of high quality applications. I think Elena may have a different perspective on that. Not every IC has an abundance of high quality grant applications. But the eye lends itself to commercialization. There are so many things that can be done to address eye diseases, visual disorders and problems of the blind and people with low vision, therapeutics, diagnostics, assistive devices, biomedical imaging. There is a whole universe of things and we have companies coming to us all the time trying to create these things. So my problem is at the end of the fiscal year sometimes we're leaving some high quality grant applications on the table because our budget just does not stretch far enough.

Peer review, again commercialization

expertise, I believe, is needed. For me, I'm seeing challenges in the submission for these small businesses. It's a daunting process for small business, especially start-up companies, especially companies that have been created by engineers who have had no experience working with NIH. Some of our small biotechs are started up by faculty members. They have got great experience in writing grant applications. Some, they don't. They come in, submit one. It doesn't do well enough. They resubmit and they get a great score they think but misses the pay line. Now what do they do? And if it was a phase 2 because they got their phase 1, they come in for the phase 2, and it didn't get funded. Now if they want to resubmit and change that whole project--well, they can't. They are still trying to develop, you know, a glaucoma device. That doesn't change but they have to come back as a phase 1 even though they've been through that already.

And then lastly access to product development resources. A lot of our grants--you know, efficacy of the product. Yes, it looks like it is going to work in animal models or with limited human subjects. Then now you've got to do the grunt

work as it were, pharmacokinetics, toxicology, formulation, manufacturing if it's a device. That takes extra money, especially if it's therapeutics. A lot of money.

And one thing that's critical is that for most of these biomedical companies they are developing devices that need to be approved by the FDA, Federal Drug Administration--Food and Drug Administration. Of course, small companies have people who do a lot of different things but you're not going to find regulatory expertise there.

(Slide.)

So one thing that we've done very recently is to establish a regulatory assistance program and this is a pilot program. It's very small scale. We are a small institute but the eligibility is for active SBIR/STTR grantees. And it's going to help them navigate the federal regulatory pathway because we have companies that are literally true start-ups and didn't exist last year ranging all the way to established companies that have been down this road before. And even the established companies can use better help in that area. It's open to both therapeutics and medical devices. A competitive application process.

So we actually have nine companies that we just allowed into the program in this past year. They are now in the process of the initial meeting. That has just completed for all of these companies. So the questions the companies have had about the process has been asked with this meeting. The goals are now formulated, defined, refined, and now the regulatory consultant company is in the process of developing the regulatory strategy based on that initial meeting and they will go back to the company with a customized plan, here is how you should address the FDA. It's customized for a device, therapeutic. Is it a drug delivery system, et cetera, et cetera?

And then there will be a follow up and progress review. And, of course, the NEI is part of that process also. So I'll reiterate the big question will, of course, be outcomes and how to measure that.

(Slide.)

So those are the things that the NEI, as a small institute, has done and how we're trying to manage our program.

So I thank you for your time and if you have questions--

DR. BRIGGS: We have two more presentations so quick questions, very specific to Jerry's program would be fine now but I think we will also have time for all the panelists to address questions from all of you at the end.

Okay.

So our next presenter is Jodi Black from NHLBI.

Jodi B. Black, Ph.D., M.M.Sc.,

National Heart, Lung and Blood Institute

DR. BLACK: Can you hear me?

(Slide.)

So I'm from the NHLBI and I'm going to tell you about how the NHLBI is in the process of reengineering the way it manages its SBIR/STTR program. I'm just going to call it the Small Business Program.

So, first I am going to give you a little bit of background about why we decided to make some very significant and strategic changes to how we manage the program and then I want to describe a couple of initiatives that we're in the process of implementing.

(Slide.)

So back in 2010 the institute decided to

take a serious look at how it can get the maximum benefit from the small business Set-Aside Program to ensure that it was meeting the institute's mission and critical needs. We decided to do this because the small business Set-Aside is nearly ten percent of our competing grant fund and we saw this program as a translational engine that we weren't fully taking advantage of.

So our purpose--the main way we solicited our mission interest was through the omnibus solicitation, both for getting our mission interest out and for attracting applicants. But, as you know, the omnibus solicitation was a laundry list of just about anything the institute could ever possibly be interested in. It wasn't strategic and it wasn't targeted. So we decide that that needed to be change.

Also, this program has very specialized policies and processes and requirements that are very confusing to both the applicant community and to our internal grants management staff. We were constantly hearing complaints from the small business community that the path of discovery to market is very fragmented. It's confusing. It's frustrating. Frequently the technology transfer

offices do not have a sufficient level of expertise or even funding to help them navigate those processes. And then scientists are not trained to be entrepreneurs so we knew that we needed to do something to provide some help.

(Slide.)

So the institute put together an internal working group that was populated by folks from across all the extramural program divisions and the Office of Science and Technology Policy and charged that group with developing more strategic approaches to managing our SBIR/STTR grant program and to address some of those issues I just mentioned. So to help guide their thinking they mapped out the discovery to commercialization process from a very broad perspective. They layered on to that where the work usually got done and who paid for it. And they noted that in these financial times that the folks who usually are available to invest in very early stage risky technologies had become very risk averse and are more interested in much more mature technologies. The group also layered on to that the kinds of funding mechanisms we have that hit certain points along the pathway and the assistance mechanisms that we have for technology development.

And they noted two gaps in this process.

The first gap is right after an innovator thinks they discovered something that might have commercial potential and they don't know what to do. There's a gap of funding here that can get the that can get the and process driven scientific feasibility studies that are required to help define the product. This gap is before the strategy should be to spinout out a company because most academic innovators don't really have any business expertise.

The second gap was already addressed by Michael. It's the gap between the end of the phase 2 SBIR award and the phase 3 commercialization phase. We noted the same gap and we're developing the same kinds of approaches, including a Bridge Award, with a lot of help and guidance from Michael and his team so I'm not going to talk about that.

But this group also noted that it wasn't just a gap in funding. It was more than just money. There was a gap in knowledge by innovators and an understanding of how biomedical technologies are actually brought to the market and there was a lack of access to sufficient technology development and commercialization expertise that's required to both

mentor innovators on these commercialization processes and help develop the technologies according to the right path that would meet intellectual property requirements and regulatory requirements, et cetera.

(Slide.)

So the group made several recommendations which we are in the process of implementing right now and I'm going to describe those to you.

So the main recommendation was to set up a dedicated office. So we started an office last year called the Office of Translational Alliances and Coordination. And this office is charged with developing strategic initiatives and plans to help facilitate the commercialization process. We are populating that office with staff that is outside the--with expertise that's outside the scope of, you know, standard grant management. That includes business development and regulatory assistance expertise.

These folks will help both the small business community with their application process and managing their awards as well as our program staff who are managing the awards who don't have training and expertise in this area.

So our program management model has moved from a strictly distributed model where the many different program officials had very few awards and very little expertise and training to manage them beyond the scientific component to a hybrid model where the grants are still being managed by the scientific experts across our divisions of Heart, Lung and Blood Disease because we didn't think we could pull all that expertise under one umbrella. But they'll be managed in concert with input and help from the business development experts and the regulatory experts that are going to be housed in the central office.

We also used to have the Small Business Program coordinated through a couple of part time folks in the division and they did it on the side. They already had full time jobs. So we have hired a full-time regular--a full-time dedicated SBIR/STTR program coordinator that works across the divisions for policy and process requirements and is the main contact and liaison to Matt's central office.

We're also enhancing our outreach and partnership processes for two purposes. One is to enhance NHLBI staff engagement. As Michael noted, most of our program officials have very few of these

awards in their portfolios and they are usually much more interested in other more scientifically oriented awards.

So we have established what's called the Topic Review Advisory Committee which is a trans-NHLBI committee that also includes our intramural program staff to seek out ideas from the division that are ripe for developing a technology that's commercializable and will potentially impact our patient community and help them develop those ideas and bring them forward for very targeted initiatives or contracts.

We're also increasing our outreach and partnership to the external community in several ways. We're trying to enhance our presence at a variety of meetings. Not only the standard NIH and national SBIR meetings where we're starting to send more people to but we're also increasing our presence at other conferences. For example, we attended the bio-meeting this past time. We were part of the NIH booth where we talked about our programs and we helped develop a translational research forum and participated in that program to talk about our new initiatives. We're also moving along the same lines, with the Michael's help, to

establish investor forums to reach out to partnering communities.

This office is also charged with developing initiatives that address the pre- and post- SBIR gaps that I described previously. So the post SBIR gap has been taken care of and described by Michael. We also implemented a Bridge Award and we published it in the NIH Guide back in February and we're making plans for our own investor forums in partnership with the guidance and advice from Michael and his group.

The pre-SBIR initiatives that we're developing are designed to help move technologies from the academic setting out into the small business community. So we have developed what's called the SBIR/TT award, the Translational Technology Award, which is modeled after the National Institute for Standards and Technology Award that provides funding to help develop discoveries from the intramural program by an external small business and in collaboration with the intramural program investigators if necessary.

The Center for Accelerated Innovation is designed for the external community to help move technology from the academic setting into the

small business setting. And I'm going to go into that program in a little bit more detail.

(Slide.)

So back in November of 2010 the institutes convened an external working group and asked that working group to help us develop a program that would address the gaps in not just funding but also knowledge and access to expertise that hinder the very critical early steps in the technology development process. So we put together a group of stakeholders that range from academic investigators to venture capital funders, small business owners, folks who developed proof of concept and accelerator programs, and we included the FDA. And this group was co-chaired by Barry Coller and Lee Hood. And they gave us some advice about how this program, which they called the Centers Program, should operate.

And so basically the Centers Program will have agreements with research performing institutions to solicit technologies and review them for medical, scientific and business review. Those that are accepted will be given additional funding to conduct the non-hypothesis driven scientific feasibility studies that are required to define the

product. But those studies--but the study--but the technology and the innovator will be surrounded by a team of experts that can help mentor the innovator with regard to what it actually takes to move a technology from the academic setting into the commercial setting and also guide the scientific feasibility studies so that they're design in a way that meets business plan requirements, regulatory strategy requirements, intellectual property requirements and product development requirements. All monitored and managed by very stringent project management processes. So if at any point it becomes clear that the project is not going to meet its predetermined milestones, go and no go decisions can be made and we can stop investing resources in it.

The goal is to develop the technology to a point where it's able to attract the next level of independent financing and have it exit the center either through licensing through an existing for profit or not for profit or starting a new company. And we can imagine that during the development process there will be a lot of opportunity to leverage existing NIH resources that can help with those processes.

(Slide.)

For example, we see integration with the federal programs to look something like this: Innovations that are discovered through our investigator- or institute-initiated programs can move into the center to be developed and have bilateral relationships with existing NIH resources that can help develop the technology. For example, NHLBI has a program that helps with IND enabling requirements. We can help coordinate our relationships with the CTSA program. When the technology is developed in those areas it can move back into the center for further development and sometimes accessing our clinical research networks for early phase kinds of studies.

We realize that partnerships are going to be critical for the success of this program so we brought the FDA in very early. They are part of the program management team and they are going to help provide regulatory expertise and advice to our awardees. And not only are they going to be giving something to the program but what they'll be able to get from the program is a sense of what's coming down the pike so it can help them think about their review processes.

The Department of Commerce is also on

board with the Office of Innovation and Entrepreneurship and the U.S. Patent and Trademark Office. And they're going to be providing an access to their IP assessment programs and their IP education programs. And CMS has recently joined us to provide the payer perspective.

That group is all part of the program management team. This is a cooperative agreement mechanism so NHLBI is going to help the awardees.

So at the end of the day we can see where these technologies will be licensed out or a new company will be formed and if the strategy for a particular technology is to form a new company what we hope to achieve is the development of a very solid company with a clear business plan in place with clear intellectual property, with a good regulatory strategy and the right management team so that at the end of the day we hope to receive more robust SBIR/STTR applications that address our mission critical needs.

So we think that there's a lot of benefit to this program and increasing the number of highly innovative scientific discoveries and translating them into marketable products for

patient benefit. We think the Centers will address these critical bottlenecks and gaps. It will decrease the time it takes to move the discovery to product. Hopefully, it will increase the chance of success. Importantly, we'll be encouraging and facilitating the required public-private partnerships and we'll be fostering the culture that's needed for sustained technology development.

(Slide.)

So I frequently get asked if we can use SBIR money to help fund this program. And historically the SBIR funds cannot be used to support these pre-company proof of concept center-like activities and centers for accelerated innovations is designed to be a proof of concept pre-company program.

However, recently the SBIR/STTR reauthorization permits NIH to use up to $5 million of its STTR funding to support pre-company proof of concept activities. And it's interesting that the Centers for Accelerated Innovation and their STTR POC goals are identical and that the language that's used in the bill is nearly identical to the language that describes how the centers should operate in the funding opportunity announcement

that we published in the NIH Guide just this past May. And so we see this as an opportunity to enable the centers program to become a trans-NIH program and since this model is there--is scalable and its disease agnostic it would be very easy to access in sort of a plug and play way.

We see a lot of benefits, though, to there being a trans-NIH program, including the ability to enhance participation of other ICs at very reduced cost, which will increase efficiency and economies of scale. We can also increase the number and geographic diversity of center locations which will help provide a broader bases for effective program evaluation.

And we've got--we've already had in place an infrastructure within the NHLBI in this new Office of Translational Alliances and Coordination to manage that program. We can make those resources available to our partners.

So in addition the program also presents opportunities to conduct technology development process research across a broader scope of technologies and also opportunities to conduct regulatory science research.

(Slide.)

So I was going to end my talk by describing some of the issues and concerns that NHLBI has with some of the reauthorization guidance but that has been pretty well taken care of. I would just like to stress that the ICs really need funding flexibility. Biomedical technologies usually require FDA approval and in order to comply with those requirements it usually takes more time and more money. I know that 83 percent of our phase 2 portfolio is developing a technology that requires FDA approval and since we are dependent on the private sector for phase 3 we need to be able to develop those programs--those particular technologies based on programmatic need and balance to a point where it's attractive to the private community to pick up.

(Slide.)

And I'll just end there.

DR. BRIGGS: Jodi, this has been terrific. I think it's a very provocative and important presentation but I think we do have to keep going.

DR. BLACK: Okay.

DR. BRIGGS: And we will, I'm sure, have some time for discussion.

Our last presenter is Elena Koustova from

NIDA.

And, Elena, I'm going to ask you to speak through. We'll give you about 10-12 minutes.

Elena Koustova, Ph.D., M.B.A.,

National Institute on Drug Abuse

DR. KOUSTOVA: Okay.

(Slide.)

As we heard already today, the effectiveness of NIH's SBIR program is rooted in its flexibility and distributed management structure. Twenty-four centers and institutes at NIH fund their own SBIR awards using different mechanisms and with various degrees of integration with other programs.

The SBIR program at NIH is effective because one-size-fits-all approach was not imposed. But for this same reason specific ICs of specific institutes may experience specific problems which are not uniform for all other ICs.

I was asked today to present to you a point of view of a niche IC and its SBIR program and to invite you to participate in celebration of our little victories and to ponder about our programs.

I think the better title for my presentation should be an exercise in innovation on a shoe string budget but in light of what the Dr.

Collins says it's probably a very timely title.

(Slide.)

So let me first introduce you to the realities in which our SBIR program is functioning.

We administer $25 million in total funding, which is four-and-a-half times less than NCI's and three times less than NHLBI's program. Our statutory authority is to conduct and support research with respect to prevention of drug abuse and the treatment of drug abusers, so our market is characterized by the general lack of commercial interest in the area of substance abuse disorders and because of this the market opportunities for small businesses are perceived to be very, very limited.

Our field is besieged by stigma, difficulties in recruiting and retaining drug users for clinical studies and the lack of support and advocacy. In absolute numbers the total substance abuse market is about $3 million compared to almost $50 for cancer treatments. So that leads to a very limited number of quality SBIR/STTR applications for NIDA. In addition to this, our SBIR program operates without dedicated program

officers, without dedicated FTEs.

(Slide.)

The absence of dedicated FTEs translates into a fact that for the last year-and-a-half I am privileged to lead a team, a very dedicated and very passionate team, which is comprised of representatives of all NIDA centers, offices and divisions whose purpose--whose goal is to provide policy assistance to NIDA staff and to work on improving our small business programs on behalf of the entire IC.

(Slide.)

So while establishing the initial strategy for improving our small business programs, we studied best practices and prior recommendations which Dr. Snyder mentioned in his introductory presentation in the morning.

So we decided to start by focusing on findings of--NRC's findings such as low relative scores, modest management and leadership engagement, burden on staff and staff reluctance to engage because those resonated the most with our internal needs.

(Slide.)

Surprisingly, addressing modest management

and senior leadership engagement was the easiest part. With the help of NIDA-IT our SBIR web page was created on the NIDA website. We secured a special allocated time for regular presentations during NIDA's senior staff meeting. So we also established a very special ceremony for program officers who would submit the best SBIR contract concept, which is called Tea with NIDA Director. So that ceremony is a hit because it guarantees a program officer an hour of undivided attention from the NIDA Director during which people may elect to discuss their professional aspirations and projects or to discuss good books or theater performance.

We also established separate funding meetings which are now transparent.

We installed a NIDA SBIR Idea Board which allows NIDA program officers to release their inner geek and to act as entrepreneurs. So, in general, visibility of the program was highly raised.

(Slide.)

Our work in improving relative scores and numbers of our applications started with a very simple yellow T-shirt campaign that the yellow T-shirt has a description of every single SBIR program that we fund on the back and is worn by the members

of the SBIR team during any of the meetings that we attend. It seems trivial but the number of web hits and the number of inquiries increased by 500 percent during that campaign.

So we also established our presence in multiple professional sites, such as LinkedIn where we have our prominent place and iBridge, this is the database that is supported by many entrepreneurial foundation, corporate foundation, and can you get really quick access to almost 200 companies.

So we also identified a Link Application Extension strategy as our main recruitment strategy and now we assist small business concerns with alternative path development if anybody is interested about any of the business terms and business strategies, I would be delighted to explain to you what it all means.

And, of course, we scout.

(Slide.)

So one of our examples of our scouting and outreach activities is our work with the most unlikely collaborator, with the Library of Congress. So that's what you have to do when you don't have budget and you don't have any money.

(Laughter.)

So we submitted the request to the Library of Congress asking for help in identifying small businesses with appropriate expertise which could be able to conduct research in areas of NIDA's strategic interest. Surprisingly, we received an invitation to visit the Library of Congress and the head of Business Reference Section of Library of Congress conducted a very special training session with us using specialized databases and business search engines. So we were able to search 17 subscription databases and we are able to identify NAICS (sic) for all potential small business concerns, both public and private, which can conduct research in NIDA's areas of interest. So those NAICS based, very, very, specific targeted outreach lists were created for NIDA.

(Slide.)

So as a result of implementing all those-- as a result of complementing activities in which we match prospective small business applicants with NIDA needs, we saw a very significant increase in number and in quality of applications. So, for example, one of the contract concepts attracted more than 20 offers. More than ever in NIDA's history for a single topic. And the score of the top

company was 94 out of possible 100. So another interesting development is that in addition to formal recommendation by NIDA divisions, topics for SBIR contracts are now nominated by NIDA's informal work and interest groups.

For example, Translational-Oriented Approaches, Devices and Strategy, TOADS, work group recently nominated the concept entitled Products for Home Deactivation of Psychoactive Prescription Medicines, which eventually was selected as a winner for Tea with NIDA Director Ceremony.

(Slide.)

So NIDA SBIR program covers a very, very wide range of topics, including basic behavioral, clinical research, drug development, training, epidemiology, services and prevention research. As a result, NIDA grants even submitted for one due date are being typically reviewed by 14 different study sections. So during those reviews only 17 out of 100 applications that are received by NIDA are being discussed. And, in addition to that, because approaches to proposal evaluation very significantly from one study section to another are ranged in the entire portfolio of grants of scored application in any kind of ascending or descending of order is

often meaningless and a lot of time later is spared by justifying the skips in finding and by communicating with very displeased applicants.

So applicants often complain about the lack of appropriate substance abuse expertise in study sections. We know that some ICs, some of NIH's ICS, already operate through special emphasis panels. So we know that NIDCR and NIAMS does it and for NCI, for example, I was able to identify at least four specialized study sections. So we believe that our niche IC would benefit greatly if all our SBIR applications would be reviewed by one study section.

(Slide.)

So a major effort of our SBIR team is educating staff on commercialization issues. You mentioned today it's very important to determine the commercial potential of application. So, in addition to going to NIH SBIR policy 101, we also utilize multiple tools of technology management, such as Commercialization Assessment Index, Market Opportunity Analysis and, most importantly, Strategic Technology Evaluation Program Model. So this model, especially STEP model, is known to predict with at least 80 degrees certainty the

potential commercial success of an application. So all those practices were incorporated in evaluating our internal ideas for SBIR RFPs and RFAs. So, for example, all the proposals submitted now are being evaluated on a special rating scale and market size and urgency and deliveries and other business aspects of a proposal are being discussed.

(Slide.)

So we also are working on decreasing the burden of staff and multiple templates and manuals and materials were designed to assist NIDA program officers.

(Slide.)

But that still leaves us with some issues and challenges in addition to issues and challenges identified by previous speakers, identified by NCI and NHLBI and NEI. So we obviously have our own issues. And so that is that building the SBIR program without FTEs and administrative budget for unsympathetic market is very difficult. But at the same time it also gives us a very interesting opportunity for internal innovation.

So we also are struggling with finding a balance between stick and carrot approach when we

talk about staff engagement. So we are concerned about our peer review and we would like to see a special emphasis panel established for each IC. And we are still struggling with a limited number of quality grant applications.

Thank you.

PANEL I DISCUSSION

DR. BRIGGS: Thank you very much, Elena.

So I think these four presentations have given you, the panel, a good sense of the very large range of the challenges that small and large ICs, and a range of approaches that are being developed.

Certainly, one of the issues that the SMRB can be valuable to us is in some of the people power issues that these very different examples illustrate with the pros and cons of greater administrative centralization as being one of the challenges that we'll have to talk about.

I think we are now five minutes behind our allocated time.

Sol and Norm, I defer to you in what should be our next steps.

DR. SNYDER: Norm and I discussed maybe instead of having a global discussion now, maybe we'll just have questions from people--questions of

the speakers briefly and then after that take an abbreviated break and then we might be back on target instead of having a global discussion.

DR. CASSELL: I guess we should point out that our representative from NASA is not going to be able to be here so we may pick up a bit of time in the second panel as I mention that in the interest of time.

DR. SNYDER: Okay. So the floor is open for anybody who wants to ask questions of the panelists.

DR. CASSELL: Jodi, I was really impressed with your Centers concept and I just wanted to clarify this would be centers that are outside of Heart, Lung and Blood. Would they be regional Centers? They would be awarded on a competitive basis? Or could you just clarify that for me?

DR. BLACK: Sure. So the Centers program is a grant award program. So they are external to the NHLBI but we're doing it as a cooperative agreement. So we'll help the Centers process along the way and we'll be making awards to Centers that put together, you know, appropriate applications and can show that they have access to the resources and expertise that are required to develop technologies.

So, you know regional is not really the right word but the Centers will actually be little mini-consortiums but, you know, taking advantage of the ecosystem resources is going to be really important.

DR. CASSELL: So as a follow up of that, I was pleased to see you suggest that these may be a place for regulatory science research and I wonder if you could just elaborate on that just a little bit. I know the joint program between NIH and FDA and regulatory science is a very small one. Do you see that growing or how do you see that happening within the Centers?

DR. BLACK: Well, I see that as the Centers are developing technologies and developing regulatory strategies based on advice from our FDA program management partners that there will be opportunity to conduct, you know, sort of cutting edge regulatory science research that is already-- you know, similar to what's already going on at NIH, you know. Whether this can be done as, you know, R01s in a more competitive basis rather than using set aside funds is unclear but the opportunity does present itself.

DR. COLLINS: I would just make a comment about that. I think again the opportunity for NIH

and FDA to engage more closely in regulatory science has never been better and especially with the NIH-FDA Leadership Council, which Peggy Hamburg and I co-chair, we're constantly looking for opportunities to build on research programs to both help them and help us in terms of trying to accelerate success in commercialization and getting through the regulatory process of therapeutics and also devices and diagnostics.

DR. RODGERS: Let me address the question to Michael but others can certainly chime in. You mentioned this nice Investors Forum that you have been holding once a year in which you bring in small businesses and link them with investors. Do you have a particular program where you regularly get together with sort of a third arm of that, academic institutions, to sort of tell them about opportunities in the program at NCI and potentially completing a small business venture capital with academics,
and others can comment as well.

MR. WEINGARTEN: Yes. So that's an excellent point.

So universities are going to be our primary source of technologies in most cases. So

we--when we come out--particularly when we come out with our targeted solicitations like our contract opportunities, which come out in the summer, we usually go all over the country. We speak at universities. We speak in local--to the local biotech community. But that's a very important target for getting good and new applications in. And really they understand the NIH peer review process typically but what they don't know as well as, you know, the whole process of starting up a company, which is why Jodi's idea for the centers, I think, is such a valuable one.

So, yeah, they are a very important community that we reach out too. We do it all over the country in terms of putting on seminars and workshops at universities as well as with the local state bio-organizations, too.

CHAIRMAN AUGUSTINE: I'd like to hear a little more if we could on the intellectual property subject with regard to what sort of problems you've run into, how the system might be changed to make it work better and also, just for my own edification, if you follow the current rules for the rights to the intellectual property and then there's a follow on discovery or invention that is based on the work

that was covered by the original work, how is the intellectual property aspect of the second, the follow on, handled? If that's clear as a question.

DR. BLACK: I'll take that. So for the Centers program, as an example, we're requiring that the agreements between the Center and the research performing institution that has the academic investigators have very clear agreements in place about how the intellectual property is going to be handled right from the beginning. And that--that the way it's handled and developed initially will need to include the ability for the Centers to have a sustainability element in them so that if there are any downstream royalties that come back to the host institution the agreement between what goes to the center and what goes to the investigator and what goes to the host institution is all worked out upfront.

For the technology transfer program, which is the program that we're using to help move technologies out of the NIH, the NHLBI intramural program, where the intellectual property is already owned by the intramural investigators, out into the small business communities, they get a royalty free license to continue developing, everything they

develop on top of what was initially discovered in theirs. But what we're probably going to see much more frequently done is CRADAs formed between the intramural investigator and the external small business investigators to jointly develop intellectual property.

So the expectation is that streamlined agreements will be developed upfront and for the centers program it's a requirement and it's very clearly delineated in the funding opportunity announcement.

DR. BRIGGS: Jodi, I think all of us are struck with the real need for providing to these various communities the kinds of regulatory expertise that the program will do but are struggling with ways to fund that within the context of the set aside and I wonder if you have any thoughts for the SMRB, or actually anyone, on ways in which we could develop more flexibility to provide that kind of needed expertise within the context of our sense.

DR. BLACK: So we can't really use that money for solely that purpose because the set aside is designed to go to already established companies. What the centers--the strategy that the

centers program is taking to ensure that all the assistance is provided that's required is to make it a matching program where we're providing some of the funds to develop the technologies and to gather, you know, access to the expertise but that we know that we're not giving them enough for the entire comprehensive program and so they're going to have to find some nonfederal resources to add value to the program. And that also gives them--that also gives them the requirement of having some skin in the game and being really invested in the success of the program.

And so having partnerships in funding is a strategy that we can use to ensure those--that that kind of expertise is available.

DR. BRIGGS: Gail?

DR. CASSELL: Jodi, one possible suggestion would be that in the private sector that you would have individuals in the regulatory bodies within companies that might be willing to offer their expertise in the form of an advisory panel or a group that could be convened, you know, to provide input and help and it might be an easy way to gain some expertise and maybe on such a panel you could also have members from FDA serve as well

to give advice.

DR. BLACK: So for the Centers program the FDA is on board. They are definite members of our management team. They are going to have full and open interaction with the centers employees.

What NHLBI decided to do for its small business community is to hire that expertise on staff and to have them readily available.

DR. BRIGGS: Garry?

DR. NEIL: So I had a similar thought in wondering if we could leverage the FNIH in some way to do that for in-kind contributions.

DR. BLACK: Yes, we have initiated conversations with them.

DR. NEIL: Yes. But if I could just follow on too quickly because I think the centers concept is fantastic. I wonder how much of it has been implemented already and how much is yet to come?

DR. BLACK: So the funding opportunity announcement was published in the NIH Guide in May. So we're right at the beginning.

DR. NEIL: Okay. Good. And you might want to consider--you have people from CMS, which is a great idea, you might also want to consider

involving people from the private insurance industry as well.

DR. BLACK: So we are in the midst of having discussions with Kaiser.

DR. BRIGGS: Richard?

DR. HODES: Jodi, can you comment on what you see presently or in the future, the opportunities as you alluded to, for this serving of course primarily NHLBI interest but more broadly across NIH?

DR. BLACK: So we've had--you know, Susan Shurin has helped us have many discussions with most of the institute directors across the NIH and many of them have expressed a lot of enthusiasm for this program. But, I mean, frankly everybody is afraid of their budgets. And so, you know, I think they are having a sort of wait and see approach. I know that there's a lot of excitement especially with my counterparts in those institutes to join this program but, like I said, the budget constraints are scaring everybody. And so I think that they're taking sort of a wait and see attitude but this $5 million in the STTR reauthorization could actually help us solve their problems by using those funds to help support the infrastructure requirements and

allowing the ICs to come in with very specific needs in a plug and play model sort of like a country club. And so we're hoping to figure out, you know, how we can do that.

DR. : (Not at microphone.)

(Laughter.)

DR. BRIGGS: (Not at microphone.)

CHAIRMAN AUGUSTINE: (Not at microphone.)

I give all these instructions and then ignore them.

(Laughter.)

I was saying that I think people have sort of taking breaks as we went along so unless there's an insurrection here I'd suggest we continue on and if people do need to take a break they can take it.

DR. SNYDER: Okay. So then we'll introduce the next panel and it's going to be moderated by Dan Goldin and Gail.

PANEL PRESENTATION II

PROGRAMS WITHIN OTHER FEDERL AGENCIES

Moderators: Hon. Daniel S. Goldin, SMRB Member and Gail H. Cassell, Ph.D., SMRB Member

DR. CASSELL: So, Dan, I'll defer to you, you're listed first, to lead us off.

HON. GOLDIN: Ladies go first.

(Laughter.)

Ladies first.

DR. CASSELL: Well, then we'll have three presenters from three different agencies, very different agencies, which is exciting to hear how some of the other agencies manage the SBIR/STTR program. So we would welcome them to start.

And since our representative from NASA is not able to be here because of, I guess, a very quickly called meeting this morning, maybe we could ask Michael from DARPA to tell us about your exciting program.

Michael Mutty,

Defense Advanced Research Projects Agency

MR. MUTTY: So good morning, everybody.

My name is Mike Mutty. And, as you can tell, I'm a bit long in the tooth, which means I'm old and I'm not much of a power point builder so I don't have any slides. I'm just going to talk this morning.

(Laughter.)

The other thing I want to mention is that I'm not the world's best public speaker so I've been to a lot of public speaking courses and the--as you know, one of the things the instructors always

recommend you do is tell a joke at the beginning of the presentation and just to try to build a rapport with the audience, but the problem is that I'm a U.S. government contracting officer and I don't have a sense of humor so I'm not going to tell you a joke.

(Laughter.)

Actually I do have a sense of humor.

I'm coming at this--I'm not the SBIR person at DARPA. I'm actually a contracting officer, division director of contracting officers, and my presentation this morning was--I knew you were going to get a lot of information from the SBIR community and I wanted to give you a contracting officer's perspective.

My background is that I worked for about 20 years for the Naval Air Systems Command. I was involved in writing contracts for very complex development programs for fighter aircraft primarily but I've been at DARPA for a few years now and I've just recently been exposed to the SBIR program. It strikes me that if you are buying an airplane, if you're buying a submarine, if you're buying food services for marines in Iraq, if you're buying grass cutting services for a military base or an SBIR,

it's basically the same process. It's requirements development acquisition planning, source selection, contract award and post award management. I'm going to try to do a little bit of comparison which I thought about yesterday in my mind.

In the NAVAIR world where I used to work you would have the requirements definition that would meet an emerging threat. So you'd say you want an airplane that flies Mach 1.6 with no afterburner, at flight level 450 it has range of so many miles and so forth.

In the SBIR world at DARPA the requirements definition is simply developing an SBIR topic. What area does the program manager at DARPA want small business to investigate for them?

The acquisition planning in terms of the airplane can be very, very difficult and complex. We're going to have full and open competition. What kind of programs do we want? Do we want total systems integration? Do we want logistic support, so on and so forth?

The acquisition planning for the SBIR is we have a standard operating procedure at DARPA which follows the standard operating procedure that DOD has put out. It is a cookie cutter approach.

Source selection, I'll get into those in a few minutes what the source selection criteria are but you have very complex--sometimes very complex source selection criteria for an airplane but we actually have just three selection criteria for our SBIRs that are quite simple. Contractor award in the fighter aircraft world takes forever. When you have Lockheed Martin you could probably attest to that. SBIRs, we get the contract awarded after source selection within a couple of months.

And in the post management in the aircraft world it's very, very complex. We actually have resident offices at General Dynamics and Boeing and so forth. But in the SBIR world it's minimal oversight. It really depends on the program manager and what the program manager wants to do.

So I was looking at a recent solicitation for SBIR topics and the longest thing--again it's true in the aircraft--the longest time was the topic development process. It took--the timeline for that was zero to six months. I looked at it and there's a lot of back and forth. You know, the program managers at DARPA define what the topic should be. It gets vetted through the office director and, in turn, gets vetted up through the Deputy Director of

the Agency. Then it goes over to the Pentagon to the Assistant Secretary of Defense for Research and Engineering. Some are selected, some are not selected. There's a requirement period. So it's kind of a lengthy period of six months.

But once the solicitation--after the six month period, the topics are dropped into the solicitation and the solicitation is on the street from month six to month eight.

Source selection--and we don't do peer review. I'll talk a little bit more about that in a minute. But source selection period is from month eight to month ten and actual contract award is from month ten to month twelve. So it's a 12 month period from when we initiate the program until we actually have our performers under contract.

So I was asked to answer some specific questions which I'll will get into now.

And not only can I not do power point, I have to put my glasses on to read.

So basically how are your SBIR/STTR proposals reviewed? What are your evaluation criteria?

So all DOD agencies have three criteria. There are technical merit; personnel qualifications,

facilities and ability to commercialize; and, three, potential for commercialization and expected benefits.

What's interesting is the reviewers that look at the proposals are selected by the program manager who put the topic in. The program manager, if he or she so choose, they can be the sole reviewer of the SBIR topic and that really cuts-- obviously it cuts a lot of time off from trying to coordinate calendars for a large group of people coming in.

How does your agency define program success?

What process milestones does your agency put into place?

And from DARPA's perspective we like to just start the fun science projects and once we get a foot or get some traction we transfer them over to some of the other military agencies, Air Force, Navy, Army and so forth. So basically our metric for success is that it's transitioned to another DOD agency or another commercial agency if you will.

Let's see. So is the staff of your agency trained?

Yes, they are.

Does your agency monitor outcome of projects after they have left the SBIR/STTR process?

Yes, the projects are monitored as part of the transition--as much as the transition commercialization support allows. We basically, you know, look at the company success and I don't think we have any really hard metrics and that's probably something we need to look at a little bit more.

So I think from listening to this morning's discussion--and, yes, in fact, we still can do grants and contracts in ten days if the stars are aligned. I have done it. But usually the long pole in the tent--if you actually lay out and do the analysis of the whole process, it's not the contracting perspective, it's the requirements definition and the source selection. So from what little I know about NIH just sitting in the audience this morning that seems to me like the place you might want to concentrate on. Could you bifurcate the SBIR/STTR programs where you have one with a simple program manager review and then you have the other one where it's appropriate to have a peer review? I don't know. That's something I'd look into for sure.

That's really all I have so I'm going to

open it up to questions if have you any.

DR. CASSELL: I think we probably have plenty of questions.

MR. MUTTY: I was afraid of that.

(Laughter.)

DR. CASSELL: And I guess the most striking one for those of us that have been mainly focused on NIH is your comment about the lack of peer review and the ability to have a single reviewer. And also in terms of your measurement of success, which is the transition to another agency.

MR. MUTTY: Right.

DR. CASSELL: And one might raise the question what have been the actual quality of the results from these programs that DARPA administers and what can you tell us about the transition to the other agencies? What percentage of the SBIRs that you fund get transitioned? What's their success rate?

And I guess the other thing is do the other agencies then track the outcomes of these programs that have been seeded through DARPA's SBIR program.

And as I introduced you, Mike, I said tell us about your exciting program. I think those of us

that are somewhat familiar with DARPA are impressed by the speed with which you normally operate and really the innovation in a lot of the programs that you fund. Again, it's interesting that you tell us you have no peer review of this SBIR program.

MR. MUTTY: Even our normal--

DR. CASSELL: So can you tell us how this actually operates and functions and more about the quality of that.

MR. MUTTY: Yes. Well, even in our normal solicitations we don't do peer review. We have general three program managers and the appropriate number of subject matter experts advising them.

One of the things to remember about DARPA is that it's okay to fail. I mean we're pushing the technology as far out as we can get and if we don't--if we don't take chances like that and fail once in a while we're not going to be pushing the technology. So I think that's one of the major differences between the organizations.

So I don't have the actual statistics for you. I can see if I can find them for you.

But usually it's sometimes difficult to get a program transferred to the services and I think back to the story--I've only been there for a

few years but talking to some of the other folks there that when GPS was developed at DARPA nobody wanted to touch it. When unmanned vehicles were developed at DARPA nobody wanted to touch it. So sometimes you've got to push a little bit hard. Some of the admirals and generals are--you know, they grew up with a certain technology and they don't want to deal with the new technology. But things like GPS and unmanned vehicles sometimes after a while it speaks for themselves and they pull them in.

So they're pulled into a service I would suggest that there's a very, very high success rate because the services won't touch them unless there's a really good proof of concept in there. I can get you that data but I just don’t have it in front of me.

DR. CASSELL: I think it would be good if there were some way to get that data.

MR. MUTTY: Yes. We have--actually we have an SBIR program manager and she wasn't able to make it so I'm kind of the tin shooter for this one.

DR. CASSELL: And we appreciate your being here and I hope you appreciate I'm in part kidding you but I guess again another question would be the

needs versus mission. How many or how much of your needs dictate the awards that are made versus say I guess opportunities for new ideas and new programs to come forth?

MR. MUTTY: Well, it's an interesting question and DARPA is very different from any of the others. I've worked in the Office of the Secretary of Defense. I've worked at NAVAIR. I have worked for the Marine Corps. And it's--you know, I can't remember the exact words but the mission of DARPA is to prevent technological surprises for the Department of Defense.

So what does the Department of Defense broadly think about it? I mean the military medicine is probably one of the largest HMOs. If not the largest HMO in the world, it's close to it. We have a supermarket chain, our commissaries. We have retail operations. We have chaplains. We have undertakers. We buy bullets. We buy planes.

So, you know, almost any one of those--maybe with the exception of chaplains, I'm not sure how the science would work in that one but--you know, there's medicine issues where not only do you have a large population of, you know, active duty military members but you have got retirees, their

families, spouses and children and so forth. But then you've got soldiers deploying to a country that has a very unique disease relative only to that country and obviously big pharma doesn't see a commercial application for that. So, you know, we try to develop certain platforms or certain ways to make a particular vaccine or something like that.

I've kind of lost the thought. What was your question again?

(Laughter.)

DR. CASSELL: I think you sort of touched on it.

Dan?

HON. GOLDIN: DARPA, like NASA and the Department of Defense, has a different set of issues. They develop products to help in their mission. So they end up becoming the ultimate customer. I think we have to be very careful for NIH. Their basic job is research and then they have to bring in private resources for financing that. So it's two different issues and it's very tempting to say let's take a look at what is being done at DARPA. They have the ability to take a lot more risk and they could fail. When you're dealing with cures and disease you don't have that luxury.

So I was listening to what you had to say and I started taking notes and I said stop that.

(Laughter.)

Because I believe that NIH has among the more difficult situations and they have that regulatory process that follows behind. So some of the comments we had before about getting together with the regulatory folks I think bears a lot of discussion because if you don't set it up right and you don't have people trained, there is a real problem.

MR. MUTTY: But is there a subset of the research you're doing that might--just a small subset for example that might fit that, like the program manager review rather than peer review?

I'm just asking a question. I'm not familiar enough to know to make an educated guess.

DR. CASSELL: I think the--well, NIH can speak for itself but I think what the challenge would be is from the extramural community and the argument that it wouldn't be a fair review perhaps and perhaps the expertise that might be needed wouldn’t be there and then the lack of transparency might also be an issue. That's my one answer to that.

HON. GOLDIN: One thought comes to mind in addressing a suggestion that was just made. There may be some tools or instruments, especially for some of the support of the programs, physics-based tools, where you could break them out separately where you don't have the regulatory process associated with it. And I was going to start talking to people to see if I could build such a list but if you don’t have regulation and you are developing tools to help in the research that's a place where you might be able to apply the principles that they have developed at DARPA. It will be a little sticky wicket for the NIH because of the peer review process but it's okay. You could declare open territory.

At NASA we broke away from the peer review process because we wanted to do things that were not modular improvements but leapfrog improvements and we set up the Advanced Concepts Organization, which was a five percent fraction or a three percent of what we were doing, and we said, "You don't have to do peer review and you could use the processes that we have--they have at DARPA." And we had some very exciting activities take place.

DR. CASSELL: So, Francis, can you tell us

if that might be possible to even take into consideration for NIH?

DR. COLLINS: So certainly in a couple of instances we're exploring kind of adopting a DARPA attitude to programs that would benefit from that approach. So we have a collaboration right now with DARPA on this preclinical toxicology approach developing a biochip that can be loaded up with human cells and then wired up with various outputs to assess whether a particular compound is likely to be safe or not. And having our staff work with DARPA on that joint effort which is about to have its awards announced any day now I think is going to be, I think, a good experience in terms of looking at the different culture of how to support such activities.

Yes, I think we're very open to creative ideas about how to do things of this sort when it fits the science appropriately recognizing everything has benefits and risks. And the benefit is being able to move quickly in a circumstance where you have a commercial opportunity that can't just linger on the vine but also risks that the peer review process which we depend on so heavily can't probably be done in quite the same rigorous way if

you're trying to do something in three months instead of a year but those are tradeoffs.

And certainly speaking for myself I think for our SBIR program one of the things we ought to really be looking at as part of this review is how to speed up the process because I think we are missing out on a fair number of potential applicants and partnerships just because it seems to take so darn long for us to get an answer.

DR. SNYDER: The interesting question-- when Dan said at--he said at NASA in order to do really far creative things you got rid of peer review.

(Laughter.)

And, of course, we, at the NIH, really would like to do far creative things and a good case could be made that if you see typical what comments are made by people in study sections you might come to the conclusion that if NIH wants to do anything innovative it should get rid of peer review.

In the case of the SBIR stuff, you know, some institutes, as we already heard this morning, are relying largely on contracts and contracts don't have to have peer review. So maybe following the NASA model might not be out of the question.

DR. CASSELL: Susan?

DR. SHURIN: So I think the key issue in something like this where you're looking at something which is very focused and trying to achieve a certain goal is establishing the criteria upfront. And that may be the better place to have the peer review process and the input so that you're not missing things and you're making sure that you've got that right. But once you've got that right the added benefit of external peer review is probably very, very small.

We don't--of course, I mean for most of what we do in our RPG line we don't do that at all. You know, we just--is it in the mission of our institute and, if so, we'll take it. But this is a very different focus.

DR. CASSELL: Sol, do we have good data on each of the institutes in terms of what percent of the awards are through the contract mechanism? And maybe this--you know, we should further explore that we--

DR. SNYDER: Matt, I think, can answer that question.

DR. PORTNOY: Sure. Yes, we have--we do have the data on the fraction of awards. Around

five percent of the NIH portfolio in dollars is on contracts. Twenty-five percent at NCI.

DR. CASSELL: Of the SBIR?

DR. PORTNOY: Of the SBIR.

DR. CASSELL: So I guess the question is should it be more than five percent?

DR. PORTNOY: I mean that number isn't set in stone. That's just how it has worked out.

I might also like to address Sol's comment on contracts at NIH do need peer review and institutes conduct their own peer review panels with external peer reviewers for contracts that come into an RFP.

To follow on something that Michael said about NCI, I want to clarify they use internal--what he meant by using internal review means that NCI conducts the review, not CSR but NCI agency to conducting its own review does use external peer reviewers and has to follow the peer review regulations. That's an important note to make.

DR. BRIGGS: Dan?

(Simultaneous discussion.)

HON. GOLDIN: There's another mechanism that was talked about in some of our phone interviews with the institutes. There was a lot of

positive response for cooperative agreements as a funding mechanism because a cooperative agreement you could hold back money, you could make a judgment based upon the milestones.

So one of the criteria for selection is do they have the right milestones? And then as they go along if they miss milestones you could hold back money and you could also terminate. So it gives a very, very powerful tool. And some institutes seem to be using the cooperative agreement to a very, very good end and others may not have been aware of it. But the NIH has that vehicle and it ought to be looked at in a little bit more depth.

MR. MUTTY: I've also been told that NIH has authority for other transactions now. I'm not sure that's--

DR. COLLINS: On a rather limited basis but, yes, it's part of the NCATS and the Cures Acceleration Network. We've had it actually before and used it sparingly to say the least--I don't know--in our Common Fund Nanomedicine Program.

HON. GOLDIN: But we had a lot of positive feedback from some of the people that talked about using it on the SBIRs.

DR. COLLINS: Yes. Kathy Hudson is here

and is the Acting Deputy Director of NCATS and might want to comment about the fact that with our interactions with DARPA they've often told us that some of the things we want to do don't really need other transactions authority. We actually have the authority to do it without that special input.

Do you want to say something about that?

DR. HUDSON: Yes. So we're actually learning a lot at DARPA's knee about how to use other transactions authority. And one of the things that they do, do is this EZ DARPA award where, as I understand it, the awards are made six weeks after the application is received and I think that that really speaks to an opportunity to explore how they do their business on focused SBIR programs that we might be able to mimic.

MR. MUTTY: Yes. And I'm not sure--I've been on several phone calls with NIH about OTs. I'm not sure if I've been in some with you but I think that the misconception is that the OT is just this magical thing but you still have all the, you know, competitive rules you've got to deal with and source selection.

When I was at the Naval Air Systems Command the contracting office was always blamed as

being the bottleneck because it took so long to get contracts out. And then one three-star once said, "Well, let's do an analysis of the entire process." And it was really the requirements generation and source selection process. The contracting process actually was very short.

DR. HUDSON: It would be interesting to do that same analysis on our end and see if the time equation is the same.

DR. CASSELL: Michael, did you have something you wanted to add from NCI's perspective?

MR. WEINGARTEN: So we are a little bit different in that we--about 25 percent of our budget, probably close to 30 percent of our budget is going to be spent through contracts this year.

So I mentioned that we go through this really extensive process internally to find out what are the areas that we want to solicit. Generally, the numbers of proposals that you receive per topic are much more manageable. So you can do a quicker review on the proposals that come in. We probably average somewhere between 15 and 20, I want to say, in response.

If you look at some of the time factors, though--I mean, I agree with what Dr. Collins says.

I mean, there are some strategies that we can certainly explore for how do we speed up the overall review and the actual funding of awards.

One of our limitations deals with the whole budget issue. You don't typically have a budget until February-March timeframe. So companies who apply in April or in August have to wait until we get the budget to actually be able to make those awards. So we have to be--I mean all of us have that same constraint. But I think there are a number of things we can explore for how--you know, pilots that we could explore for using SBIR--maybe this easy one-page contract is an idea. We'd love to explore that at the NCI certainly if we have the ability to do so. But I think there are some promising things with other transactions that we certainly would like to explore.

DR. CASSELL: Norm?

CHAIRMAN AUGUSTINE: Yes. I want to comment on a few of the comments.

The peer review system certainly is given a lot of credit for the quality of American science today and I think deservedly so. Although in my experience the peer review system, particularly more recent times, has tended to lead to more

conservative outcomes.

One of the things that DARPA does rather effectively is they will put out a requirement that sets a very tough target. I think back when most of the industry was trying build airplanes that could stay aloft for eight hours. DARPA came out with a request for an airplane that would stay up for a week and it causes you--you have to think totally in a totally different way. Some of those failed. In that case people came up with airplanes that could stay up for a week but I don't think we ever would have gotten there with the normal process or the peer review system or what have you.

So to me there's a role for peer review but there's also a role in another cases probably not for peer review.

Dan, to your comments, I was thinking of ARPA-E, which is the Department of Energy's ARPA. It has--it's more analogous to the situation here in that they're not their own customer and they have struggled with that but they have done a good job. I think they are highly regarded. And one of the things they did was to provide bridges to get from the results that they produced to the--all of the--the user of the product. They provide these

bridges and I think that's the--one of the key factors.

The subject of fairness came up. It isn't viewed as fair the way DARPA--I'm showing my age. It was ARPA. DARPA.

MR. MUTTY: It goes back and forth. It's DARPA now.

CHAIRMAN AUGUSTINE: Yes, it does go back and forth. You're right.

The way DARPA makes awards--as one who has been on the other side of that fence, I think there's a fair amount of belief that we would be willing to sacrifice a little bit of the rigor or fairness for quicker results because in many cases, particularly with smaller companies, an answer three months from now is no answer. It's totally unfair.

And so I think the idea of putting together a timeline on how the SBIR awards work in NIH would be a very instructive thing.

And I guess the last thing was really a question for you and that is some of the ideas that come out of DARPA come out sort of internally like an airplane to fly for a week. On the other hand, sometimes people come in and knock on the door and say, "I've got this great idea." And my question is

sort of what's the mix of the two in your experience among those programs that have been successful?

MR. MUTTY: I would say maybe five to ten percent of the people knock on the door. Mostly because of budget pressures. But we have a mechanism that--you know, we solicit with a broad agency announcement and we have two kinds of broad agency announcements at DARPA. One is a program specific and one is building an airplane that can stay aloft for a week. And the other one is what we call office-wide broad agency announcements.

I support an office that's called The Defense Science Office, which is biology, physics, materials.

So this particular broad agency announcement is so wide you can almost--anything is acceptable. You know, I want to do whatever. So there--if somebody sends a program manager an email and, "Hey, that's really a pretty good idea." The program manager would usually go back to the potential performer and say direct--I'll direct his attention to the office-wide broad agency announcement. And then if a proposal comes in through that and it's acceptable and we can find the funds, we go ahead and award it.

We have a new program manager or a new office director and I've made a commitment to him that as he--you know, there's about 20 program managers I support but he is the office director and if he has a good idea and he wants something done in a couple of weeks I have guaranteed him I would get it done in a couple of weeks once he has made the source selection.

So the mechanism of the office-wide BAA is--we consider it to be competition so we have met the competition in contracting act regulations. And it's a very fast way to get a new idea under contract quickly.

CHAIRMAN AUGUSTINE: Do you want to see if either Bill or Gil have any comments?

DR. CASSELL: Sure.

Bill or Gil, questions or comments?

Well, I think, Manny, Norm gave you a perfect lead-in to tell us a little bit about ARPAE and the DOE SBIR program.

Manny Oliver, Ph.D., Department of Energy

DR. OLIVER: Thank you.

(Slide.)

Again thanks for the invitation to talk about the DOE programs today.

Actually I'll just give some background. I actually joined DOE about a year-and-a-half ago. I come from the private sector and, in fact, they were looking for somebody with commercialization experience to, you know, head the SBIR/STTR programs.

(Slide.)

I just have three things I want to talk about. We run our programs a little differently than NIH so I thought I would just spend a little time talking about that. And the two areas I want to look at is really looking at improving how we operate the program and then, finally, discussing how we--what we are trying to do to improve the outcome.

(Slide.)

Here's the org chart for DOE which you can't read. I just want to highlight there in the color there are the 12 different program offices within DOE that participate in the SBIR/STTR programs. And they are spread--and they are colored differently because we have basically three different mission areas. One going from left to right there, Nuclear Security. We have an Office of Science that primarily funds basic science, and

that's about two-thirds of the R&D budget within the Department of Energy. And then we have the Office of the Undersecretary of Energy on the right there. So these three different offices also have very different missions but all of them participate in the program.

The office I run, the SBIR/STTR programs office, sits in the Office of Science and administers the program.

(Slide.)

Again in terms of how we run it--so we have a--our office is kind of a single point of contact for administering the program. So we develop the funding opportunity announcements and we administer the review and selection process. We do have one grants office. We do grants, not contracts for DOE, Our Chicago office handles that for--again although many different program offices participate, we just have all of the awards go through one office.

And then, finally, we work with these 12 different program offices. Their responsibility is on the technical side developing the topics, identifying reviewers. We do, do scientific peer review. They also select the awardees and manage

the projects once they're underway.

I would just also comment that the funding actually flows through our office through the central administrative office. So it is a little different from the central office at NIH. So we do manage all the funding for the program.

(Slide.)

And I thought I would just give you a brief snapshot of the statistics. These from FY11.

In terms of the phase 1s, which are $150K, nine months, for DOE--again the pie chart shows the disposition of the applications. About 20 percent are actually declined without review. About half are not recommended for funding. And for every one we do award there are two additional ones that are recommended for funding. So I think, as was mentioned earlier today, we have plenty of opportunity to fund high quality applications.

For phase 2, only the phase 1s are eligible and they do go through peer review again. About a third of those are not recommended for funding and we fund about half the applications. So there are some that are still recommended for funding that are not because of funding limitations

(Slide.)

So here is our timeline in terms of looking at phase 1 and phase 2 processes. You know, going first with phase 1. The chart here is in months with the zero point being the point at which the funding opportunity announcement here closes. You know, in FY11 we had about six weeks from the time we issued topics and opened up the funding opportunity announcement. It was about five-and-a-half months for award notification.

We give our grants office six weeks before we start the budget period so companies can start the work within six weeks.

It turns out when we looked at the data the actual release of funds by that office typically for the average awardee is about a month after that.

Small businesses are actually very conservative. They won't start until they see the money appear and so we got some feedback from the businesses that, you know, this cap was a problem as well. So even though they were allowed to, many of them did not start work until they saw the funds.

Our phase 2 process is much quicker. Primarily because during phase 1 we have identified the reviewer pool. We use typically the same reviewers in the phase 2 process and so the time

frame--the selection period is much shorter. It's only about three months.

Again, we give six weeks until they can start the project and start costing the--award.

Again, we had a problem here where the release of funds is typically occurring later and the companies still wait for the release of funds.

So this was the situation when I came on board in FY11 and I will talk about some of the changes we made to improve that.

(Slide.)

One of the--you know, the big challenge I saw is that, gee, we only have six weeks. We are putting out a topic. We expect a full application with all the partners and subcontracts lined up. And we in many cases looking for breakthrough ideas. So this is really not a lot of time to do that. And we--again, the six week time is also not a lot of time for applicants to really understand the technical topics and what we're looking for. Especially since the communications while the funding opportunity is out has to go through a Fed connect system where all the questions and answers are posted for everyone to see. So this was a little bit cumbersome so we wanted to improve the

frontend process here and provide more time.

Again, coming from the private sector, this five-and-a-half month time is way out of line. You know, in the private sector we are changing projects and those decisions again are made in days and weeks, not in months.

Now, we do have some constraints because of the requirements for peer review and ability to do that. Again, we often, I think, in many other cases use people who voluntarily--we do not pay our peer reviewers and so that provides a challenge as well in trying to meet strict timelines when this is done on a voluntary basis.

And again we do want this release of funds date here to align with the start of the budget period and so we have taken some activities to improve that. So I'll go into some of that.

(Slide.)

One of the first things we did was actually to post our topics four weeks in advance of the funding opportunity announcement. And this--what this did is allowed, based on DOE policy, allowed for applicants to speak directly with the program managers so they can have, you know, unrestricted conversation on what is the topic

you're looking for. You know, what it's about. As I noted before, we decline about 20 percent of our applicants without review. We get a lot of people shoving applicants in and hoping it fits with the topic and we're trying to--you know, there's a lot of work going into the applications so we don't want that to happen if they really don't understand what we're looking for.

We also implemented a topics webinar to relieve some of the burden of the topic managers asking--you know, answering the same questions over again for all the different applicants who are applying to the topics. So this session the topic managers would briefly discuss the topic and what they're looking for and people registering for the webinar can submit questions in advance, as well as asking in real time during the webinar. And we held this for the first time, you know, this year and we really have a lot of very positive feedback. So applicants really like this direct channel to the actual program manager who is going to identify reviewers and actually be involved in, you know, selecting the awards.

(Slide.)

In the past we actually only had one phase

1 solicitation a year. I think among the big five agencies, us and NASA, had operated on a single Phase 1 solicitation every year. I think the bigger programs like DOD and NIH have rolling deadlines and multiple opportunities.

So one of the things we did primarily from an efficiency point of view is to, you know, switch from a single, and usually we're going to go to two, we ended up with three for FY12. So this did provide applicants an opportunity to apply throughout the year.

Again I would mention here that the way we implemented this so we didn't get a lot of pushback from our programs is we basically split up the topics. So for the first release we had about half the programs, the science programs. In the second release the non-science programs.

And we did this third one--I'll talk a little bit about the differences here. So traditionally DOE topics are very focused. A typical topic has a three page description. We provide references so people understand what we're looking for and what the state-of-the-art is, you know, in that area. You know, the role of the program managers is to identify what are the sort of

breakthrough areas we're looking for and to provide those very focused topic areas.

One of the--you know, one of the feedback, of course, we get from small businesses is, "Hey, you know, what you think is a breakthrough you might be leaving out some important ideas. Can you put out something broader so we can submit our ideas?" The fundamental tension there, of course, is if there is broad solicitations we just get flooded with applications, you know, more than we can really handle.

So we did release the third one. This was a pilot this year posting very broad topics. Again these will be one or two sentence topics compared to our two to three page descriptions in the past. So it might be focused on solar but we were just putting a specific performance target. I think you referenced the plane flying for a week. So we would put in a solar one but just to prevent everything in solar coming in we would put a very aggressive performance target in terms of cutting, for example, the cost of solar by a factor of six from where it is today. So again looking for more ideas.

(Slide.)

I think the other thing we did is we--

since we're making a lot of changes we did another webinar just with each FOA. This was to discuss the changes in the application process that we're making, especially with the reauthorization coming on board. We're working on some of those already in FY12 and we wanted to make sure applicants were aware of all the administrative changes. And the feedback on that has been very positive.

I think one of the challenges we've seen with outreach, and there are a lot of national and regional places for us to go, but that's very hit or miss. And again for the small businesses, you know, it's a lot of time on their part where they're usually very pressed for time. So these webinars are actually required. If they can't make it, they can always go back and listen to them.

(Slide.)

The other thing we implemented--this was really to drive down our award selection time--was letters of intent and pre-applications. The primary purpose of this is--before the full applications are viewed--to understand how many applications we should anticipate in each of these topic areas so that we can start to

identify the reviewer pool. So here--so with the letters of intent, which we did those for the first two releases, we required a technical abstract and applicants were instructed that the purpose of the technical abstract is to assign reviewers. So please put in the technical detail you need to make that happen.

We actually did use the letter of intent to provide feedback to people on what appears to be nonresponsive to the topic. Again this idea was so that they are not sending in full applications thinking that it was actually an appropriate fit. I do use the word "appear" because they are only sending in a technical abstract. We don't see enough detail to essentially reject their letter of intent. And so we tell them you can submit a full application. We're not prohibiting it but from what we see in the application it appears to be nonresponsive. And people who get this message, about 80 percent of them choose not to apply and submit a full application. About 20 percent do go on to submit full applications. And this year actually a few of those were funded so it was not a case of they are out a game. Some of them may have chosen to, you know, take another look at the topic

and contact the program manager to make sure they were, you know, on track with that submission.

And, finally, for Release 3 of the pilot we actually went to a pre-application process. And again this--again, those who were declined from the pre-application could not submit a full application. This one is still ongoing and so, you know, we're looking at these two different approaches and their effectiveness in terms of both the small business feedback as well as the--you know, our--impact on us in terms of improving our award cycle time.

(Slide.)

I just put up a chart here showing here this is a typical application we receive from the program. You know, with the letters of intent we were seeing again a much bigger level of interest but in terms of the applications that came in that did drop. So I think we are providing some benefits to small business who otherwise in the past would have submitted an application and not even have it reviewed.

(Slide.)

So here are the improvements. Again this was the schedule in the phase 1 in FY11. Here is where we are for 12.

Again, what we have done on the application side is to lengthen this period. Again, provide more discussion during the time between topic submission of the FOA, implemented a letter of intent requirement. So we've doubled the time essentially when applicants can learn about the topics. The selection time was reduced two months. So we brought this down to three-and-a-half months for this year.

And, also, working with our Chicago office, over eighty percent of the grants were negotiated prior to the grant start date. So, in total, from '11 to '12 we have taken about three months, you know, from the small business perspective off the process. We are one of the agencies that, as Matt mentioned, are subject to the 90 day requirement starting FY13. So we'll be taking another three weeks off the process for next year so that the selection process does comply with the reauthorization.

(Slide.)

Next I just want to talk briefly about outcomes.

Again, there has been, you know, a lot of emphasis, I guess, over time with the SBIR/STTR

programs to emphasize commercialization. You know, this past year we did modify the application selection process to, you know, increase this emphasis on commercialization potential. I think, like NIH, we have a lot of program managers who are--really have science backgrounds but not very strong commercialization backgrounds.

And so we were looking to put in place processes really to highlight sort of the commercialization aspects of the program and we also did--we completed our Commercialization Assistance Program and I'll mention that briefly.

And then I think this whole issue of sort of measuring and improving outcomes--I just have a couple of slides that discuss that.

(Slide.)

The processes--one of the changes we made--actually we implemented a commercialization plan requirement for phase 1. You know, we found that--actually the previous National Academy study found that one-third of our awardees post Phase 2 discovered, "Hey, this market is really small. You know, this is not something we should pursue." So we find that that is a very late point in time to make that discovery so we want to make sure coming

in the front door they make that discovery when they submit their phase 1 proposal.

And then again in terms of the process, the review and selection process, what we've done is really try to highlight in our reviewer forum or in the program manager's forum where they're doing the recommendation for funding, what are the commercialization issues with those applications.

So companies who have poor commercialization histories, you know, companies that have received multiple SBIR awards but have really no commercialization outcomes, positive outcomes. In their phase 1 commercialization plan if their revenue forecast is really low, again we have some where those revenue forecasts are less than the investment that we're planning to make through the SBIR program. And, again, those that have very low commercial potential through our phase 2 commercialization plan review.

I would indicate that for phase 2, in addition to the scientific peer review, our office does a commercialization review and that review is focused on the commercialization plan that's required for phase 2. So that goes out to the private sector and not through the technical peer

review process.

So when we see things that are very poor we also flag that to the program managers.

(Slide.)

We did re-compete our commercialization assistance program. Two aspects to that.

One, we put a greater emphasis on assessing the companies. So we have asked our commercialization assistance vendor here right out the gate really to assess these companies so that we understand what are the commercialization strengths and weaknesses of our applicant or awardee or actually of our awardee pool. You know, what are the areas that they need, you know, assistance.

And most of the phase 1 assistance is really focused on developing their phase 2 commercialization plans.

Phase 2--in the past, you know, DOE had a forum. Actually the--what we refer to as the forum--to help move technologies to the private sector. Because of the breadth of our mission really only a very limited number of companies were able to take advantage of that and it wasn't as flexible in helping really all of the companies that we fund in phase 2. So we have changed the phase 2 program to

really provide a very broad range of services that those companies can select based on their needs if they're following a licensing path versus a manufacturing path and what might be appropriate for them. We're still just using one vendor to do this.

And also with reauthorization companies are actually allowed to select their own commercialization assistance vendor so the $5,000 that are in addition to their award can go directly to them in place of going to a commercialization assistance vendor.

So we did implement that. Actually we've already issued a couple of solicitations where we've had companies do that.

In our feedback we receive from small businesses in many cases they have very--you know, they are specific niche industries and they would like to utilize consultants and people who really know their industry while, you know, the companies who supply this broader expertise can't do that. So we think that is a useful, you know, upgrade to the program.

(Slide.)

In terms of measuring outcomes, you know, we have started this past year to look at the

historical data. Most of the data is coming in through commercialization histories. Those are supplied by the applicants and when they submit. Their application discusses all their prior SBIR awards and the sales and licensing revenue that might result.

DOE did an annual survey through 2007. I'm not sure why that was stopped but it was stopped. We have gone back to OMB and received approval to reinitiate that this year.

When looking at this--the data here, we actually went back, I should say, about 5 years from today, giving people time to commercialize from the awards, and then went back 15. So we looked in a window from five to 15 years. Through the data that we already have we have about 70 percent of the companies on the phase 2 awards that were made and looking at what happened to commercialization. So we are starting to look at some of the issues like how long does it take them to commercialize. So where should we--when we begin setting metrics, you know, where should this window be when we define that?

We can also see what's happening in terms of, you know, defining commercialization. We see a

broad range. Of the companies--approximately 1,000 companies, actually about 38 percent of them have sales and licensing revenue associated, you know, post phase 2 awards, which is actually quite high. But then you start looking at details and the numbers, and most of those are relatively small. Most of those are actually less than the investment we made, you know, in terms of the SBIR awards that we provided.

And, again, we do have the couple, you know, wild success stories, you know, of companies with an excess of, you know, half a billion dollars in sales resulting from these SBIR awards.

You know, one of the challenges we see is that we really do have to go out and reach out to the companies. The two most successful companies, of course, had one phase 1 and one phase 2 and they're gone, you know. The typical model of the SBIR companies are coming back again and again for R&D funds. It is not really tied to, you know, the really star success stories. Although we understand that, you know, a single one is often not enough to get them going.

(Slide.)

I think for next year we are planning to

look a little more closely at how we're going to define, you know, success for the program. I think the commercialization success, you know, is an important attribute. It's not the only one but given the mission essentially of the SBIR program we do have to look at that but we also want to consider the mission impact. I think that actually for us provides the biggest challenge just because we have diverse submissions looking at clean energy, you know, basic science, as well as nuclear security. How do we define the mission impact criteria. And, in fact, those are often much more difficult to quantify.

Again, we've also been tagged with looking at other economic benefits such as job creation. And I've always liked the NSF slide they put up where they discuss how the tax revenues are coming out from all these SBIR/STTR companies are actually making this program basically self-funded.

(Slide.)

The other thing we need to do is probably develop better topics. You know, our topics are really what's driving the applications we receive. I think we can learn a lot from our historical outcomes. Just the analysis we did it turned out

actually one of our basic sciences program actually is one of the more successful in terms of funding SBIR. It wasn't always really the applied programs such as fossil energy and renewable energy that had the highest success rates.

I think, as Mike alluded to earlier, we do need to get greater input from the private sector in developing our topics.

And we have started to leverage tech transfer opportunities. In FY13 we actually introduced topics. Again, this was initially piloted by Clare Asmail at NIST. Again, NIH has already introduced some of this as well. So next year we will have tech transfer opportunities from DOE labs included in our topics.

In FY14 we plan to extend this to universities. So we'll look at DOE funded research at universities that has resulted in IP at the Tech Transfer offices there and put those in as topics as well.

(Slide.)

Again, just summarizing--you know, a focus on improving the operations. You know, a lot of that is not always speed in terms of award selection but also a little more transparency, better

communication with the applicants. And then again the future focus is really going to be looking at improving some of the outcomes for the program.

HON. GOLDIN: Thank you.

We're going to switch now.

I'd like to ask that we hold comments. We're a little bit behind schedule. I just spoke to Grace Wang and she needs about 15 minutes, which will give us a little over 15 minutes for comments so we can get it on both speakers, and we'll end on time.

Grace?

Grace J. Wang, Ph.D., National Science Foundation

DR. WANG: Thank you.

(Slide.)

My name is Grace Wang. I am the Division Director of Industrial Innovation and Partnerships Division at NSF.

The division is about $190 million budget this year for Fiscal Year 2012. And about $14 million goes to the universities and that's to help universities develop long-term partnerships with industry. And the majority of the division, about $152 million right now are actually devoted to SBIR/STTR program. So I'm going to talk to you

about SBIR/STTR programs here of course.

(Slide.)

So this is actually the model that Manny was just talking about. NSF SBIR/STRR program only support the phase 1 and the Phase 2 programs. The phase 1 is $150,000 for both SBIR and STTR. SBIR is six months and STTR is 12 months. Only the phase 1 grantee can apply for phase 2 award. Of course, I think that's the same for all the agencies.

The phase 2 focuses on research towards the prototype. The award level is a half million dollars right now and the duration is 24 months.

A flagship program we have is actually the the phase 2b. And the reason of that is because NSF only supports phase 1 and phase 2. We do not support phase 3, which is actually a critical step for the small businesses, especially for the small startups to bring the technology to the market. And to do this actually from here to phase 2 through phase 3, especially the money needed, we usually--is actually way beyond where government can pullout. And that's the reason that it's very critical for the--and that's both SBIR and STTR grantees to be able to attract private sector funding. And to stimulate our companies to think about that and

motivate them to do the fund raising from private sectors, we have this program. Actually it's published, I believe, in 1998 way before I joined NSF. This is to give our grantees half million dollars if they can attract one million dollars private sector funding to help them move forward.

And we also have a Commercialization Assistance Program. We actually have a program here at phase 1 level but that's actually really just helping our grantees to come up with a more viable market plan.

One we have is called Innovation Accelerator. This is actually to provide more hands-on commercialization assistance to our grantees and newly phase 2 grantees. What they do is actually help our grantees to talk to the venture capitalists and come up with the right message, the right presentation to talk to the venture capital firms or the angel firms and also help them to recruit board members, to help them recruit a new CEO and help them analyze their IP portfolio and see if they have any loopholes there.

So that's how the program is structured.

(Slide.)

The funding mechanism is a grant. We--

actually it's a 100 percent grant. There's no contract at all and this is really because NSF is not a mission agency. We are a funding agency. And we--of course, we are not a final customer for any of the product or services our SBIR grantee will develop. And NSF is--absolutely this program is not for procurement purposes.

What we are focusing on is the technology commercialization and this aligns very well with NSF's mission. It's actually one of the--the NSF mission is to capitalize fundamental research. And actually this is our focus to how to actually move fundamental research into something that's market viable and also to accelerate this process because right now if you take a look at how long it takes from the concept of the concept, the fundamental concept, in the fundamental research level, until it becomes a viable product on the market sometimes will take 30 years or 20 years, and that's way too long. It's probably okay for the biomedical area which I'm not an expert but I think for most of what we support--

(Laughter.)

HON. GOLDIN: That's not acceptable anywhere.

(Laughter.)

DR. WANG: Yes. It's not acceptable. So that's actually our focus.

We are not--I know that we are talking about the process of getting our grantee awards in that time but six months is too long. I agree.

But I think the time of--from fundamental research to the market that time is way too long and that's our focus. How to accelerate the process there.

(Slide.)

So let me share with you about our review criteria. We have two review criteria just like any other NSF proposals, intellectual merit and broader impact, but we actually change the broader impacts to broader/commercial impacts. And, as you can see, actually we focus a lot more on the commercial aspects here.

(Slide.)

And we have, of course, a very long review criteria for phase 2 and I don't want to go through that here so I'm going to give you a very high level highlight about what kind of proposals we are really looking for when we do panel review and also program review. The first thing is the proposal

must demonstrate a very sound technical plan and also innovative concept. It doesn't need to be--there is no preliminary results needed but it has to be really sound. At least appear to be feasible and can be executed.

And the second thing is very important. The proposal must demonstrate that there is--the company is well qualified, not only well qualified technical team but also a well qualified business team. Actually the first part is very easy. Most of the programs--most of the proposals we got, they had very good--very, very strong technical team and usually the business team is really weak. And so that's why we emphasize on the business part.

And the third thing is whatever the company is proposing, if they are proposing just to develop some--just to do some research we're not interested. Actually we're interested while the company is developing a product service, services or software or process that can lead with--actually that's marketable and also has a significant market potential.

So that's the three really high level review criteria. And if you are interested in the details I can send it to you.

(Slide.)

And in the phase 2 commercialization plan--in phase 1 we only require about two to three page commercialization potential statement. So it's very short and it may not be sufficient but just to give us some taste about what the company is really thinking about and especially what product they are developing. But at phase 2 level we are developing--actually we ask the company to submit a full 15 page business plan.

And in this business plan we ask them to address really four aspects. The first one is the market opportunity or market potential. And the second one is the company and the team. The third is product/technology and competition, especially here we need to make it very clear exactly what is the valued proposition of their product. The fourth one is financing and revenue model.

How they are going to do the fund raising and how they are going to generate revenue and eventually become not only a self-sustainable business but also a business that can actually eventually realize this exponential growth of revenue and actually generate jobs and stimulate economy.

(Slide.)

So our funding criteria is high--we fund high risk, high payback innovations and high commercialization potential is a must. Actually these funding criteria comes very close to where we position our program. We position our program--actually looking at high risk and high payback is because--the reason for that is because of where we are. And you can see that--if you think this is actually the research in the laboratory or research in the university, this is where NSF wants to put SBIR/STTR grants trying to bridge a little bit of the valley of the death. There is no way that we can help a company totally cross the valley of death. It needs a lot of money to go through this.

So somehow they will get to this end of the valley of the death but actually we--our goal is we need to help the companies take the risk, build technology, their team and also their business situation so that they can be much more attractive to the private sector so that they can attract private sector funding and move on. So we can see through this process the most important part is not only help them to develop technology but help them to develop a market viable technology and help them

to develop the entrepreneurs that can move forward.

(Slide.)

And so based on all of that how do we make our funding decisions is very challenging because we are looking at how they--actually beyond NSF or how--what they are going to be doing. And so let me talk to you about the peer review process. I know you already have a lot of discussions in there.

(Slide.)

So Step 1 is the program directors will go through the project summaries after receiving the proposals and group them into the panels based on the technical areas. And then the program directors will start to select panelists. And we have two groups of panelists.

(Slide.)

In phase 1 we really engage in technical reviews and we invite--we actually are focusing on the technical expertise and research interests. So where they and are and what technology trends they are following. And, also, if they have any relevant industry experience that will be very helpful. And also the diversity. We want to make sure that our panelists are not only having that research

expertise but also geographically and also from the underrepresented communities. So they represent many different aspects and perspectives.

And another group is commercial reviewers and this is really in the phase 2 panels that we focus on their business experience and also the market knowledge relevant to the product the companies are developing and also, of course, the third is the diversity.

And based on that we will invite the panelists and start up the panel. We usually give the panelists three to four weeks to review the proposals and the panelists provide their individual reviews before the panel meeting and they cannot see each other's reviews before the panel meeting. And after that they come to our panels. The program directors will convene the panel and so they are there and they listen to the panel discussions. And the panel will reach the concurrence about which proposal they want to highly recommend, recommend or do not consider but that's not the final decision. The final decision is actually made by NSF program directors so that may change.

(Slide.)

During the phase 2 panel we usually put

three technical reviewers there and three business reviewers there, and we put equal emphasis on the technical and the business aspects. And most of our business reviewers are usually either from venture capital firms or they are individual investors, serial entrepreneurs, corporate executives. And so we usually--and some of them are the university tech transfer office.

(Slide.)

And Step 4 is the program for director due diligence. Especially at the phase 2 but also a lot at the phase 1 level we did a lot work here. After the panel review, because the program directors already know the team at phase 1 level, they will start to do the due diligence. First, they will ask the PI to address--the PI means the principal investigator. I'm not sure if you guys use the same term. It means the company.

So we will ask the company to address the panel's concerns first. It's usually both technical and also the business concerns. And after that the program directors will go through the proposal one more time and this is actually the time to take a look at exactly what problems, what weaknesses the company has especially at a business perspective.

So we continue to request if they didn't provide enough revenue history. Usually they don't have much but if they do we really need that. And what's the IP status? Do we have the freedom of operation and what's the business model, what's the revenue model, what's the financing model.

And from there we also requested additional demonstrative information, especially for Phase 2 because we need to financially audit the company.

And at phase 1 level, after this, the program director should be able to make the decision. And for phase 2 we will continue for--unfortunately, this is actually our--it slows down our phase 2 process timeline. This will take at least two months for ours to wait. Actually our program directors just sit there and wait for the CPA firms to conduct a financial audit of the companies and make sure they are financially viable to receive federal funding.

So that's our peer review process.

(Slide.)

The phase 1 takes about five months and 99 percent of the companies will receive our notification by five months but they usually start

at about six months because, like many, they love to receive the money before they start. And phase 2 takes about nine months right now.

(Slide.)

So you probably wonder how we can do this and we can do this quickly. We take a lot of pride into what kind of team we have and we have a really excellent team of program directors and that's because they are the technical and the business contact to the SBIR companies.

And when we recruit them one thing that we--actually this is to emphasize here. When we are recruiting our program directors they must have strong technical expertise in the technical portfolio area they are managing and also they need to have extensive business or industry experience. And currently we have seven program directors, one senior advisor, Dr. Joe Hennessey, because many of you know that--you know him. And so among seven program directors, six of them were former funders of startups and six of them have very extensive research experience. Actually three of them were former faculty members who created a faculty job and started a company and became very successful, sold the company and joined NSF.

And four of them have very successful fundraising and investment experience. And four of them previously worked at large companies.

(Slide.)

So what do our program directors do?

If you take a look at the small businesses here--this is our PI or the applicants or grantees. And this is our program directors. Again we are using our program directors as the sole technical and business contact.

And, of course, we do a lot of work behind the scene with the program directors, including myself. I have to concur the award so we put out administrative support, financial audit, financing office to make the payment, and also the grant office to release the grant, everything--and probably I didn't list everything here but they are--most of them, except sometimes they interact a little bit with the grant officer, most of the time the small business--it's very clear to them that there's only one person at NSF.

They need to follow up and they need to listen to--and that's their program director. So it's actually--this is the person who is going to make a decision and also manage the portfolio. And

that actually puts a lot in there because we actually use this process to develop a lot of trust between our program directors and the small business community. Because when they ask the right questions during the due diligence they develop this trust and so that our program directors can provide the right business advice to them.

(Slide.)

And this is their responsibilities. I'm not going to read them all but I want to emphasize that the program director is also the person who approves the report if there is an interim report. If they don't approve the interim and final report the company cannot get a payment. We have to sign the payment. Otherwise, we can hold it back if the company is not performing.

And, also, a big deal we are doing is actually managing the portfolio. The program director is managing the portfolio very, very closely. And, if in review, the company is not performing, especially it is not moving forward in the business aspect, they actually give them--in this perspective and also they--the program directors are in charge of the solicitation. And also the outreaching activity I'm going to tell you

in a few minutes.

(Slide.)

So actually it is right here, outreaching activities. What we do is about 40 percent of our portfolio companies are related or have a very strong tie to the universities. So this is actually a very important part of our portfolio. So we actually do a lot of work to reach out to the university spinoffs. And that's why our program directors actually do go to the academic conference and present and help them to think about how to start a company. I'm talking about faculty members. And also the NSF conference and workshops, of course, the majority of the participants are faculty members. And also we go to the large technology-based incubators all the time to give them more information about our program and help them to develop proposals if they need to know more information about how to write a proposal.

And for other technology based startups we are not related to the university but actually someone is sitting in their living room or in their garage and come up with good ideas. We have a lot of successful grantees who are like that and those are--this actually is where our program directors

will go out and actually work with a lot of industry networks and also the investor network. We frequently go to the venture fairs and also networking with the VC firms and angels.

The reason I'm talking about this is not because we have overlap with the portfolio, it's because many of the companies don't--because they don't want to take the risk--actually are the right companies to ours. And so this is actually the flow but we do actually send a lot of companies to the private sector but they come down. A lot of companies, they think it's a great idea but it's way too early for me. They can send them to NSF and many of them became very, very successful. And, also, we go to trade shows. NSF in the last year--actually this year, at the beginning of this year, in January, had some 28 companies to consumer electronics show in Las Vegas and generating a lot of interest from the media and also, most importantly, from potential customers.

(Slide.)

And the assistance we gave to our applicants before--for the proposal preparation. The first thing is that before the proposal submission we do request them to contact their

program director with a one page or two page executive summary. And actually, very similar to DOE and what Manny has just mentioned, we use this actually what kind of proposals we're looking for and what kind of companies we're looking for. And we don't want to--we really don't want to waste our time to prepare a proposal if they are not a good fit to our program.

Another thing we do is that we put step-by-step instructions about a proposal submission on our website to help them--especially the first time user of Fastlane (sic). That's our system for proposal submission. And also we provide line by line budget instruction to make sure--make it a little bit easier for the entrepreneurs and we make our review on the funding criteria very transparent and it is posted on our website. Everybody knows that. This is what they're going to use and they can see. So if we do it right they know what factors they need to address.

And, also, during the phase 1 grantees conference the emphasis of our phase 1 grantees conference is really to help them to provide very comprehensive instructions, including the financial audit and also the fund raising. Everything that we

are--we emphasize and we are looking for we actually pull out instructions during our phase 1 grantees conference to help our company to develop a much more successful Phase 2 proposal.

And after declination of both phase 1 and phase 2 level we actually send them the panel reviews and the panel summaries. This is actually to give the feedback even if we cannot fund them or actually we want the companies to learn something from this experience and help them to move forward if we can.

(Slide.)

And the problem, as I already said probably a few times, is it's very commercialization driven. We have a phase 2b program. I already talked about it. Another supplement that we had recently was called Technology Enhancement for Commercial Partnerships, so-called TECP. This is a $100,000 supplement to help our grantees to form strategic partnerships with potential customers and to develop a product that's really tuned to meet a customer's need. So to really help them and stimulate the conversations between our grantees and their customers. So we allow them to go out and actually form the partnerships and come back and get

this $100,000 if we can.

(Slide.)

And also through our grantees conference we pull out entrepreneurial training. We started this about two years ago. So it now is about two years that we actually use our phase 2 grantees conference which is a three day conference to talk to our phase 2 grantees. It's all about business because NSF covers a very broad technical area.

We practically stopped making any technical presentations during our phase 2 grantees. Instead actually we focus very strongly on entrepreneurial training and this is actually from IP management to peer building to the board of governors and also to fund raising to strategic partnerships. We actually try to cover all the aspects of entrepreneur or the challenge an entrepreneur may face. And we strongly encourage them to apply all the skills they may acquire from other grantees conference to their companies. conference.

(Slide.)

And outcome evaluation. This is my last page if you already becoming impatient.

So we do external evaluation with National

Academy of Sciences and we also do internal evaluation. You might wonder why because the last time we had--the last one we had, the evaluation we had from NAS, that was actually in 2007--published in 2007.

So if we do our assessment every five years or six years, that's way too long. So we have actually one internal expert focusing on the internal evaluation and this is actually ongoing assessment efforts.

What he does is he actually takes a look at our grantees within the last ten years, the Phase 2 grantees, and he put the three year anniversary, five year anniversary and eight year anniversary there on his chart. And on those anniversary dates--I'm talking about anniversary after their graduation from NSF so after they finish the Phase 2. And even make phone calls to these grantees to find out first off if they are still existing. That means they did survive. And, second of all, what is the results they have generated?

And, of course, how much jobs they have or how many jobs they have generated and other questions. So we use this to give us a lot of insights about how we--this is totally internal

information but we use this to see how we want to link our technology--move our program forward and continuously re-innovate our program.

So that's all I have.

Thank you.

PANEL II DISCUSSION

HON. GOLDIN: Thank you, Grace.

We now have time for questions.

CHAIRMAN AUGUSTINE: Are you going to be taking questions for the whole panel or for Grace specifically?

HON. GOLDIN: For the whole panel.

DR. SNYDER: I have a question.

You commented, Grace, about the $45 million from SBIR funds that go to universities. Could you comment more about that? I didn't even know that you're allowed to use SBIR funds to go to universities?

DR. WANG: No, no, it's not $40 million. I'm commenting about my division. My division is called Industry Innovation and Partnerships Division. The budget is $190. $40 million goes to the universities, that's academic awards. Just like other NSF awards but it's focusing on industrial partnerships. And $150 million goes to

the SBIR program. No, we do not mix. That's not allowed.

DR. SNYDER: Right.

DR. WANG: Yes.

DR. SNYDER: But in that sense though you are using actual NSF money to--for giving new grants that are going to be for universities but for commercially--

DR. WANG: That's correct.

DR. SNYDER: Okay.

DR. WANG: Yes, that's what NSF put aside for industry partnerships.

DR. SNYDER: Yes.

DR. COLLINS: So I wanted to ask DOE in terms of its impressive shortening of the timetables that you're achieving, how exactly are your review panels conducted? Are these done in real time in the same room or is this all done electronically? Can you just walk us through how your peer review process works?

DR. OLIVER: Actually our programs run their own process. Again the majority--some of the programs--really only one is all panels. The majority are mail reviews. Some--again some of our bigger programs will have a mix within their

programs. Some are panels, some are not. But typically it's--you know, most typical is a mail review. It's a minimum of three technical reviewers. Our office actually handles that process in terms of sending out the forms and the applications and receiving them. We work with the programs to identify the reviewers and get replacement reviewers when they back out and things like.

And we typically give the reviewers three weeks to complete their reviews of the applications. And any individual reviewer, depending on program, may go from one to maybe as many as six applications at a time typically.

DR. COLLINS: But the reviewers don't interact with each other then. They send in--

DR. OLIVER: Right. So those are--

DR. COLLINS: --mail reviews.

DR. OLIVER: Those are independent--

DR. COLLINS: When you have a big discrepancy in the opinions it's up to the program people to sort that through?

DR. OLIVER: Right.

HON. GOLDIN: Norm?

CHAIRMAN AUGUSTINE: I wanted to pursue

the issue on the DOE approach. Supposing that I were working on a small start-up and we had really a terrific idea that is totally different from anything you've been working on and everybody agrees it's a terrific idea but it doesn't fit any of your FOAs so that I wouldn't have an opportunity to come in and compete but the idea is sufficiently unique. I don't want you to go put out a FOA on it because you would be giving away my idea so I want to protect the commercial aspect of it.

What happens to me?

DR. OLIVER: Well, you know, we generally advise those companies--again because of this competition requirement we have to put out an FOA in order to fund something. So we advise them to talk to the program managers to see if they can work it into a future topic. Now, again, they are not going to disclose--they can't--they also can't write topics so specific. You know, the guidelines wouldn't--that it's restricted to one company to apply. So even if they came in, we couldn't write a specific topic that just targeted that technology. It would have to be broad. So if it's in an area of say energy efficiency or solar energy or whatever, we would just broaden our solar

energy to incorporate if it fit. If it's way out in left field it would probably need a new topic but because of the competition requirement, yes, we would never put out a topic that really only one company could apply for.

DR. KATZ: I would like to ask Grace a question of when you talked about significant return on investment, what did you mean by significant?

DR. WANG: Actually a very good question. If you take a look at what our assessment effort internally--you know, assessment efforts, we usually consider if the company after three years or five years after the phase 2 project is completed, if they can generate a half million dollar revenue based on the technology we will say--of course, they are continuously working on that. We will say that's a--we consider that as a success and that's just in terms--that is just for the short term.

But the significant commercial potential we are talking about is really for the long-term. It's very hard, I guess, for all of ours to follow and there's actually two things. One is the visible. The visible value like the NSF former grantee, Qualcomm and Symantec or GT Solar or Blue Star Solar. These are the companies we generate

hundreds or millions or billions of revenue and that's, of course, very significant.

Another significant we are talking about is what I call invisible, invisible value. NSF has put in through other SBIR and STTR grantees is actually--actually I mentioned a little bit. It is help other companies to de-risk and also help them to survive during this time and develop into a much more sustainable and viable business. And I can give you the example of this is--there is a company in the Bay area that has been recently acquired by Dupont and it was called Novolyte. Novolyte is a former NSF grantee. We actually gave them an award to develop something--I believe it was in solid state lighting and they never made so they were struggling. They were--they were really struggling and never made it to that point. And during that time using NSF grant and also developing they find out the technology is viable for something else. And that's where they start taking off.

So we do now consider them as our success but their CEO I know is a venture capital partner--their former CEO told me that he said there are many nights that I cannot sleep and the NSF saved me because we could have closed the doors so many times

and every time--it was actually twice NSF gave them the phase 2 awards. So we have faith in their team and they made it. So that's the invisible value that we cannot count but actually is very, very significant.

DR. CASSELL: Grace, it was a very good presentation. I was impressed with the number of times it seems that your staff do a financial audit in terms of viability of the companies.

And I just wondered if maybe Manny could comment on that and possibly some of the NIH institutes in terms of how often that happens in the cycle of funding and by whom is it performed?

DR. OLIVER: In terms of--I guess I just want to understand the financial audit. I mean there are some financial audits that are performed by the--by our contracts office which are separate from the--I think what you're talking about is whether there is viability as the business is going forward. Is that--

DR. CASSELL: Yes.

DR. OLIVER: --that the intent?

DR. CASSELL: I think that's what she meant, yes.

DR. WANG: Yes, we actually--the financial

audit for NSF grantees are done by the contractor CPA firm.

DR. CASSELL: Yes.

DR. COLLINS: But to follow up on that, it sounded as if that actually adds some substantial time to the ability to give a phase 2 award at NSF as part of your process of making a decision and I didn't hear that same kind of time devoted to this financial audit from some of the other agencies. So I'm just wondering did you get burned at one point? Is there some reason why in the Phase 2 process this is insisted upon? Because it sounds like it costs you quite a few months.

DR. WANG: Yes. Actually I don't know the history there but we have been doing this for a long time and I think that's requested by NSF, the requirement, because it's a fixed amount grant. But at the same time I believe this actually can be done in the shorter time and that's why I'm looking into a review towards actually trying to revise the process here. It is taking too long.

DR. HODES: And just to follow up, the way it was described it happens at the end which was puzzling. So it's guaranteed to delay rather than having be incorporated in an earlier step in the

process.

DR. COLLINS: Does DARPA do this kind of financial audit?

MR. MUTTY: Yes. We have a Defense Contract Audit agency that just goes in and makes sure that they're viable and they're not--you know, they've got certain ratios that they test and it's not a lengthy process to do that.

DR. COLLINS: So it doesn't add to your timetable for getting the work--

MR. MUTTY: Not significantly, no.

DR. CASSELL: Does NIH do this?

DR. PORTNOY: Yes, all grants management staff do--we don't do an audit in the CPA sense of the word but they do extensive financial checking on companies in phase 1 but much more extensively in phase 2 looking at the ratio balance sheets to make sure that the companies can handle the grant, it has the controls in place and is financially viable. And companies, of course, are required to conduct their own audits as part of a standard term of award.

HON. GOLDIN: Just to follow up. Again in discussing this issue with a number of the different institutes, some of them said they selected the

contractor but they get held up in the formality of the grants office dotting the I's and crossing the T's to deal with a lot of these issues. And there was a general feeling among the ICs that one to two months could be taken off the process if the adequate work was done upfront.

DR. PORTNOY: So, you know, that's--you know, so as that--certainly there is time in the pre-award phase to be saved. And--but you don't want to do that type of work only for the companies you intend to fund. Otherwise, you're doing quite a bit of work for something that's not going to lead anywhere.

I do think there's room in the pre-award phase, though, to save time. A lot of NIH specific requirements and much of our technology requires that appropriate human vertebrate animal biohazard regulations are followed and in compliance. And when there are many, many types of our grant applications have these items flagged in review, that typically needs to be cleared pre-award. And so there is a back and forth among that and many other areas with companies in the pre-award phase that can in some cases lead to a lag or as time marches on a restricted award when we

want to make the award. But I think there are pre-award timing to be gained.

Additionally, at NIH, as far as I know, while certain institutes have a dedicated SBIR staff, grants management staff, typically SBIR/STTR is a small part of what they do. And, as can you no doubt imagine, the amount of time grants management spends on working up SBIR/STTR awards is disproportionate to the amount of dollars in proportion of their work load.

So there's a matter of dedicated staffing at the pre-award level also for increasing timeline that is an issue.

HON. GOLDIN: And just to finish the subject, another comment that was made is in the case of NIH many of these new companies are college professors who have--are making the transition from research into business and they need a lot of help.

And, again, it was felt that if more work could be done upfront with this extra three percent set aside and do better training that could also help do this compression in allowing the award to occur.

DR. PORTNOY: We agree and, you know, we

would like to use some of that three percent as a--I mean as a direct effect to try to shorten the timelines.

DR. BRIGGS: Just one comment listening to all of these presentations. One of the NIH dogmas in a way in a way is the separation of church and state, separation of program and review. And as I was listening to this I was thinking that this may be a setting in which that dogma doesn't always serve us well.

HON. GOLDIN: If there are no more comments, thank you so much to the panelists. It was very, very informative.

DR. SNYDER: Okay. So now we'll have a working lunch. So the lunch--that is go out, get lunch, come back and then we'll actually have--while we're eating, I suppose, Sally Rockey will be presenting to us.

CHAIRMAN AUGUSTINE: Let me--those of you who have made arrangements ahead of time, your meal is in the little room to the right outside the door. Those who did not, the cafeteria on the first floor, I understand is outstanding.

(Laughter.)

I've never eaten there.

And, please--I'm told you can bring your meal back up here so we continue on.

Let me also thank all of the members of the panel. It has been an extremely instructive session.

And you've noted Steve joined us a little bit earlier.

Steve, welcome. I'm glad to have you here.

And we will take a 30 minute break. So let's pick up at a quarter of 1:00.

(Whereupon, at 12:10 p.m., a break was taken.)

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

CHAIRMAN AUGUSTINE: Okay.

Thank you, everybody, for returning promptly.

To those on the telephone, let me just kind of check and see who is there.

Bill, are you there?

DR. BRODY: Yes, I am.

CHAIRMAN AUGUSTINE: Terrific, Bill. We want to give you the opportunity to speak or interrupt. Is there anything you'd like to say at this point?

DR. BRODY: No. I guess I continue to be struck by the lack of any understanding of the success, you know, the outcomes of the program. I think I got that sense from everybody. It seems to me, you know, it's hard enough to measure the outcome of what the NIH does in terms of research but it's a whole lot easier to measure the outcomes of venture capital. That's sort of how I would propose the SBIR program to be looked at. And, you know, I think it's hard to say much about it.

I mean you hear everybody implemented all the different ways but in the end nobody has collected enough data on how this works. I agree it

should be high risk so it should be a high failure rate, which is fine. The question is, you know, what's the success rate and is it at the right level?

CHAIRMAN AUGUSTINE: All good points.

Thanks, Bill.

Gil, are you there?

Clyde, are you there?

DR. YANCY: I've joined in, yes. I'm on now.

CHAIRMAN AUGUSTINE: Terrific. We heard you come on earlier. Is there anything you'd like to say at this point?

DR. YANCY: I didn't hear any of the preceding conversation. I'm sorry if there was a connection there but I joined in while you all were out at lunch.

CHAIRMAN AUGUSTINE: Oh, okay.

Well, is anyone else on the line?

Hearing none, Bill and Clyde, please feel free to interrupt any time you have a question or a comment.

We'll proceed then with the afternoon's session.

Sol, it's back to you.

WORKING LUNCH

CHARACTERISTICS OF A SUCCESSFUL SBIR/STTR PROGRAM

DR. SNYDER: Okay. We're going to have two talks followed by our third panel.

The first talk--in fact, one of the big issues that we're going to deal with this afternoon is outcomes metrics and how are things handled.

So, Sally Rockey will speak to us at this time.

DEFINING METRICS AND OUTCOMES OF SUCCESS

Sally J. Rockey, Ph.D.

Deputy Director for Extramural Research

National Institutes of Health

DR. ROCKEY: Okay.

(Slide.)

So thanks very much for having me.

I want to talk to you a little bit about our SBIR program and STTR program and how we define metrics and outcomes of success. I will say from the start, as the previous person on the phone just mentioned, that measuring--having metrics and defining outcomes for the SBIR program has not been an easy task for us. And we have struggled to do so but we have some things in place and we're hoping with the advent of the new authorization which

provides us with additional administrative funds that we will be able to hone our abilities to define our metrics and to measure our outcomes of success for the program in a better way.

(Slide.)

I also was very interested in the current--in the just previous conversation that you had on the phone with individuals because the idea of SBIR being high risk is certainly important. I think it should be high risk and cutting edge but when you think about that these are for-profit small businesses, being high risk can be extraordinarily dangerous for a small business who may have a very large investment in that particular study.

So we have to weigh that with the ability of a company, which is one of the major goals of this program, to become profitable and have profits from the technologies or services or the outcomes of their research is at the forefront of what we do, along with aligning those with our mission and assuring that NIH is getting what it thinks should be the outcomes of these programs.

(Slide.)

So let me start out with little caveats about what I'm going to talk about today. We have

had a number of studies through the NRC, the National Research Council, at the Academy regarding SBIR. And, as you know, in the reauthorization there is also a requirement that we have a study--continuing study by the NRC over--about every four years, I believe, on the SBIR program.

We have been under scrutiny by the NRC for many, many years and it has been a really great relationship that we've had with them. They have done very in-depth studies not only on our processes and policies and also on the outcomes of our SBIR/STTR programs.

We have a Commercial Assistance Program, our CAP program, and I'm going to tell a little about that and how we track under that. Our outcomes are often underestimated because we don't have the full cadre of our awardees in our outcomes database. So I'll talk to you a little bit more about that. And remember that we do also require, as the terms with all of our awards, whether it be SBIR or STTR or other awards, that invention reporting is a requirement of a term and condition. So if there should be an invention we also have information about licensing, et cetera. That has to come through our typical invention

reporting requirements.

(Slide.)

So, we had evaluations ourselves of the SBIR program outcomes in 2003. We had our National Survey to evaluate the SBIR program. And we survey companies that received phase 2 awards between 1992 and 2001. And of the respondents, 73 percent reported commercializing new or improved product, processes, usages and/or service in health-related fields.

Now, of course, it went into more depth than this in the discussion of what commercialization is and what we surveyed them on but a simple question was "have you commercialized anything," and we had a result there of 73 percent. But, of course, that was over almost a ten year period.

In 2009, we did this again and we surveyed companies that received phase 2 awards between 2002 and 2006. And under that survey that we did, about 61 percent reported commercializing a core technology or information supported by their awards.

(Slide.)

Now, when the NRC evaluated our program--first of all, they evaluated as to whether or not

we were meeting our program and legislative goals, which was of course supporting the NIH mission and supporting small businesses. Our goals, as the legislation provides, are simulating technological innovation using small business to meet federal research and development needs, fostering and encouraging participation by minority and disadvantaged persons in technology innovation and increase private sector commercialization of federal R&D. So that is actually the goals as set by legislation.

So what they found was we were achieving significant commercialization. You have to remember, too, that the NRC has looked at the STTR/SBIR program as a whole across all the different agencies, and maybe Sean will be able to talk to us a little bit about that, to look at how NIH has done in comparison to other groups. While it's not a clear comparative analysis that they did, they found that about 40 percent of our SBIR funded projects reached the marketplace, which actually is quite high.

A smaller number of these projects, about three to four percent, generated more than $5 million in revenues. That's really a skew. That is

not typical for this really early stage technology funding. And 58 percent of the phase 2 surveyed responded attracted additional investment. So when we talk about what is commercialization or what is success, bringing on additional investment is oftentimes, particularly in the SBIR program, considered a success that you bring in venture capital or bring in some other form of investment that is going to continue you down the road towards commercialization.

(Slide.)

Now, we have what is called CAP, our Commercialization Assistance Program. It is a specialized technical assistance program for SBIR phase 2 awardees and we established it in 2004. It is funded by NIH and we manage it through a contract with the Larta Institute.

We have had 690 SBIR programs--excuse me, companies take advantage of this program to date. And grantees from the past five years are eligible for the program. And we have had two different tracks. We had our Advanced Commercialization Training Track and our Commercialization Training Track. So these are two different programs that are offered. It's a 10-

month long program that includes a personal one-on-one mentoring and development industry connection. So depending on the maturity of the small business, they can take advantage of this program or not. They may not feel like they need that advantage if they have end roads into other industries or into additional sources of capital for their program. They may not need it but we have had almost 700 companies take advantage of this.

We have another program called TAP, which is our Technical Assistance Program. I'm really not going to talk to you much about that but I do want to talk to you a little bit more about CAP.

(Slide.)

So we use an online portal to track the company's performance over 18 months after the program ends. And these are the kind of things that we track. So they have gone through the CAP program and our real emphasis on our tracking SBIR/STTR to this date has been those individuals who are part of the CAP program because we have a captured audience at that point and we require them to provide us additional information after the program is over.

So the metrics we use are investment funds

raised. The grants or loans that they might have received otherwise in addition to what we have provided to them. New jobs created, Partnerships they may have developed. New products. Product sales. Financial indicators and qualitative assessment. So how are they feeling like they are doing?

(Slide.)

Here are some examples of some of our tracking, although our 2010-11 tracking is not complete at this point. This shows you from 2004 up to 2010 tracking.

And here is some examples of things that have happened. The orange bar here represents contracts or contacts with investors and partners. So that obviously is the most common thing that is happening out of the shoot after they get our SBIR award and have gone through the CAP program.

CDAs or confidential disclosure agreements are here. Initial proposals and term sheets, which are in the blue, and then deals. Now, as can see, the deals--because of the later date--have gone down slightly and we expect that more of those will occur. A deal can be a signed legal document. Essential that means that they are committing the

partner--committing partners to a process, a timeframe and outcomes. So, for example, in that you can include things like license agreements, technical collaborations, distribution agreements, acquisitions. Any of those types of things are considered in deals. Okay. So, we feel that this CAP program and the requirements we have for tracking after the CAP program are a good way to be able to see outcomes and measurements. However, remember that we are going for 18 months after the CAP program is over.

(Slide.)

This is again more. We have--this is non-government funding raised. Again, this tells you how much--with those companies that were involved in our CAP program--how much additional revenue that they raised towards their projects. And, again, because we're a little bit behind on some of these, and I'm not sure we see what happened here in 2008 and 2009, we all know what was happening with the economy at that time so that is, I think, quite understandable. But look at what we have seen here in 2010 and '11.

Now, remember this is only a subset of our SBIR/STTR recipients. So these are only those

individuals that are part of the CAP program. So that does make them a very specialized group. There are those that don't need to take advantage of the CAP program that may have additional revenue and may be a larger set of the revenue generated by a program.

(Slide.)

This is employment. This shows that we had since that time about 1,500 new jobs created by 355 companies. Fifty-one percent of our CAP companies reported an increase in employment. So we hope--and we take credit for that because of the funding that they received through the NIH SBIR/STTR program.

(Slide.)

Now, we have had what we call the Performance Outcomes and Data Systems, the PODS database, for quite a while. This is a database that's available internally. It is not available externally at this point. This is one that we feel, very importantly, that we would like to put additional administrative funds towards developing in a much more complicated way and ways that will allow us to do better tracking for both our--for all of our SBIR/STTR program.

And, also, once it is more mature, this database is more mature, we feel that we could actually allow a piece of this database to be visible publicly. We have had a lot of conversation with Sean at SBA because there is some interest in sharing the types of databases that we have together that will allow us as a federal government to be able to track our SBIR/STTR programs.

So this is an integrative flexible tool for program managers. Again, it's only for NIH internal use. It allows users to save reports and choose to share them with others and all data in PODS are primarily linked to our project numbers. So to our project numbers in our SBIR/STTR program--projects. And it allows us to report on the capabilities of some commercial outcomes.

(Slide.)

So currently in PODS we have SBIR/STTR award data source from our IMPAC II system. That's our internal grant system.

We have 2002 and 2008 national surveys of the program's legacy data.

We have all that information I just told you about from our CAP program is in our PODS database.

We have success stories.

We have other publicly available data that we and the recipient organizations have put in there regarding patents, publications, clinicaltrial.gov data, et cetera.

And it has a Google search link to each company.

And then it has a query ability to save or share and export these features.

One of the things I wanted to point out here, and I had to ask Matt what this was, was Quad Chards or charts. I hope it is charts. And so this--the Quad Chart includes things like the specific company information, the management team, the overview of the technology and its competitive advantages and your company's pipeline of products under development or a detailed description of the technology. So instead of having to look through a grant application, you have a quick and dirty on the company and on the type of technology that they are developing.

The Quad Chart also serves as the CEO summary that will be somewhat of a distillation presented at feedback sessions so we have a number of feedback sessions that go on.

(Slide.)

So that is it.

Let me talk to you a little bit about our next steps.

Now, as you see from what I presented to you, our approach to metrics and measuring success and outcomes has been somewhat piecemeal. And we have relied very heavily on NRC studies, on our own studies at different year intervals. And what we would really like to do is to implement a routine tracking of all the awards using multiple metrics, including long-term commercialization outcomes.

Now, again, we face the same problem with measuring outcomes with SBIR/STTR programs as we do with any of our grant programs. Once the grant is over the ability to track it throughout the course of its life becomes more difficult and what might be a technology that is developed seven years after the SBIR/STTR grant that NIH provided is over doesn't often link back with the NIH grant. I mean you can get it some way if you work through the patent database or other ways but it's not just an intuitive natural way to track these things.

So we are looking towards our additional resources. One of the things we very

much want to do is once we have the ability to use administrative funds, which the new reauthorization has allowed to enhance our programs, this would be one of our big targeted areas that we would like to go after. And, also, we will have to have OMB approval to track things in different ways, of course, than we normally do. As you all know, when we track and ask for information from our grantees, we have to go through OMB approval.

(Slide.)

And then the reauthorization, though, does require companies to provide updates on the commercialization outcomes both on the previous awards and going forward. So there is a much clearer edict by the reauthorization to say when you--to find a way to get those commercialization as outcomes from an award that already has resulted and/or that company comes back for further awards, we want to see what those outcomes have been.

And we also want to expand our CAP program to STTR. Right now it's only for SBIR phase 2. So remember we want to extend that CAP to the STTR. And we want to enhance and revise the final report. Remember that all grants at NIH have to have a final report. We think that, if we can, we would like to

revise that so we can have specific metrics that we could ask the winners, the SBIR/STTR winners, to report on in their final report. And that would be at the end of the award. But then we could in some way use that to do the follow on tracking. We have to figure out a way that down the road we are able to track these technologies.

Like we have talked about with tracking individuals that are supported by NIH where we need somehow to barcode them and be able to track them through the life of their career, these technologies that are developed at different stages and at different times based on support they have received from the SBIR/STTR program, we need to be able to track that through time as well.

So that is, I think, all I have.

Yes.

And I don't know if you wanted to let Sean go ahead because he's on a tight schedule or if you want to ask me questions and then go to the panel.

Okay.

DR. SNYDER: Yes.

Since there is this tight schedule maybe Sean will speak now and then we can have questions afterwards.

PERSPECTIVES FROM THE

SMALL BUSINESS ADMINISTRATION (SBA)

Sean Green, Associate Administrator,

SBA Office of Technology

MR. GREENE: Hi.

I am Sean Greene. I'm the Associate Administrator for Investment and Innovation at the Small Business Administration.

First of all, thank you for taking the time and inviting me to join. I'm very excited to be here and be as helpful as I can be.

Let me start just by giving my email address so that if at any point anybody wants to follow-up on anything, please feel free. It's sean.greene@SBA.gov.

Now, I have made a radical decision not to use a power point because I was once told that if power corrupts, power point corrupts absolutely.

(Laughter.)

And I have to say that's a standard line I use whenever I'm speaking and I always get some laughs with the exception when I said it at a Microsoft developer's conference.

(Laughter.)

Silence in the room and so I just moved

on.

So, what I'd like to do in my remarks, and then potentially leave time for questions, but I'll also be on the final panel, is talk about three things.

One is a little bit of context of both my background, what SBA does in the SBIR program and why this really is a critical time for the SBIR program.

Secondly, talk about reauthorization in general. And I know Matt covered a fair bit so I think we can be pretty quick on that.

But then, third, be very focused on implications on some particularly relevant issues for NIH in the SBIR reauthorization.

So quickly in terms of my background, I come to this as a private sector person. I spent 20 years in the private sector. I had been a management consultant at McKinsey. Please don't hold that against me. But I've been an entrepreneur and then after selling one of my companies I became a seed stage investor. So I come to this out of the entrepreneurial ecosystem. At SBA I run the Office of Investment and Innovation but broadly speaking I'm responsible for SBA's efforts in high growth

entrepreneurship. So more specifically within that portfolio I have the SBIR program but also the SBIC program, which is a $16 billion fund of funds, and I have been very involved in the administration's Start Up America effort, which is largely focused on mobilizing government resources, as well as private sector resources on behalf of high growth entrepreneurship across the country.

The reason that is important right now is all the data shows that if you're looking at net new job creation in the economy, not only is it disproportionately concentrated in smaller businesses, but it's even more concentrated in the tiny subset, four to five percent of those small businesses, who effectively contribute all of the net new jobs in the economy.

So in general, we need to be doing everything we can to stimulate not only the start-up of new companies but the scale-up of existing companies but particularly in the economic environment we are in that is particularly critical.

And, for context, what we have seen since 2007 is the decline by approximately 25 percent of the number of new start-ups per year and some estimates have traced that to a drop of about two

million jobs. And not only a decline of start-ups but a marked acceleration of the death rate of companies. So now more than ever we really need to focus on these kind of programs.

Also, for context, again within the broader administration initiatives, as we're talking about the SBIR program, we need to think not only about the reauthorization but broader administration efforts on things like improving the commercialization of federally funded technologies to get more ideas out of the lab and into the marketplace. And the President issued an executive memorandum focusing on a range of things that can be done across the government to do that. As well as a broader set of presidential initiatives focusing on streamlining and simplification with a recurring theme for entrepreneurs and small businesses the federal government is incredibly hard to navigate. And so it's incumbent upon us to make these programs more effective and to continually be looking for ways to streamline and simplify.

So in terms of--and let me also clarify that I am not an expert in health or sciences. My entrepreneurial background is in other disciplines so I'm clearly not an expert here. That being said,

I'm going to be talking about the ecosystem. One of the things we did in the Start Up America effort, for instance, was the first thing was a radical idea of getting out and listening to our customers.

So we spent several months talking to over 1,000 entrepreneurs and investors in the ecosystem asking them the question "what barriers are you facing to growing your companies and creating jobs and what are the concrete things that we can do to change that? We got great ideas. I won't give you all of them all but radical ideas like, hey, why doesn't the government just pay customers faster? So the President issued an executive order to pay in 15 days all small businesses.

Somebody gave us the idea of, hey, if we want the government to be more entrepreneurial why don't we get more entrepreneurs in the federal government. So we created an Entrepreneur in Residence Program that was actually piloted at HHS within FDA and that we're rolling out at the White House level. Literally, we have just announced five projects. We have got 18 presidential innovation fellows we are looking to fill. We have had over 1,000 applicants. So lots of good other stuff happening but again largely focused on this.

So, specifically, I think for the SBIR program there is a moment in time now to have a tremendous impact on this ecosystem. And to give you context, across all 11 agencies we are talking about $2.5 billion of financing or cash within the form of grants or contracts to entrepreneurial companies. The entire venture capital industry at the seed stage only puts $1.6 billion in. So what we are seeing in venture is going to later and later stage, in general, let alone--since we've seen marked decline since the financial crisis. So again now more than ever the capital coming out of the SBIR program has a potentially massive impact on the early stage innovative technology companies.

So I won't belabor the basics of the SBIR program. You all know it at this point. You know, four primary objectives, increasing innovation, driving higher levels of commercialization of federally funded research, allowing small businesses to participate in federal R&D spending, and then increasing participation of minority and competitively disadvantaged businesses in federal R&D.

So, with those high-level goals--and, again, I think you have all seen the National

Academies studies that basically conclude that the program is, you know, sound in concept and effective in practice. There's lots of other data that highlights success of the program. We saw this question earlier. The National Academies studies have shown that across all agencies approximately 50 percent of awardees actually get a product to market. Other studies have shown things like the R&D 100, which is evaluated each year, the 100 most innovative technology breakthroughs in the R&D space. You know, a full 25 percent of those that have been cited by the R&D 100 were companies that were funded by the SBIR program.

So lots of good progress.

I think with all that being said, my evaluation is what we have here is a good program that can still be a lot better. And in the context of the reauthorization what we have is both a mandate from congress to improve the program, as well as a targeted set of opportunities to improve it in a meaningful way.

So quickly on the reauthorization side, you know, I think--before we go to reauthorization, coming back SBA's role.

So SBA has a very specific role in the

program.

Obviously, the primary action, the decisions on the companies, how the programs are run happen at the agencies. But SBA has kind of four discreet roles in the program.

The first is to set policies for the program. So the SBIR is authorized as part of the Small Business Act. And so when it comes time to translate the statute into policy directives, et cetera, we have primary responsibility for that. So first of all is policy role.

The second role is a reporting and a performance--oversight and performance measurement role. So while a lot of the data gets collected at an individual agency in terms of looking at the performance of the program as a whole, we have responsibility for that and reporting that out to the public and to congress.

The third role is an outreach role. Again, each agency can do targeted outreach relevant and consistent with the mission of that agency. We do a broader set of outreach to small businesses across the board. We do things like SBIR.gov which again provides news and information about the program as a whole across all agencies.

And then, finally, there's a role--a convener or facilitator, whatever the right word is, to work among the agencies to do things like share best practices, identify best practices and share best practices and help foster collaboration among those agencies. So, again, the two decisions happen at the agencies but we work very closely with the program managers across all those agencies to do that.

So, I guess, the final point before I jump into the reauthorization, I think that coming back to this broader opportunity at a time when the administration is saying it's a key priority to drive higher rates of commercialization of federally funded research, and we really need to do more to get the ideas out of the lab and into the market. Here we have a program through its fundamental construct is well suited to do that. So trying to turn every scientist into an entrepreneur isn't necessarily going to happen but it is a program that can support and fund people who are already both scientists and entrepreneurs. As well as potentially and particularly through the STTR program, partner entrepreneurs and scientists in creative ways, again to get more ideas out of the

lab and into the market.

So in terms of reauthorization, I think probably at this point most of you know the history. Fourteen successive temporary extensions that took place over, I believe, three years. Lots of disagreement and in Washington where you're used to seeing Republicans and Democrats disagree, this was largely more the House and the Senate disagreeing with each other and it wasn't a political party issue. A handful of key changes that were largely debated. The good news is now the President has signed the statute into law and we are very busy working with the program managers to implement it. It was signed into law by December 31st. So we are smack in the middle of the implementation.

In terms of the process of where we are, and I think Matt gave a snapshot of this. Really quickly, the standard joke I have been using, that grammar rock cartoon that told us how a bill becomes a law, they never did the sequel in terms of how detailed regs get written after the law is implemented. But we kind of have two parallel processes going on. One is part of the reauthorization deals with SBA size standards about how we define a small business. And so all of the

issues of venture capital participation, affiliation, foreign ownership are part of that. So we have got one timetable for that and these are a broader set of regulations that SBA uses across all of its programs. As you can imagine, those are complex set of rules keenly debated, et cetera, et cetera.

Those rules we have issued proposed rules for. They are out for public comment now. The public comment period ends next week. And then after getting the public comments, we will then revise the rules and we have a statutory mandate to issue the final rules by the end of the calendar year.

Separately, then there is a policy directive, which is more an internal set of rules that SBA issues to the agency as guidance and rules about how to administer the program. We are very close to getting those rules out. Our deadline was June 30th so we're a week or two late but we are very close to getting those out.

So that is on the process side.

In terms of the substance--and again, I think, Matt, you went through most of this.

Just really quickly, obviously long term

commitment to the program, six year reauthorization. That was critically important in our view because it's hard for the agencies to plan and it's hard for small businesses not knowing if the program is going to be around. They are clearly increasing the set asides. As you know, there are some changes in the rules, including venture capital participation in CAPs and we talked about that.

Clearly an important part of the reauthorization mandate is a higher sense of tracking performance, measuring performance and tracking it over time. And then, equally importantly, a targeted set of initiatives and guidelines of ways to improve performance. Simplification, faster turnaround times, more support for commercialization, higher levels of fraud, waste and abuse management, and so on.

And just as critically, as I'm sure you have heard the folks from NIH tell you, administrative funding to actually get the resources to put in place.

I will put the caveat that the administrative funding is a pilot program for three years, which kind of sets the pressure to say on all those performance issues it's going to be

critically important that over the next three years we move the needle, whether it's on the timelines, and commercialization is going to move the needle in three years for timeline, but we move the needle in some of these areas to show that funding is being put to good use.

So from my perspective, you know, without going through the full list of everything, the reauthorization bill focused, in particular, on some areas that I think are especially relevant for NIH and, in particular, relevant for this advisory committee. I think in some ways the timing of your effort at the advisory committee here is actually perfect and I don't know the full history.

I understand that you are evaluating this not knowing when reauthorization was going to happen. But even with reauthorization being done there is still a tremendous amount of work to do to implement the changes that are going to drive this. And I think what I have seen in working with NIH folks is you've got a group of talented dedicated staff, both in the individual institutes as well as at the center, working in this program. The list of things that they have on their plate is incredibly hot. So I think a couple of places where you, as an

advisory committee can be tremendously helpful, is prioritizing and your guidance and view on the places that you think are most critically important to move the needle.

And then, secondly, I know from having been inundated with all of the daily, you know, to do lists to get stuff done, having a fresh set of eyes looking at out of the box solutions to addressing some of the issues here across the 101 changes that have to happen. And so I think your timing as the implementation is really just in its infancy is great.

So, in terms of focus, a couple of very specific places that in my mind are particularly relevant for NIH.

One thing that I'm sure you've heard before, I hear over and over again when I'm hearing from small businesses, is cycle times in the program as a whole but also at NIH are just way too long. And for small businesses where time is money, right, and, you know, a year can be four life times for many of these companies, anything that we can do to shorten cycle times is critically important.

And then, secondly, is to increase the role of commercialization not only in post award

support but how we evaluate commercialization potential in the companies themselves.

So let me drill down a little bit more specifically.

First of all, on timelines again there's clear statutory mandates in terms of the selection process that for most agencies there's a statutory mandate to say from the close of the solicitation to the decision on the company should take 90 days. For NIH the mandate was one year. I would challenge the group to say out of their opportunities to do it even faster than a year and how can you beat the statutory mandate.

Secondly, there's another set of challenges from the time of decision to the time of funding. How can that be as fast as possible? Right? And again this is something that we're tackling in other agencies as well.

I don't pretend to have the answers of what the right solution is. There's a range of ideas being put out there but this is a place where third party outside view of where there are opportunities is incredibly important. Some of the ideas that we're hearing from the outside, from other agencies are things like can--you know, is it

okay for this program to be slightly different than other R&D programs within NIH? Is there a way to differentiate phase 1, which is a small dollar amount, from phase 2 in terms of that process and looking for maybe a condensed--a more condensed or aggressive cycle on phase 1 where 150K is at stake rather than a million plus award.

Where are the opportunities for ever green solicitations? I know this is one of these that scares program managers because they think of the additional workload but an idea that has come to us is, look, it's not just about the time from the close of solicitation to an actual award. But if you spend six months waiting for the solicitation deadline, we have to--you know, that's how an entrepreneur looks at it as well. So where are there opportunities for potentially more rolling solicitation closes rather than--you know, that will require resources. That will require a redesign of the processes. So none of these are easy but those are potential kind of broader out of the box solutions of how we can tackle timing issues.

Second is--a huge issue obviously is commercialization. Clearly just from the 30 minutes I just saw I know that's a critical issue

for you.

Within the reauthorization there is an authorization for pilot program for up to 10 percent of the total award specifically targeting commercialization. You guys already do a matching program that has been identified as a best practice across all federal agencies. So looking and saying how can we can do more with that. That is another lever.

Other transactions authority is a specific vehicle that other agencies, including DARPA, have looked at as again a specific technical mechanism to help.

And, you know, a third broader idea is where are there ways for more aggressive partnerships with third parties, whether those are on the investor side or, in particular, with accelerators and universities. So as one targeted example of this we are seeing across the country a proliferation of accelerators and proof of concept centers. One example, the Deshpande Center at MIT, right, who is already doing a lot of work to identify promising research in the labs at MIT and running a competitive process and evaluating the commercialization potential of those ideas.

How can you work with and piggyback off the work being done, not just at MIT, in universities across the country via these to say, here, look at here, a third party validation and commercialization potential. But just as importantly, post-award they already have ecosystems of support with mentoring from alumni, et cetera, et cetera, built into it. Where are those kind of partnership opportunities?

A third kind of targeted area for focus is simplification. And while we all want Ph.D.s to be doing the research and the science, we shouldn't need Ph.D.s in federal grant writing to apply to the SBIR program, right? So where are there targeted ways to reduce the complexity for newcomers coming into the program? So how can we make this so people don't have to rely on third party grant consultants and writers to help and navigate the process?

How can we do it so that promising inventors and scientists aren't turned off from the complexity of the application process that precludes them from applying in the first place? Again, this isn't something that happens overnight but where are there targeted opportunities to do that?

A fourth concrete idea is the STTR

program. To look at it as a potential pilot program. So you have an existing process for all of these things. Modifying and changing it will take time. We all love the notion of clean sheeting and designing things from scratch but very often in a large organization that's hard to do simultaneously with running the day-to-day business.

Where with STTR, because it's smaller, are there opportunities to try more out of the box clean sheet approaches there, demonstrate that they can work and then potentially look to scale in replicating the SBA program where relevant?

And then, finally, the issue of performance management metrics I think that we don't need to get into great detail there. We'll talk a little bit more. Just a couple of thoughts following up on Sally's presentation.

The thinking that we have on performance metrics is first we need to do this across the program as a whole. Secondly, as opposed to relying only on surveys the notion that when people apply require them to update performance on past awards becomes the single best carrot, right, in order to get the data. And then you are building on a database over time on a consistent ongoing basis

that can be supplemented by surveys and other techniques.

And then to have a standardized set of metrics that work across all agencies at a baseline but then can be customized agency by agency to be relevant for them.

So those are a few kind of concrete places that I think are particularly relevant. Just some final broader thoughts.

I believe in your process, kind of what we want in the next steps is to communicate actively with other third parties. I think this is incredibly important. I have found, whenever I get out of Washington and go listen, it's tremendously valuable. I would encourage you as you do that to not only talk to awardees, critically important, but talk to promising innovative companies who have chosen not to apply and understand why they're not applying.

I would encourage you to talk to not only venture capitalists but angel investors because they're an incredibly important part of the ecosystem as well.

Not just the buyers of the world but there are other smaller business coalitions and

associations who have a clear set of ideas and viewpoints as well.

And I would also recommend specifically to talk to another federal advisory committee, NACIE. So there's probably a complex set of rules of how one federal advisory committee can talk to another that none of us--no one understands. But NACIE is the National Advisory Council on Innovation and Entrepreneurship that has been run out of the Department of Commerce.

They have looked at a range of issues focusing on innovation and entrepreneurship but the issue of driving higher levels of commercialization of federally finished research has been one of their areas. Some of the people involved include the Mary Sue Coleman, the President of the University of Michigan; Holden Thorp from UNC; Chuck Vest, the former President of MIT; Desh Deshpande, who is a successful entrepreneur, who funded the Deshpande Center that I mentioned. And so they've been thinking about these sets of issues, not specifically about SBIR but more broadly, and I think there's a potentially useful collaboration there as well.

And then clearly I think, you know, to the

extent possible, and you're already doing it, by bringing in other agencies who have perspectives, ideas and things to learn as well.

So, with that, I will stop.

Again, I don't know if I should take questions now, if the chair defers, or just stay for the panel. Whatever works for you.

DR. SNYDER: Why don't we open up the floor for questions for both speakers?

Okay.

DR. CASSELL: Could you tell us a little more about this Committee for Innovation in the Commerce Department, what its function is, how long they've been in existence and maybe some of their accomplishments?

MR. GREENE: Sure.

So, the committee was founded, I would say, about a year-and-a-half ago. Three co-chairs. Steve Case, founder of AOL; Desh Deshpande, founder of Sycamore Networks; and Mary Sue Coleman.

So their charter was a relatively broad one to say what can we do to stimulate more innovation and entrepreneurship? They really did zero in on two targeted topics initially. One was access to capital issues and then, secondly, the

question of improving commercialization of federally-funded research.

On the access to capital one of the big successes that we have had in the last year was the passage of the Jobs Act, which was focusing on a legislative change that changed a bunch of rules really at the Securities and Exchange Commission about enabling higher levels of capital formation for small businesses, both at early stage funding like crowd funding, as well as opening up IPO markets again. So the recommendations of NACIE were fundamentally supported by what ultimately wound up in the legislation.

On the commercialization side, one of the big successes was organizing a letter signed by-- I think the latest count is over 150 university presidents explicitly committing to a set of actions to drive higher levels of innovation and entrepreneurship.

And so there is still work to be done to say how do we go from the letter to a detailed playbook of what's to be done. But in terms of mobilizing a commitment really from the highest level of the universities to do this, I think it's a phenomenal start.

DR. SNYDER: Other questions?

HON. GOLDIN: I read through all the documents. I went through the metrics. I heard all the discussions here. I really feel there is a big weakness in the metrics and there is lots of discussions about it. I took the trouble of reducing the metrics to specific numbers that I could understand. I took a look at how much was spent on SBIR versus how much was reported out the backend in terms of number of jobs. The number of jobs that went into supporting SBIR was significantly larger than the claimed number of jobs coming out.

I don't even want to repeat the numbers but it seems to me the challenge--if you can't measure it, you can't manage it. And there needs to be some very deep thinking at all levels on this SBIR program or else a day of reckoning will be coming.

And when one looks at the magnitude of the dollars and the budget that the NIH has, I think it's very important to be able to work across the government and with the help of entrepreneurs and venture capitalists and those that are involved in the process end to end to come up with metrics that

are realistic, not over the top, not over promising, and this seems to be, to me, the most important task we could undertake together.

MR. GREENE: I strongly agree. I think a few thoughts. The systematic collection--so we have struggled--my personal opinion at least is we struggled a lot with what's the appropriate definition and my personal bias is let's not let the enemy--you know, the perfect be the enemy of the good. Let's start getting the data on a consistent basis even with--you know, getting 80 percent of the way there, to just start moving on that is critically important.

We have worked now across the agencies to have a starting point of what I believe is a good definition. We collectively have been underfunded to do that. We don't have that excuse anymore. With the administrative funding in reauthorization we have that.

Let me also say when I said the program is a good one that can be much better, I think SBA, in particular, on the question of performance management data, you know, historically has not funded and supported that in a way that it needs to. And so, you know, we're part of the problem and we

have to be part of the solution.

I think the good news on that is my boss, the administrator, who has now been elevated to Cabinet Secretary, personally understands the importance of this program, personally understands the importance of this issue and is making the resources and people available to work on it.

It's not going to happen overnight but it has got to be a high priority.

DR. SNYDER: Other questions or shall we keep moving?

DR. COLLINS: So thanks for a really informative presentation.

One of the things we talked about this morning was with the new authorization the problem in terms of a cap on the amount of dollars that can be awarded in a phase 2 without getting a waiver from SBA, and certainly for many of the projects that we are most excited about, a $1.5 million cap is going to be a serious problem in terms of being able to live out the hopes. So I guess I'm curious to know how SBAS intends to handle those waiver requests because we're likely to be on your doorstep a lot.

MR. GREENE With great trepidation.

(Laughter.)

No, a central issue and critical issue for NIH.

Two issues that I didn't really talk about but that are critical for NIH. One is venture capital participation, which obviously has been a very important issue and we can talk more about that if necessary but specifically the caps. And so we're kind of, you know, in the middle trying to make it work on both sides. Right? So the folks at NIH have been very clear that that is important--the importance to commercialization and outcomes is tied to the ability to, you know, giver larger awards to promising--you know, at the same time Congress was very clear in the mandate in setting the caps.

So here is our approach and how we're thinking about it, right? There's an opportunity to look at a bunch of levers, right, as opposed to just kind of one large award to say, well, where is there opportunities within the ten percent commercial--the civilian commercialization pilot program to give larger awards with that?

There are opportunities for us to give targeted waivers but, by the way, we don't want to be in the business of micromanaging, you know, any

agency at the individual award level to determine what is an appropriate waiver or not.

The third lever is the opportunity to do subsequent awards to the same awardee to further pursue and then obviously there's a potential to use non-SBIR dollars or to matching dollars as part of the matching program to get more capital.

So there's a range of arrows in the quiver, if you will, that may be harder to manage but that's a starting point.

Secondly, though, as part of the reauthorization, there was created an interagency policy committee that is designed to look at policy issues across the program as a whole. That policy committee has been given--has been charged with a targeted number of reports on specific and important issues to the program as a whole.

One of those issues is evaluating and making recommendations on the importance of flexibility in award sizes to the program as a whole. And that report is due a year from now.

So there's an opportunity even within the construct of what has been mandated in the statute to say, "Let's do a detailed study that demonstrates the importance of larger awards and more flexible

awards, whichever way they come to the program." And it may be that for that kind of study that's a great opportunity to use the National Academies or some other third party to conduct that.

So in the short term we've got a bunch of arrows in our quiver. At the same time let's be doing the study to demonstrate the importance of more flexible award sizes to the program as a whole.

DR. SNYDER: One other question. Is there waiver possibility for the venture capital 25 percent cap?

MR. GREENE: No.

DR. SNYDER: No.

Gail?

DR. COLLINS: Just to be clear, that's 25 percent of the total SBIR budget can't go to companies that have more than 50 percent venture capital participation. It isn't that you can't fund a company that has more than 25 percent VC.

DR. SNYDER: I know.

DR. ROCKEY: Right, and I just wanted to just add that in the past when we looked historically when we had venture capital backed companies, we ran around, I think it was, 15 percent of our companies have VC. So we weren't even

bumping up at that cap. It could be more now but we don't know.

DR. CASSELL: Sally, in your presentation you mentioned something that I think is critical and that is in terms of next steps would be OMB approval for being able to attract the awardees after the end of the award. Is that a given that you'll be given that approval? How difficult do you think this is going to be to get that? Because without it, it seems you're not ever going to be able to have the metrics that you really want to measure success and impact.

DR. ROCKEY: So it's part of the Paperwork Reduction Act that you have to have approval to collect information from more than ten people. So whenever we add additional elements to our reports that we require, like our final reports or our annual reports, we have to go through a process to have that approved. In general, we get it approved but it is a process and you have to go through it. So that was just to put that on the table. If we collect additional information, particularly if we're going to try to collect information--this is true for all NIH grants--beyond the award--I mean once they no longer have NIH funding--then it

becomes even more difficult to not only get approval but also figure out how you're going to do that. Where are the entry points to collect that information?

MR. GREENE: Let me just add while I would never use the word "given" and "OMB" together in one sentence at any time, particularly given the statutory mandate to collect the information, you know, we do feel good that--and then tactically we're doing two things. In addition to the agency submitting their own, we're trying to submit this on behalf of all agencies to do a parallel processing and get the foundation established as well.

HON. GOLDIN: The NIH, in our discussions with a lot of the different institutes, they really feel caught between a rock and a hard place. They want to collect this further out data and the Paperwork Reduction Act is preventing people from doing their job.

So it would seem to me that if the SBA worked together with the White House for special dispensation, a lot of good people will get a lot better work done and that, by the way, may be the biggest problem with the metrics.

DR. ROCKEY: So, I totally agree with you.

I think it's--and one of the most critical aspects of that is that if we are going to ask for more information, we need to only ask for that information that we think is critical and that's why defining what those metrics would be would be of utmost importance and then go forward to ask to be able to collect that information.

MR. GREENE: I think also practically while we're getting all these approvals for the data fields, we've got to be building up the system. So it's happening in parallel. We're not going to be sitting around tooling our thumbs waiting for the approvals.

DR. SNYDER: Gail, you get the last word.

DR. CASSELL: Well, I was just going to say along those lines it would be really nice in terms of job creation, getting back to Dan's point earlier, to know a little bit more about what types of jobs are being created, the duration of those jobs. I mean this is being looked at as one of the main mechanisms for stimulating economic development, both at state and national levels.

CHAIRMAN AUGUSTINE: Yes, I would just add a word of caution that supposing one of the results of SBIR grant were that it led to the

prevention of a very serious disease but created no jobs. It seems like that would be worth something.

(Laughter.)

DR. ROCKEY: Also I think you have to remember the scale. I think on average our SBIR companies that we support at NIH are 15 people or less. So the idea that they are experiencing growth and even adding one or two jobs to their company is actually pretty significant. So we have to keep that in context of how small many of these companies are that we do business with.

DR. NEIL: I'm speaking figuratively now but you need some way of radio labeling the dollars so you can follow them through the economy, and think about that paradigm.

DR. ROCKEY: We've got a job for you now.

(Laughter.)

DR. NEIL: Could I ask just one more question of Sean? I mean, in all this talking about waivers and grants and so on, I mean how is SBA thinking about this. Is it to fund projects or to lower the cost of capital for nascent companies that want to try to grow or try to do a project?

MR. GREENE: Yes. I think this is a

question of lowering the cost of capital. When I put my private sector hat on or investor hat on, in many of the cases what we're talking about is funding R&D projects that are--where there is fundamental technology risk that's prior to where most investors want to invest. They want to see some level of proven technology and then investing against the business risk. So you're talking about kind of part of the ecosystem that many private sector companies aren't ready to support because of the fundamental risk involved.

That being said, linkages to the private sector in which there are investors who see powerful commercialization potential if the technology can be proven is a great partnership. And, similarly, even in the context of venture capital funded companies, as I'm sure you know, it may be that the venture capital has gone in for the development of certain drugs but the grant is supporting the development of completely related but different drugs that the venture capital doesn't want to fund. They want to fund getting to the next phase of clinical trials for that drug.

So I think it's very complementary and it really isn't a question of lowering the cost of

capital. It's funding projects that wouldn't have gotten funded otherwise.

DR. NEIL: Okay. You could look at it that way but I still see it as lowering the cost of capital if you are attracting capital from private sources by reducing risk--

MR. GREENE: Sure, because this is nondiluted complementary capital that, you know, complements their capital and provides more resources to the partner; yes. Particularly in the matching environment by the way--to the matching program, yes.

DR. SNYDER: We will move into our panel number three, which will be moderated by Susan Shurin and which Sean will join the people up at the stage.

PANEL III DISCUSSION

Moderator: Susan Shurin, M.D., SMRB Member

DR. SHURIN: So we have a challenge in this panel, which is to talk--actually it's to talk about metrics.

(Slide.)

I'd just like to make the point that the challenge that we have in terms of metrics of return on investment for the NIH is not in any sense unique

to the SBIR program. This is derived from a book from 1997 by Donald Stokes. It's called *Pasteur's Quadrant: Basic Science and Technological Innovation*. The point he makes is that there are sort of two main drivers. One is the quest for knowledge and the other is quest for application. Quest for knowledge is on the Y axis, quest for application is on the X axis here, and there's no and yes.

So if you have the major goal being pure basic research, primarily a quest for basic knowledge, with no particular aim of application at all, he calls this Bohr's Quadrant.

If it's a quest for application with no quest for basic knowledge, he calls it Edison's Quadrant. This is the pure applied research.

If it's doing both, he calls it Pasteur's Quadrant. And I think he named the book that because I think that's what really he was aiming for.

Chuck Vest, who was just mentioned by Sean, talks about this and he likes to call the one that has neither a quest for basic knowledge nor application the Vest Quadrant.

(Laughter.)

So I didn't--I thought he could say that but I wasn't going to.

So our goal obviously is to stay out of that lower left quadrant where we're not trying to get anything out but the challenge that we have in terms of trying to look at what the return on our investment is, is not unique to this area.

On the other hand, I think what we're really talking about is Edison's Quadrant on this, the pure applied research. We have a lot of work--virtually all of the work that has ended up yielding Nobel Prizes is ultimately in Pasteur's Quadrant, including a tremendous amount that primarily was aimed at getting basic research which ended up later being applied.

So this panel has the longest set of instructions, the most people, the least time and so really what we're supposed to focus on are how do we measure the success of the programs, to define commercialization and is commercialization an adequate metric for the programs that you guys are--that you're involved in, and what is the timeline or the time course to measure success.

So trying to focus on sort of those major topics. How do you define success? How do you

define commercialization? Is commercialization--is that an adequate metric? I think we've already made--heard several comments and people saying they don't think that is--it's not the total story. And then what the time course is.

And I'd like to start, I think, with Sean as our first panelist and last speaker.

If you could each aim for something on the order of five to seven minutes we'll stay more or less on time.

Sean Greene, Small Business Administration

MR. GREENE: I'll just keep it one to two because I just spoke.

But on the way we're thinking about commercialization across all agencies is in terms of standard definitions. It is first the definition of did you get a product to market. And that then gives you the ability to assess the issue if you had a useful product even if it wasn't sold commercially but that had major impact in terms of curing diseases, et cetera. You'd be able to evaluate it.

So did you get a product to market?

And then separately a set of financial metrics.

Now, in defining did a product get to

market across DOD, NIH, National Science Foundation, there are obviously many different definitions.

We then would recommend at that point you give flexibility to the agency. So for NIH did you get FDA approval; whereas in the clinical trials there's much greater detail. But that's one core way to think about it.

And then, secondly, there are a set of financial metrics. Whether that's ultimately revenue derived from direct sale or licensing, et cetera, or from investment--and in our mind investment is an intra-milestone. The investment is ultimately only useful if, again, you get more products out to market or generate sales from it. But particularly given the timelines for NIH, it's a critically important metric that should be measured.

So that's our basic approach that we're adapting--trying to adapt and capture consistently across all 11 agencies and then give each agency the ability to fine tune. And we shouldn't be telling NIH what's the appropriate set of metrics to define market success in terms of clinical trials, et cetera, for their agency.

DR. SHURIN: Terrific. Thanks very much.

Richard Leshner is not here so we only

have six. Okay.

Michael Mutty has just got up and left.

(Laughter.)

Matthew?

If Michael comes back, we'll--

Matthew E. Portnoy, Ph.D.,

National Institutes of Health

DR. PORTNOY: Thanks.

So Michael had to leave for another engagement and Rich Leshner from NASA is on the Hill for an emergency session.

DR. SHURIN: Yes, right.

DR. PORTNOY: So I'd like to echo the things that have been said already in terms of there is--what's required--so there's levels. There's what's required in the legislation. You have to track commercialization. We have to track it both at the agency, report it to SBA, make certain types of information available to the public. And we can have discussions about the type of metrics and we've talked about some of those already, sales, licensing, revenues, FDA patents, et cetera. But it also will tie into, I think, in some cases the new charge that you'll receive shortly is what--how does this technology meet the NIH mission as a pseudo-

less tangible, something you really can't grab a hold of, you know, in terms of these other more data driven metrics and to the point you have a technology that doesn't make it to market but in one form or another may actually make a big difference.

Well, some folks who look at the data will consider that a failure but we might for other reasons consider it as a success. So how we move forward to define the different parameters of success, commercialization versus mission oriented versus perhaps some other metrics is going to be important. And we're looking forward to working with everyone on that.

DR. SHURIN: Thanks so much.

Manny?

Manny Oliver, Ph.D., Department of Energy

DR. OLIVER: I briefly touched on this at the end of my presentation. So, you know, our philosophy is, you know, the commercial potential has to be there. So I think in terms of the quadrants, you know, and this is the instructions we have given to our programs, if there is no commercial potential it really doesn't belong, you know, in the SBIR/STTR being funded. There are the other 97 percent of the dollars that's, you know,

free to fund things without commercial potential.

I think in terms of is commercialization sufficient, I think that's, you know, clearly no. I think that has been echoed here today. I think, you know, most of the agencies have their missions. And, as I mentioned before, I think looking at the commercialization side--you know, I think we have to have a lot of discussions on what the right metrics are. We can get to that.

The two issues I see there: You know, one, I, coming from the private sector, still look at commercialization success. Not really worried about defining commercialization but defining what is success.

So I agree with--I see a lot of things from other agencies where they look at, you know, additional investment and say, hey, that's the end of my process, I was successful. And, you know, I don't think that's really the end of the story, that those are truly interim metrics for--you know, you're digging a bigger hole. So if you're getting additional investment somebody is actually putting more money in this and this is potentially a bigger failure, not necessarily a bigger success. So I think we have to be careful and be consistent in

terms of how we're defining success.

I agree we need to get to the market and I guess I'd take a more return on investment point of view as what was the investments that went into this and what were the positive cash flows that came back that said, "Hey, this investment actually resulted in a positive return." But there are lots of challenges with that in terms of how we get at that data. You know, inside a company we can get at return of investment.

It's still very challenging. Once we're outside at an agency trying to come back a few years later, you know, there are the companies that are acquired. We don't know what they're acquired for. We don't see any of the future sales so we have no ability to measure that kind of return on investment. So we have lots of issues, I think, once we get down to the details of saying, "Okay. Yes, even if we reach some common definitions, how do we get that data or how do we simplify that data collection process?"

Coming back to the mission impact, I think that's--as we discussed before--a much harder problem. Across all the agencies we have different missions. Within the agencies, within DOE, as I

mentioned, you know, clean energy goals, you know, do we reduce CO_2 emissions, everything from the nuclear side of our programs where we're looking at nuclear nonproliferation. You know, how do we define those mission impact metrics? They're not as easy to get at as the financial metrics like return on investment or just sales and, you know, incremental investment. I think that's really the bigger challenge for us.

DR. SHURIN: Could you address the issue of the timeline? When you're looking at this from the standpoint of the Department of Energy, what kind of timeline do you look at?

DR. OLIVER: Again I think we would expect to start looking at investments. You know, there are some companies--and again this varies with technology because we fund everything from software to, you know, enhancements to nuclear reactors where they need, you know, NRC approvals and they take maybe five to eight years just by themselves. Similar to your FDA approval issue.

So I think we have--we're going to have a spread through our program in terms of what is the right window to look at and say, "Hey, did they achieve commercialization success in this window?"

We will have to have a range of windows or a very broad window to cover everything in DOE. But I think, you know, that's going to be really in the five to 15 year timeframe, I guess, if I have to give a rough estimate.

DR. SHURIN: Thanks very much.

Grace?

Grace J. Wang, Ph.D., National Science Foundation

DR. WANG: So let me comment on this chart first. Actually I use this before also so I actually really like this on.

What we want to do at NSF is really move the technologies in the Pasteur Quadrant into the market. That's really the total analogy that we are focusing on. And I mentioned earlier that on top of the SBIR grant NSF also set up set aside, $40 million, in my division just to build long-term partnerships between the universities and the industries, including small businesses.

That one is actually focusing on how to move the pure basic research, the right quadrant, the Bohr Quadrant, into the Pasteur and actually trying to catalyze that and take a look. From the fundamental research concept it looks like it is a science fictional concept. Is there any application

or anything--any prototype, any proof of concept that we can do to move that into the next quadrant and be more SBIR ready. I just wanted to comment on that.

And regarding the assessment, I think it's a -- I agree with all the points that have already been said and just I didn't get a chance to say it myself. And I think it's actually the same thing as what Manny and Matt and also Sean have said. It's very difficult. Measuring the long term impact of the SBIR program, especially using the doubler amount, is a challenge. At the same time and also I think it's risky. The reason I'm saying that is when we are talking about the dollar amount, we need to put a dollar amount in there, is we actually will be driven by that because otherwise why are measuring it. And that's why we always have to be very cautious. Don't get me wrong. We actually put extensive efforts doing assessment at NSF but at the same time I think we always need to be very cautious about our assessment results because we can never lose the bottom line that we are funding--we are trying to or trying very hard to fund high-risk innovations for our country. And if we are being driven by this, driving new numbers, so actually we

are--we are pulling them in as a short-term impact. And most of the SBIR companies are looking at way beyond--probably--usually beyond five years, beyond ten years. And if you are losing that, we are probably not going to be taking the risk of putting investments into the company that we should have been.

So I just want to make that point but I agree making the assessment and also all the parameters that have been mentioned are great ideas.

DR. SHURIN: Thank you.

Sally?

Sally J. Rockey, Ph.D., National Institutes of Health

DR. ROCKEY: I also agree with everyone, although I will say that I might have a little disagreement with Manny because I think one of the reasons that we push so hard for the idea that VC venture backed capital companies are part of our program is that they are very savvy individuals who are betting usually on those companies that more likely are going to be successful.

So I think at least as an interim measure you can measure follow on investment, particularly by VCs as an indication of a product that is more

likely going to go all the way.

I agree with the basic assessment of how we should do this.

I did want to take this opportunity because I may not have another chance to just talk about another complication in the whole tracking of the process. Remember these are small businesses and the construct of the small business and the whole enterprises is fluctuating and changing daily. Companies are coming in and coming out, being acquired. There are subsidiaries. There are mergers. There's all sorts of things that are happening which makes our job infinitely more difficult to follow those technologies all the way through.

I mean, we even have problems, you know, two years later. A company has disappeared off the face of the earth and we are trying to go back and find out some issue and we have to track it in all sorts of different ways.

So when we think about tracking, you know, we're tracking a technology; yes. But when we're thinking about tracking the companies it becomes very, very difficult over the long term, particularly if you're talking about a five and 15

year where the technology may result in commercialization. You have got to have a very sophisticated system in order to do that. It has a baseline to be able to track companies that may change in their construct a few times in a couple years.

So just to put that on the table as something to think about for our recommendations of how to define this.

DR. SHURIN: Can you--is there something that would help you to be able to track to make that easier?

DR. ROCKEY: Well, we have a lot of help with the SBA. I mean, this is one of the ways that we do it.

But we, like everyone else, we use all the mechanisms to our disposal to try to pick up pieces of companies that have gone elsewhere.

DR. SHURIN: What about radio labeling the investigator as Garry suggested?

(Laughter.)

DR. ROCKEY: So sometimes it's just a matter of a company has changed its title. Sometimes it has totally become something different. Sometimes they have a different person at the helm.

All sorts of things can happen. So when we figure out the system--and, SBA, I'm sure you--Sean--you all face this in the tracking of even companies. We have to take that into account of how we are going to consider that in the future and we do want to try to do the best of our ability. Again we're able--you know, my idea--and I know everyone laughs at me--is to put a little chip in everybody's neck for the electronic health records like your dog gets but we can do that for all our grantees, too, you know, so we can track them wherever they are.

MR. GREENE: We also have to get OMB approval for that.

(Laughter.)

DR. ROCKEY: And IRB approval.

(Laughter.)

MR. GREENE: So one--just one additional thought. I think again in the let's get moving--and the definitional questions are so challenging. I think the worst thing we can do is get paralyzed by the definitional questions and not start moving forward.

One thought on the critical issue of impact measured beyond just the financial side, which I think we all agree is critically

important, if you go back to the financial metrics, what most of the programs have seen is the really big successes--you know it's a small number who have a disproportionate or large impact. I would guess that that is true on the broader societal impact beyond the financial side as well.

So what we see when we, you know, had a hall of fame for the SBIR program are companies like Qualcomm, companies like Genzyme. So one opportunity in the nonfinancial impact is to say maybe we don't need to collect ten different data points from every company on those broader set of things but stay in touch and track and look for the really big successes and then be looking for the program as a whole across the full portfolio to say, hey, when you have got Irwin Jacobs, the founder of Qualcomm, who now has a $16 billion public company but a technology that is in 800 million handsets or Genzyme saying if it weren't for SBIR they would not have survived. That's a pretty compelling part of the overall impact as well.

DR. SHURIN: So I have one other question, which is I was struck, Sally, by the fact that you're tracking success stories. Should we be tracking failure stories?

I mean it seems--it just seems to me we're leaving a lot--what could we learn from the things that aren't working? Maybe I say that because we're spending a lot of time doing that in my institute.

DR. ROCKEY: Right. I would say that oftentimes when we have a failure it's exactly that. The company does use that to see what is working and not working and come back with another proposal. So we don't necessarily have them, you know, illuminating their failures on the web but they--we see it with their next SBIR proposal.

DR. SHURIN: Yes, and some of them don't. And I guess--

DR. ROCKEY: And some of them don't.

DR. SHURIN: --so the question is are there things that we could learn from the things that don't play off no matter what metric you use that would help us make these decisions in a more intelligent way?

DR. OLIVER: Yes, I think--just to follow up. I think that is one of the uses we would like to get out of the next round of the National Academies studies is to do some of this, you know, looking backwards at the companies and understand not just success but what are the failures and what

are the common themes that run through that. You know, were there really topics that came out of the agencies that really didn't have high commercial potential? What is the reason behind that?

DR. SHURIN: Thank you.

All right.

Discussion?

Sol?

DR. SNYDER: Yes. This metric issue for the numbers that were given from the earlier studies, like 75 percent of the companies did blah, blah, blah and 61 percent did this and got that, we know that in little companies--I know in the biotech area you don't have 65 percent or 75 percent successes of anything. And that the anecdotal stories like Genzyme and Qualcomm you say, well, you know, that's just anecdotal stories.

But actually I think that that is a meaningful metric because in the biotech and all the other high tech arenas it's venture capital calculations. I mean it's very, very realistic. Venture capitalists assume that nine out of ten of the companies that they will invest in will fail. One of them will be a success and will return 100-fold on its investment and, therefore, overall the

investors will get a tenfold return if it's a good venture capital company. And that's actually a very realistic thing.

So I think in terms of the metrics if you--and tracking people, it's not that hard to track the Qualcomms and Genzymes or even things that are not quite so successful. And that can be a reasonable metric.

And even put numbers in the denominator and diddle around with it and I think you would come up with honest rigorous data that qualifies for what we want and which we can sell to congress about why the NIH is fulfilling its mission.

DR. SHURIN: Francis?

DR. COLLINS: I think we do use those anecdotes. I certainly have been known to mention in a hearing that Affymetrix was founded on an SBIR grant and they did pretty well.

I want to ask a question that's related to the metrics but it's slightly off where we were at the moment. And that is about this category of SBIR applicants that some of us are not so happy about, the SBIR mills, which was mentioned already by somebody. And I assume all of the agencies that have this authority run into the circumstance of

companies which they are repeatedly at our doorstep with applications that generally, because there are so many of them, some of them get through and yet it is very hard to see that much is coming out of that except keeping the company going on taxpayer's dollars with relatively little in the way of commercialization. And I've never quite understood why it's so hard for us to say no after a while to those applicants, especially because one of the criteria for whether we fund a project should be its commercialization potential. But maybe we haven't had the tools that are as strong as they need to be to be able to make that distinction.

So I'd be curious in what the panel thinks as we go forward now maybe with more attention to metrics with this new reauthorization. Are we going to be in a better position to say no thank you to applications of that sort which we think have relatively low chance of yielding up very much?

DR. ROCKEY: So one of the things in the reauthorization bill is that we are--it's asking us to look and have the companies tell us about their previous successes in the application as opposed to just about the project. You know, now when we receive a project it tells us about the project.

They don't necessarily have to go in their history. But by using that as a metric and requiring that as a metric on the application stage, we will know more about the company itself. Again with all of the added notes that companies oftentimes change.

We also track--Francis, we track how many of our Phase 1's come in for a phase 2 because that's the real indication. If they live on phase 1's they are a truly one of these SBIR mills. If they come in on phase 2 then we have--they are going on to the next phase to a much bigger and larger project that they have to be working towards some commercialization.

So that is really essential to keep track of that as well.

MR. GREENE: This was a key element of the reauthorization as well.

So, first, it's important to note that the issue of mills has been long present in the SBIR program. The best data that has looked at this question has come from the National Academies and they have concluded that the actual incidents of the "mills" is less than the common vision may suggest. That being said, why tolerate it at all?

And so I think--and we should differentiate frequent award winners because it's not necessarily a problem when somebody is getting a lot of awards versus someone who has gotten a lot of awards and hasn't done anything with them.

And so in the reauthorization there is a specific mandate that each agency should set a benchmark and a threshold for transitioning both from phase 1 to phase 2, as well as from phase 2 and beyond of a minimum floor of transition that every applicant must meet. And if they don't meet those floors--and by allowing each agency to set their own benchmark then people--you know, agencies who have had different histories or focus n commercialization can adjust accordingly and they can evolve over time. But we're setting a floor. And for those applicants who don't meet that will be put in--not the statutory term but a penalty box for a year.

So with the notion of we should take a proactive stand to say companies who are receiving awards and are not doing anything with them should not be part of the program.

Now, each agency in setting the floor may still in the actual selection of awardee be looking for much higher rates of historical

commercialization well above the floor. But, again, agency by agency can make that call.

DR. SHURIN: Dr. Cassell?

DR. CASSELL: Well, I was just going to say as a member of the NAS committee that at a former review one of the things that was amazing to me was how often you encountered the mills and it was across the agencies. It wasn't just NIH. In fact, I've often heard Roy Vagelos refer to these as the bottom feeders so to speak. And I think that's one of the best things about the reauthorization is that you've taken this into account and tried to provide the tools. I do think it's a really important thing to do because there were obviously companies that did nothing but just survive. And we are just using the money for survival and not necessarily even trying that hard to get to the next phase.

DR. SHURIN: Dan?

HON. GOLDIN: I have been talking and we've been talking about problems but there's an observation I made over the last few months about the statement good to great. The level of seriousness that your staff engages in this subject, Francis, is really very positive. The issue that

was striking to me was the heads of the institutes got on the phones with us for a few hours and they were the ones who spoke to these issues. So there is a serious deep effort going on. And when you have the leadership of the institute engaged to this level, I think only good things are going to happen.

DR. SHURIN: Other comments?

DR. WANG: I have a comment about mills. Do you have a few minutes?

DR. SHURIN: Yes.

DR. WANG: NSF has been tracking the commercialization history and ask are we--single phase 2 application make--listed their commercialization track record there and list every single Phase 2 award they got from all federal government agencies and they had to list their sales and licensing revenue generated based on that project. And we do use that to reject a lot of companies who write really good proposals but they didn't do anything about the phase 2 award.

And the reason that that is--we are a very small percentage. I have to say we probably still have a few, one or two, at least one or two actually based on a name I know, are in our portfolio but the problem there is the other is small but to me I

think the detrimental impact they have on our portfolio is actually much bigger than their number because actually it delivers a bad message to our grantees. Especially at the grantees conference when they talk to each other and they figure out, okay, it's okay to live on taxpayer's money without doing anything. So that's why I think my opinion is we absolutely need to get rid of it and that's why I think that the new policy directive is actually going to be very helpful also.

DR. OLIVER: I will just echo that. Again in advance of reauthorization we implemented our own commercialization metric which is flagged in the selection process. And again the intent--most of the companies are submitting commercialization histories but there are multiple pages buried in the applications and the program managers aren't seeing that so we are pulling that out right for them to see and so we are addressing that prior to reauthorization.

I think reauthorization will just give us a little more authority in terms of what we can do as a result of that.

DR. SHURIN: Other comments or questions?

Sol?

PUBLIC COMMENTS

DR. SNYDER: Okay.

Now, at this point I think we've had a good bit of discussion on this. So the issue is now we are actually ready if there are public comments.

Did anybody line up to be provide any public comments?

Okay. So there is actually no public comments.

So actually we can move forward and I can turn the chair over to you, Norm, for discussing the next issue.

BOARD DISCUSSION AND NEXT STEPS

Norman R. Augustine, Chair, Scientific Management Review Board

CHAIRMAN AUGUSTINE: Okay. That sounds fine.

First of all, let me thank, once again, the members of the panel. This really has been an instructive session and as we talked it became more and more apparent to me how complex this issue is. And I'm a strong believer in the program but I will say that it's got its imperfections.

And I--just as an aside, I recall some

years ago where we were competing against a company that had a small business--it was actually a different circumstance but a small business advantage that they were given and it turned out that they had hired the Ford Motor Company to do all their work for them.

(Laughter.)

And--but they were getting extra points because they were a small business. And there are those who will take advantage of every loophole they can find and we need to guard against that.

Sol, thank you very much for chairing this effort. We look forward to your conclusion that will bring great clarity to the topic.

(Laughter.)

So with that, if there are no public comments to be made--let's see. I'm on the wrong agenda here.

No, I'm not. I've got mine here.

We--I think it's time to go to our new topic. And in May we talked about the fact that we now have in the lap of the management of NIH carrying out our earlier recommendation, we have the panel that you have just heard from underway, and some might say it's how much we want to pile on.

I think the other aspect to that though is by the legislation we have to meet at least five times on every topic before we make a recommendation.

(Laughter.)

And if you wait--if you wait in line and there's a train car by car, we will die of old age before we get done here. So Francis and I and others have had conversations about this and I think both Francis and I and the group as a whole is anxious to move ahead. And he has identified an area that is of substantial importance.

And so probably this is a good time just to turn to you and let you make whatever comments you'd like to in that regard.

NEW CHARGE

ASSESSING THE VALUE OF BIOMEDICAL RESEARCH

ISSUANCE OF NEW CHARGE TO THE SMRB

Francis S. Collins, M.D., Ph.D., Director, NIH

DR. COLLINS: Well, thanks, Norm.

I'm happy to do so.

And, again, I want to thank the panel and all of the important discussions that have gone on in the course of today about the SBIR/STTR program. I don't think we would have asked the SMRB to tackle this if we thought it was already perfect and

you've gotten a pretty good sense of both the opportunity and the challenge of trying to take this important part of our portfolio and really optimize the outcomes that we believe can be further optimized. And I'm sure there will be more iterations here in terms of the kinds of recommendations you might make to us about that. Certainly it seemed to me there were a number of themes especially here as we were talking about metrics and the importance of defining those and figuring out how best to track outputs so that we know whether our metrics are actually giving us the outcomes we hope for.

Maybe I was one of the people but I'm not the only one also emphasizing how critical it is that we look carefully at our cycle times for SBIR applications and awards and certainly we heard an exhortation from the SBA individual that we shouldn't take this one year that's in the statute as if that is really just good enough because I do believe we can probably draw in more exciting projects if we could be more quick in our responsiveness. Even though that may require us to do some different things in terms of how we conduct reviews. But I'm looking forward to hearing

what the SMRB might think in terms of options there that we could institute for this program that we probably wouldn't want to use for a typical RO1 but in this situation might make a lot of sense. So I'm looking forward to the next iteration.

Sol, thank you for your able leadership of this particular working group.

(Slide.)

So, yes, I'm going on.

Norm and I did, in fact, talk a couple of times about the possibility of another charge and settled upon this being the right time and the right topic to ask SMRB to consider. And this one is being sort of laid out here for your reaction as a topic which I think is particularly at this time in history important to get a better handle on than what we currently do. And that really is to try to define in the most careful, rigorous, economically defensible way what is the value of biomedical research anyway?

We already had a bit of that conversation about the SBIR program. What is the value that we could point to that is being rendered by the investment of these hundreds of millions of dollars? And I appreciated Norm weighing in that we

shouldn't just think about this in terms of dollars, whether they are radioactively labeled or whatever, but also about what this does for human health. That is after all our major mission.

I must say when I came to this role as NIH Director I hadn't really thought about the fact that I spend so much of my time defending NIH on the basis of economics. But it is what it is given the circumstances we find ourselves in and the current fiscal situation of our country and the world.

So there have been some efforts made to try to identify those economic benefits of NIH supported research.

(Slide.)

And we claim, therefore, that among the things that NIH does is to improve public health and stimulate economic gains and advance scientific knowledge and strengthen the biomedical workforce. And there you see various photographs of Susan and myself testifying in front of various hearings on making those cases based upon information that has been assembled by various groups in various ways.

(Slide.)

We certainly can argue that the health benefits have very substantially extended lifespan

and reduced illness by any measure, prolonging life and reducing disability when you consider lifespan is nearly three decades longer now than it was 100 years ago. When you look at survival rates for various diseases--here the example being breast cancer. When we look at the dramatic advances in HIV/AIDS, which will be much talked about later this month with the International AIDS Conference in Washington, where if somebody diagnosed today is HIV positive that's age 21 has a life expectancy of about 70 years. Contrast that to the death sentence that such a person would have received in 1985 or '86. And many other examples. This is just a smattering of such cases that can be made.

And, of course, here the case is being made on the basis of human impacts in terms of survival and freedom from disease. But each one of these could also be translated into some sort of dollar figure in terms of how lives being saved is also resulting in economic benefits. And people have taken a stab at those for all of these and many more.

(Slide.)

There certainly have been some more extensive efforts in the last couple of years to

quantitate the economic value of what NIH does in terms of support of biomedical research not just for one disease here or there but more across the board. This is one which came out initially about two years ago. It was recently updated--well, recently, last year by this economist, Everett Ehrlich. If you haven't looked at this, it will probably be an interesting starting point for some of what I'm hoping the SMRB can tackle. And not being myself somebody who ever took a course in economics it's hard for me reading through these kinds of analyses to judge the rigor with which they have been conducted and certainly there are critics of virtually all of these analyses in terms of the nitty gritty about their methods.

(Slide.)

We recently tried to put some of these analyses in a place where they are easier to find. Placed on our homepage under the button that says "Impact" a long list of such analyses with hot links to the actual reports. And that would include one which just came out about a month ago from the Information Technology Innovation Foundation, ITIF, jointly with UMR called Leadership in Decline. Very much sort of along the lines of the

gathering storm reports that Norm has been so central to. And they basically in that report document the way in which American contributions in biomedical research had been dwindling even as other countries, China, India, Singapore, the United Kingdom and Germany are all featured in that report, have been ratcheting upward. In some instances at rather dramatic levels.

That report did seem to attract some attention by the documentation of the very strong difference between what's happening in different parts of the world and the threat that it seemed to propose as far as America's global leadership but it certainly also has come under some criticism for the ways in which the analyses were done.

(Slide.)

So we have some things to work from here but I think these questions are not going away. I don't think the concern about taxpayer's dollars providing a return on investment is a short-lived concern. I think this is going to be with us. It has probably always been with us at some level. It's at a heightened level right now but I don't think the level of attention is likely to be diminished in the next few years.

So from the perspective of those of us at NIH, it would be really valuable to have from this group some guidance here. Not that we expect the SMRB to turn into an economic think tank and actually do the analyses that maybe need to be done but to identify the appropriate kinds of parameters and approaches to assess and communicate the value of biomedical research, which I guess we're going to call VOBR.

(Laughter.)

Which is supported by NIH.

Everything has to have an acronym around here.

DR. : (Not at microphone.)

(Laughter.)

DR. COLLINS: You're going to become VOBR-ites or something like that.

(Laughter.)

We'll have VOBR-1, VOBR-2 and then by VOBR-5 we'll know what we've said.

(Laughter.)

(Slide.)

Now, along with that, specifically asking you all to analyze the current strategies that are being used to assess the value of biomedical

research, examining both the national and international methodologies because there are groups outside the U.S. that are doing this that we don't know that much about. And evaluate the strengths and weaknesses of both the approaches that have been used as well as others that maybe haven't been to evaluate this question. And then help us by identifying fundamental principles that should guide any comprehensive and rigorous approach. Again, not asking the SMRB to actually conduct such an analysis but lay out the parameters, the principles, that ought to be adhered to in such analyses if they're going to have the full credibility that we need at the present time.

(Slide.)

So that's a pretty broad stroke about what I hope you would be willing to take on. Obviously in this instance, no doubt, you would want to call on lots of outside expertise and there are lots of folks out there that have written about this. I can imagine a pretty interesting set of meetings drawing upon their expertise and getting them to let their hair down about what parts of the analysis they are confident in and which parts could be done in a more effective way. But I think we would all learn

something from this and certainly from my perspective as NIH Director having this kind of analysis could be very useful as we try over and over again to make the case for the economic value of what we do, as well as the medical value.

So that's the proposal.

Back to you, Norm.

DISCUSSION AND NEXT STEPS

CHAIRMAN AUGUSTINE: Thanks, Francis.

During the telephone conference we had this was briefly introduced and I think the panel was supportive of undertaking such an effort. As you point out, everybody who has done this in the past winds up with a few arrows in their back and that I think is inevitable with this topic. It's hard to do this work without some kind of a flaw and so I think that's just something we'll have to deal with.

Gail, did you want to make a comment?

DR. CASSELL: I do.

I think this is very important needless to say but I would ask you to consider, Francis, maybe asking the board to do one additional analysis. And that is to look at the current processes for translating the results of NIH research into

practice.

There will be a report released later from the Institute of Medicine on the Learning Health Care System. I think what you'll--I mean they are--well, anyway, I can't say too much but the point is I think that right now that it takes years in some cases for results to get translated in practice.

The best example I can think of is from the time we learn that Group B Strep was the cause of neonatal sepsis and death until the time it was accepted--the practice guidelines were accepted and routine screening for Group B Strep actually started was about eleven years. You can imagine the number of infant deaths during that time period.

So is there a better way once the data seem to be really solid and clear that you could implement this into practice sooner?

And it just seems to me that if you're going to be trying to assess the impact, whether it be in lives saved or health care costs reduced or whatever, that you have to take that into account because if that part of the system is broken then you're not going to ever realize the full potential of the results that are obtained through funding of

either basic or clinical research.

DR. COLLINS: So that's a very important problem to be sure. And one that I have been drawn into on many occasions by many different groups is what are we going to do about this? Because we don't have a learning health system right now. We have a health system that refuses to learn where new information, even when very well documented and justified, as you say, takes forever to find its way into practice. And, obviously, this is a huge issue that relates to our whole health care system. And one which NIH has a couple of levers to pull in terms of conducting, for instance, implementation research to document how you can introduce new approaches in the real world and show that they work.

But in terms of the broader application, this is obviously a huge enterprise that goes well beyond anything that we have control over.

I think in terms of the economic analysis that is probably in there but to try to fold that in as a major focus of this charge, I think, would cause it probably to sink underneath the weight of what is probably the toughest problem in all of health care and one where NIH doesn't actually

control a lot of the outcomes.

I grant you this is an issue that needs serious attention. I'm not sure I can quite see how to merge it with this charge.

DR. CASSELL: I understand.

I happen to have been in a Congressional hearing, I won't name the NIH Director at the time or the CDC Director at the time, when in fact one of the members asked, "Okay. Whose responsibility is it?" The NIH Director said, "Not ours." The CDC Director said, "Not ours." And the member says, "Well, then who in the heck is responsible for improving the public health based on this research?"

DR. COLLINS: CMS.

(Laughter.)

DR. CASSELL: And so--well, CMS didn't exist at the time.

(Laughter.)

Okay. I've made my point. I've made my plea but I think maybe it needs to be a separate and additional charge to the board.

DR. COLLINS: Having--

DR. CASSELL: But somebody at--even maybe in the form of consensus conferences that have occasionally been used at the end of a, you know,

series of studies or some mechanism that NIH could rather forcefully say, you know, this should change medical practice ASAP.

DR. ROPER: Having had a couple of those jobs I would just say I don't think any federal agency is responsible for translating and changing the practice of medicine. That's not the federal government's role. But your point is a very good one and deserves a lot of attention. I guess I would associate myself with Francis though in saying that's a different issue than the value of medical research.

And I just thank you, Francis, for asking the SMRB to take this issue on.

I think it's an extremely important matter. I know it's of great federal import but at the state level our legislature is very interested in getting me as the dean of a public medical school to answer the question, "Well, what is it that--why are we putting all this money into your university?"

So I thank you for asking this to be taken on and I hope the SMRB will be serious about it.

CHAIRMAN AUGUSTINE: Are there others who would--

DR. KATZ: I agree with Bill's point

wholeheartedly but I just wanted to ask you, Francis, since a lot of the--what you've asked is couched in sort of economic terms, just to be explicit, you are really asking the SMRB to go beyond just economic terms, the value of biomedical research. Is that correct? Because it's important in the charge to know that we're not just focusing on the dollars.

DR. COLLINS: Well, you notice I put those things up there as the impact of research and I mentioned that each of these could be converted also to an economic argument. I think a theme here because it's where we are constantly being pressured ought to be how do we inform the construction of those economic arguments to be as rigorous and bullet proof as they can be but you can't really do that without documenting the benefits to human health and what that does for society, both in terms of families who no longer are having to care for sick individuals and people who are back at work instead of being somewhere else.

So, yes, it's all folded together but again I think the particular focus fitting this all together and the particular need right now is to try to see how all that information falls into an

economic--

DR. OMENN: It's Gil Omenn.

CHAIRMAN AUGUSTINE: Please, the one who joined, I wonder if you could put that on mute.

DR. OMENN: It's just me. It's Gil Omenn again.

I'd just like to make a comment. That's all.

CHAIRMAN AUGUSTINE: Please. If you would like to comment now, that would be fine.

I guess not.

Dan?

HON. GOLDIN: I'd like to say it this way: Francis, I feel your pain--

(Laughter.)

--when you go testify. And I just want to compliment you on asking the panel to look at this because if you don't present the information, someone else will and it won't have the deep thought that is necessary and the research that is necessary to put issues into context. And because of the digital age that we are in, everything gets broken down into numbers and times and put in very simplistic form. And you having the bully pulpit to be able to talk in the broad sense but summarize

for the members of congress and the American public this important issue--I can't think of anything more important in protecting this very valuable research. It's very valuable so I'm glad the committee has it.

DR. RODGERS: I just want to have those slides up. I just want to kind of point out that--

DR. OMENN: I can't hear.

DR. RODGERS: Am I on? Can you hear me?

DR. OMENN: Is somebody making a comment?

DR. RODGERS: Yes.

Let me try this one.

What about now? Can you hear me?

DR. OMENN: Yes.

DR. RODGERS: It sounds like a telephone commercial.

(Laughter.)

You had a slide up that tells us about, you know, how there has been this change and this is very important in terms of survival, for example. It might be the time to actually consider that not only has NIH research contributed to this change but also to the rate of change and even the rate of the rate of the change. In fact, you know, I think a point you were making is we sort of are living in

exponential times now and since heretofore NIH's mission has been in acquisition of knowledge, this knowledge is changing at a rate, you know, that is also exponential. It really touches a little bit upon what Gail was saying. In a way you want to acquire the knowledge but you want the knowledge to be diffused in a way that benefits directly health. And so maybe that's something that we should consider coming back to. I think Gail's point is well taken.

DR. COLLINS: So not just the static picture but the first and second derivative of the curve.

DR. RODGERS: Right.

CHAIRMAN AUGUSTINE: Are there other comments on this topic?

DR. BRODY: This is Bill Brody.

I just want to echo. I think Steve Katz made a comment. The audio is not great but--and I know that you have to do the economic analysis and it's important but I'm just reminded when my son was in a small liberal arts college we went for family weekend and they had the financial officer present the data on what the true costs of education were at a private liberal arts college and why, you know,

parents were only paying half of the actual costs even though the tuition was in the stratosphere. And then he presented data that if you went to one of these small liberal arts colleges "you would be financially better off." And one of the parents raised her hand and said, "Well, my daughter wants to do public health work in Africa. Does it mean I'm wasting my money sending her to this school?"

(Laughter.)

So I think that, you know, we have to weave into whatever we do the non-economic benefits, including public health in the world, which we do. I mean it does have a benefit--an economic benefit but, you know, it's a bit of a slippery slope if we just get completely hooked on the dollars and cents.

And some of the investments pay off so many years later that it's sometimes hard to measure, as somebody said, the radioactivity of the dollars to trace.

DR. COLLINS: Very well said.

There's a lot of nodding heads around the table, Bill.

CHAIRMAN AUGUSTINE: Thank you, Bill.

Other comments?

Please?

DR. SHURIN: I wonder if this still has to do with what you consider in the entire equation because people who are employed and not receiving medical care and not on welfare and whatnot, I mean I think one of the key issues is what questions we're asking. Because what you don't want is just sort of, "Well, we invested this much and we got this much money back for it." The broader you view the economic context the better off you're going to be.

I remember seeing an analysis of what happened with hemophilia when hemophilia patients went on to concentrate and got treated regularly. They went from having 90 percent unemployment to 85 percent employment virtually all with insurance.

I mean those kinds of things are the sorts of things that actually matter and in some ways looking at the metrics that will matter--not just impressive numbers but the metrics that will matter to the people who make policy I think is going to be one of the most important things. Those are hard to get at but we can get at some examples of them.

DR. COLLINS: Yes. If I could just comment.

If you go to that impact site where we

have tried to accumulate a lot of these analyses, you're quite right. They come at various levels. There are analyses that look at the sort of immediate or within a year return on investment and economic goods and services that are generated because of an NIH dollar and those actually are fairly encouraging but that's a far smaller picture than what you want to have available.

And then you can go all the way to calculating what is the value of the fact that--as I mentioned--that heart attacks and stroke deaths are down by 70 percent in the last 30 or 40 years and that is in the range of $50-70 trillion or something like that. But, obviously, that isn't because of the economic goods and services. That's because of lives saved and the ability of people to continue to be productive.

DR. SHURIN: But, again, it's a lot how you present that. Because the issue isn't that there are that many fewer heart attacks and strokes. People still mostly die from heart attacks but they are dying at 80 and 85. They are not dying at 40. And so some of those kinds of things are the things that make the big differences.

DR. HODES: Just following up on that,

just be prepared for all that we are going to have--just the example you mentioned, some very caring and good humanitarian economists are going to point to that example and I'd argue that there is a net loss of funds, that people surviving at a point, for example, beyond the time when they are employed and not being--having more people smoke and dying early. You know, sort of the classic perverse example is cost savings. So that's only to say we are going to have to be very careful and understanding of the complexity of the answers we are going to get by people who are going to look at every dimension of what we ask of them.

CHAIRMAN AUGUSTINE: Please?

DR. BRIGGS: Just another kind of thought about the complexity that Gail mentioned of the defects in our health care system and how so much of the implementation processes are not happening effectively. We also have to be careful not to short sell our own substantial investment in implementation and dissemination work through the CTSA program, through other large implementation and dissemination programs. So I think this is going to be a constant tightrope in thinking about this, to both capture the value we are bringing to health

care systems without letting our processes be stymied by some of the failures in the health care system.

I don't have an answer. I just think we can't ignore it.

CHAIRMAN AUGUSTINE: Gail?

DR. CASSELL: If I could just add to what you said. I'm showing my age for sure in more ways than one but having been involved in the NIH strategic planning process under Bernadine Healy from day one to the end, you know, one of the recurring things was the need to broader communicate the research. And I think this is an area where NIH--I mean it has excelled in many areas. Many of the things actually have transpired that were proposed in the plan but the communication, the education, the public access to information--my gosh, I can't tell you the number--and I know everybody can say that--of our friends and relatives that use NIH and what NIH says. So somehow that has to--I don't know how you place a value on it but it's I'm sure a huge investment or a significant investment and we need to figure out how to showcase that even more.

I think this new initiative in terms of

diseases of unknown etiology through the Clinical Center is huge if you look at the number of individuals that go for years without a diagnosis and what the value of even that program is going to be. It's hard to place a dollar sign on it but in terms of overall impact it will be huge.

CHAIRMAN AUGUSTINE: Others?

If not, I'd like to make a few comments just myself.

I suffer from the fact that to me the benefits of what NIH does is obvious. And so I have to get that out of my mind and become a skeptic here if I'm going to be constructive.

I see a couple of dilemmas that we will need to deal with. One is, as Dan points out, NIH is perhaps the only organization or certainly one of the few that has the knowledge to be able to do this kind of an effort constructively that has been called for. At the same time NIH does not have a lot of credibility on this particular topic of the value of investment at NIH. And so maybe that's where this particular group, with some of us being--or the majority of us being outsiders, so to speak, we may be able to make a contribution here.

There's also the issue that, Gail, you

raised, I thought very well, about some of these other matters that get into the discussion. The business of if you don't translate the research or if it takes too long, that's a big problem.

Including that sort of thing complicates matters an enormous amount, Francis, as you point out.

But I think we could have our cake and eat it here because undoubtedly there are going to be many topics like that that will spill out where you can make a list that if you would do better at this--we don't need to tell how but we could prepare a list, I think, that says if you do these then the answer turns out to be much better.

On the subject of economics, I'm of the school that it says that we do want to think of things beyond economics here. But also Francis has to deal with the fact that here in Washington economics is the coin of the realm at this point in time so to speak. And so that issue has got to be answered.

And along with that I would hope we can broaden the topic to other benefits.

Also, I would emphasize the point Francis made that he is not asking us to do the analysis but

rather--I guess maybe, Francis, the way to say it is to lay the groundwork for doing such an analysis. And then presumably the people who work at this as a full time job could undertake it and I would offer, if that happens, our services or the services of this group to oversee such an effort and to try to add a bit of credibility to it on our behalf.

It does seem to me that there are some interesting things you could do. I have been thinking about this a bit.

One question I asked myself was supposing the NIH hadn't existed the last 20 years or 25 years, whatever. What would be the impact on people's lifestyle today? For example, what would be the impact on how long you would live? And let's say it lowered the life expectancy to 60 or something. Then you go to John Q. on the street and say, "It has cost you 25 cents a day for the last 25 years to have an NIH. You're 65 years old today. Are you getting your money's worth?"

And I think we've got to put it somewhat in some of this context that--the benefit to the individual. As I thought about this, I was thinking when my mother was born, the life--she was born in Colorado. The life expectancy was 48 years

in this country. And, you know, today it's 79 I think. And I don't know how much of that you could attribute to the NIH but it's probably no small part. And somehow we need to make these connections.

I guess full disclosure requires me to say that there is always somebody who blows away the argument, "My mom lived to be 105."

(Laughter.)

God bless her.

But anyway I'll be here at this table long after you folks are gone.

(Laughter.)

DR. OMENN: May I make a comment?

CHAIRMAN AUGUSTINE: Yes, Gil, please do.

DR. OMENN: Sorry to cut in but I have been enjoying the conversation and the earlier presentations all day by webcast and some by phone also but I wanted to stay on mute all the time that I could.

I love this topic. I know how much pressure Francis and others get from the Congress. You know, what have we bought with the doubling of the NIH budget? What will we buy with further increments that the scientific community strongly

recommends? So it's a worthy subject and it certainly is at a level of broad view that is perfect for this board.

I don't know if anybody mentioned yet. I couldn't quite hear everything. But there was a study commissioned by the Lasker Foundation under the funding of first initiative in 1999 with nine prominent economists, not really health economists but very prominent economists from the University of Chicago and from several other institutions. And they came up with a startling really credible estimate of trillions of dollars of benefit to the American population from investing in biomedical research.

There was a very nice follow on article also by Neil Rosenberg in which he broadened the investment to include all sources of investment in the United States, meaning pharmaceutical and biotech and foundations, as well as the NIH itself. And sometimes that's wise to broaden the sense of the investment portfolio. This strategy of identifying the gains in the health status and the more effective use of medicine in public health is a very credible approach. There are sometimes triggers--you always see--several of you made

comments about the rebuttals that might be laid on us. There is always the notion that you have incompletely implemented many things we know to do in medicine and in public health and in self improvement for healthy behaviors and, also, environmental protection from health research. So that needs to be acknowledged. And there is a sense in which our partners or implementation sites are all free to society are very important to realizing the full value of new knowledge and new techniques and new drugs and new investors and new everything. So that is important and one which is perfectly fair to include in the recommended analysis.

I think we could add quite a lot to this. Not just by trying to put absolute numbers, estimates on the broad analyses but to take a cost effectiveness approach also and to possibly make a few recommendation of how the NIH resources or the national resources could give even greater benefit with certain kinds of improvements.

For example, there has been a lot of discussion lately triggered by comments from leaders of the FDA and leaders of R&D in industry and quite a few academics about how many papers published in

our leading biomedical journals have been unreproducible. And there was a discussion just yesterday or Monday actually in which I was a participant at Stamford by the National Research Council panel, which is revisiting the 1992 report called "*Responsible Conduct of Research.*" This is a topic in which NIH has been very active and very forward-looking I would say, in general, over the years and it's their responsibility as the institution.

So this is a 20 year reprise and asking-- to look at the landscape and what are the parameters and what can be recommended to improve the culture and the performance of research across all fields, not just biomedical. And there are things like that which probably need to be addressed.

There was an article from industry leaders saying that of 53 studies that led to product licensing or research licensing by biotech companies but only six could be reproduced when the companies exercised their duty as they have learned it to actually try to reproduce what they've purchased from academic or small company or even large company research groups that has been published in top journals. So this is beside the issue of fraud and

misconduct, which of course that's a whole important subject that could be managed on its own.

And there's a report from the Institute of Medicine, which I had the privilege of chairing, that just came out in March called "*Evolution of Translational 'omics: Lessons Learning and the Path Forward*." We are very eager to improve medical diagnosis, individualized or at least define some groups of patients for more specific treatment with higher benefit to risk ratio. And we are confident that molecular signatures will enhance our capacity to deliver such service to patients and to populations.

It's been tough so far and it's just one of many areas where we should look and see how the cost effectiveness of the research investment could, in fact, be enhanced. You've already stated that we're not going to do this ourselves but identifying certain kinds of questions and certain kinds of analyses, I think, would be responsive to Francis' charge.

Thank you.

CHAIRMAN AUGUSTINE: Thank you. Those are very helpful comments and you have obviously thought about this some in the past and it will be

useful to get your input on some of the work that others have done that we should be aware of and study before we start out so we don't reinvent the wheel here.

DR. OMENN: I should have said the title of that University of Chicago led report and the Lasker Foundation was "*Exceptional Economic Returns from Investment in Biomedical Research*." It's right to the topic.

DR. COLLINS: Just a point of information since Gil raised this issue about the lack of reproducibility of research studies when tested in an independent way to try to assess whether a company should invest in a long-term project. There are lots of concerns expressed about this in multiple venues. The NCI is organizing a significant meeting about this in September which, I think, is an opportunity to actually look a little closer at the actual examples because right now it is very puzzling to figure out exactly what might be at the basis of such a disturbing frequency of failure to confirm whether these are things that can be readily explained once you get into the details of the reagents and the buffer and the protocols or whether there is something even more complicated

going on.

But certainly it has gotten our attention to say the least that this is a topic that has to be addressed and addressed rigorously.

CHAIRMAN AUGUSTINE: Gail?

DR. CASSELL: Norm, I know sometimes on NIH Director's Advisory Committees when you take on special topics where, in fact, the expertise doesn't lie within the council that you can add that expertise by ad hoc membership. I'm wondering if maybe this is not a subject where the board might benefit by adding two or three individuals with deep expertise in this area. I realize we're not going to be doing the analyses but laying the groundwork. But just to develop that blueprint it might be something to think about. I don’t know if others would agree but somebody like Don Berwick comes to mind. I know he's trying to decide now exactly what he's going to do but having given CMS a heck of a lot of thought maybe he would have some ideas about the things that I mentioned earlier as an example.

CHAIRMAN AUGUSTINE: That's a terrific point. We'll take that aboard and that's a good introduction to--we've had several folks who previously volunteered to work on this project. The

ones I'm aware of are Gail, Eric, Griff, Bill Roper, Arthur Rubenstein and myself. And I'm told that I'm--I realize I am an ad hoc member so I guess I automatically am on. Dan, too. So we'll add Dan.

Anyway, as an ad hoc member, I guess I'm involved whether I volunteer or not but I'd like to volunteer for this one. I think this will be important.

If anyone else is interested in serving in this or if you have ideas as to people who might fit the bill for what Gail has said, Francis, Amy and I will get together here very shortly and put together a list of a committee and we'll come up with a volunteer chair.

I use volunteer in the--since we are almost at the end, I guess we can stand a story.

I took my--it turns out at the Museum of Natural History Downtown every day at 2:00 o'clock the tarantula is fed what they describe as a volunteer cricket.

(Laughter.)

And I had just returned from taking one of my grandchildren to see the volunteer cricket be eaten by the tarantula.

Anyway, we will pick a volunteer.

(Laughter.)

That's a bad analogy to start out with, isn't it?

(Laughter.)

HON GOLDIN: Thank you so much for that image.

CLOSING REMARKS AND ADJOURNMENT

CHAIRMAN AUGUSTINE: Yes, right.

The next meeting will be October 3rd here on the campus. We will continue discussions of the SBIR/STTR topic. We will start our efforts on the current discussion we just had.

And before we adjourn there are two things.

One, I want to thank, Amy and all your colleagues for the sensational job you do and keeping things on track between meetings and arranging our meetings and for all your good work and professionalism.

And, as is our custom, I'd like to go around the room and give everybody a chance, if you have anything you would like to say or any additional observations on any topic, complaints, whatever, this would be a great time.

Dan, I know you've got an airplane to

catch so maybe you could start and we'll go down the table.

HON. GOLDIN: The comments that I made before I just want to repeat about sometimes we get so into the issues and the problems we lose sight of the incredible staff at the NIH. Every time I interact with these folks--Amy, she is always there. She is always available. She is always helpful.

Lyric? Where is she? Oh, there she is back there. Yes, Lyric goes around the clock.

(Laughter.)

But it is the attitude of the leadership of this organization that really distinguishes it and everyone who is engaged with this organization ought to be really proud for what they do.

CHAIRMAN AUGUSTINE: Richard?

DR. HODES: No comment.

CHAIRMAN AUGUSTINE: Sol?

Sol, we owe you a special thanks for your part in leading us today and your colleagues of the individual panels.

Steve?

Bill is gone.

Josie?

Garry, anything at all?

Anything you'd like to say, Gail?

DR. CASSELL: To go back to the NAS committee and NIH was always held up as one of the best success stories of the SBIR program and I think now we know exactly why. We've heard today.

CHAIRMAN AUGUSTINE: Griff?

DR. RODGERS: Nothing to add.

Bill Brody?

DR. BRODY: Yes. I'm here.

CHAIRMAN AUGUSTINE: Do you want to make any last minute comments before we close?

DR. BRODY: No, I think it was actually a very interesting meeting and I could hear most everything so it was great. I appreciate the webcast also.

CHAIRMAN AUGUSTINE: Okay. Thank you, Bill.

Gil?

DR. OMENN: I think I had my say. I really enjoyed the session and obviously I'll be happy to work on this new topic.

CHAIRMAN AUGUSTINE: Okay. Good. We will add you and that's terrific. We will look forward to seeing you at the next meeting.

DR. OMENN: You bet.

CHAIRMAN AUGUSTINE: As always, Francis, you get the final word.

DR. COLLINS: When I testified in front of the House Energy and Commerce Health Subcommittee, which was just about three weeks ago, this is--you may or may not remember--the committee that actually was responsible primarily for the reauthorization of NIH in 2006 that created the SMRB. And so the members of that committee were very interested in knowing whether the features of that NIH Reform Act had turned out the way that they hoped and they particularly were interested in knowing about the SMRB. Former Chairman Barton, in particular, wanted a full description of how this particular function had served.

And I was very happy to tell them that this particular construct, which was controversial and at the time it was put in place caused a fair amount of anxiety, had actually been extremely valuable to me. And I don't think that is, frankly, because the construct itself was so perfect. Those five meetings, maybe they could have thought about that one a little longer before putting that one into the statute.

(Laughter.)

What has really made this work is the dedication of the people involved and all of the members who have served with no compensation to speak of and, as you saw today, not even coffee or bagel or anything for your trouble unless you got it out of the vending machine since we are in a new austerity as far as anything that could be called food.

But you have given of yourselves. You've spent time on issues that were important to us. You've thought through complex circumstances and come up with very wise advice on multiple different topics. And you're at it again here with the things that have been talked about today and that will be talked about in October.

And so I just really want to say, from my perspective, how grateful I am for this kind of really high-level input on topics that we couldn't possibly sort through without your help.

And, Norm, I particularly want to thank you for all of the ways that you let this so ably and I'm glad to hear you're going to live to 105 because I'm hoping to do that, too, and I'm going to still need your advice.

CHAIRMAN AUGUSTINE: My dad only lived to

be 96.

(Laughter.)

Okay. Well, thank you all very much.

The meeting is adjourned.

(Whereupon, at 3:11 p.m., the proceedings were adjourned.)

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