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NATIONAL INSTITUTES OF HEALTH

NIH SCIENTIFIC MANAGEMENT REVIEW BOARD

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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.

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

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

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

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

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

25 Dr. Gilbert Omenn, who is a professor of

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

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

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

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

10 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 CHAIRMAN AUGUSTINE: Okay.

8 DR. BRODY: Norm?

9 CHAIRMAN AUGUSTINE: Yes, Bill?

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

12 CHAIRMAN AUGUSTINE: Are you at the
13 Institute right now?

14 DR. BRODY: Yes, can you hear me?

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

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

20 CHAIRMAN AUGUSTINE: Great to have you
21 here, Bill.

22 DR. BRODY: Thank you.

23 CHAIRMAN AUGUSTINE: Amy?

24 DR. PATTERSON: Amy Patterson, NIH.
25 Thank you.

1 CHAIRMAN AUGUSTINE: Okay. I already
2 introduced myself.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

21 So thank you.

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

1 So thank you.

2 CHAIRMAN AUGUSTINE: Francis, thank you.

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

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

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

1 seriously.

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

6 (Laughter.)

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

12 And then let's see.

13 The minutes for the meeting we held on May
14 29th were completed and we need to thank Drs.
15 Pettigrew and Rubenstein for reviewing those and
16 attesting as best they can to the accuracy of them.

17 And I would welcome a motion to approve those
18 minutes.

19 DR. RODGERS : So moved.

20 DR. SHURIN : Second.

21 CHAIRMAN AUGUSTINE: Thank you.

22 Is there discussion?

23 Those in favor please say aye?

24 (Chorus of aye.)

25 Opposed?

1 All right.

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

7 **REVIEW OF NIH CONFLICT OF INTEREST POLICY**

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

10 DR. PATTERSON: All right.

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

14 (Laughter.)

15 All right.

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

25 But at every meeting, in addition to you

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

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

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

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

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

7 CHAIRMAN AUGUSTINE: Thank you, Amy.

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

10 And, Sol, I turn the chair to you.

11 **OVERVIEW OF SMRB SBIR/STTR WORKING GROUP PROCESS**

12 *Solomon H. Snyder, M.D.*

13 *Chair, SMRB SBIR/STTR Working Group*

14 DR. SNYDER: Okay.

15 (Slide.)

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

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

1 as for other government agencies.

2 So let me begin.

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

7 (Slide.)

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

12 The question is why are we doing this?

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

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

1 (Slide.)

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

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

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

13 (Slide.)

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

20 (Slide.)

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

24 (Slide.)

25 We're trying to address the issues of how

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

11 (Slide.)

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

16 (Slide.)

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

23 (Slide.)

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

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

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

16 (Slide.)

17 What's depicted on this slide is the ways
18 in which we're approaching handling all of this,
19 which has to do with the simple steps in SBIR grants
20 that are addressed. And each of them is important.

21 The first one is how do you promulgate the notion
22 that there is a need for applications. And the two
23 models are you just have a call for applications and
24 people just send in whatever they want to send it,
25 sort of like NIH investigator-initiated grants, and

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

9 (Slide.)

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

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

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

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

15 (Slide.)

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

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

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

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

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

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

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

8 (Slide.)

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

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

15 (Slide.)

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

21 (Slide.)

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

1 are eager to let us know what they think.

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

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

11 DR. SNYDER: Thank you.

12 **SBIR/STTR REAUTHORIZATION UPDATE**

13 ***Matthew E. Portnoy, Ph.D.***

14 ***Manager, NIH SBIR/STTR Programs***

15 DR. PORTNOY: Good morning.

16 (Slide.)

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

22 (Slide.)

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

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

4 Thank you very much.

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

13 (Slide.)

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

25 Separately, there's all of the rest of the

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

5 And so the size rules were issued. The
6 eligible rules were issued by SBA on May 15th and
7 they are currently open for public comment. The
8 public comment period closes in a few days on July
9 16th. This is the chance for everyone in this room,
10 everyone who happens to be on the video cast or on
11 the phone to provide comment to the SBA on what they
12 think about the size rules. This addresses, as I
13 said, the venture provision. It address when
14 companies need to be eligible. It addresses
15 everything with affiliation, how companies who have
16 other companies working with them are counted.

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

1 way that they are part of the government.

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

8 (Slide.)

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

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

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

6 (Slide.)

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

15 (Slide.)

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

23 (Slide.)

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

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

3 (Slide.)

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

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

17 The hard caps are essentially 50 percent
18 over these guidelines and for--and would now be
19 225,000 for Phase 1, 1.5 million for Phase 2, and
20 these are hard caps, cannot exceed, cannot make an
21 award over that amount.

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

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

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

8 (Slide.)

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

25 (Slide.)

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

14 (Slide.)

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

22 (Slide.)

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

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

10 (Slide.)

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

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

20 (Slide.)

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

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

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

13 (Slide.)

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

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

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

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

20 (Slide.)

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

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

18 (Slide.)

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

1 commercialization rate, all of which are defined
2 in statute.

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

14 (Slide.)

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

22 (Slide.)

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

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

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

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

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

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

25 There are many other reporting

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

7 (Slide.)

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

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

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

5 (Slide.)

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

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

11 Yes, Gail?

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

14 DR. PORTNOY: Yes.

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

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

25 DR. CASSELL: Was initially introduced.

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

3 DR. CASSELL: Yes.

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

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

17 DR. PORTNOY: So we have--

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

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

1 can't issue joint solicitations.

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

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

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

22 DR. PORTNOY: Yes.

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

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

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

14 Yes?

15 HON. GOLDIN: I notice that there was a
16 \$5,000 research technical support--

17 DR. PORTNOY: Yes.

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

1 that \$5,000 is a very confusing number.

2 DR. PORTNOY: Right.

3 HON. GOLDIN: It goes away very fast.

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

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

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

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

5 Yes, Dr. Collins?

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

12 DR. PORTNOY: Sure. So I don't have the--
13 the language from the statute is relatively concise
14 and I didn't paste it in here because you wouldn't
15 be able to read it. But what it does--and it allows
16 the agencies to spend 10 percent of SBIR or roughly
17 \$63 million at the NIH, across the agency, for
18 awards to small businesses that allows them to move
19 further along the commercialization path. A key
20 provision in there, it allows us to make these
21 awards under the Commercialization Readiness
22 pilot up to three times the guidelines without the
23 need for a waiver from SBA. So the guideline is \$1
24 million, anything above \$1.5 million we need
25 a waiver. This allows us to make \$3 million awards

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

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

16 DR. SNYDER: Garry?

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

22 DR. PORTNOY: Sure.

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

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

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

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

25 DR. PORTNOY: Mm-hum.

1 DR. SNYDER: (Not at microphone.)

2 **PANEL PRESENTATIONS**

3 **INNOVATION WITHIN THE SBIR/STTR PROGRAMS**

4 **PANEL PRESENTATION I - PILOT INITIATIVES ACROSS NIH**

5 ***Moderators: Josephine P. Briggs, M.D., SMRB Member***

6 ***and Solomon H. Snyder, M.D., SMRB Member***

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

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

12 (Laughter.)

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

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

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

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

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

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

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

8 DR. BRIGGS: And Michael?

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

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

14 So, please, Dr. Weingarten.

15 ***Michael Weingarten, National Cancer Institute***

16 MR. WEINGARTEN: Okay. Thank you.

17 (Slide.)

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

24 (Slide.)

25 We've actually been working at making some

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

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

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

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

25 And then I'll close with some suggestions

1 on issues for the SMRB to consider.

2 (Slide.)

3 So why do we care about the SBIR program
4 at the NCI? We really use this as a resource,
5 really as our primary resource for helping enable
6 the commercialization of some of the promising
7 technologies, many of which come out of a lot of our
8 other programs at the NCI. So we actually use SBIR
9 to support technology development, small molecules
10 and biologics, diagnostics imaging technologies, as
11 well as electronic health and education tools. So
12 essentially the program is there to support many of
13 the technology areas that are already being
14 supported at a basic research level by the R01
15 community, as well as by the small business
16 community.

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

19 (Slide.)

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

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

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

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

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

23 (Slide.)

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

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

5 (Slide.)

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

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

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

5 (Slide.)

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

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

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

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

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

16 (Slide.)

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

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

3 (Slide.)

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

7 (Slide.)

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

24 (Slide.)

25 The reason that we did that is because of

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

9 (Slide.)

10 So how does the Bridge Award work?

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

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

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

7 (Slide.)

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

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

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

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

9 (Slide.)

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

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

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

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

10 (Slide.)

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

17 (Slide.)

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

20 (Slide.)

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

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

4 And we really--what we're finding--we
5 created the opportunity but the companies are all
6 finding different ways to go out and raise capital.

7 So a third of the capital is coming from the
8 venture capital community. A third of it is coming
9 from strategic partners, like pharma. And then a
10 third of it is actually coming from the angel
11 investment community.

12 (Slide.)

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

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

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

12 (Slide.)

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

18 (Slide.)

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

1 milestones.

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

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

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

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

19 (Slide.)

20 Some issues for the SMRB to consider.

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

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

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

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

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

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

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

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

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

23 That's--those are some of our suggestions.

24 I would be happy to take any questions that you
25 have.

1 DR. BRIGGS: Thank you very much.

2 This was terrific.

3 Comments or questions for Dr. Weingarten?

4 Dan?

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

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

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

16 MR. WEINGARTEN: Right.

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

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

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

11 DR. BRIGGS: Gail?

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

17 MR. WEINGARTEN: Yes, they can.

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

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

25 DR. BRIGGS: Francis?

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

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

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

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

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

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

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

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

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

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

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

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

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

7 MR. WEINGARTEN: Yes, absolutely.

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

24 DR. BRIGGS: So we've got Norm.

25 CHAIRMAN AUGUSTINE: I have a question but

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

3 We had a chance to welcome you formerly
4 before.

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

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

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

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

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

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

3 So, Jerry, I think you're next.

4 ***Jerome Wujek, Ph.D., National Eye Institute***

5 DR. WUJEK: All right.

6 (Slide.)

7 Can everybody hear me okay?

8 Okay. I'll take that as a yes.

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

15 (Slide.)

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

22 (Slide.)

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

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

14 (Slide.)

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

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

11 And then lastly we have a crosscutting
12 management.

13 (Slide.)

14 So simply put, of course, you can take--
15 this is the Division of Extramural Research at NEI.

16 So we have portfolios to fund the research--the
17 vision research throughout the country. You can
18 divide it up simply by anatomy and disease, and
19 that's one simple way to do it but, of course, life
20 is complex and as you dig deeper you realize it's
21 not that simple.

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

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

6 (Slide.)

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

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

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

8 (Slide.)

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

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

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

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

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

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

25 Peer review, again commercialization

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

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

1 work as it were, pharmacokinetics, toxicology,
2 formulation, manufacturing if it's a device. That
3 takes extra money, especially if it's therapeutics.

4 A lot of money.

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

12 (Slide.)

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

1 So we actually have nine companies that we
2 just allowed into the program in this past year.

3 They are now in the process of the initial meeting.

4 That has just completed for all of these companies.

5 So the questions the companies have had about the
6 process has been asked with this meeting. The goals
7 are now formulated, defined, refined, and now the
8 regulatory consultant company is in the process of
9 developing the regulatory strategy based on that
10 initial meeting and they will go back to the company
11 with a customized plan, here is how you should
12 address the FDA. It's customized for a device,
13 therapeutic. Is it a drug delivery system, et
14 cetera, et cetera?

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

20 (Slide.)

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

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

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

6 Okay.

7 So our next presenter is Jodi Black from
8 NHLBI.

9 *Jodi B. Black, Ph.D., M.M.Sc.,*
10 *National Heart, Lung and Blood Institute*

11 DR. BLACK: Can you hear me?

12 (Slide.)

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

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

24 (Slide.)

25 So back in 2010 the institute decided to

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

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

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

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

6 (Slide.)

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

1 And they noted two gaps in this process.

2 The first gap is right after an innovator
3 thinks they discovered something that might have
4 commercial potential and they don't know what to do.

5 There's a gap of funding here that can get the
6 that can get the and process driven scientific
7 feasibility studies that are required to help define
8 the product. This gap is before the strategy
9 should be to spinout out a company because most
10 academic innovators don't really have any business
11 expertise.

12 The second gap was already addressed by
13 Michael. It's the gap between the end of the phase
14 2 SBIR award and the phase 3 commercialization
15 phase. We noted the same gap and we're developing
16 the same kinds of approaches, including a Bridge
17 Award, with a lot of help and guidance from Michael
18 and his team so I'm not going to talk about that.

19 But this group also noted that it wasn't
20 just a gap in funding. It was more than just money.

21 There was a gap in knowledge by innovators and an
22 understanding of how biomedical technologies are
23 actually brought to the market and there was a lack
24 of access to sufficient technology development and
25 commercialization expertise that's required to both

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

6 (Slide.)

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

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

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

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

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

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

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

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

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

1 establish investor forums to reach out to partnering
2 communities.

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

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

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

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

3 (Slide.)

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

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

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

16 The goal is to develop the technology to a
17 point where it's able to attract the next level
18 of independent financing and have it exit the center
19 either through licensing through an existing for
20 profit or not for profit or starting a new company.

21 And we can imagine that during the development
22 process there will be a lot of opportunity to
23 leverage existing NIH resources that can help with
24 those processes.

25 (Slide.)

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

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

25 The Department of Commerce is also on

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

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

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

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

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

9 (Slide.)

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

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

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

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

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

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

25 (Slide.)

1 So I was going to end my talk by
2 describing some of the issues and concerns that
3 NHLBI has with some of the reauthorization guidance
4 but that has been pretty well taken care of. I
5 would just like to stress that the ICs really need
6 funding flexibility. Biomedical technologies
7 usually require FDA approval and in order to comply
8 with those requirements it usually takes more time
9 and more money. I know that 83 percent of our phase
10 2 portfolio is developing a technology that requires
11 FDA approval and since we are dependent on the
12 private sector for phase 3 we need to be able to
13 develop those programs--those particular
14 technologies based on programmatic need and balance
15 to a point where it's attractive to the private
16 community to pick up.

17 (Slide.)

18 And I'll just end there.

19 DR. BRIGGS: Jodi, this has been terrific.

20 I think it's a very provocative and important
21 presentation but I think we do have to keep going.

22 DR. BLACK: Okay.

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

25 Our last presenter is Elena Koustova from

1 NIDA.

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

4 ***Elena Koustova, Ph.D., M.B.A.,***
5 ***National Institute on Drug Abuse***

6 DR. KOUSTOVA: Okay.

7 (Slide.)

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

14 The SBIR program at NIH is effective
15 because one-size-fits-all approach was not imposed.

16 But for this same reason specific ICs of specific
17 institutes may experience specific problems which
18 are not uniform for all other ICs.

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

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

1 Collins says it's probably a very timely title.

2 (Slide.)

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

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

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

1 officers, without dedicated FTEs.

2 (Slide.)

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

12 (Slide.)

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

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

24 (Slide.)

25 Surprisingly, addressing modest management

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

14 We also established separate funding
15 meetings which are now transparent.

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

20 (Slide.)

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

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

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

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

18 And, of course, we scout.

19 (Slide.)

20 So one of our examples of our scouting
21 and outreach activities is our work with the most
22 unlikely collaborator, with the Library of Congress.

23 So that's what you have to do when you don't have
24 budget and you don't have any money.

25 (Laughter.)

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

17 (Slide.)

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

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

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

12 (Slide.)

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

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

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

14 (Slide.)

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

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

8 (Slide.)

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

13 (Slide.)

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

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

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

6 Thank you.

7 **PANEL I DISCUSSION**

8 DR. BRIGGS: Thank you very much, Elena.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 DR. BRIGGS: Gail?

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

1 to give advice.

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

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

9 DR. BRIGGS: Garry?

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

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

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

20 DR. BLACK: So the funding opportunity
21 announcement was published in the NIH Guide in May.

22 So we're right at the beginning.

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

1 involving people from the private insurance industry
2 as well.

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

5 DR. BRIGGS: Richard?

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

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

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

5 DR. : (Not at microphone.)

6 (Laughter.)

7 DR. BRIGGS: (Not at microphone.)

8 CHAIRMAN AUGUSTINE: (Not at microphone.)

9 I give all these instructions and then
10 ignore them.

11 (Laughter.)

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

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

19 **PANEL PRESENTATION II**

20 **PROGRAMS WITHIN OTHER FEDERAL AGENCIES**

21 **Moderators: Hon. Daniel S. Goldin, SMRB Member and**

22 **Gail H. Cassell, Ph.D., SMRB Member**

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

25 HON. GOLDIN: Ladies go first.

1 (Laughter.)

2 Ladies first.

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

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

13 *Michael Mutty,*

14 *Defense Advanced Research Projects Agency*

15 MR. MUTTY: So good morning, everybody.

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

21 (Laughter.)

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

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

7 (Laughter.)

8 Actually I do have a sense of humor.

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

16 My background is that I worked for about
17 20 years for the Naval Air Systems Command. I was
18 involved in writing contracts for very complex
19 development programs for fighter aircraft primarily
20 but I've been at DARPA for a few years now and I've
21 just recently been exposed to the SBIR program. It
22 strikes me that if you are buying an airplane, if
23 you're buying a submarine, if you're buying food
24 services for marines in Iraq, if you're buying grass
25 cutting services for a military base or an SBIR,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 How does your agency define program
13 success?

14 What process milestones does your agency
15 put into place?

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

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

25 Yes, they are.

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

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

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

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

1 open it up to questions if have you any.

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

4 MR. MUTTY: I was afraid of that.

5 (Laughter.)

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

12 MR. MUTTY: Right.

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

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

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

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

6 MR. MUTTY: Even our normal--

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

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

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

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

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

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

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

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

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

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

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

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

13 So what does the Department of Defense
14 broadly think about it? I mean the military
15 medicine is probably one of the largest HMOs. If
16 not the largest HMO in the world, it's close to it.

17 We have a supermarket chain, our commissaries. We
18 have retail operations. We have chaplains. We have
19 undertakers. We buy bullets. We buy planes.

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

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

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

10 (Laughter.)

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

13 Dan?

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

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

3 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (Laughter.)

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

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

1 DR. CASSELL: Susan?

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

12 We don't--of course, I mean for most of
13 what we do in our RPG line we don't do that at all.

14 You know, we just--is it in the mission of our
15 institute and, if so, we'll take it. But this is a
16 very different focus.

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

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

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

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

3 DR. CASSELL: Of the SBIR?

4 DR. PORTNOY: Of the SBIR.

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

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

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

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

21 DR. BRIGGS: Dan?

22 (Simultaneous discussion.)

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

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

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

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

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

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

25 DR. COLLINS: Yes. Kathy Hudson is here

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

7 Do you want to say something about that?

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

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

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

1 being the bottleneck because it took so long to get
2 contracts out. And then one three-star once said,
3 "Well, let's do an analysis of the entire process."

4 And it was really the requirements generation and
5 source selection process. The contracting process
6 actually was very short.

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

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

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

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

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

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

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

18 DR. CASSELL: Norm?

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

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

1 conservative outcomes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 DR. CASSELL: Sure.

17 Bill or Gil, questions or comments?

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

21 ***Manny Oliver, Ph.D., Department of Energy***

22 DR. OLIVER: Thank you.

23 (Slide.)

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

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

7 (Slide.)

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

16 (Slide.)

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

1 that's about two-thirds of the R&D budget within the
2 Department of Energy. And then we have the Office
3 of the Undersecretary of Energy on the right there.

4 So these three different offices also have very
5 different missions but all of them participate in
6 the program.

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

10 (Slide.)

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

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

1 the projects once they're underway.

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

7 (Slide.)

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

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

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

25 (Slide.)

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

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

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

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

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

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

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

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

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

11 (Slide.)

12 One of the--you know, the big challenge I
13 saw is that, gee, we only have six weeks. We are
14 putting out a topic. We expect a full application
15 with all the partners and subcontracts lined up.
16 And we in many cases looking for breakthrough ideas.

17 So this is really not a lot of time to do that.

18 And we--again, the six week time is also not a lot
19 of time for applicants to really understand the
20 technical topics and what we're looking for.

21 Especially since the communications while the
22 funding opportunity is out has to go through a Fed
23 connect system where all the questions and
24 answers are posted for everyone to see. So this was
25 a little bit cumbersome so we wanted to improve the

1 frontend process here and provide more time.

2 Again, coming from the private sector,
3 this five-and-a-half month time is way out of line.

4 You know, in the private sector we are changing
5 projects and those decisions again are made in days
6 and weeks, not in months.

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

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

18 (Slide.)

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

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

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

24 (Slide.)

25 In the past we actually only had one phase

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

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

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

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

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

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

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

24 (Slide.)

25 I think the other thing we did is we--

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

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

18 (Slide.)

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

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

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

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

3 And, finally, for Release 3 of the pilot
4 we actually went to a pre-application process. And
5 again this--again, those who were declined from the
6 pre-application could not submit a full application.

7 This one is still ongoing and so, you know, we're
8 looking at these two different approaches and their
9 effectiveness in terms of both the small business
10 feedback as well as the--you know, our--impact on us
11 in terms of improving our award cycle time.

12 (Slide.)

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

22 (Slide.)

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

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

10 And, also, working with our Chicago
11 office, over eighty percent of the grants were
12 negotiated prior to the grant start date. So, in
13 total, from '11 to '12 we have taken about three
14 months, you know, from the small business
15 perspective off the process. We are one of the
16 agencies that, as Matt mentioned, are subject to the
17 90 day requirement starting FY13. So we'll be
18 taking another three weeks off the process for next
19 year so that the selection process does comply with
20 the reauthorization.

21 (Slide.)

22 Next I just want to talk briefly about
23 outcomes.

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

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

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

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

16 (Slide.)

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

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

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

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

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

1 review process.

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

4 (Slide.)

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

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

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

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

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

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

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

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

23 (Slide.)

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

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

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

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

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

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

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

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

24 (Slide.)

25 I think for next year we are planning to

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

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

20 (Slide.)

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

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

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

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

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

21 (Slide.)

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

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

4 HON. GOLDIN: Thank you.

5 We're going to switch now.

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

12 Grace?

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

14 DR. WANG: Thank you.

15 (Slide.)

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

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

1 about SBIR/STTR programs here of course.

2 (Slide.)

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

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

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

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

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

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

23 So that's how the program is structured.

24 (Slide.)

25 The funding mechanism is a grant. We--

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

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

23 (Laughter.)

24 HON. GOLDIN: That's not acceptable
25 anywhere.

1 (Laughter.)

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

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

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

11 (Slide.)

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

19 (Slide.)

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

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

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

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

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

1 (Slide.)

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

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

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

1 (Slide.)

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

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

1 to develop the entrepreneurs that can move forward.

2 (Slide.)

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

9 (Slide.)

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

17 (Slide.)

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

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

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

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

24 (Slide.)

25 During the phase 2 panel we usually put

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

9 (Slide.)

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

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

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

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

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

21 So that's our peer review process.

22 (Slide.)

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

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

4 (Slide.)

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

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

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

4 (Slide.)

5 So what do our program directors do?

6 If you take a look at the small businesses
7 here--this is our PI or the applicants or grantees.

8 And this is our program directors. Again we are
9 using our program directors as the sole technical
10 and business contact.

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

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

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

8 (Slide.)

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

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

1 in a few minutes.

2 (Slide.)

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

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

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

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

21 (Slide.)

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

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

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

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

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

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

12 (Slide.)

13 And the problem, as I already said
14 probably a few times, is it's very commercialization
15 driven. We have a phase 2b program. I already
16 talked about it. Another supplement that we had
17 recently was called Technology Enhancement for
18 Commercial Partnerships, so-called TECP. This is a
19 \$100,000 supplement to help our grantees to form
20 strategic partnerships with potential customers and
21 to develop a product that's really tuned to meet a
22 customer's need. So to really help them and
23 stimulate the conversations between our grantees and
24 their customers. So we allow them to go out and
25 actually form the partnerships and come back and get

1 this \$100,000 if we can.

2 (Slide.)

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

10 We practically stopped making any
11 technical presentations during our phase 2 grantees.

12 Instead actually we focus very strongly on
13 entrepreneurial training and this is actually from
14 IP management to peer building to the board of
15 governors and also to fund raising to strategic
16 partnerships. We actually try to cover all the
17 aspects of entrepreneur or the challenge an
18 entrepreneur may face. And we strongly encourage
19 them to apply all the skills they may acquire from
20 other grantees conference to their companies.
21 conference.

22 (Slide.)

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

25 So we do external evaluation with National

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

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

11 What he does is he actually takes a look
12 at our grantees within the last ten years, the Phase
13 2 grantees, and he put the three year anniversary,
14 five year anniversary and eight year anniversary
15 there on his chart. And on those anniversary dates--
16 -I'm talking about anniversary after their
17 graduation from NSF so after they finish the Phase
18 2. And even make phone calls to these grantees to
19 find out first off if they are still existing. That
20 means they did survive. And, second of all, what is
21 the results they have generated?

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

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

4 So that's all I have.

5 Thank you.

6 **PANEL II DISCUSSION**

7 HON. GOLDIN: Thank you, Grace.

8 We now have time for questions.

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

12 HON. GOLDIN: For the whole panel.

13 DR. SNYDER: I have a question.

14 You commented, Grace, about the \$45

15 million from SBIR funds that go to universities.

16 Could you comment more about that? I didn't even

17 know that you're allowed to use SBIR funds to go to
18 universities?

19 DR. WANG: No, no, it's not \$40 million.

20 I'm commenting about my division. My division is

21 called Industry Innovation and Partnerships

22 Division. The budget is \$190. \$40 million

23 goes to the universities, that's academic awards.

24 Just like other NSF awards but it's focusing on

25 industrial partnerships. And \$150 million goes to

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

3 DR. SNYDER: Right.

4 DR. WANG: Yes.

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

9 DR. WANG: That's correct.

10 DR. SNYDER: Okay.

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

13 DR. SNYDER: Yes.

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

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

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

10 And we typically give the reviewers three
11 weeks to complete their reviews of the applications.

12 And any individual reviewer, depending on program,
13 may go from one to maybe as many as six applications
14 at a time typically.

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

17 DR. OLIVER: Right. So those are--

18 DR. COLLINS: --mail reviews.

19 DR. OLIVER: Those are independent--

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

23 DR. OLIVER: Right.

24 HON. GOLDIN: Norm?

25 CHAIRMAN AUGUSTINE: I wanted to pursue

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

11 What happens to me?

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

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

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

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

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

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

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

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

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

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

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

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

21 DR. CASSELL: Yes.

22 DR. OLIVER: --that the intent?

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

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

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

3 DR. CASSELL: Yes.

4 DR. COLLINS: But to follow up on that, it
5 sounded as if that actually adds some substantial
6 time to the ability to give a phase 2 award at
7 NSF as part of your process of making a decision and
8 I didn't hear that same kind of time devoted to this
9 financial audit from some of the other agencies. So
10 I'm just wondering did you get burned at one point?

11 Is there some reason why in the Phase 2 process
12 this is insisted upon? Because it sounds like it
13 costs you quite a few months.

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

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

1 process.

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

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

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

11 MR. MUTTY: Not significantly, no.

12 DR. CASSELL: Does NIH do this?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 (Laughter.)

25 I've never eaten there.

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

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

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

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

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

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

14

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

2 CHAIRMAN AUGUSTINE: Okay.

3 Thank you, everybody, for returning
4 promptly.

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

7 Bill, are you there?

8 DR. BRODY: Yes, I am.

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

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

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

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

5 CHAIRMAN AUGUSTINE: All good points.

6 Thanks, Bill.

7 Gil, are you there?

8 Clyde, are you there?

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

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

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

18 CHAIRMAN AUGUSTINE: Oh, okay.

19 Well, is anyone else on the line?

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

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

25 Sol, it's back to you.

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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

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

5 (Slide.)

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

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

23 (Slide.)

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

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

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

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

1 reporting requirements.

2 (Slide.)

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

11 Now, of course, it went into more depth
12 than this in the discussion of what
13 commercialization is and what we surveyed them on
14 but a simple question was "have you commercialized
15 anything," and we had a result there of 73 percent.

16 But, of course, that was over almost a ten year
17 period.

18 In 2009, we did this again and we surveyed
19 companies that received phase 2 awards between 2002
20 and 2006. And under that survey that we did, about
21 61 percent reported commercializing a core
22 technology or information supported by their awards.

23 (Slide.)

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

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

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

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

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

11 (Slide.)

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

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

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

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

14 (Slide.)

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

25 So the metrics we use are investment funds

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

8 (Slide.)

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

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

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

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

12 (Slide.)

13 This is again more. We have--this is non-
14 government funding raised. Again, this tells you
15 how much--with those companies that were involved in
16 our CAP program--how much additional revenue that
17 they raised towards their projects. And, again,
18 because we're a little bit behind on some of these,
19 and I'm not sure we see what happened here in 2008
20 and 2009, we all know what was happening with the
21 economy at that time so that is, I think, quite
22 understandable. But look at what we have seen here
23 in 2010 and '11.

24 Now, remember this is only a subset of our
25 SBIR/STTR recipients. So these are only those

1 individuals that are part of the CAP program. So
2 that does make them a very specialized group. There
3 are those that don't need to take advantage of the
4 CAP program that may have additional revenue and may
5 be a larger set of the revenue generated by a
6 program.

7 (Slide.)

8 This is employment. This shows that we
9 had since that time about 1,500 new jobs created by
10 355 companies. Fifty-one percent of our CAP
11 companies reported an increase in employment. So we
12 hope--and we take credit for that because of the
13 funding that they received through the NIH SBIR/STTR
14 program.

15 (Slide.)

16 Now, we have had what we call the
17 Performance Outcomes and Data Systems, the PODS
18 database, for quite a while. This is a database
19 that's available internally. It is not available
20 externally at this point. This is one that we feel,
21 very importantly, that we would like to put
22 additional administrative funds towards developing
23 in a much more complicated way and ways that will
24 allow us to do better tracking for both our--for all
25 of our SBIR/STTR program.

1 And, also, once it is more mature, this
2 database is more mature, we feel that we could
3 actually allow a piece of this database to be
4 visible publicly. We have had a lot of conversation
5 with Sean at SBA because there is some interest in
6 sharing the types of databases that we have together
7 that will allow us as a federal government to be
8 able to track our SBIR/STTR programs.

9 So this is an integrative flexible tool
10 for program managers. Again, it's only for NIH
11 internal use. It allows users to save reports
12 and choose to share them with others and all data in
13 PODS are primarily linked to our project numbers.
14 So to our project numbers in our SBIR/STTR program--
15 projects. And it allows us to report on the
16 capabilities of some commercial outcomes.

17 (Slide.)

18 So currently in PODS we have SBIR/STTR
19 award data source from our IMPAC II system. That's
20 our internal grant system.

21 We have 2002 and 2008 national surveys of
22 the program's legacy data.

23 We have all that information I just told
24 you about from our CAP program is in our PODS
25 database.

1 We have success stories.

2 We have other publicly available data that
3 we and the recipient organizations have put in there
4 regarding patents, publications, clinicaltrial.gov
5 data, et cetera.

6 And it has a Google search link to each
7 company.

8 And then it has a query ability to save or
9 share and export these features.

10 One of the things I wanted to point out
11 here, and I had to ask Matt what this was, was Quad
12 Chards or charts. I hope it is charts. And so
13 this--the Quad Chart includes things like the
14 specific company information, the management team,
15 the overview of the technology and its competitive
16 advantages and your company's pipeline of products
17 under development or a detailed description of the
18 technology. So instead of having to look through a
19 grant application, you have a quick and dirty on the
20 company and on the type of technology that they are
21 developing.

22 The Quad Chart also serves as the CEO
23 summary that will be somewhat of a distillation
24 presented at feedback sessions so we have a number
25 of feedback sessions that go on.

1 (Slide.)

2 So that is it.

3 Let me talk to you a little bit about our
4 next steps.

5 Now, as you see from what I presented to
6 you, our approach to metrics and measuring success
7 and outcomes has been somewhat piecemeal. And we
8 have relied very heavily on NRC studies, on our own
9 studies at different year intervals. And what we
10 would really like to do is to implement a routine
11 tracking of all the awards using multiple metrics,
12 including long-term commercialization outcomes.

13 Now, again, we face the same problem with
14 measuring outcomes with SBIR/STTR programs as we
15 do with any of our grant programs. Once the grant
16 is over the ability to track it throughout the
17 course of its life becomes more difficult and what
18 might be a technology that is developed seven years
19 after the SBIR/STTR grant that NIH provided is over
20 doesn't often link back with the NIH grant. I mean
21 you can get it some way if you work through the
22 patent database or other ways but it's not just an
23 intuitive natural way to track these things.

24 So we are looking towards our
25 additional resources. One of the things we very

1 much want to do is once we have the ability to use
2 administrative funds, which the new reauthorization
3 has allowed to enhance our programs, this would
4 be one of our big targeted areas that we would like
5 to go after. And, also, we will have to have
6 OMB approval to track things in different ways, of
7 course, than we normally do. As you all know, when
8 we track and ask for information from our grantees,
9 we have to go through OMB approval.

10 (Slide.)

11 And then the reauthorization, though, does
12 require companies to provide updates on the
13 commercialization outcomes both on the previous
14 awards and going forward. So there is a much
15 clearer edict by the reauthorization to say when
16 you--to find a way to get those commercialization as
17 outcomes from an award that already has resulted
18 and/or that company comes back for further awards,
19 we want to see what those outcomes have been.

20 And we also want to expand our CAP program
21 to STTR. Right now it's only for SBIR phase 2.

22 So remember we want to extend that CAP to the STTR.

23 And we want to enhance and revise the final report.
24 Remember that all grants at NIH have to have a final
25 report. We think that, if we can, we would like to

1 revise that so we can have specific metrics that we
2 could ask the winners, the SBIR/STTR winners, to
3 report on in their final report. And that would be
4 at the end of the award. But then we could in some
5 way use that to do the follow on tracking. We have
6 to figure out a way that down the road we are able
7 to track these technologies.

8 Like we have talked about with tracking
9 individuals that are supported by NIH where we need
10 somehow to barcode them and be able to track them
11 through the life of their career, these technologies
12 that are developed at different stages and at
13 different times based on support they have received
14 from the SBIR/STTR program, we need to be able to
15 track that through time as well.

16 So that is, I think, all I have.

17 Yes.

18 And I don't know if you wanted to let Sean
19 go ahead because he's on a tight schedule or if you
20 want to ask me questions and then go to the panel.

21 Okay.

22 DR. SNYDER: Yes.

23 Since there is this tight schedule maybe
24 Sean will speak now and then we can have questions
25 afterwards.

1 on.

2 So, what I'd like to do in my remarks, and
3 then potentially leave time for questions, but I'll
4 also be on the final panel, is talk about three
5 things.

6 One is a little bit of context of both my
7 background, what SBA does in the SBIR program and
8 why this really is a critical time for the
9 SBIR program.

10 Secondly, talk about reauthorization in
11 general. And I know Matt covered a fair bit so I
12 think we can be pretty quick on that.

13 But then, third, be very focused on
14 implications on some particularly relevant issues
15 for NIH in the SBIR reauthorization.

16 So quickly in terms of my background, I
17 come to this as a private sector person. I spent 20
18 years in the private sector. I had been a
19 management consultant at McKinsey. Please don't
20 hold that against me. But I've been an entrepreneur
21 and then after selling one of my companies I became
22 a seed stage investor. So I come to this out of the
23 entrepreneurial ecosystem. At SBA I run the Office
24 of Investment and Innovation but broadly speaking
25 I'm responsible for SBA's efforts in high growth

1 entrepreneurship. So more specifically within that
2 portfolio I have the SBIR program but also the SBIC
3 program, which is a \$16 billion fund of funds, and I
4 have been very involved in the administration's
5 Start Up America effort, which is largely focused on
6 mobilizing government resources, as well as private
7 sector resources on behalf of high growth
8 entrepreneurship across the country.

9 The reason that is important right now is
10 all the data shows that if you're looking at net new
11 job creation in the economy, not only is it
12 disproportionately concentrated in smaller
13 businesses, but it's even more concentrated in the
14 tiny subset, four to five percent of those small
15 businesses, who effectively contribute all of the
16 net new jobs in the economy.

17 So in general, we need to be doing
18 everything we can to stimulate not only the start-up
19 of new companies but the scale-up of existing
20 companies but particularly in the economic
21 environment we are in that is particularly critical.

22 And, for context, what we have seen since
23 2007 is the decline by approximately 25 percent of
24 the number of new start-ups per year and some
25 estimates have traced that to a drop of about two

1 million jobs. And not only a decline of start-ups
2 but a marked acceleration of the death rate of
3 companies. So now more than ever we really need to
4 focus on these kind of programs.

5 Also, for context, again within the
6 broader administration initiatives, as we're talking
7 about the SBIR program, we need to think not only
8 about the reauthorization but broader administration
9 efforts on things like improving the
10 commercialization of federally funded technologies
11 to get more ideas out of the lab and into the
12 marketplace. And the President issued an executive
13 memorandum focusing on a range of things that can be
14 done across the government to do that. As well as a
15 broader set of presidential initiatives focusing on
16 streamlining and simplification with a recurring
17 theme for entrepreneurs and small businesses the
18 federal government is incredibly hard to navigate.
19 And so it's incumbent upon us to make these programs
20 more effective and to continually be looking for
21 ways to streamline and simplify.

22 So in terms of--and let me also clarify
23 that I am not an expert in health or sciences. My
24 entrepreneurial background is in other disciplines
25 so I'm clearly not an expert here. That being said,

1 I'm going to be talking about the ecosystem. One of
2 the things we did in the Start Up America effort,
3 for instance, was the first thing was a radical idea
4 of getting out and listening to our customers.

5 So we spent several months talking to over
6 1,000 entrepreneurs and investors in the ecosystem
7 asking them the question "what barriers are you
8 facing to growing your companies and creating jobs
9 and what are the concrete things that we can do to
10 change that? We got great ideas. I won't give you
11 all of them all but radical ideas like, hey, why
12 doesn't the government just pay customers faster?
13 So the President issued an executive order to pay in
14 15 days all small businesses.

15 Somebody gave us the idea of, hey, if we
16 want the government to be more entrepreneurial why
17 don't we get more entrepreneurs in the federal
18 government. So we created an Entrepreneur in
19 Residence Program that was actually piloted at HHS
20 within FDA and that we're rolling out at the White
21 House level. Literally, we have just announced five
22 projects. We have got 18 presidential innovation
23 fellows we are looking to fill. We have had over
24 1,000 applicants. So lots of good other stuff
25 happening but again largely focused on this.

1 So, specifically, I think for the SBIR
2 program there is a moment in time now to have a
3 tremendous impact on this ecosystem. And to give
4 you context, across all 11 agencies we are talking
5 about \$2.5 billion of financing or cash within the
6 form of grants or contracts to entrepreneurial
7 companies. The entire venture capital industry at
8 the seed stage only puts \$1.6 billion in. So
9 what we are seeing in venture is going to later and
10 later stage, in general, let alone--since we've seen
11 marked decline since the financial crisis. So again
12 now more than ever the capital coming out of the
13 SBIR program has a potentially massive impact on the
14 early stage innovative technology companies.

15 So I won't belabor the basics of the SBIR
16 program. You all know it at this point. You know,
17 four primary objectives, increasing innovation,
18 driving higher levels of commercialization of
19 federally funded research, allowing small businesses
20 to participate in federal R&D spending, and then
21 increasing participation of minority and
22 competitively disadvantaged businesses in
23 federal R&D.

24 So, with those high-level goals--and,
25 again, I think you have all seen the National

1 Academies studies that basically conclude that the
2 program is, you know, sound in concept and effective
3 in practice. There's lots of other data that
4 highlights success of the program. We saw this
5 question earlier. The National Academies studies
6 have shown that across all agencies approximately 50
7 percent of awardees actually get a product to
8 market. Other studies have shown things like the
9 R&D 100, which is evaluated each year, the 100 most
10 innovative technology breakthroughs in the R&D
11 space. You know, a full 25 percent of those that
12 have been cited by the R&D 100 were companies that
13 were funded by the SBIR program.

14 So lots of good progress.

15 I think with all that being said, my
16 evaluation is what we have here is a good program
17 that can still be a lot better. And in the context
18 of the reauthorization what we have is both a
19 mandate from congress to improve the program, as
20 well as a targeted set of opportunities to improve
21 it in a meaningful way.

22 So quickly on the reauthorization side,
23 you know, I think--before we go to reauthorization,
24 coming back SBA's role.

25 So SBA has a very specific role in the

1 program.

2 Obviously, the primary action, the
3 decisions on the companies, how the programs are run
4 happen at the agencies. But SBA has kind of four
5 discreet roles in the program.

6 The first is to set policies for the
7 program. So the SBIR is authorized as part of the
8 Small Business Act. And so when it comes time to
9 translate the statute into policy directives, et
10 cetera, we have primary responsibility for that.
11 So first of all is policy role.

12 The second role is a reporting and a
13 performance--oversight and performance measurement
14 role. So while a lot of the data gets collected at
15 an individual agency in terms of looking at the
16 performance of the program as a whole, we have
17 responsibility for that and reporting that out to
18 the public and to congress.

19 The third role is an outreach role.
20 Again, each agency can do targeted outreach relevant
21 and consistent with the mission of that agency. We
22 do a broader set of outreach to small businesses
23 across the board. We do things like SBIR.gov which
24 again provides news and information about the
25 program as a whole across all agencies.

1 And then, finally, there's a role--a
2 convener or facilitator, whatever the right word is,
3 to work among the agencies to do things like share
4 best practices, identify best practices and share
5 best practices and help foster collaboration among
6 those agencies. So, again, the two decisions
7 happen at the agencies but we work very closely with
8 the program managers across all those agencies to do
9 that.

10 So, I guess, the final point before I jump
11 into the reauthorization, I think that coming back
12 to this broader opportunity at a time when the
13 administration is saying it's a key priority to
14 drive higher rates of commercialization of federally
15 funded research, and we really need to do more to
16 get the ideas out of the lab and into the market.
17 Here we have a program through its fundamental
18 construct is well suited to do that. So trying to
19 turn every scientist into an entrepreneur isn't
20 necessarily going to happen but it is a program that
21 can support and fund people who are already both
22 scientists and entrepreneurs. As well as
23 potentially and particularly through the STTR
24 program, partner entrepreneurs and scientists in
25 creative ways, again to get more ideas out of the

1 lab and into the market.

2 So in terms of reauthorization, I think
3 probably at this point most of you know the history.

4 Fourteen successive temporary extensions that took
5 place over, I believe, three years. Lots of
6 disagreement and in Washington where you're used to
7 seeing Republicans and Democrats disagree, this was
8 largely more the House and the Senate disagreeing
9 with each other and it wasn't a political party
10 issue. A handful of key changes that were largely
11 debated. The good news is now the President has
12 signed the statute into law and we are very busy
13 working with the program managers to implement
14 it. It was signed into law by December 31st. So we
15 are smack in the middle of the implementation.

16 In terms of the process of where we are,
17 and I think Matt gave a snapshot of this. Really
18 quickly, the standard joke I have been using, that
19 grammar rock cartoon that told us how a bill becomes
20 a law, they never did the sequel in terms of how
21 detailed regs get written after the law is
22 implemented. But we kind of have two parallel
23 processes going on. One is part of the
24 reauthorization deals with SBA size standards about
25 how we define a small business. And so all of the

1 issues of venture capital participation,
2 affiliation, foreign ownership are part of
3 that. So we have got one timetable for that and
4 these are a broader set of regulations that SBA uses
5 across all of its programs. As you can imagine,
6 those are complex set of rules keenly debated, et
7 cetera, et cetera.

8 Those rules we have issued proposed rules
9 for. They are out for public comment now. The
10 public comment period ends next week. And then
11 after getting the public comments, we will then
12 revise the rules and we have a statutory mandate to
13 issue the final rules by the end of the calendar
14 year.

15 Separately, then there is a policy
16 directive, which is more an internal set of rules
17 that SBA issues to the agency as guidance and rules
18 about how to administer the program. We are very
19 close to getting those rules out. Our deadline was
20 June 30th so we're a week or two late but we are
21 very close to getting those out.

22 So that is on the process side.

23 In terms of the substance--and again, I
24 think, Matt, you went through most of this.

25 Just really quickly, obviously long term

1 commitment to the program, six year
2 reauthorization. That was critically important in
3 our view because it's hard for the agencies to plan
4 and it's hard for small businesses not knowing if
5 the program is going to be around. They are clearly
6 increasing the set asides. As you know, there are
7 some changes in the rules, including venture capital
8 participation in CAPs and we talked about that.

9 Clearly an important part of the
10 reauthorization mandate is a higher sense of
11 tracking performance, measuring performance and
12 tracking it over time. And then, equally
13 importantly, a targeted set of initiatives and
14 guidelines of ways to improve performance.
15 Simplification, faster turnaround times, more
16 support for commercialization, higher levels of
17 fraud, waste and abuse management, and so on.

18 And just as critically, as I'm sure you
19 have heard the folks from NIH tell you,
20 administrative funding to actually get the resources
21 to put in place.

22 I will put the caveat that the
23 administrative funding is a pilot program for three
24 years, which kind of sets the pressure to say on all
25 those performance issues it's going to be

1 critically important that over the next three years
2 we move the needle, whether it's on the timelines,
3 and commercialization is going to move the needle in
4 three years for timeline, but we move the needle in
5 some of these areas to show that funding is being
6 put to good use.

7 So from my perspective, you know, without
8 going through the full list of everything, the
9 reauthorization bill focused, in particular, on some
10 areas that I think are especially relevant for NIH
11 and, in particular, relevant for this advisory
12 committee. I think in some ways the timing of your
13 effort at the advisory committee here is actually
14 perfect and I don't know the full history.

15 I understand that you are evaluating this
16 not knowing when reauthorization was going to
17 happen. But even with reauthorization being done
18 there is still a tremendous amount of work to do to
19 implement the changes that are going to drive this.

20 And I think what I have seen in working with NIH
21 folks is you've got a group of talented dedicated
22 staff, both in the individual institutes as well as
23 at the center, working in this program. The list of
24 things that they have on their plate is incredibly
25 hot. So I think a couple of places where you, as an

1 advisory committee can be tremendously helpful, is
2 prioritizing and your guidance and view on the
3 places that you think are most critically important
4 to move the needle.

5 And then, secondly, I know from having
6 been inundated with all of the daily, you know, to
7 do lists to get stuff done, having a fresh set of
8 eyes looking at out of the box solutions to
9 addressing some of the issues here across the 101
10 changes that have to happen. And so I think your
11 timing as the implementation is really just in its
12 infancy is great.

13 So, in terms of focus, a couple of very
14 specific places that in my mind are particularly
15 relevant for NIH.

16 One thing that I'm sure you've heard
17 before, I hear over and over again when I'm hearing
18 from small businesses, is cycle times in the program
19 as a whole but also at NIH are just way too long.
20 And for small businesses where time is money,
21 right, and, you know, a year can be four life times
22 for many of these companies, anything that we can do
23 to shorten cycle times is critically important.

24 And then, secondly, is to increase the
25 role of commercialization not only in post award

1 support but how we evaluate commercialization
2 potential in the companies themselves.

3 So let me drill down a little bit more
4 specifically.

5 First of all, on timelines again there's
6 clear statutory mandates in terms of the selection
7 process that for most agencies there's a statutory
8 mandate to say from the close of the solicitation to
9 the decision on the company should take 90 days.
10 For NIH the mandate was one year. I would challenge
11 the group to say out of their opportunities to do it
12 even faster than a year and how can you beat the
13 statutory mandate.

14 Secondly, there's another set of
15 challenges from the time of decision to the time of
16 funding. How can that be as fast as possible?
17 Right? And again this is something that we're
18 tackling in other agencies as well.

19 I don't pretend to have the answers of
20 what the right solution is. There's a range of
21 ideas being put out there but this is a place where
22 third party outside view of where there are
23 opportunities is incredibly important. Some of the
24 ideas that we're hearing from the outside, from
25 other agencies are things like can--you know, is it

1 okay for this program to be slightly different than
2 other R&D programs within NIH? Is there a way to
3 differentiate phase 1, which is a small dollar
4 amount, from phase 2 in terms of that process and
5 looking for maybe a condensed--a more condensed or
6 aggressive cycle on phase 1 where 150K is at stake
7 rather than a million plus award.

8 Where are the opportunities for ever green
9 solicitations? I know this is one of these that
10 scares program managers because they think of the
11 additional workload but an idea that has come to us
12 is, look, it's not just about the time from the
13 close of solicitation to an actual award. But if
14 you spend six months waiting for the solicitation
15 deadline, we have to--you know, that's how an
16 entrepreneur looks at it as well. So where are
17 there opportunities for potentially more rolling
18 solicitation closes rather than--you know, that will
19 require resources. That will require a redesign of
20 the processes. So none of these are easy but those
21 are potential kind of broader out of the box
22 solutions of how we can tackle timing issues.

23 Second is--a huge issue obviously is
24 commercialization. Clearly just from the 30
25 minutes I just saw I know that's a critical issue

1 for you.

2 Within the reauthorization there is an
3 authorization for pilot program for up to 10 percent
4 of the total award specifically targeting
5 commercialization. You guys already do a matching
6 program that has been identified as a best practice
7 across all federal agencies. So looking and saying
8 how can we can do more with that. That is another
9 lever.

10 Other transactions authority is a specific
11 vehicle that other agencies, including DARPA, have
12 looked at as again a specific technical mechanism to
13 help.

14 And, you know, a third broader idea is
15 where are there ways for more aggressive
16 partnerships with third parties, whether those are
17 on the investor side or, in particular, with
18 accelerators and universities. So as one targeted
19 example of this we are seeing across the country a
20 proliferation of accelerators and proof of concept
21 centers. One example, the Deshpande Center at MIT,
22 right, who is already doing a lot of work to
23 identify promising research in the labs at MIT and
24 running a competitive process and evaluating the
25 commercialization potential of those ideas.

1 How can you work with and piggyback off the work
2 being done, not just at MIT, in universities
3 across the country via these to say, here, look at
4 here, a third party validation and commercialization
5 potential. But just as importantly, post-award they
6 already have ecosystems of support with mentoring
7 from alumni, et cetera, et cetera, built into it.
8 Where are those kind of partnership opportunities?

9 A third kind of targeted area for focus is
10 simplification. And while we all want Ph.D.s to
11 be doing the research and the science, we shouldn't
12 need Ph.D.s in federal grant writing to apply to the
13 SBIR program, right? So where are there targeted
14 ways to reduce the complexity for newcomers coming
15 into the program? So how can we make this so people
16 don't have to rely on third party grant consultants
17 and writers to help and navigate the process?

18 How can we do it so that promising
19 inventors and scientists aren't turned off from the
20 complexity of the application process that
21 precludes them from applying in the first place?
22 Again, this isn't something that happens overnight
23 but where are there targeted opportunities to do
24 that?

25 A fourth concrete idea is the STTR

1 program. To look at it as a potential pilot
2 program. So you have an existing process for all of
3 these things. Modifying and changing it will take
4 time. We all love the notion of clean sheeting and
5 designing things from scratch but very often in a
6 large organization that's hard to do simultaneously
7 with running the day-to-day business.

8 Where with STTR, because it's smaller, are
9 there opportunities to try more out of the box clean
10 sheet approaches there, demonstrate that they can
11 work and then potentially look to scale in
12 replicating the SBA program where relevant?

13 And then, finally, the issue of
14 performance management metrics I think that we don't
15 need to get into great detail there. We'll talk a
16 little bit more. Just a couple of thoughts
17 following up on Sally's presentation.

18 The thinking that we have on performance
19 metrics is first we need to do this across the
20 program as a whole. Secondly, as opposed to relying
21 only on surveys the notion that when people apply
22 require them to update performance on past awards
23 becomes the single best carrot, right, in order to
24 get the data. And then you are building on a
25 database over time on a consistent ongoing basis

1 that can be supplemented by surveys and other
2 techniques.

3 And then to have a standardized set of
4 metrics that work across all agencies at a baseline
5 but then can be customized agency by agency to be
6 relevant for them.

7 So those are a few kind of concrete places
8 that I think are particularly relevant. Just some
9 final broader thoughts.

10 I believe in your process, kind of what we
11 want in the next steps is to communicate actively
12 with other third parties. I think this is
13 incredibly important. I have found, whenever I get
14 out of Washington and go listen, it's tremendously
15 valuable. I would encourage you as you do that to
16 not only talk to awardees, critically important, but
17 talk to promising innovative companies who have
18 chosen not to apply and understand why they're not
19 applying.

20 I would encourage you to talk to not only
21 venture capitalists but angel investors because
22 they're an incredibly important part of the
23 ecosystem as well.

24 Not just the buyers of the world but there
25 are other smaller business coalitions and

1 associations who have a clear set of ideas and
2 viewpoints as well.

3 And I would also recommend specifically to
4 talk to another federal advisory committee, NACIE.
5 So there's probably a complex set of rules of how
6 one federal advisory committee can talk to another
7 that none of us--no one understands. But NACIE is
8 the National Advisory Council on Innovation and
9 Entrepreneurship that has been run out of the
10 Department of Commerce.

11 They have looked at a range of issues
12 focusing on innovation and entrepreneurship but
13 the issue of driving higher levels of
14 commercialization of federally finished research has
15 been one of their areas. Some of the people
16 involved include the Mary Sue Coleman, the President
17 of the University of Michigan; Holden Thorp from
18 UNC; Chuck Vest, the former President of MIT; Desh
19 Deshpande, who is a successful entrepreneur, who
20 funded the Deshpande Center that I mentioned. And
21 so they've been thinking about these sets of issues,
22 not specifically about SBIR but more broadly, and I
23 think there's a potentially useful collaboration
24 there as well.

25 And then clearly I think, you know, to the

1 extent possible, and you're already doing it, by
2 bringing in other agencies who have
3 perspectives, ideas and things to learn as well.

4 So, with that, I will stop.

5 Again, I don't know if I should take
6 questions now, if the chair defers, or just stay for
7 the panel. Whatever works for you.

8 DR. SNYDER: Why don't we open up the
9 floor for questions for both speakers?

10 Okay.

11 DR. CASSELL: Could you tell us a little
12 more about this Committee for Innovation in the
13 Commerce Department, what its function is, how long
14 they've been in existence and maybe some of their
15 accomplishments?

16 MR. GREENE: Sure.

17 So, the committee was founded, I would
18 say, about a year-and-a-half ago. Three co-chairs.
19 Steve Case, founder of AOL; Desh Deshpande, founder
20 of Sycamore Networks; and Mary Sue Coleman.

21 So their charter was a relatively broad
22 one to say what can we do to stimulate more
23 innovation and entrepreneurship? They really did
24 zero in on two targeted topics initially. One was
25 access to capital issues and then, secondly, the

1 question of improving commercialization of
2 federally-funded research.

3 On the access to capital one of the big
4 successes that we have had in the last year was the
5 passage of the Jobs Act, which was focusing on a
6 legislative change that changed a bunch of rules
7 really at the Securities and Exchange Commission
8 about enabling higher levels of capital formation
9 for small businesses, both at early stage funding
10 like crowd funding, as well as opening up IPO
11 markets again. So the recommendations of NACIE were
12 fundamentally supported by what ultimately wound up
13 in the legislation.

14 On the commercialization side, one of the
15 big successes was organizing a letter signed by-- I
16 think the latest count is over 150 university
17 presidents explicitly committing to a set of actions
18 to drive higher levels of innovation and
19 entrepreneurship.

20 And so there is still work to be done to
21 say how do we go from the letter to a detailed
22 playbook of what's to be done. But in terms of
23 mobilizing a commitment really from the highest
24 level of the universities to do this, I think it's a
25 phenomenal start.

1 DR. SNYDER: Other questions?

2 HON. GOLDIN: I read through all the
3 documents. I went through the metrics. I heard all
4 the discussions here. I really feel there is a big
5 weakness in the metrics and there is lots of
6 discussions about it. I took the trouble of
7 reducing the metrics to specific numbers that I
8 could understand. I took a look at how much was
9 spent on SBIR versus how much was reported out the
10 backend in terms of number of jobs. The number of
11 jobs that went into supporting SBIR was
12 significantly larger than the claimed number of jobs
13 coming out.

14 I don't even want to repeat the numbers
15 but it seems to me the challenge--if you can't
16 measure it, you can't manage it. And there needs to
17 be some very deep thinking at all levels on this
18 SBIR program or else a day of reckoning will be
19 coming.

20 And when one looks at the magnitude of the
21 dollars and the budget that the NIH has, I think
22 it's very important to be able to work across the
23 government and with the help of entrepreneurs and
24 venture capitalists and those that are involved in
25 the process end to end to come up with metrics that

1 are realistic, not over the top, not over
2 promising, and this seems to be, to me, the most
3 important task we could undertake together.

4 MR. GREENE: I strongly agree. I think a
5 few thoughts. The systematic collection--so we
6 have struggled--my personal opinion at least is we
7 struggled a lot with what's the appropriate
8 definition and my personal bias is let's not let the
9 enemy--you know, the perfect be the enemy of the
10 good. Let's start getting the data on a consistent
11 basis even with--you know, getting 80 percent of the
12 way there, to just start moving on that is
13 critically important.

14 We have worked now across the agencies to
15 have a starting point of what I believe is a good
16 definition. We collectively have been underfunded
17 to do that. We don't have that excuse anymore.
18 With the administrative funding in reauthorization
19 we have that.

20 Let me also say when I said the program is
21 a good one that can be much better, I think SBA, in
22 particular, on the question of performance
23 management data, you know, historically has not
24 funded and supported that in a way that it needs to.

25 And so, you know, we're part of the problem and we

1 have to be part of the solution.

2 I think the good news on that is my boss,
3 the administrator, who has now been elevated to
4 Cabinet Secretary, personally understands the
5 importance of this program, personally understands
6 the importance of this issue and is making the
7 resources and people available to work on it.

8 It's not going to happen overnight but it
9 has got to be a high priority.

10 DR. SNYDER: Other questions or shall we
11 keep moving?

12 DR. COLLINS: So thanks for a really
13 informative presentation.

14 One of the things we talked about this
15 morning was with the new authorization the problem
16 in terms of a cap on the amount of dollars that can
17 be awarded in a phase 2 without getting a waiver
18 from SBA, and certainly for many of the projects
19 that we are most excited about, a \$1.5 million cap
20 is going to be a serious problem in terms of being
21 able to live out the hopes. So I guess I'm curious
22 to know how SBAS intends to handle those waiver
23 requests because we're likely to be on your doorstep
24 a lot.

25 MR. GREENE With great trepidation.

1 (Laughter.)

2 No, a central issue and critical issue for
3 NIH.

4 Two issues that I didn't really talk about
5 but that are critical for NIH. One is venture
6 capital participation, which obviously has been a
7 very important issue and we can talk more about that
8 if necessary but specifically the caps. And so
9 we're kind of, you know, in the middle trying to
10 make it work on both sides. Right? So the folks at
11 NIH have been very clear that that is important--the
12 importance to commercialization and outcomes is tied
13 to the ability to, you know, give larger awards to
14 promising--you know, at the same time Congress was
15 very clear in the mandate in setting the caps.

16 So here is our approach and how we're
17 thinking about it, right? There's an opportunity
18 to look at a bunch of levers, right, as opposed to
19 just kind of one large award to say, well, where is
20 there opportunities within the ten percent
21 commercial--the civilian commercialization pilot
22 program to give larger awards with that?

23 There are opportunities for us to give
24 targeted waivers but, by the way, we don't want to
25 be in the business of micromanaging, you know, any

1 agency at the individual award level to determine
2 what is an appropriate waiver or not.

3 The third lever is the opportunity to do
4 subsequent awards to the same awardee to further
5 pursue and then obviously there's a potential to use
6 non-SBIR dollars or to matching dollars as part of
7 the matching program to get more capital.

8 So there's a range of arrows in the
9 quiver, if you will, that may be harder to manage
10 but that's a starting point.

11 Secondly, though, as part of the
12 reauthorization, there was created an interagency
13 policy committee that is designed to look at policy
14 issues across the program as a whole. That policy
15 committee has been given--has been charged with a
16 targeted number of reports on specific and important
17 issues to the program as a whole.

18 One of those issues is evaluating and
19 making recommendations on the importance of
20 flexibility in award sizes to the program as a
21 whole. And that report is due a year from now.

22 So there's an opportunity even within the
23 construct of what has been mandated in the statute
24 to say, "Let's do a detailed study that demonstrates
25 the importance of larger awards and more flexible

1 awards, whichever way they come to the program."
2 And it may be that for that kind of study that's a
3 great opportunity to use the National Academies or
4 some other third party to conduct that.

5 So in the short term we've got a bunch of
6 arrows in our quiver. At the same time let's be
7 doing the study to demonstrate the importance of
8 more flexible award sizes to the program as a whole.

9 DR. SNYDER: One other question. Is there
10 waiver possibility for the venture capital 25
11 percent cap?

12 MR. GREENE: No.

13 DR. SNYDER: No.

14 Gail?

15 DR. COLLINS: Just to be clear, that's 25
16 percent of the total SBIR budget can't go to
17 companies that have more than 50 percent venture
18 capital participation. It isn't that you can't fund
19 a company that has more than 25 percent VC.

20 DR. SNYDER: I know.

21 DR. ROCKEY: Right, and I just wanted to
22 just add that in the past when we looked
23 historically when we had venture capital backed
24 companies, we ran around, I think it was, 15 percent
25 of our companies have VC. So we weren't even

1 bumping up at that cap. It could be more now but we
2 don't know.

3 DR. CASSELL: Sally, in your presentation
4 you mentioned something that I think is critical and
5 that is in terms of next steps would be OMB approval
6 for being able to attract the awardees after the end
7 of the award. Is that a given that you'll be given
8 that approval? How difficult do you think this is
9 going to be to get that? Because without it, it
10 seems you're not ever going to be able to have the
11 metrics that you really want to measure success and
12 impact.

13 DR. ROCKEY: So it's part of the Paperwork
14 Reduction Act that you have to have approval to
15 collect information from more than ten people. So
16 whenever we add additional elements to our reports
17 that we require, like our final reports or our
18 annual reports, we have to go through a process to
19 have that approved. In general, we get it approved
20 but it is a process and you have to go through it.
21 So that was just to put that on the table. If we
22 collect additional information, particularly if
23 we're going to try to collect information--this is
24 true for all NIH grants--beyond the award--I mean
25 once they no longer have NIH funding--then it

1 becomes even more difficult to not only get approval
2 but also figure out how you're going to do that.
3 Where are the entry points to collect that
4 information?

5 MR. GREENE: Let me just add while I would
6 never use the word "given" and "OMB" together in one
7 sentence at any time, particularly given the
8 statutory mandate to collect the information, you
9 know, we do feel good that--and then tactically
10 we're doing two things. In addition to the agency
11 submitting their own, we're trying to submit this on
12 behalf of all agencies to do a parallel processing
13 and get the foundation established as well.

14 HON. GOLDIN: The NIH, in our discussions
15 with a lot of the different institutes, they really
16 feel caught between a rock and a hard place. They
17 want to collect this further out data and the
18 Paperwork Reduction Act is preventing people from
19 doing their job.

20 So it would seem to me that if the SBA
21 worked together with the White House for special
22 dispensation, a lot of good people will get a lot
23 better work done and that, by the way, may be the
24 biggest problem with the metrics.

25 DR. ROCKEY: So, I totally agree with you.

1 I think it's--and one of the most critical aspects
2 of that is that if we are going to ask for more
3 information, we need to only ask for that
4 information that we think is critical and that's why
5 defining what those metrics would be would be of
6 utmost importance and then go forward to ask to be
7 able to collect that information.

8 MR. GREENE: I think also practically
9 while we're getting all these approvals for the data
10 fields, we've got to be building up the system. So
11 it's happening in parallel. We're not going to be
12 sitting around tooling our thumbs waiting for the
13 approvals.

14 DR. SNYDER: Gail, you get the last word.

15 DR. CASSELL: Well, I was just going to
16 say along those lines it would be really nice in
17 terms of job creation, getting back to Dan's point
18 earlier, to know a little bit more about what types
19 of jobs are being created, the duration of those
20 jobs. I mean this is being looked at as one of the
21 main mechanisms for stimulating economic
22 development, both at state and national levels.

23 CHAIRMAN AUGUSTINE: Yes, I would just
24 add a word of caution that supposing one of the
25 results of SBIR grant were that it led to the

1 prevention of a very serious disease but created no
2 jobs. It seems like that would be worth something.

3

4 (Laughter.)

5 DR. ROCKEY: Also I think you have to
6 remember the scale. I think on average our SBIR
7 companies that we support at NIH are 15 people or
8 less. So the idea that they are experiencing growth
9 and even adding one or two jobs to their company is
10 actually pretty significant. So we have to keep
11 that in context of how small many of these companies
12 are that we do business with.

13 DR. NEIL: I'm speaking figuratively now
14 but you need some way of radio labeling the dollars
15 so you can follow them through the economy, and
16 think about that paradigm.

17 DR. ROCKEY: We've got a job for you now.

18 (Laughter.)

19 DR. NEIL: Could I ask just one more
20 question of Sean? I mean, in all this talking about
21 waivers and grants and so on, I mean how is SBA
22 thinking about this. Is it to fund projects or to
23 lower the cost of capital for nascent companies that
24 want to try to grow or try to do a project?

25 MR. GREENE: Yes. I think this is a

1 question of lowering the cost of capital. When I
2 put my private sector hat on or investor hat on, in
3 many of the cases what we're talking about is
4 funding R&D projects that are--where there is
5 fundamental technology risk that's prior to where
6 most investors want to invest. They want to see
7 some level of proven technology and then investing
8 against the business risk. So you're talking about
9 kind of part of the ecosystem that many private
10 sector companies aren't ready to support because of
11 the fundamental risk involved.

12 That being said, linkages to the private
13 sector in which there are investors who see powerful
14 commercialization potential if the technology can be
15 proven is a great partnership. And, similarly, even
16 in the context of venture capital funded companies,
17 as I'm sure you know, it may be that the venture
18 capital has gone in for the development of certain
19 drugs but the grant is supporting the development of
20 completely related but different drugs that the
21 venture capital doesn't want to fund. They want to
22 fund getting to the next phase of clinical trials
23 for that drug.

24 So I think it's very complementary and it
25 really isn't a question of lowering the cost of

1 capital. It's funding projects that wouldn't have
2 gotten funded otherwise.

3 DR. NEIL: Okay. You could look at it
4 that way but I still see it as lowering the cost of
5 capital if you are attracting capital from private
6 sources by reducing risk--

7 MR. GREENE: Sure, because this is
8 nondiluted complementary capital that, you know,
9 complements their capital and provides more
10 resources to the partner; yes. Particularly in the
11 matching environment by the way--to the matching
12 program, yes.

13 DR. SNYDER: We will move into our panel
14 number three, which will be moderated by Susan
15 Shurin and which Sean will join the people up at the
16 stage.

17 **PANEL III DISCUSSION**

18 **Moderator: Susan Shurin, M.D., SMRB Member**

19 DR. SHURIN: So we have a challenge in
20 this panel, which is to talk--actually it's to talk
21 about metrics.

22 (Slide.)

23 I'd just like to make the point that the
24 challenge that we have in terms of metrics of return
25 on investment for the NIH is not in any sense unique

1 to the SBIR program. This is derived from a book
2 from 1997 by Donald Stokes. It's called *Pasteur's*
3 *Quadrant: Basic Science and Technological*
4 *Innovation*. The point he makes is that there are
5 sort of two main drivers. One is the quest for
6 knowledge and the other is quest for application.
7 Quest for knowledge is on the Y axis, quest for
8 application is on the X axis here, and there's no
9 and yes.

10 So if you have the major goal being pure
11 basic research, primarily a quest for basic
12 knowledge, with no particular aim of application at
13 all, he calls this Bohr's Quadrant.

14 If it's a quest for application with no
15 quest for basic knowledge, he calls it Edison's
16 Quadrant. This is the pure applied research.

17 If it's doing both, he calls it Pasteur's
18 Quadrant. And I think he named the book that
19 because I think that's what really he was aiming
20 for.

21 Chuck Vest, who was just mentioned by
22 Sean, talks about this and he likes to call the one
23 that has neither a quest for basic knowledge nor
24 application the Vest Quadrant.

25 (Laughter.)

1 So I didn't--I thought he could say that
2 but I wasn't going to.

3 So our goal obviously is to stay out of
4 that lower left quadrant where we're not trying to
5 get anything out but the challenge that we have in
6 terms of trying to look at what the return on our
7 investment is, is not unique to this area.

8 On the other hand, I think what we're
9 really talking about is Edison's Quadrant on this,
10 the pure applied research. We have a lot of work--
11 virtually all of the work that has ended up yielding
12 Nobel Prizes is ultimately in Pasteur's Quadrant,
13 including a tremendous amount that primarily was
14 aimed at getting basic research which ended up later
15 being applied.

16 So this panel has the longest set of
17 instructions, the most people, the least time and so
18 really what we're supposed to focus on are how do we
19 measure the success of the programs, to define
20 commercialization and is commercialization an
21 adequate metric for the programs that you guys are--
22 that you're involved in, and what is the timeline or
23 the time course to measure success.

24 So trying to focus on sort of those major
25 topics. How do you define success? How do you

1 define commercialization? Is commercialization--is
2 that an adequate metric? I think we've already
3 made--heard several comments and people saying they
4 don't think that is--it's not the total story. And
5 then what the time course is.

6 And I'd like to start, I think, with Sean
7 as our first panelist and last speaker.

8 If you could each aim for something on the
9 order of five to seven minutes we'll stay more or
10 less on time.

11 ***Sean Greene, Small Business Administration***

12 MR. GREENE: I'll just keep it one to two
13 because I just spoke.

14 But on the way we're thinking about
15 commercialization across all agencies is in terms of
16 standard definitions. It is first the definition of
17 did you get a product to market. And that then
18 gives you the ability to assess the issue if you had
19 a useful product even if it wasn't sold commercially
20 but that had major impact in terms of curing
21 diseases, et cetera. You'd be able to evaluate it.

22 So did you get a product to market?

23 And then separately a set of financial
24 metrics.

25 Now, in defining did a product get to

1 market across DOD, NIH, National Science Foundation,
2 there are obviously many different definitions.

3 We then would recommend at that point you
4 give flexibility to the agency. So for NIH did you
5 get FDA approval; whereas in the clinical trials
6 there's much greater detail. But that's one core
7 way to think about it.

8 And then, secondly, there are a set of
9 financial metrics. Whether that's ultimately
10 revenue derived from direct sale or licensing, et
11 cetera, or from investment--and in our mind
12 investment is an intra-milestone. The investment is
13 ultimately only useful if, again, you get more
14 products out to market or generate sales from it.
15 But particularly given the timelines for NIH, it's a
16 critically important metric that should be measured.

17 So that's our basic approach that we're
18 adapting--trying to adapt and capture consistently
19 across all 11 agencies and then give each agency the
20 ability to fine tune. And we shouldn't be telling
21 NIH what's the appropriate set of metrics to define
22 market success in terms of clinical trials, et
23 cetera, for their agency.

24 DR. SHURIN: Terrific. Thanks very much.

25 Richard Leshner is not here so we only

1 have six. Okay.

2 Michael Mutty has just got up and left.

3 (Laughter.)

4 Matthew?

5 If Michael comes back, we'll--

6 **Matthew E. Portnoy, Ph.D.,**

7 **National Institutes of Health**

8 DR. PORTNOY: Thanks.

9 So Michael had to leave for another
10 engagement and Rich Leshner from NASA is on the Hill
11 for an emergency session.

12 DR. SHURIN: Yes, right.

13 DR. PORTNOY: So I'd like to echo the
14 things that have been said already in terms of there
15 is--what's required--so there's levels. There's
16 what's required in the legislation. You have to
17 track commercialization. We have to track it both
18 at the agency, report it to SBA, make certain types
19 of information available to the public. And we can
20 have discussions about the type of metrics and we've
21 talked about some of those already, sales,
22 licensing, revenues, FDA patents, et cetera. But it
23 also will tie into, I think, in some cases the new
24 charge that you'll receive shortly is what--how does
25 this technology meet the NIH mission as a pseudo-

1 less tangible, something you really can't grab a
2 hold of, you know, in terms of these other more data
3 driven metrics and to the point you have a
4 technology that doesn't make it to market but in one
5 form or another may actually make a big difference.

6 Well, some folks who look at the data will
7 consider that a failure but we might for other
8 reasons consider it as a success. So how we move
9 forward to define the different parameters of
10 success, commercialization versus mission oriented
11 versus perhaps some other metrics is going to be
12 important. And we're looking forward to working
13 with everyone on that.

14 DR. SHURIN: Thanks so much.

15 Manny?

16 ***Manny Oliver, Ph.D., Department of Energy***

17 DR. OLIVER: I briefly touched on this at
18 the end of my presentation. So, you know, our
19 philosophy is, you know, the commercial potential
20 has to be there. So I think in terms of the
21 quadrants, you know, and this is the instructions we
22 have given to our programs, if there is no
23 commercial potential it really doesn't belong, you
24 know, in the SBIR/STTR being funded. There are the
25 other 97 percent of the dollars that's, you know,

1 free to fund things without commercial potential.

2 I think in terms of is commercialization
3 sufficient, I think that's, you know, clearly no. I
4 think that has been echoed here today. I think, you
5 know, most of the agencies have their missions.
6 And, as I mentioned before, I think looking at the
7 commercialization side--you know, I think we have to
8 have a lot of discussions on what the right metrics
9 are. We can get to that.

10 The two issues I see there: You know,
11 one, I, coming from the private sector, still look
12 at commercialization success. Not really worried
13 about defining commercialization but defining what
14 is success.

15 So I agree with--I see a lot of things
16 from other agencies where they look at, you know,
17 additional investment and say, hey, that's the end
18 of my process, I was successful. And, you know, I
19 don't think that's really the end of the story, that
20 those are truly interim metrics for--you know,
21 you're digging a bigger hole. So if you're getting
22 additional investment somebody is actually putting
23 more money in this and this is potentially a bigger
24 failure, not necessarily a bigger success. So I
25 think we have to be careful and be consistent in

1 terms of how we're defining success.

2 I agree we need to get to the market and I
3 guess I'd take a more return on investment point of
4 view as what was the investments that went into this
5 and what were the positive cash flows that came back
6 that said, "Hey, this investment actually resulted
7 in a positive return." But there are lots of
8 challenges with that in terms of how we get at that
9 data. You know, inside a company we can get at
10 return of investment.

11 It's still very challenging. Once we're
12 outside at an agency trying to come back a few years
13 later, you know, there are the companies that are
14 acquired. We don't know what they're acquired for.

15 We don't see any of the future sales so we have no
16 ability to measure that kind of return on
17 investment. So we have lots of issues, I think,
18 once we get down to the details of saying, "Okay.
19 Yes, even if we reach some common definitions, how
20 do we get that data or how do we simplify that data
21 collection process?"

22 Coming back to the mission impact, I think
23 that's--as we discussed before--a much harder
24 problem. Across all the agencies we have different
25 missions. Within the agencies, within DOE, as I

1 mentioned, you know, clean energy goals, you know,
2 do we reduce CO₂ emissions, everything from the
3 nuclear side of our programs where we're looking at
4 nuclear nonproliferation. You know, how do we
5 define those mission impact metrics? They're not as
6 easy to get at as the financial metrics like return
7 on investment or just sales and, you know,
8 incremental investment. I think that's really the
9 bigger challenge for us.

10 DR. SHURIN: Could you address the issue
11 of the timeline? When you're looking at this from
12 the standpoint of the Department of Energy, what
13 kind of timeline do you look at?

14 DR. OLIVER: Again I think we would expect
15 to start looking at investments. You know, there
16 are some companies--and again this varies with
17 technology because we fund everything from software
18 to, you know, enhancements to nuclear reactors where
19 they need, you know, NRC approvals and they take
20 maybe five to eight years just by themselves.
21 Similar to your FDA approval issue.

22 So I think we have--we're going to have a
23 spread through our program in terms of what is the
24 right window to look at and say, "Hey, did they
25 achieve commercialization success in this window?"

1 We will have to have a range of windows or a very
2 broad window to cover everything in DOE. But I
3 think, you know, that's going to be really in the
4 five to 15 year timeframe, I guess, if I have to
5 give a rough estimate.

6 DR. SHURIN: Thanks very much.

7 Grace?

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

9 DR. WANG: So let me comment on this chart
10 first. Actually I use this before also so I
11 actually really like this on.

12 What we want to do at NSF is really move
13 the technologies in the Pasteur Quadrant into the
14 market. That's really the total analogy that we are
15 focusing on. And I mentioned earlier that on top of
16 the SBIR grant NSF also set up set aside, \$40
17 million, in my division just to build long-term
18 partnerships between the universities and the
19 industries, including small businesses.

20 That one is actually focusing on how to
21 move the pure basic research, the right quadrant,
22 the Bohr Quadrant, into the Pasteur and actually
23 trying to catalyze that and take a look. From the
24 fundamental research concept it looks like it is a
25 science fictional concept. Is there any application

1 or anything--any prototype, any proof of concept
2 that we can do to move that into the next quadrant
3 and be more SBIR ready. I just wanted to comment on
4 that.

5 And regarding the assessment, I think it's
6 a -- I agree with all the points that have already
7 been said and just I didn't get a chance to say it
8 myself. And I think it's actually the same thing as
9 what Manny and Matt and also Sean have said. It's
10 very difficult. Measuring the long term impact
11 of the SBIR program, especially using the doubler
12 amount, is a challenge. At the same time and also I
13 think it's risky. The reason I'm saying that is when
14 we are talking about the dollar amount, we need to
15 put a dollar amount in there, is we actually will be
16 driven by that because otherwise why are measuring
17 it. And that's why we always have to be very
18 cautious. Don't get me wrong. We actually put
19 extensive efforts doing assessment at NSF but at the
20 same time I think we always need to be very
21 cautious about our assessment results because we can
22 never lose the bottom line that we are funding--we
23 are trying to or trying very hard to fund high-risk
24 innovations for our country. And if we are being
25 driven by this, driving new numbers, so actually we

1 are--we are pulling them in as a short-term impact.

2 And most of the SBIR companies are looking at way
3 beyond--probably--usually beyond five years, beyond
4 ten years. And if you are losing that, we are
5 probably not going to be taking the risk of putting
6 investments into the company that we should
7 have been.

8 So I just want to make that point but I
9 agree making the assessment and also all the
10 parameters that have been mentioned are great ideas.

11 DR. SHURIN: Thank you.

12 Sally?

13 ***Sally J. Rockey, Ph.D., National Institutes of***
14 ***Health***

15 DR. ROCKEY: I also agree with everyone,
16 although I will say that I might have a little
17 disagreement with Manny because I think one of the
18 reasons that we push so hard for the idea that VC
19 venture backed capital companies are part of our
20 program is that they are very savvy individuals who
21 are betting usually on those companies that more
22 likely are going to be successful.

23 So I think at least as an interim measure
24 you can measure follow on investment, particularly
25 by VCs as an indication of a product that is more

1 likely going to go all the way.

2 I agree with the basic assessment of how
3 we should do this.

4 I did want to take this opportunity
5 because I may not have another chance to just talk
6 about another complication in the whole tracking of
7 the process. Remember these are small businesses
8 and the construct of the small business and the
9 whole enterprises is fluctuating and changing daily.
10 Companies are coming in and coming out, being
11 acquired. There are subsidiaries. There are
12 mergers. There's all sorts of things that are
13 happening which makes our job infinitely more
14 difficult to follow those technologies all the way
15 through.

16 I mean, we even have problems, you know,
17 two years later. A company has disappeared off the
18 face of the earth and we are trying to go back and
19 find out some issue and we have to track it in all
20 sorts of different ways.

21 So when we think about tracking, you know,
22 we're tracking a technology; yes. But when we're
23 thinking about tracking the companies it becomes
24 very, very difficult over the long term,
25 particularly if you're talking about a five and 15

1 year where the technology may result in
2 commercialization. You have got to have a very
3 sophisticated system in order to do that. It has a
4 baseline to be able to track companies that may
5 change in their construct a few times in a
6 couple years.

7 So just to put that on the table as
8 something to think about for our recommendations of
9 how to define this.

10 DR. SHURIN: Can you--is there something
11 that would help you to be able to track to make that
12 easier?

13 DR. ROCKEY: Well, we have a lot of help
14 with the SBA. I mean, this is one of the ways that
15 we do it.

16 But we, like everyone else, we use all the
17 mechanisms to our disposal to try to pick up pieces
18 of companies that have gone elsewhere.

19 DR. SHURIN: What about radio labeling the
20 investigator as Garry suggested?

21 (Laughter.)

22 DR. ROCKEY: So sometimes it's just a
23 matter of a company has changed its title.
24 Sometimes it has totally become something different.
25 Sometimes they have a different person at the helm.

1 All sorts of things can happen. So when we figure
2 out the system--and, SBA, I'm sure you--Sean--you
3 all face this in the tracking of even companies.
4 We have to take that into account of how we are
5 going to consider that in the future and we do want
6 to try to do the best of our ability. Again we're
7 able--you know, my idea--and I know everyone laughs
8 at me--is to put a little chip in everybody's neck
9 for the electronic health records like your dog gets
10 but we can do that for all our grantees, too, you
11 know, so we can track them wherever they are.

12 MR. GREENE: We also have to get OMB
13 approval for that.

14 (Laughter.)

15 DR. ROCKEY: And IRB approval.

16 (Laughter.)

17 MR. GREENE: So one--just one additional
18 thought. I think again in the let's get moving--and
19 the definitional questions are so challenging. I
20 think the worst thing we can do is get paralyzed
21 by the definitional questions and not start moving
22 forward.

23 One thought on the critical issue of
24 impact measured beyond just the financial side,
25 which I think we all agree is critically

1 important, if you go back to the financial metrics,
2 what most of the programs have seen is the really
3 big successes--you know it's a small number who have
4 a disproportionate or large impact. I would guess
5 that that is true on the broader societal impact
6 beyond the financial side as well.

7 So what we see when we, you know, had a
8 hall of fame for the SBIR program are companies like
9 Qualcomm, companies like Genzyme. So one
10 opportunity in the nonfinancial impact is to
11 say maybe we don't need to collect ten different
12 data points from every company on those broader set
13 of things but stay in touch and track and look for
14 the really big successes and then be looking for the
15 program as a whole across the full portfolio to say,
16 hey, when you have got Irwin Jacobs, the founder of
17 Qualcomm, who now has a \$16 billion public company
18 but a technology that is in 800 million handsets or
19 Genzyme saying if it weren't for SBIR they would not
20 have survived. That's a pretty compelling part
21 of the overall impact as well.

22 DR. SHURIN: So I have one other question,
23 which is I was struck, Sally, by the fact that
24 you're tracking success stories. Should we be
25 tracking failure stories?

1 I mean it seems--it just seems to me we're
2 leaving a lot--what could we learn from the things
3 that aren't working? Maybe I say that because we're
4 spending a lot of time doing that in my institute.

5 DR. ROCKEY: Right. I would say that
6 oftentimes when we have a failure it's exactly that.

7 The company does use that to see what is working
8 and not working and come back with another proposal.

9 So we don't necessarily have them, you know,
10 illuminating their failures on the web but they--we
11 see it with their next SBIR proposal.

12 DR. SHURIN: Yes, and some of them don't.

13 And I guess--

14 DR. ROCKEY: And some of them don't.

15 DR. SHURIN: --so the question is are
16 there things that we could learn from the things
17 that don't play off no matter what metric you use
18 that would help us make these decisions in a more
19 intelligent way?

20 DR. OLIVER: Yes, I think--just to follow
21 up. I think that is one of the uses we would like
22 to get out of the next round of the National
23 Academies studies is to do some of this, you know,
24 looking backwards at the companies and understand
25 not just success but what are the failures and what

1 are the common themes that run through that. You
2 know, were there really topics that came out of the
3 agencies that really didn't have high commercial
4 potential? What is the reason behind that?

5 DR. SHURIN: Thank you.

6 All right.

7 Discussion?

8 Sol?

9 DR. SNYDER: Yes. This metric issue for
10 the numbers that were given from the earlier
11 studies, like 75 percent of the companies did blah,
12 blah, blah and 61 percent did this and got that, we
13 know that in little companies--I know in the biotech
14 area you don't have 65 percent or 75 percent
15 successes of anything. And that the anecdotal
16 stories like Genzyme and Qualcomm you say, well, you
17 know, that's just anecdotal stories.

18 But actually I think that that is a
19 meaningful metric because in the biotech and all the
20 other high tech arenas it's venture capital
21 calculations. I mean it's very, very realistic.
22 Venture capitalists assume that nine out of ten of
23 the companies that they will invest in will fail.
24 One of them will be a success and will return 100-
25 fold on its investment and, therefore, overall the

1 investors will get a tenfold return if it's a good
2 venture capital company. And that's actually a very
3 realistic thing.

4 So I think in terms of the metrics if you-
5 -and tracking people, it's not that hard to track
6 the Qualcomms and Genzymes or even things that are
7 not quite so successful. And that can be a
8 reasonable metric.

9 And even put numbers in the denominator
10 and diddle around with it and I think you would come
11 up with honest rigorous data that qualifies for what
12 we want and which we can sell to congress about why
13 the NIH is fulfilling its mission.

14 DR. SHURIN: Francis?

15 DR. COLLINS: I think we do use those
16 anecdotes. I certainly have been known to mention
17 in a hearing that Affymetrix was founded on an SBIR
18 grant and they did pretty well.

19 I want to ask a question that's related
20 to the metrics but it's slightly off where we were
21 at the moment. And that is about this category of
22 SBIR applicants that some of us are not so happy
23 about, the SBIR mills, which was mentioned already
24 by somebody. And I assume all of the agencies that
25 have this authority run into the circumstance of

1 companies which they are repeatedly at our doorstep
2 with applications that generally, because there are
3 so many of them, some of them get through and yet it
4 is very hard to see that much is coming out of that
5 except keeping the company going on taxpayer's
6 dollars with relatively little in the way of
7 commercialization. And I've never quite understood
8 why it's so hard for us to say no after a while to
9 those applicants, especially because one of the
10 criteria for whether we fund a project should be its
11 commercialization potential. But maybe we haven't
12 had the tools that are as strong as they need to be
13 to be able to make that distinction.

14 So I'd be curious in what the panel thinks
15 as we go forward now maybe with more attention to
16 metrics with this new reauthorization. Are we going
17 to be in a better position to say no thank you to
18 applications of that sort which we think have
19 relatively low chance of yielding up very much?

20 DR. ROCKEY: So one of the things in the
21 reauthorization bill is that we are--it's asking us
22 to look and have the companies tell us about their
23 previous successes in the application as opposed to
24 just about the project. You know, now when we
25 receive a project it tells us about the project.

1 They don't necessarily have to go in their history.
2 But by using that as a metric and requiring that as
3 a metric on the application stage, we will know more
4 about the company itself. Again with all of the
5 added notes that companies oftentimes change.

6 We also track--Francis, we track how many
7 of our Phase 1's come in for a phase 2 because
8 that's the real indication. If they live on phase
9 1's they are a truly one of these SBIR mills. If
10 they come in on phase 2 then we have--they are going
11 on to the next phase to a much bigger and larger
12 project that they have to be working towards some
13 commercialization.

14 So that is really essential to keep track
15 of that as well.

16 MR. GREENE: This was a key element of the
17 reauthorization as well.

18 So, first, it's important to note that the
19 issue of mills has been long present in the
20 SBIR program. The best data that has looked at
21 this question has come from the National Academies
22 and they have concluded that the actual incidents of
23 the "mills" is less than the common vision may
24 suggest. That being said, why tolerate it
25 at all?

1 And so I think--and we should
2 differentiate frequent award winners because it's
3 not necessarily a problem when somebody is getting a
4 lot of awards versus someone who has gotten a lot of
5 awards and hasn't done anything with them.

6 And so in the reauthorization there is a
7 specific mandate that each agency should set a
8 benchmark and a threshold for transitioning both
9 from phase 1 to phase 2, as well as from phase 2 and
10 beyond of a minimum floor of transition that every
11 applicant must meet. And if they don't meet those
12 floors--and by allowing each agency to set their own
13 benchmark then people--you know, agencies who have
14 had different histories or focus n commercialization
15 can adjust accordingly and they can evolve over
16 time. But we're setting a floor. And for those
17 applicants who don't meet that will be put in--not
18 the statutory term but a penalty box for a year.

19 So with the notion of we should take a
20 proactive stand to say companies who are receiving
21 awards and are not doing anything with them should
22 not be part of the program.

23 Now, each agency in setting the floor may
24 still in the actual selection of awardee be looking
25 for much higher rates of historical

1 commercialization well above the floor. But, again,
2 agency by agency can make that call.

3 DR. SHURIN: Dr. Cassell?

4 DR. CASSELL: Well, I was just going to
5 say as a member of the NAS committee that at a
6 former review one of the things that was amazing to
7 me was how often you encountered the mills and it
8 was across the agencies. It wasn't just NIH.
9 In fact, I've often heard Roy Vagelos refer to these
10 as the bottom feeders so to speak. And I think
11 that's one of the best things about the
12 reauthorization is that you've taken this into
13 account and tried to provide the tools. I do think
14 it's a really important thing to do because there
15 were obviously companies that did nothing but just
16 survive. And we are just using the money for
17 survival and not necessarily even trying that hard
18 to get to the next phase.

19 DR. SHURIN: Dan?

20 HON. GOLDIN: I have been talking and
21 we've been talking about problems but there's an
22 observation I made over the last few months about
23 the statement good to great. The level of
24 seriousness that your staff engages in this subject,
25 Francis, is really very positive. The issue that

1 was striking to me was the heads of the institutes
2 got on the phones with us for a few hours and they
3 were the ones who spoke to these issues. So there
4 is a serious deep effort going on. And when you
5 have the leadership of the institute engaged to this
6 level, I think only good things are going to happen.

7 DR. SHURIN: Other comments?

8 DR. WANG: I have a comment about mills.
9 Do you have a few minutes?

10 DR. SHURIN: Yes.

11 DR. WANG: NSF has been tracking the
12 commercialization history and ask are we--single
13 phase 2 application make--listed their
14 commercialization track record there and list every
15 single Phase 2 award they got from all federal
16 government agencies and they had to list their sales
17 and licensing revenue generated based on that
18 project. And we do use that to reject a lot of
19 companies who write really good proposals but they
20 didn't do anything about the phase 2 award.

21 And the reason that that is--we are a very
22 small percentage. I have to say we probably still
23 have a few, one or two, at least one or two actually
24 based on a name I know, are in our portfolio but the
25 problem there is the other is small but to me I

1 think the detrimental impact they have on our
2 portfolio is actually much bigger than their number
3 because actually it delivers a bad message to our
4 grantees. Especially at the grantees conference
5 when they talk to each other and they figure out,
6 okay, it's okay to live on taxpayer's money without
7 doing anything. So that's why I think my opinion is
8 we absolutely need to get rid of it and that's why I
9 think that the new policy directive is actually
10 going to be very helpful also.

11 DR. OLIVER: I will just echo that. Again
12 in advance of reauthorization we implemented our own
13 commercialization metric which is flagged in the
14 selection process. And again the intent--most of
15 the companies are submitting commercialization
16 histories but there are multiple pages buried in the
17 applications and the program managers aren't seeing
18 that so we are pulling that out right for them to
19 see and so we are addressing that prior to
20 reauthorization.

21 I think reauthorization will just give us
22 a little more authority in terms of what we can do
23 as a result of that.

24 DR. SHURIN: Other comments or questions?

25 Sol?

1 years ago where we were competing against a company
2 that had a small business--it was actually a
3 different circumstance but a small business
4 advantage that they were given and it turned out
5 that they had hired the Ford Motor Company to do all
6 their work for them.

7 (Laughter.)

8 And--but they were getting extra points
9 because they were a small business. And there are
10 those who will take advantage of every loophole they
11 can find and we need to guard against that.

12 Sol, thank you very much for chairing this
13 effort. We look forward to your conclusion that
14 will bring great clarity to the topic.

15 (Laughter.)

16 So with that, if there are no public
17 comments to be made--let's see. I'm on the wrong
18 agenda here.

19 No, I'm not. I've got mine here.

20 We--I think it's time to go to our new
21 topic. And in May we talked about the fact that we
22 now have in the lap of the management of NIH
23 carrying out our earlier recommendation, we have the
24 panel that you have just heard from underway, and
25 some might say it's how much we want to pile on.

1 I think the other aspect to that though is by the
2 legislation we have to meet at least five times on
3 every topic before we make a recommendation.

4 (Laughter.)

5 And if you wait--if you wait in line and
6 there's a train car by car, we will die of old age
7 before we get done here. So Francis and I and
8 others have had conversations about this and I think
9 both Francis and I and the group as a whole is
10 anxious to move ahead. And he has identified an
11 area that is of substantial importance.

12 And so probably this is a good time just
13 to turn to you and let you make whatever comments
14 you'd like to in that regard.

15 **NEW CHARGE**

16 **ASSESSING THE VALUE OF BIOMEDICAL RESEARCH**

17 **ISSUANCE OF NEW CHARGE TO THE SMRB**

18 Francis S. Collins, M.D., Ph.D., Director, NIH

19 DR. COLLINS: Well, thanks, Norm.

20 I'm happy to do so.

21 And, again, I want to thank the panel and
22 all of the important discussions that have gone on
23 in the course of today about the SBIR/STTR program.

24 I don't think we would have asked the SMRB to
25 tackle this if we thought it was already perfect and

1 you've gotten a pretty good sense of both the
2 opportunity and the challenge of trying to take this
3 important part of our portfolio and really optimize
4 the outcomes that we believe can be further
5 optimized. And I'm sure there will be more
6 iterations here in terms of the kinds of
7 recommendations you might make to us about that.
8 Certainly it seemed to me there were a number of
9 themes especially here as we were talking about
10 metrics and the importance of defining those and
11 figuring out how best to track outputs so that we
12 know whether our metrics are actually giving us the
13 outcomes we hope for.

14 Maybe I was one of the people but I'm not
15 the only one also emphasizing how critical it is
16 that we look carefully at our cycle times for SBIR
17 applications and awards and certainly we heard an
18 exhortation from the SBA individual that we
19 shouldn't take this one year that's in the statute
20 as if that is really just good enough because I do
21 believe we can probably draw in more exciting
22 projects if we could be more quick in our
23 responsiveness. Even though that may require us
24 to do some different things in terms of how we
25 conduct reviews. But I'm looking forward to hearing

1 what the SMRB might think in terms of options there
2 that we could institute for this program that we
3 probably wouldn't want to use for a typical ROI but
4 in this situation might make a lot of sense. So I'm
5 looking forward to the next iteration.

6 Sol, thank you for your able leadership of
7 this particular working group.

8 (Slide.)

9 So, yes, I'm going on.

10 Norm and I did, in fact, talk a couple of
11 times about the possibility of another charge and
12 settled upon this being the right time and the
13 right topic to ask SMRB to consider. And this one
14 is being sort of laid out here for your reaction as
15 a topic which I think is particularly at this time
16 in history important to get a better handle on than
17 what we currently do. And that really is to try to
18 define in the most careful, rigorous, economically
19 defensible way what is the value of biomedical
20 research anyway?

21 We already had a bit of that conversation
22 about the SBIR program. What is the value that we
23 could point to that is being rendered by the
24 investment of these hundreds of millions of
25 dollars? And I appreciated Norm weighing in that we

1 shouldn't just think about this in terms of dollars,
2 whether they are radioactively labeled or whatever,
3 but also about what this does for human health.
4 That is after all our major mission.

5 I must say when I came to this role as NIH
6 Director I hadn't really thought about the fact that
7 I spend so much of my time defending NIH on the
8 basis of economics. But it is what it is given the
9 circumstances we find ourselves in and the current
10 fiscal situation of our country and the world.

11 So there have been some efforts made to
12 try to identify those economic benefits of NIH
13 supported research.

14 (Slide.)

15 And we claim, therefore, that among the
16 things that NIH does is to improve public health and
17 stimulate economic gains and advance scientific
18 knowledge and strengthen the biomedical workforce.
19 And there you see various photographs of Susan and
20 myself testifying in front of various hearings on
21 making those cases based upon information that has
22 been assembled by various groups in various ways.

23 (Slide.)

24 We certainly can argue that the health
25 benefits have very substantially extended lifespan

1 and reduced illness by any measure, prolonging life
2 and reducing disability when you consider lifespan
3 is nearly three decades longer now than it was 100
4 years ago. When you look at survival rates for
5 various diseases--here the example being breast
6 cancer. When we look at the dramatic advances in
7 HIV/AIDS, which will be much talked about later this
8 month with the International AIDS Conference in
9 Washington, where if somebody diagnosed today is HIV
10 positive that's age 21 has a life expectancy of
11 about 70 years. Contrast that to the death
12 sentence that such a person would have received in
13 1985 or '86. And many other examples. This is just
14 a smattering of such cases that can be made.

15 And, of course, here the case is being
16 made on the basis of human impacts in terms of
17 survival and freedom from disease. But each one of
18 these could also be translated into some sort of
19 dollar figure in terms of how lives being saved is
20 also resulting in economic benefits. And people
21 have taken a stab at those for all of these and many
22 more.

23 (Slide.)

24 There certainly have been some more
25 extensive efforts in the last couple of years to

1 quantitate the economic value of what NIH does in
2 terms of support of biomedical research not just for
3 one disease here or there but more across the board.
4 This is one which came out initially about two years
5 ago. It was recently updated--well, recently, last
6 year by this economist, Everett Ehrlich. If you
7 haven't looked at this, it will probably be an
8 interesting starting point for some of what I'm
9 hoping the SMRB can tackle. And not being myself
10 somebody who ever took a course in economics it's
11 hard for me reading through these kinds of analyses
12 to judge the rigor with which they have been
13 conducted and certainly there are critics of
14 virtually all of these analyses in terms of the
15 nitty gritty about their methods.

16 (Slide.)

17 We recently tried to put some of these
18 analyses in a place where they are easier to find.
19 Placed on our homepage under the button that says
20 "Impact" a long list of such analyses with hot
21 links to the actual reports. And that would include
22 one which just came out about a month ago from
23 the Information Technology Innovation Foundation,
24 ITIF, jointly with UMR called Leadership in
25 Decline. Very much sort of along the lines of the

1 gathering storm reports that Norm has been so
2 central to. And they basically in that report
3 document the way in which American contributions in
4 biomedical research had been dwindling even as
5 other countries, China, India, Singapore, the United
6 Kingdom and Germany are all featured in that report,
7 have been ratcheting upward. In some instances at
8 rather dramatic levels.

9 That report did seem to attract some
10 attention by the documentation of the very strong
11 difference between what's happening in different
12 parts of the world and the threat that it seemed to
13 propose as far as America's global leadership but it
14 certainly also has come under some criticism for the
15 ways in which the analyses were done.

16 (Slide.)

17 So we have some things to work from here
18 but I think these questions are not going away. I
19 don't think the concern about taxpayer's dollars
20 providing a return on investment is a short-lived
21 concern. I think this is going to be with us. It
22 has probably always been with us at some level.
23 It's at a heightened level right now but I don't
24 think the level of attention is likely to be
25 diminished in the next few years.

1 So from the perspective of those of us at
2 NIH, it would be really valuable to have from this
3 group some guidance here. Not that we expect the
4 SMRB to turn into an economic think tank and
5 actually do the analyses that maybe need to be
6 done but to identify the appropriate kinds of
7 parameters and approaches to assess and communicate
8 the value of biomedical research, which I guess
9 we're going to call VOBR.

10 (Laughter.)

11 Which is supported by NIH.

12 Everything has to have an acronym around
13 here.

14 DR. : (Not at microphone.)

15 (Laughter.)

16 DR. COLLINS: You're going to become
17 VOBR-ites or something like that.

18 (Laughter.)

19 We'll have VOBR-1, VOBR-2 and then by
20 VOBR-5 we'll know what we've said.

21 (Laughter.)

22 (Slide.)

23 Now, along with that, specifically asking
24 you all to analyze the current strategies that are
25 being used to assess the value of biomedical

1 research, examining both the national and
2 international methodologies because there are groups
3 outside the U.S. that are doing this that we don't
4 know that much about. And evaluate the strengths
5 and weaknesses of both the approaches that have been
6 used as well as others that maybe haven't been to
7 evaluate this question. And then help us by
8 identifying fundamental principles that should guide
9 any comprehensive and rigorous approach. Again, not
10 asking the SMRB to actually conduct such an analysis
11 but lay out the parameters, the principles, that
12 ought to be adhered to in such analyses if they're
13 going to have the full credibility that we need at
14 the present time.

15 (Slide.)

16 So that's a pretty broad stroke about what
17 I hope you would be willing to take on. Obviously
18 in this instance, no doubt, you would want to call
19 on lots of outside expertise and there are lots of
20 folks out there that have written about this. I can
21 imagine a pretty interesting set of meetings drawing
22 upon their expertise and getting them to let their
23 hair down about what parts of the analysis they are
24 confident in and which parts could be done in a more
25 effective way. But I think we would all learn

1 something from this and certainly from my
2 perspective as NIH Director having this kind of
3 analysis could be very useful as we try over and
4 over again to make the case for the economic value
5 of what we do, as well as the medical value.

6 So that's the proposal.

7 Back to you, Norm.

8 **DISCUSSION AND NEXT STEPS**

9 CHAIRMAN AUGUSTINE: Thanks, Francis.

10 During the telephone conference we had
11 this was briefly introduced and I think the panel
12 was supportive of undertaking such an effort. As
13 you point out, everybody who has done this in the
14 past winds up with a few arrows in their back and
15 that I think is inevitable with this topic. It's
16 hard to do this work without some kind of a flaw and
17 so I think that's just something we'll have to deal
18 with.

19 Gail, did you want to make a comment?

20 DR. CASSELL: I do.

21 I think this is very important needless to
22 say but I would ask you to consider, Francis, maybe
23 asking the board to do one additional analysis. And
24 that is to look at the current processes for
25 translating the results of NIH research into

1 practice.

2 There will be a report released later from
3 the Institute of Medicine on the Learning Health
4 Care System. I think what you'll--I mean they are--
5 well, anyway, I can't say too much but the point
6 is I think that right now that it takes years
7 in some cases for results to get translated in
8 practice.

9 The best example I can think of
10 is from the time we learn that Group B Strep was the
11 cause of neonatal sepsis and death until the time it
12 was accepted--the practice guidelines were accepted
13 and routine screening for Group B Strep actually
14 started was about eleven years. You can imagine the
15 number of infant deaths during that time period.

16 So is there a better way once the data
17 seem to be really solid and clear that you could
18 implement this into practice sooner?

19 And it just seems to me that if you're
20 going to be trying to assess the impact, whether it
21 be in lives saved or health care costs reduced or
22 whatever, that you have to take that into account
23 because if that part of the system is broken then
24 you're not going to ever realize the full potential
25 of the results that are obtained through funding of

1 either basic or clinical research.

2 DR. COLLINS: So that's a very important
3 problem to be sure. And one that I have been drawn
4 into on many occasions by many different groups is
5 what are we going to do about this? Because we
6 don't have a learning health system right now. We
7 have a health system that refuses to learn where new
8 information, even when very well documented and
9 justified, as you say, takes forever to find its way
10 into practice. And, obviously, this is a huge issue
11 that relates to our whole health care system.
12 And one which NIH has a couple of levers to pull in
13 terms of conducting, for instance, implementation
14 research to document how you can introduce new
15 approaches in the real world and show that they
16 work.

17 But in terms of the broader application,
18 this is obviously a huge enterprise that goes well
19 beyond anything that we have control over.

20 I think in terms of the economic analysis
21 that is probably in there but to try to fold that in
22 as a major focus of this charge, I think, would
23 cause it probably to sink underneath the weight of
24 what is probably the toughest problem in all of
25 health care and one where NIH doesn't actually

1 control a lot of the outcomes.

2 I grant you this is an issue that needs
3 serious attention. I'm not sure I can quite see how
4 to merge it with this charge.

5 DR. CASSELL: I understand.

6 I happen to have been in a Congressional
7 hearing, I won't name the NIH Director at the time
8 or the CDC Director at the time, when in fact one of
9 the members asked, "Okay. Whose responsibility is
10 it?" The NIH Director said, "Not ours." The CDC
11 Director said, "Not ours." And the member says,
12 "Well, then who in the heck is responsible for
13 improving the public health based on this research?"

14 DR. COLLINS: CMS.

15 (Laughter.)

16 DR. CASSELL: And so--well, CMS didn't
17 exist at the time.

18 (Laughter.)

19 Okay. I've made my point. I've made my
20 plea but I think maybe it needs to be a separate and
21 additional charge to the board.

22 DR. COLLINS: Having--

23 DR. CASSELL: But somebody at--even maybe
24 in the form of consensus conferences that have
25 occasionally been used at the end of a, you know,

1 series of studies or some mechanism that NIH could
2 rather forcefully say, you know, this should change
3 medical practice ASAP.

4 DR. ROPER: Having had a couple of those
5 jobs I would just say I don't think any federal
6 agency is responsible for translating and changing
7 the practice of medicine. That's not the federal
8 government's role. But your point is a very good
9 one and deserves a lot of attention. I guess I
10 would associate myself with Francis though in saying
11 that's a different issue than the value of medical
12 research.

13 And I just thank you, Francis, for asking
14 the SMRB to take this issue on.

15 I think it's an extremely important
16 matter. I know it's of great federal import but at
17 the state level our legislature is very interested
18 in getting me as the dean of a public medical school
19 to answer the question, "Well, what is it that--why
20 are we putting all this money into your university?"

21 So I thank you for asking this to be taken
22 on and I hope the SMRB will be serious about it.

23 CHAIRMAN AUGUSTINE: Are there others who
24 would--

25 DR. KATZ: I agree with Bill's point

1 wholeheartedly but I just wanted to ask you,
2 Francis, since a lot of the--what you've asked is
3 couched in sort of economic terms, just to be
4 explicit, you are really asking the SMRB to go
5 beyond just economic terms, the value of biomedical
6 research. Is that correct? Because it's important
7 in the charge to know that we're not just focusing
8 on the dollars.

9 DR. COLLINS: Well, you notice I put those
10 things up there as the impact of research and I
11 mentioned that each of these could be converted also
12 to an economic argument. I think a theme here
13 because it's where we are constantly being pressured
14 ought to be how do we inform the construction of
15 those economic arguments to be as rigorous and
16 bullet proof as they can be but you can't really do
17 that without documenting the benefits to human
18 health and what that does for society, both in terms
19 of families who no longer are having to care for
20 sick individuals and people who are back at work
21 instead of being somewhere else.

22 So, yes, it's all folded together but
23 again I think the particular focus fitting this all
24 together and the particular need right now is to try
25 to see how all that information falls into an

1 economic--

2 DR. OMENN: It's Gil Omenn.

3 CHAIRMAN AUGUSTINE: Please, the one who
4 joined, I wonder if you could put that on mute.

5 DR. OMENN: It's just me. It's Gil Omenn
6 again.

7 I'd just like to make a comment. That's
8 all.

9 CHAIRMAN AUGUSTINE: Please. If you would
10 like to comment now, that would be fine.

11 I guess not.

12 Dan?

13 HON. GOLDIN: I'd like to say it this way:

14 Francis, I feel your pain--

15 (Laughter.)

16 --when you go testify. And I just want to
17 compliment you on asking the panel to look at this
18 because if you don't present the information,
19 someone else will and it won't have the deep thought
20 that is necessary and the research that is necessary
21 to put issues into context. And because of the
22 digital age that we are in, everything gets broken
23 down into numbers and times and put in very
24 simplistic form. And you having the bully pulpit
25 to be able to talk in the broad sense but summarize

1 for the members of congress and the American public
2 this important issue--I can't think of anything
3 more important in protecting this very valuable
4 research. It's very valuable so I'm glad the
5 committee has it.

6 DR. RODGERS: I just want to have those
7 slides up. I just want to kind of point out that--

8 DR. OMENN: I can't hear.

9 DR. RODGERS: Am I on? Can you hear me?

10 DR. OMENN: Is somebody making a comment?

11 DR. RODGERS: Yes.

12 Let me try this one.

13 What about now? Can you hear me?

14 DR. OMENN: Yes.

15 DR. RODGERS: It sounds like a telephone
16 commercial.

17 (Laughter.)

18 You had a slide up that tells us about,
19 you know, how there has been this change and this is
20 very important in terms of survival, for example.
21 It might be the time to actually consider that not
22 only has NIH research contributed to this change but
23 also to the rate of change and even the rate of the
24 rate of the change. In fact, you know, I think a
25 point you were making is we sort of are living in

1 exponential times now and since heretofore NIH's
2 mission has been in acquisition of knowledge, this
3 knowledge is changing at a rate, you know, that is
4 also exponential. It really touches a little bit
5 upon what Gail was saying. In a way you want to
6 acquire the knowledge but you want the knowledge to
7 be diffused in a way that benefits directly health.

8 And so maybe that's something that we should
9 consider coming back to. I think Gail's point is
10 well taken.

11 DR. COLLINS: So not just the static
12 picture but the first and second derivative of the
13 curve.

14 DR. RODGERS: Right.

15 CHAIRMAN AUGUSTINE: Are there other
16 comments on this topic?

17 DR. BRODY: This is Bill Brody.

18 I just want to echo. I think Steve Katz
19 made a comment. The audio is not great but--and I
20 know that you have to do the economic analysis and
21 it's important but I'm just reminded when my son was
22 in a small liberal arts college we went for family
23 weekend and they had the financial officer present
24 the data on what the true costs of education were at
25 a private liberal arts college and why, you know,

1 parents were only paying half of the actual costs
2 even though the tuition was in the stratosphere.
3 And then he presented data that if you went to
4 one of these small liberal arts colleges "you would
5 be financially better off." And one of the parents
6 raised her hand and said, "Well, my daughter wants
7 to do public health work in Africa. Does it mean
8 I'm wasting my money sending her to this school?"

9 (Laughter.)

10 So I think that, you know, we have to
11 weave into whatever we do the non-economic benefits,
12 including public health in the world, which we do.
13 I mean it does have a benefit--an economic benefit
14 but, you know, it's a bit of a slippery slope if we
15 just get completely hooked on the dollars and cents.

16 And some of the investments pay off so
17 many years later that it's sometimes hard to
18 measure, as somebody said, the radioactivity of the
19 dollars to trace.

20 DR. COLLINS: Very well said.

21 There's a lot of nodding heads around
22 the table, Bill.

23 CHAIRMAN AUGUSTINE: Thank you, Bill.

24 Other comments?

25 Please?

1 DR. SHURIN: I wonder if this still has to
2 do with what you consider in the entire equation
3 because people who are employed and not receiving
4 medical care and not on welfare and whatnot, I mean
5 I think one of the key issues is what questions
6 we're asking. Because what you don't want is just
7 sort of, "Well, we invested this much and we got
8 this much money back for it." The broader you view
9 the economic context the better off you're going to
10 be.

11 I remember seeing an analysis of what
12 happened with hemophilia when hemophilia patients
13 went on to concentrate and got treated regularly.
14 They went from having 90 percent unemployment to 85
15 percent employment virtually all with insurance.

16 I mean those kinds of things are the sorts
17 of things that actually matter and in some ways
18 looking at the metrics that will matter--not just
19 impressive numbers but the metrics that will matter
20 to the people who make policy I think is going to be
21 one of the most important things. Those are hard to
22 get at but we can get at some examples of them.

23 DR. COLLINS: Yes. If I could just
24 comment.

25 If you go to that impact site where we

1 have tried to accumulate a lot of these analyses,
2 you're quite right. They come at various levels.
3 There are analyses that look at the sort of
4 immediate or within a year return on investment and
5 economic goods and services that are generated
6 because of an NIH dollar and those actually are
7 fairly encouraging but that's a far smaller picture
8 than what you want to have available.

9 And then you can go all the way to
10 calculating what is the value of the fact that--as I
11 mentioned--that heart attacks and stroke deaths are
12 down by 70 percent in the last 30 or 40 years and
13 that is in the range of \$50-70 trillion or something
14 like that. But, obviously, that isn't because of
15 the economic goods and services. That's because of
16 lives saved and the ability of people to continue to
17 be productive.

18 DR. SHURIN: But, again, it's a lot how
19 you present that. Because the issue isn't that
20 there are that many fewer heart attacks and strokes.
21 People still mostly die from heart attacks but they
22 are dying at 80 and 85. They are not dying at
23 40. And so some of those kinds of things are the
24 things that make the big differences.

25 DR. HODES: Just following up on that,

1 just be prepared for all that we are going to have--
2 just the example you mentioned, some very caring and
3 good humanitarian economists are going to point to
4 that example and I'd argue that there is a net loss
5 of funds, that people surviving at a point, for
6 example, beyond the time when they are employed and
7 not being--having more people smoke and dying early.

8 You know, sort of the classic perverse example is
9 cost savings. So that's only to say we are going to
10 have to be very careful and understanding of the
11 complexity of the answers we are going to get by
12 people who are going to look at every dimension of
13 what we ask of them.

14 CHAIRMAN AUGUSTINE: Please?

15 DR. BRIGGS: Just another kind of thought
16 about the complexity that Gail mentioned of the
17 defects in our health care system and how so much of
18 the implementation processes are not happening
19 effectively. We also have to be careful not to
20 short sell our own substantial investment in
21 implementation and dissemination work through the
22 CTSA program, through other large implementation and
23 dissemination programs. So I think this is going to
24 be a constant tightrope in thinking about this, to
25 both capture the value we are bringing to health

1 care systems without letting our processes be
2 stymied by some of the failures in the health care
3 system.

4 I don't have an answer. I just think we
5 can't ignore it.

6 CHAIRMAN AUGUSTINE: Gail?

7 DR. CASSELL: If I could just add to what
8 you said. I'm showing my age for sure in more ways
9 than one but having been involved in the NIH
10 strategic planning process under Bernadine Healy
11 from day one to the end, you know, one of the
12 recurring things was the need to broader communicate
13 the research. And I think this is an area where
14 NIH--I mean it has excelled in many areas. Many of
15 the things actually have transpired that were
16 proposed in the plan but the communication, the
17 education, the public access to information--my
18 gosh, I can't tell you the number--and I know
19 everybody can say that--of our friends and relatives
20 that use NIH and what NIH says. So somehow that has
21 to--I don't know how you place a value on it but
22 it's I'm sure a huge investment or a significant
23 investment and we need to figure out how to showcase
24 that even more.

25 I think this new initiative in terms of

1 diseases of unknown etiology through the Clinical
2 Center is huge if you look at the number of
3 individuals that go for years without a diagnosis
4 and what the value of even that program is going to
5 be. It's hard to place a dollar sign on it but in
6 terms of overall impact it will be huge.

7 CHAIRMAN AUGUSTINE: Others?

8 If not, I'd like to make a few comments
9 just myself.

10 I suffer from the fact that to me the
11 benefits of what NIH does is obvious. And so I have
12 to get that out of my mind and become a skeptic
13 here if I'm going to be constructive.

14 I see a couple of dilemmas that we
15 will need to deal with. One is, as Dan points out,
16 NIH is perhaps the only organization or certainly
17 one of the few that has the knowledge to be able to
18 do this kind of an effort constructively that
19 has been called for. At the same time NIH does not
20 have a lot of credibility on this particular topic
21 of the value of investment at NIH. And so maybe
22 that's where this particular group, with some of us
23 being--or the majority of us being outsiders, so to
24 speak, we may be able to make a contribution here.

25 There's also the issue that, Gail, you

1 raised, I thought very well, about some of these
2 other matters that get into the discussion. The
3 business of if you don't translate the research or
4 if it takes too long, that's a big problem.

5 Including that sort of thing complicates
6 matters an enormous amount, Francis, as you point
7 out.

8 But I think we could have our cake and eat
9 it here because undoubtedly there are going to be
10 many topics like that that will spill out where you
11 can make a list that if you would do better at this-
12 -we don't need to tell how but we could prepare a
13 list, I think, that says if you do these then the
14 answer turns out to be much better.

15 On the subject of economics, I'm of the
16 school that it says that we do want to think of
17 things beyond economics here. But also Francis has
18 to deal with the fact that here in Washington
19 economics is the coin of the realm at this point in
20 time so to speak. And so that issue has got to be
21 answered.

22 And along with that I would hope we can
23 broaden the topic to other benefits.

24 Also, I would emphasize the point Francis
25 made that he is not asking us to do the analysis but

1 rather--I guess maybe, Francis, the way to say it is
2 to lay the groundwork for doing such an analysis.
3 And then presumably the people who work at this as a
4 full time job could undertake it and I would offer,
5 if that happens, our services or the services of
6 this group to oversee such an effort and to try to
7 add a bit of credibility to it on our behalf.

8 It does seem to me that there are some
9 interesting things you could do. I have been
10 thinking about this a bit.

11 One question I asked myself was supposing
12 the NIH hadn't existed the last 20 years or 25
13 years, whatever. What would be the impact on
14 people's lifestyle today? For example, what would
15 be the impact on how long you would live? And
16 let's say it lowered the life expectancy to 60 or
17 something. Then you go to John Q. on the street and
18 say, "It has cost you 25 cents a day for the last 25
19 years to have an NIH. You're 65 years old today.
20 Are you getting your money's worth?"

21 And I think we've got to put it somewhat
22 in some of this context that--the benefit to the
23 individual. As I thought about this, I was
24 thinking when my mother was born, the life--she was
25 born in Colorado. The life expectancy was 48 years

1 in this country. And, you know, today it's 79 I
2 think. And I don't know how much of that you could
3 attribute to the NIH but it's probably no small
4 part. And somehow we need to make these
5 connections.

6 I guess full disclosure requires me to
7 say that there is always somebody who blows away the
8 argument, "My mom lived to be 105."

9 (Laughter.)

10 God bless her.

11 But anyway I'll be here at this table long
12 after you folks are gone.

13 (Laughter.)

14 DR. OMENN: May I make a comment?

15 CHAIRMAN AUGUSTINE: Yes, Gil, please do.

16 DR. OMENN: Sorry to cut in but I have
17 been enjoying the conversation and the earlier
18 presentations all day by webcast and some by phone
19 also but I wanted to stay on mute all the time that
20 I could.

21 I love this topic. I know how much
22 pressure Francis and others get from the Congress.
23 You know, what have we bought with the doubling of
24 the NIH budget? What will we buy with further
25 increments that the scientific community strongly

1 recommends? So it's a worthy subject and it
2 certainly is at a level of broad view that is
3 perfect for this board.

4 I don't know if anybody mentioned yet. I
5 couldn't quite hear everything. But there was a
6 study commissioned by the Lasker Foundation under
7 the funding of first initiative in 1999 with nine
8 prominent economists, not really health economists
9 but very prominent economists from the University of
10 Chicago and from several other institutions. And
11 they came up with a startling really credible
12 estimate of trillions of dollars of benefit to the
13 American population from investing in biomedical
14 research.

15 There was a very nice follow on article
16 also by Neil Rosenberg in which he broadened
17 the investment to include all sources of investment
18 in the United States, meaning pharmaceutical and
19 biotech and foundations, as well as the NIH itself.

20 And sometimes that's wise to broaden the sense of
21 the investment portfolio. This strategy of
22 identifying the gains in the health status and the
23 more effective use of medicine in public health is a
24 very credible approach. There are sometimes
25 triggers--you always see--several of you made

1 comments about the rebuttals that might be laid on
2 us. There is always the notion that you have
3 incompletely implemented many things we know to do
4 in medicine and in public health and in self
5 improvement for healthy behaviors and, also,
6 environmental protection from health research.
7 So that needs to be acknowledged. And there is a
8 sense in which our partners or implementation
9 sites are all free to society are very important to
10 realizing the full value of new knowledge and new
11 techniques and new drugs and new investors and new
12 everything. So that is important and one which is
13 perfectly fair to include in the recommended
14 analysis.

15 I think we could add quite a lot to this.
16 Not just by trying to put absolute numbers,
17 estimates on the broad analyses but to take a cost
18 effectiveness approach also and to possibly make a
19 few recommendation of how the NIH resources or the
20 national resources could give even greater benefit
21 with certain kinds of improvements.

22 For example, there has been a lot of
23 discussion lately triggered by comments from leaders
24 of the FDA and leaders of R&D in industry and quite
25 a few academics about how many papers published in

1 our leading biomedical journals have been
2 unreproducible. And there was a discussion just
3 yesterday or Monday actually in which I was a
4 participant at Stamford by the National Research
5 Council panel, which is revisiting the 1992 report
6 called "*Responsible Conduct of Research.*" This is
7 a topic in which NIH has been very active and very
8 forward-looking I would say, in general, over the
9 years and it's their responsibility as the
10 institution.

11 So this is a 20 year reprise and asking--
12 to look at the landscape and what are the parameters
13 and what can be recommended to improve the culture
14 and the performance of research across all fields,
15 not just biomedical. And there are things like that
16 which probably need to be addressed.

17 There was an article from industry leaders
18 saying that of 53 studies that led to product
19 licensing or research licensing by biotech companies
20 but only six could be reproduced when the companies
21 exercised their duty as they have learned it to
22 actually try to reproduce what they've purchased
23 from academic or small company or even large company
24 research groups that has been published in top
25 journals. So this is beside the issue of fraud and

1 misconduct, which of course that's a whole important
2 subject that could be managed on its own.

3 And there's a report from the Institute of
4 Medicine, which I had the privilege of chairing,
5 that just came out in March called "*Evolution of*
6 *Translational 'omics: Lessons Learning and the Path*
7 *Forward.*" We are very eager to improve medical
8 diagnosis, individualized or at least define some
9 groups of patients for more specific treatment with
10 higher benefit to risk ratio. And we are confident
11 that molecular signatures will enhance our capacity
12 to deliver such service to patients and to
13 populations.

14 It's been tough so far and it's just one
15 of many areas where we should look and see how the
16 cost effectiveness of the research investment could,
17 in fact, be enhanced. You've already stated that
18 we're not going to do this ourselves but identifying
19 certain kinds of questions and certain kinds of
20 analyses, I think, would be responsive to Francis'
21 charge.

22 Thank you.

23 CHAIRMAN AUGUSTINE: Thank you. Those
24 are very helpful comments and you have obviously
25 thought about this some in the past and it will be

1 useful to get your input on some of the work that
2 others have done that we should be aware of and
3 study before we start out so we don't reinvent the
4 wheel here.

5 DR. OMENN: I should have said the title
6 of that University of Chicago led report and the
7 Lasker Foundation was "*Exceptional Economic Returns*
8 *from Investment in Biomedical Research.*" It's right
9 to the topic.

10 DR. COLLINS: Just a point of information
11 since Gil raised this issue about the lack of
12 reproducibility of research studies when tested in
13 an independent way to try to assess whether a
14 company should invest in a long-term project. There
15 are lots of concerns expressed about this in
16 multiple venues. The NCI is organizing a
17 significant meeting about this in September which, I
18 think, is an opportunity to actually look a little
19 closer at the actual examples because right now it
20 is very puzzling to figure out exactly what might be
21 at the basis of such a disturbing frequency of
22 failure to confirm whether these are things that can
23 be readily explained once you get into the details
24 of the reagents and the buffer and the protocols or
25 whether there is something even more complicated

1 going on.

2 But certainly it has gotten our
3 attention to say the least that this is a topic that
4 has to be addressed and addressed rigorously.

5 CHAIRMAN AUGUSTINE: Gail?

6 DR. CASSELL: Norm, I know sometimes on
7 NIH Director's Advisory Committees when you take on
8 special topics where, in fact, the expertise doesn't
9 lie within the council that you can add that
10 expertise by ad hoc membership. I'm wondering if
11 maybe this is not a subject where the board might
12 benefit by adding two or three individuals with deep
13 expertise in this area. I realize we're not going
14 to be doing the analyses but laying the groundwork.

15 But just to develop that blueprint it might be
16 something to think about. I don't know if others
17 would agree but somebody like Don Berwick comes to
18 mind. I know he's trying to decide now exactly what
19 he's going to do but having given CMS a heck of a
20 lot of thought maybe he would have some ideas about
21 the things that I mentioned earlier as an example.

22 CHAIRMAN AUGUSTINE: That's a terrific
23 point. We'll take that aboard and that's a good
24 introduction to--we've had several folks who
25 previously volunteered to work on this project. The

1 ones I'm aware of are Gail, Eric, Griff, Bill Roper,
2 Arthur Rubenstein and myself. And I'm told that
3 I'm--I realize I am an ad hoc member so I guess I
4 automatically am on. Dan, too. So we'll add Dan.

5 Anyway, as an ad hoc member, I guess I'm
6 involved whether I volunteer or not but I'd like to
7 volunteer for this one. I think this will be
8 important.

9 If anyone else is interested in serving in
10 this or if you have ideas as to people who might fit
11 the bill for what Gail has said, Francis, Amy and I
12 will get together here very shortly and put together
13 a list of a committee and we'll come up with a
14 volunteer chair.

15 I use volunteer in the--since we are
16 almost at the end, I guess we can stand a story.

17 I took my--it turns out at the Museum of
18 Natural History Downtown every day at 2:00 o'clock
19 the tarantula is fed what they describe as a
20 volunteer cricket.

21 (Laughter.)

22 And I had just returned from taking one of
23 my grandchildren to see the volunteer cricket be
24 eaten by the tarantula.

25 Anyway, we will pick a volunteer.

1 (Laughter.)

2 That's a bad analogy to start out with,
3 isn't it?

4 (Laughter.)

5 HON GOLDIN: Thank you so much for that
6 image.

7 **CLOSING REMARKS AND ADJOURNMENT**

8 CHAIRMAN AUGUSTINE: Yes, right.

9 The next meeting will be October 3rd here
10 on the campus. We will continue discussions of the
11 SBIR/STTR topic. We will start our efforts on the
12 current discussion we just had.

13 And before we adjourn there are two
14 things.

15 One, I want to thank, Amy and all your
16 colleagues for the sensational job you do and
17 keeping things on track between meetings and
18 arranging our meetings and for all your good work
19 and professionalism.

20 And, as is our custom, I'd like to go
21 around the room and give everybody a chance, if you
22 have anything you would like to say or any
23 additional observations on any topic, complaints,
24 whatever, this would be a great time.

25 Dan, I know you've got an airplane to

1 catch so maybe you could start and we'll go down the
2 table.

3 HON. GOLDIN: The comments that I made
4 before I just want to repeat about sometimes we get
5 so into the issues and the problems we lose sight of
6 the incredible staff at the NIH. Every time I
7 interact with these folks--Amy, she is always there.
8 She is always available. She is always helpful.

9 Lyric? Where is she? Oh, there she is
10 back there. Yes, Lyric goes around the clock.

11 (Laughter.)

12 But it is the attitude of the leadership
13 of this organization that really distinguishes it
14 and everyone who is engaged with this organization
15 ought to be really proud for what they do.

16 CHAIRMAN AUGUSTINE: Richard?

17 DR. HODES: No comment.

18 CHAIRMAN AUGUSTINE: Sol?

19 Sol, we owe you a special thanks for your
20 part in leading us today and your colleagues of the
21 individual panels.

22 Steve?

23 Bill is gone.

24 Josie?

25 Garry, anything at all?

1 Anything you'd like to say, Gail?

2 DR. CASSELL: To go back to the NAS
3 committee and NIH was always held up as one of the
4 best success stories of the SBIR program and I think
5 now we know exactly why. We've heard today.

6 CHAIRMAN AUGUSTINE: Griff?

7 DR. RODGERS: Nothing to add.

8 Bill Brody?

9 DR. BRODY: Yes. I'm here.

10 CHAIRMAN AUGUSTINE: Do you want to make
11 any last minute comments before we close?

12 DR. BRODY: No, I think it was actually a
13 very interesting meeting and I could hear most
14 everything so it was great. I appreciate the
15 webcast also.

16 CHAIRMAN AUGUSTINE: Okay. Thank you,
17 Bill.

18 Gil?

19 DR. OMENN: I think I had my say. I
20 really enjoyed the session and obviously I'll be
21 happy to work on this new topic.

22 CHAIRMAN AUGUSTINE: Okay. Good. We will
23 add you and that's terrific. We will look forward
24 to seeing you at the next meeting.

25 DR. OMENN: You bet.

1 CHAIRMAN AUGUSTINE: As always, Francis,
2 you get the final word.

3 DR. COLLINS: When I testified in front of
4 the House Energy and Commerce Health Subcommittee,
5 which was just about three weeks ago, this is--you
6 may or may not remember--the committee that actually
7 was responsible primarily for the reauthorization of
8 NIH in 2006 that created the SMRB. And so the
9 members of that committee were very interested in
10 knowing whether the features of that NIH Reform Act
11 had turned out the way that they hoped and they
12 particularly were interested in knowing about the
13 SMRB. Former Chairman Barton, in particular, wanted
14 a full description of how this particular function
15 had served.

16 And I was very happy to tell them that
17 this particular construct, which was controversial
18 and at the time it was put in place caused a fair
19 amount of anxiety, had actually been extremely
20 valuable to me. And I don't think that is,
21 frankly, because the construct itself was so
22 perfect. Those five meetings, maybe they could
23 have thought about that one a little longer before
24 putting that one into the statute.

25 (Laughter.)

1 be 96.

2 (Laughter.)

3 Okay. Well, thank you all very much.

4 The meeting is adjourned.

5 (Whereupon, at 3:11 p.m., the proceedings
6 were adjourned.)

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