NWX-OD DIRS

Moderator: Amy Patterson
May 29, 2012
11:15 am CT

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen only mode. Today's conference is being recorded. If you have any objections you may disconnect at this time.

And now I'd like to introduce your host for today's conference, Mr. Norm Augustine. Sir, you may begin.

Chair Augustine: Thank you very much and good afternoon everyone. This is Norm Augustine and this is the 11th meeting of our full Board plus many meetings of our committees, so some indication I guess of the activity.

I do want to welcome all the Board Members, and especially welcome any members of the public that have joined us today. We have a very good agenda. I'm not sure we'll need the full two hours, but we have a number of substantive issues that we want to deal with.

During the initial part of the meeting the public will be in a listen only mode, but we will have an opportunity later for public comment, and I will point that out at the appropriate time.

Let's begin with a roll call if we might. And perhaps you could also introduce people around the room. Let me call on Dr. Patterson to do that.

Dr. Patterson: All right thank you, Mr. Augustine. I'd like to call roll for the SMRB members. Bill Brody? Bill Brody are you on the line?

Coordinator: Ma'am you have this, all the lines are muted. Do you want the lines opened?

Dr. Patterson: Yes, for the speakers.

Coordinator: Okay, just for the speakers, okay. Well everybody who's dialed in as a speaker has an open line. If you are a speaker please star 0.

Dr. Patterson: Okay, we'll try this again. Good morning everyone and I'll take a quick roll call. Bill Brody? All right, Gail Cassell? Bill Roper?

Member Roper: Here, I'm here.

Dr. Patterson: Arthur Rubenstein?

Member Rubenstein: Yes, I'm here.

Dr. Patterson: Thank you, Arthur. Sol Snyder?

Member Snyder: Here.

Dr. Patterson: All right, Dan Goldin?

Member Goldin: I'm disconnected on...

Dr. Patterson: All right, hope you get reconnected.

Member Fauci: Amy, sorry this is Tony. There's a little confusion about who's a speaker and not so...

Dr. Patterson: All the members are speakers.

Member Fauci: Yes, I know that but they, when we signed in when we said NIH they immediately said, "You're on a listen only mode," even though I gave them the NIH code. So there may be other people who think they're speakers but they're not open.

Dr. Patterson: Okay.

Member Cassell: Yes, I was one of those. This is Gail, I'm here.

Dr. Patterson: Okay thank you, Gail. If you are an SMRB member and you have not dialed in and been acknowledged by the operator as a "speaker" you need to redial in and make sure you're counted as a speaker.

Member Roper: Amy, this is Bill Roper. Did you hear me?

Dr. Patterson: Yes I did. Thanks, Bill. So for I've got Gail Cassell, Dan Goldin, Bill Roper, Arthur Rubenstein, Sol Snyder. I'm going to ask again, is Bill Brody on the line?

All right we'll circle back and check and see if Bill's gotten connected. Tony Fauci?

Member Fauci: Here.

Dr. Patterson: Thank you. Eric Green?

Member Green: Here.

Dr. Patterson: Richard Hodes? Richard Hodes? Steve Katz?

Member Katz: Here.

Dr. Patterson: Thank you. Susan Shurin?

Member Goldin: This is Dan Goldin. I was disconnected. I had been on the line quite a while and for some reason they disconnected me but I...

Dr. Patterson: Okay thanks, Dan. Glad you rejoined. Susan Shurin?

Member Shurin: Here.

Dr. Patterson: Thanks, Susan.

Member Goldin: Amy, do you hear me?

Dr. Patterson: Yes I do thanks, Dan, loud and clear.

Member Goldin: Okay because I've got music again.

Dr. Patterson: Okay.

Member Brody: Lyric? Lyric? Hello?

Dr. Patterson: Hello, Bill Brody?

Member Brody: Yes, can you hear me now?

Dr. Patterson: Yes I can. Thank you, Bill.

Member Brody: Okay thanks, I redialed.

Dr. Patterson: All right, Josie Briggs?

Member Briggs: Here.

Dr. Patterson: Thank you, Josie. Griff Rodgers?

Member Rodgers: Here.

Dr. Patterson: Thank you, Griff. Rod Pettigrew?

Member Pettigrew: Roderic Pettigrew is here.

Dr. Patterson: Thank you, Rod. I don't think Harold Varmus was able to join this call but I'll call his name anyway. Harold? Okay, and Francis Collins?

Member Collins: I'm right here next to you, Amy.

Dr. Patterson: Okay all right, great. And I should also acknowledge in the room Drs. Kathy Hudson and Lyric Jorgenson, and probably joining us also Dr. Larry Tabak.

Back to you, Norm.

Chair Augustine: Okay thank you very much, Amy, and Francis if you and Amy get cut off we have a big problem (unintelligible) sitting across the table.

We've got a couple of administrative items to begin with and Francis is going to then start-up – start out the meeting to update us on actions that the NIH has taken that respond to the recommendations the Board made during the year 2010.

And as you'll recall, there were three sets of recommendations that year that were given to the NIH Director there in the reports on the subjects of translational medicine and therapeutics, the report on the NIH Clinical Center, and then the report on substance use, abuse, and addiction research. And they are available on the SMRB Web site for those in the public who are listening in.

Secondly today we are going to hear from Sol who's going to give us an update on the proceedings of the working group that was established on the NIH Small Business Innovation Research and Small Business Technology Transfer or the SBIR/STTR pronounced I guess SBIR/STTR working group.

And finally at the end of the time that we have today, we're going to touch briefly on a new topic that we would like to consider the Board undertaking. And we'll just introduce that and we'll get into greater depth when we next meet in person.

So Francis, do you have any opening comments you want to make before we get into the agenda?

Member Collins: Well only to thank everybody for the work you've done and the work you will do. And I much appreciate that all these busy people are very dedicated by

your actions in the past to this SMRB. And we have some exciting new things to talk with you about, as well as reviewing where the current recommendations stand, which I'll do in a few moments. But again, thank you for your dedication to NIH.

Chair Augustine: Thank you, Francis. And let me then turn to a couple of items that we need to deal with. First of all, as I said, the members of the public that would like to give remarks will have an offer to do so later.

There was a Federal Register Notice requesting people to sign up who did want to make remarks if there's time on the agenda. I think there will be. If there are others who would like to make comments you can do so by informing the operator who will at the appropriate time activate your line so that you can be a speaker and, to be fair to everyone who does want to make comments, we'd ask that as usual you hold your remarks to no more than five minutes.

And anyone who would like to submit longer statements or other comments we certainly welcome, can do so at any time either by email or by regular mail to the Web site that we have activated that you can find on the NIH site.

And next I'd like to ask for approval of the minutes of the meeting that were held on October 26. You all have copies of those minutes which I'm impressed with their thoroughness. And Eric Green and Griff Rodgers were kind enough to review them in advance. And I would ask at this time would anyone make a motion to approve those minutes so there can be a second?

Member Hodes: So moved.

Member Cassell: I second.

Chair Augustine: Thank you very much. Is there any comments or corrections that anyone has regarding the minutes? Very noted, none then, all in favor of approval of minutes please say aye.

(Chorus of ayes.)

Chair Augustine: Thank you very much. And then we needed in accordance with the Federal regulations to remind our group of the NIH conflict of interest rules. And Amy will do that.

Dr. Patterson: Okay thank you, Norm. Before I begin I want to acknowledge I believe Richard Hodes has joined us now. Richard?

Member Hodes: Yes.

Dr. Patterson: Okay good, so all present and accounted for. All right, it's my pleasure to as our ritual read to you the rules of conduct and conflict of interest.

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

At every meeting in addition to reminding you about the importance of following the ethics rules we always like to review the steps we take and that we ask you to take to ensure that any conflicts of interest between your public responsibilities and your private interests and activities are identified and appropriately addressed.

As you know before every meeting you provide us with information about your personal, professional, and financial interests. We use this information as the basis for assessing whether you have any real, potential, or apparent conflicts of interest that could compromise your ability to be objective in giving advice during these meetings.

If such conflicts are identified we either issue a waiver if appropriate or recuse you entirely from a particular portion of the meeting. We usually waive conflicts of interest for general matters because we believe that your ability to be objective will not be affected by your interest in such matters.

We also rely to a great degree on you to be attentive during the meeting to the possibility that an issue may arise that could affect or at least appear to affect your interest in a specific way. If this happens we ask you to recuse yourself from the discussion and let us know of course.

If you have any questions about the rules of conduct or conflict of interest our committee management officer Lisa Rustin will be happy to address them.

Thank you, Norm.

Chair Augustine: Thank you very much, Amy. Does anybody have any questions on that topic at this point?

Okay hearing none let's go into the agenda. This first item as I mentioned is to hear from Dr. Collins. For those members of the public, he of course is the Director of NIH. Francis will be giving us an update on the proposals that our Board made about a year ago. And let me then, Francis, turn to you.

Member Collins: Thanks, Norm. And thanks to all the members of the Board. Again let me express my appreciation for the time and effort you have invested to produce, so far, four thoughtful and comprehensive reports. We've accepted all of these recommendations and have been working tirelessly to ensure their implementation. And let me assure you that has been a big challenge.

The SMRB works very hard to put forward these reports and certainly, from our perspective, gave us a lot to chew on, a lot of tasks to undertake. And I want to assure you that that has been taken with great seriousness by myself and all of the other staff at NIH. Some of these changes turn out to be actually quite elaborate and complicated.

You heard a bit of a review about where we stand with those at your meeting back in October, but I thought I would give you an update of that. And so there was an attachment sent around this morning, Attachment 8, which you might want to turn to which is a series of Power Points that I'll be speaking from.

So, if you're near a computer or if you have that already printed out it would be good to pull it out in front of you and I'll try to tell you which slide I'm on as we go forward. So this is entitled on the first slide, implementing the recommendations of the SMRB NIH update.

The second slide shows the timetable of SMRB recommendations to date. And I just noticed there is a typo of one of those where the date for the TMAT recommendations on this slide says of December 2011 and it's really of December 2010.

But obviously an awful lot of hard work got done starting with the first meeting in April 2009 resulting then in the output of these four reports that

have kept us actually quite busy since that time. And now here we are at the 11th SMRB meeting as of today.

I'm going to go through the three recommendations that focused on specific aspects that SMRB put in forward. The DOCE Framework, which was the other report, will come up again as we're talking about how to approach the new charge. But I wanted to give you an update on where we are about the other three.

The NIH Clinical Center recommendations were to expand the vision and role of the Clinical Center, to come up with a streamlined governance structure, to open up the Clinical Center for additional opportunities for extramural researchers to utilize it, and to come up with a pathway towards a stable, adequate budget for fiscal viability and sustainability. That's all on Slide 3.

So what have we done? A Clinical Center Governing Board, Slide 4, has been put in place and charged with serving as a Board of Trustees.

And basically, to provide strategic and operational oversight with the objective of facilitating high quality, cost effective clinical research and budget recommendations that would promote stable funding consistent with the intent of the SMRB, recognizing that this is a very stiff challenge with budgets that have remained flat at best and with the cost of clinical care which this research hospital must deliver being anything but flat.

Going on to the next slide, Slide 5, another recommendation of the SMRB which has been put in place is the development of this Clinical Center Extramural Collaborations Committee again trying to promote the opportunities for more collaboration with investigators who are not located

here at NIH but who could take full advantage of the remarkable facility that this represents.

And so this has led to an effort to develop an FOA that would promote such collaboration. A notice of intent will be published very soon, the FOA in August and a scheduled receipt date for applications in November with awards then coming up a little more than a year from now. Again it's a very specific outreach to try to encourage these kinds of collaborations.

So that is a step in the direction. I'll just say by way of commentary in terms of one of the recommendations of the SMRB which was to try to move the Clinical Center budget line into a different location than it currently stands, we continue to wrestle with the pros and cons of what that might mean in terms of the effectiveness of being able to run the Center as well as the vulnerability of such efforts.

As well as some complicated questions that relate to what we call the color of money which make it difficult in some instances to envision how we would be able to use such resources for extramural collaborations. So at the present time we continue to fund the Clinical Center through the intramural budget line.

Let me go to the next one. Now I'm on Slide 6 which is a recommendation about substance use, abuse, and addiction research at NIH. SMRB took a great deal of pains to listen to many perspectives about this and many examples of testimony that were put forward and to address the charge whether NIH administrative and organizational changes could further optimize research into this field.

And ultimately SMRB did recommend in 2010 a new Institute that would encompass all substance use, abuse, and addiction related research dissolving

the independent existence of NIAAA and NIDA but also identifying other areas of research that fit into this particular portfolio that could be brought together in one organizational structure.

And after the recommendation that SMRB put forward we accepted this. You can see on Slide 7 here the recommendation being accepted by myself on November 18, 2010.

You would think that this would be a relatively straightforward matter, but let me assure you it's anything but. And Larry Tabak who has led this effort can certainly vouch for that. And I'm sure it's taken many hours a week for him to lead this effort to try to identify precisely how to do this in a fashion that has the best possible outcome for science.

This was initiated with a task force that was formed to gather data, consult with scientific staff of the Institutes and Centers. Draft principles were formed in April. I'm on Slide 8 now. And by Fall of this year, the task force and strategic planning committee will complete their portfolio analysis and develop an integration plan for public comment. In fact they're very far along with that already.

That will then result we hope in lots of comments. But there's already been an opportunity for that in terms of an RFI which was available from February 8 to May 11, and 494 responses have been received to that, which we are sifting through. As well as having a Web meeting on the RFI in April and a plan for meetings with targeted set of stakeholders coming up this summer. So lots and lots of input here.

Again this Fall there will be the release of this portfolio integration plan and public comment period as well as a scientific strategic plan. And then final

recommendations to the NIH Director by the end of this calendar year with the expectation this can then be folded into the President's proposed budget for 2014 which as many of you know is due to be unveiled in early February.

The target then would be to launch this new Institute of Substance Use and Addiction Disorders. That's the working name but we are not totally locked into that. It doesn't exactly trip off your tongue when you try to say it, NISUAD. So suggestions are welcome. But this would be aimed for October of 2013. That is, the beginning of fiscal year '14.

That's where we are. I should tell you that we are hearing certainly from some of the lobbying organizations that are involved in terms of promoting the use and sale of alcoholic beverages, that being both the spirits industry, the beer industry, the wine industry, that they are not particularly happy about this.

And we are going to have to see exactly what kind of response comes forward from those groups who as you probably know are pretty well connected. But we are proceeding because of your recommendation about the scientific value of this enterprise. But just as a heads up I think in terms of the political side of this it may be that there could be some noise.

Finally in terms of going through the recommendations that you have made, the Translational Medicine and Therapeutics recommendation, TMAT, which led to, after considerable deliberation and again taking a lot of public input in some of your meetings, a recommendation to create a new NIH Center with a mission of supporting and strengthening translational medicine. Now Slide 10.

This was put forward and received by NIH on December 7 of 2011, sorry 2010. That basically led to a lot of activity here to investigate how best to do that including a straw model which was assembled in January 2011 with input

from lots of leadership and also a task force that was established within NIH and reported back to the SMRB in February of 2011, final recommendations to the NIH Director in March.

And with a great deal of activity during the course of the summer, on December the 23rd with the approval and signing by the President of the Consolidation Appropriations Act of 2012, the recommendation of the SMRB became a reality with the formation of the National Center for Advancing Translational Sciences, NCATS.

That by the way is one year and 16 days from the time of the recommendation put forward by the SMRB. And many people who work in the government think that's pretty darn remarkable that you can get something of this sort done in that time table.

And it certainly was a change in our organization that was not completely unanimously embraced during the course of that year. Although I think as the understanding of what NCATS aimed to do became more clear in peoples' minds a lot of the original anxieties about what this meant for NIH began to resolve.

And I would say at this point with a few exceptions, NCATS is being seen in most quarters both public and private as an idea whose time is come and is providing some real special opportunities for accelerating the process of going from basic discoveries to clinical benefits.

On Slide 12 you will see just a brief descriptor of what some of the programs are that moved around on account of this decision to start NCATS and to take the programs that had existed within NCRR, the National Center for Research Resources, and move them to other homes putting them in places that would

be particularly good for the synergy potential with other aspects of what NIH is up to.

Those transitions have all been I think smooth and well managed. And again much credit to Larry Tabak who took a lot of the task on of figuring out how best to do this distribution of components and those new homes were identified and I think have been nicely managed.

In terms of NCATS itself, and I'm now on Slide 13, the creation on December 23rd has led to a great deal of energy and excitement here at NIH in terms of what this new Center could in fact catalyze. We have been very fortunate to have the willingness of Tom Insel to take on the role of Acting Director, continuing his leadership at NIH and still wearing his other hat as Director of NIMH.

And fortunate to have Kathy Hudson take on the role as the Acting Deputy Director also maintaining her hat as the overall NIH Deputy Director for Science, Outreach, and Policy.

And Josie Briggs, who as you may know is the Director of NCAMM and is on the phone, has well very graciously agreed to serve as the Acting Director of the Division of Clinical Innovation which is the part of NCATS where the CTSAs reside.

So all of these folks have really plunged in, rolled up their sleeves, and done a great job of getting this enterprise off the ground.

Again the goal of NCATS is to pursue opportunities for disruptive innovation. I'm on Slide 14, to catalyze the generation of innovative methods and technologies that will enhance the development, testing, and implementation

of diagnostics and therapeutics across a wide range of human diseases and conditions.

Focusing particularly therefore on bottlenecks in the translational pathway that are not specific to any given project but are more general problems that can only really be addressed by a systematic approach that ties into all of the resources that NIH and the private sector can together bring to bear on this.

In terms of what NCATS now has as part of its programs and initiatives on Slide 15, obviously the CTSAs are a huge part of this. In fact the majority part of the budget is derived from having moved that program into NCATs. There is also significant effort in rare disease research and therapeutics from the TRND program and the Office of Rare Diseases Research which have also moved into NCATS.

And the ability to reengineer translational sciences by the incorporation of the NIH Chemical Genomics Center previously at NHGRI, the Bridging Interventional Development Gaps or BrIDGs program and toxicology effort, all of those also now becoming part of this enterprise.

On Slide 16, just very briefly here, are three examples of new initiatives. Even though this Center is now only about five months old, that have been undertaken.

We have a very ambitious and I would say exciting, innovative approach to doing drug screening, working with DARPA, the Defense Advanced Research Project Agency of DoD to develop biochips that can be utilized to identify signals of toxicity of compounds before they're ever given to human patients.

And which we think over the course of time may be better predictors than animal testing since these chips will be loaded with human cells that have been differentiated into various cell types.

A second program which we just announced a few weeks ago and which has gotten I think a lot of positive response is the efforts to encourage the possibility of crowd sourcing.

Compounds that have been abandoned late in the development process by companies because of failure to show efficacy, which are known to be safe in humans and which could potentially find a new use for a new disorder if we unleashed the creative ideas of the entire research community both public and private.

And this initially was announced by Secretary Sebelius just a couple of weeks ago with three companies joining up, namely at that point Pfizer, AstraZeneca, and Lilly. I'm happy to say that several other companies have come forward since that time and are extremely likely to join so that when this is rolled out in terms of its funding opportunity coming up in June you're likely to see a longer list of companies and compounds.

And this seems like a win/win for everybody. And it's the sort of thing which NCATS is capable of stepping in and catalyzing which might otherwise have been difficult to organize.

And the third thing is target validation, much interest in the pharmaceutical industry and the biotech industry about how to do a better job of identifying the kinds of targets that will lead to successful therapeutics in the next generation of therapeutic development.

And with great opportunities now scientifically to do target validation using human cells or human genomics there has been over the course of several months an intense conversation about how we might work together with pharma on this process.

And in fact, several of us are off to Boston on Thursday and Friday of this week for a joint NIH/Industry workshop on this. Which, if it goes well, may result in laying out an actual work plan for a pretty ambitious effort to do this sort of target validation, to be supported jointly by NIH and Industry and perhaps organized through the Foundation for NIH.

All of these things can be done more quickly as it says at the bottom banner there of Slide 16, with the authorities provided by the Cures Acceleration Network which you may recall is something authorized in the Affordable Care Act and now appropriated but only at a rather modest level in its first year. And which we hope then can be scaled up.

So NCATS is moving forward. We do need to identify permanent leadership. And there's a vigorous search committee effort underway to do that. We do need to convene an advisory council and a board for the Cures Acceleration Network. And we have already identified a remarkable roster of individuals who have indicated their willingness to serve. But we have to go through the appropriate Federal processes to get those rosters approved.

We do expect to issue a new RFA in June, that's very soon, for the CTSAs and for the Therapeutic Discoveries Program.

And, as we're being asked by the appropriation language, we will plan to conduct studies through the IOM basically of what the Cures Acceleration Network can accomplish and what the goals might be, the going forward in

what we would call CTSA 2.0 to take full advantage of this network of six very important parts of NIH's investments in clinical research.

So that's a pretty quick romp through a lot that's going on here of summarizing three of the four reports that you've given. And the last slide or next to last slide, Slide 18, the big question mark is what we're really here to talk about today, is what comes next?

So, I'll stop there and I'll be glad to take questions from anybody about any of these areas of our current activity that you all have encouraged us to do and we've been really delighted to have the chance to follow your recommendations forward.

Member Cassell: Francis, this is Gail Cassell. I'd just like to say I'm really impressed with how rapidly it seems this has progressed, even though I am aware that there were a lot of challenges. But I think personally it's very exciting on all fronts.

Member Collins: Thanks, Gail. And it's really been wonderful to have the chance to be a little unleashed here. And I must say all the experiences we have had working with colleagues in the private sector about these initiatives have been really exciting. And I think we've found a partnership there that was sort of the, the time had come. And it's great to see it taking shape.

Chair Augustine: Are there other folks who would like to ask questions or make comments?

Coordinator: Yes, if you'd like to ask a question please press star 1. To withdraw your request, please press star 2. Once again, to ask a question it's star 1. And please stand by for any questions or comments.

Member Collins: Operator, this is just for the committee members. So I'm not sure why our speakers need to do any punching of star 1's or...

Coordinator: Okay, my apologies.

Dr. Patterson: Thank you.

Member Collins: Okay, so Board Members please speak without any need to hit buttons.

Member Rubenstein: Well this is Arthur. I'd like to congratulate you too. I think, you know, you handled the opposition to it very, very well. Which I think was understandable but not convincing. And I think some of the moves you've made recently together with industry has really made people feel very optimistic. So I congratulate you and think it's a really wonderful move.

Member Collins: Thank you, Arthur. And again thanks to you because you led that particular group with great skill and put us in a position I think to really see the opportunity much more clearly than we could have without that really wonderful effort that your group put forward. Thank you.

Member Rubenstein: And I'll just add one thing. I think the opportunity with the Clinical Center now that you're moving forward with will also add to this kind of new view of how the NIH can collaborate with outside people. And I think that'll be viewed very positively as well.

Member Collins: Great, thanks.

Chair Augustine: Other comments? Hearing none I'll just add my own view that having spent ten years in government myself I realize that change does not come easily, which is both good and bad. And that, you know, it takes an awful lot of effort

to do what you've done. And it also takes a lot of courage and I admire you for that.

I hope we can stay the course and complete the task that was set out here. And before we leave this topic, Francis, if it's agreeable with you, Larry, I wanted to ask you since you've been heavily involved in this, is there anything you'd like to add? We haven't warned you we're going to ask. But if there's anything you'd like to add we sure welcome hearing it.

Dr. Tabak: Oh I think Francis has summarized the current status, you know, correctly and we are continuing to move forward on the formation of the proposed new institute related to substance use, abuse, and addiction.

Member Snyder: Right. This is Sol. I have a question. I wasn't clear on why the beverage industry would be opposing the merging of the alcohol and drug abuse institutes.

Member Collins: I think their concern relates to their view that alcoholic beverages are actually a acceptable, even desirable social activity. They even consider alcoholic beverages to be a food. And that there are health benefits from moderate use thereof. And the notion that this would be lumped together with drugs of abuse which are many of them illegal rubs them the wrong way.
I think that's probably an overly simplified way to say it but I think that's the main problem.

Member Snyder: Okay, I just don't have a sinister mind. I missed it.

Member Collins: You've got to worry about that, Sol.

Dr. Hudson: You haven't lived here long enough.

Member Collins: Yes come to Building One. We can help you with that.

Chair Augustine: And I can understand that point but it is NIH's responsibility to deal with research issues and the research arguments I think are pretty compelling...

Dr. Hudson: Yes totally.

Chair Augustine: ...what the committee recommended so hopefully that, those concerns can be minimized.

And with regard to translational medicine, I've had the occasion to encounter several people lately who come from various aspects of this whole process. All of whom have been very, comment very favorably about what you're doing. So I think there is some support out there that's building.

Last chance. Anybody else have anything you want to ask before we turn to the next topic?

Okay let's go to the next topic which you'll recall at our October meeting Francis had asked the SMRB if we would give some thought to how the SBIR and STTR programs might be best utilized. There's a non-trivial sum of money that's devoted to those programs. There are real opportunities there but they sort of have to be mined. And so we set up a Working Group to deal with those questions.

That group's been hard at work under the leadership of Dr. Snyder. And he today has agreed to give us an update – this is strictly a status report – of their work to date. So Sol, let me turn the line over to you.

Member Snyder: Okay, I'll try to be relatively brief. It was very clear that the SBIR/STTR program is a success. It's working well and so when this question of having a task force on it came up I gave Amy a hard time challenging her as to if it ain't broke why fix it? Why do we have to bother with a task force?

And which provoked Amy to think hard and for me to think hard. And we came up with some very good rationales about how we could take something good and improve it. And I think that'll become evident as we start going through the slides.

The members - I'm on the third slide now - The members of the group are indicated there. And as you can see, it's about 11 of us, both Federal and non-Federal people in the SMRB. And we've had a series of meetings with people, I'd like to thank all the people on the task force who have worked what I feel above and beyond the call and been really conscientious and hardly anybody's missed any meetings.

And in terms of the background, the SBIR program was established almost exactly 30 years ago. And for any Federal agency that has more than $100 million in extramural R&D funds, 2.5% goes to SBIR. And then the STTR program came along ten years later for reasons I don't really understand but that's, we won't worry about it.

And that's about 1/10 the size, about 0.3% and similar and most of our attention has been to SBIR because that's the bulk of the money. And STTR operates analogously. An important issue is the mission indicated on Slide 5.

And it's to support excellence in science and technology dealing with major national priorities, and particularly to deal with a strong national economy. And that's why there's, we are focused on funding companies. And the as we'll

get to shortly, the how that mission fits to the NIH and to individual Institutes differentially is an important issue.

Slide 6 indicates the, what the goals are specifically and it's to stimulate technological innovation. And what that means can vary a lot with Department of Defense versus NIH. It's of course specifically designed to meet the research and development needs of the Federal government. And that's not specified for STTR but it really is anyhow.

And the goal is through working through small companies specifically that will help innovation and entrepreneurship by people who are socially or economically disadvantaged. And of course we want to enhance private, public partnerships.

So the question is why do anything to change it? Well the important thing is - or why bother examining it at all? One reason to examine it is the NIH program if you take 2-1/2% or as you'll see soon 3.6%, that's a lot of dollars. It's one of the largest really, the Defense Department is, I suppose, the biggest.

And the difference between NIH and the Defense Department in the SBIR business is that they typically have very concrete things. "build me a widget," and go and the people go out and build widgets.

And the NIH philosophy has of course been more to get fundamental knowledge about things and how you modify that mission of fundamental knowledge for a business focus is tricky. And as you'll see different IC's have handed it quite differently.

The second major reason that we should worry about it at this point in time is because the reauthorization act raises it all the way up to 3.2% for SBIR. And

STTR up to 0.45% so we're talking about 3.6% of the whole NIH budget and out of, you know, $30 billion that's not chicken feed. So our charge is to recommend ways in which we can optimize these programs and keep them within mission of the NIH.

On Slide 10 we have more considerations of how we can go about all of this in terms of how we want small companies to be innovative. We want to recognize the whole notion of small biotech companies is that they come up with ideas that big behemoths like big pharmaceutical companies that are more bureaucratic don't come up with.

But on the other hand the NIH itself has its own priorities. Every IC wants to do this, that, or the other thing. So one theme that will come up again as I, we go through the presentation is how much do we want the equivalent of RO1s, namely investigator initiated activities, versus targeted requests for proposals.

And of course we want to fund quality proposals. By quality of course we generally mean good scientific quality. But at the same time we want successful commercialization. And as we'll go ahead there's been a tension between those two things and it's an issue that our task force is wrestling with.

And then of course we want to just take existing expertise and from the NIH and elsewhere and do whatever we can to help out our grantees. And this gets into the issue of hand holding.

How much social work the NIH does to help the small businesses develop good proposals and execute them well because in the regular academic work world of research the out to the I call the mature industry where everybody in academia knows what an RO1 is and what needs to be done.

But the SBIR program is dealing with little companies that for whom government grants are something really foreign and new and they just need a lot of help to figure out how they can accomplish things like that.

There are a number of steps to take to go through and these are just common sense things on Slide 11 of how we should go about fostering the program.

On Slide 12 we address the issue of prior analyses of the program. The Government Accounting Office chose 2006 made a report evaluating the program and made recommendations. The National Research Council did it again in 2009. The NIH did its own analyses of 2009 and there was another GAO report just a year ago.

And it's because of these actually pretty good reports, pretty good analyses recommendations which have largely been acted upon that I raised the question with Amy, why are we reinventing the wheel? But as you'll see there is important things that we need to do.

Slide 13 just breaks down the whole program into the different components. And we have them in terms of seven different components which need to be evaluated. The way we've worked in our task force is to analyze these components we've split ourselves into teams of two people. Though seven times two makes 14 people but we only have ten people so some people did double duty.

And we went in twos, did a lot of background work, prepared reports, and then the teams reported to the whole task force. And we've done that fairly recently. In terms of getting outside input what we've been doing first is seeing how the different IC's handle things. We can't deal with all the IC's because there are so many of them.

But we've been dealing with several of them and again in teams of two people from our task force interviewing in a teleconference the Directors of the Institute and the relevant staff of the Institute that handles SBIRs and we've done that thus far thoroughly for NIMH, NIDCD, the Deafness Institute, and the Environmental Sciences Institute. And other ones are on line.

We'll be dealing more with SBIR staff and then over the course of the summer we'll get input from how other Federal agencies handle this. We'll deal with the Small Business Administration which is responsible for the entire program nationally. And then we'll be getting outside testimony in the course of the summer.

We'll also deal with representatives of the small business community and also grantees and the other representatives and academic investigators. So let's go through some of the preliminary findings. So the first is the programs are meeting their statutory objectives. But there are a lot of things that can be addressed.

For instance flexibility is one thing that is very good. In fact let's just go through these items which are already working. So one it's doing what it's supposed to do.

Two the way it's structured, and I'll get back to this again, is that it's pretty flexible. And different IC's handle it very differently. And as indicated below they vary a lot in terms of how they handle the budgets et cetera, et cetera.

And let me give you a few examples. In terms of how you obtain applications there are two ways. One is there is just an announcement and people come in

with their own ideas. Some of the institutes especially the small institutes use that approach predominantly because it doesn't require a large staff input.

Larger institutes which have more resources can devote a number of staff people full time to the SBIR/STTR program. And so they can just develop outreach. They can go around to meetings throughout the country and spread the word of what's available.

And then they can decide what are the key priorities of our Institute and say, "This is what we want done." And tell people, make a targeted announcement and then review. And work very closely with grantees. They can be specifically targeted. In our meeting with NIMH Tom Insel, the Director, has put forth a lot of energy he and his staff into this sort of thing. And they, speaking of flexibility, they use a lot of flexibility.

There are certain standard guidelines of how much money should be allocated in phase 1and how much in phase 2. And but those are not binding. And NIMH often disregards them on the grounds that it's better to do a few things well than to do a lot of things inadequately and so you have nothing to show for yourself.

In the case of drug development which is an important element of the SBIR programs at NIMH, drug development even for a limited activity of initial phases of a little biotech company just cost a lot of money.

And so they figure to get it to work they just have to put a lot more money into it and of course work closely with the grantees because they have more money at stake. And this is very different from some of the other Institutes that just don't do that sort of thing.

The next slide, number 16, deals with some of the specific recommendations. One important one that we spend a lot of time on has to do with establishing reliable metrics. There have been analyses of the pay off. One of the earlier reports, or the NIH itself did an analysis and the NSF I think did an analysis. And they used as a metric commercialization. And what do you mean by commercialization?

Most people think that that means you have a drug sitting there in the drugstore. But for the SBIR program which is really very small and limited dollar wise you can't use that metric. So commercialization tends to mean getting somebody to invest in the company.

And that by those standards in one study 30% were successful. Another study said 40% were successful. But our task force felt that those aren't really very rigorous metrics and we must decide what we mean.

Dan Goldin had a very good suggestion that instead of talking about commercialization as terms of money he said, "One goal might be to, our goal is to mature the technology of the company in order to secure investment by the company."

And but we're still not sure exactly what we feel is the best sort of metric. And we suspect that we need a lot of work on that to get at it.

The application process could be strengthened. And one possibility is to in terms of the outreach to secure applications as well as evaluating them perhaps consideration could be done to have some of these activities NIH wide rather than separate for each IC. But we're not sure.

In terms of and also the issue of the extent to which we want to encourage targeted outreach as opposed to just taking in applications from anybody who wants to make them is an important issue. And a very good case could be made that the present mode in which every IC just has the flexibility to do it the way that works best for them is sort of nice, avoids the notion of rigid bureaucracy.

In terms of scientific peer review there's been a big concern by the business community that the grants are reviewed as if they were regular RO1 applications and without realizing that the goals of developing a product in a business are very, very different than what you do in a research grant.

And the criticisms that we've seen of some applications are just irrational. If the request for proposal said, "We wish you to do a, b, c, d, e according to methods 1, 2, 3, and 4," and the application followed the rules exactly.

And then the criticism well, "Well there wasn't much innovation. They didn't have any new ideas." But of course in this case they were doing exactly what they were told to do.

There's also been concern about it just takes a long time to get a grant reviewed. The SBIR program is not all that much faster than a regular RO1 review process. And for little companies, you know, a year diddling around, you know, there's no more company by that time.

Though nonetheless the need for two levels of review and everything else makes it hard to speed it up a great deal and those kinds of issues. So in terms of next steps we're going to continue, this is Slide 17, the last slide, consultation. We'll have our first stake holder meeting July 1 and we'll prepare

findings and we'll have another stake holder meeting in October. And that's where we are.

Chair Augustine: Sol, thank you very much. And it sounds like you have gotten off to a quick start here. With the first meeting after this one which will be our meeting in July we'll have a chance to hear from a number of stakeholders which should I think be very interesting in this regard.

And at this point let me open the lines to the members of the SMRB for any questions you might want to raise at this point or any comments you might have.

I thought I heard someone trying to say something. Okay if not I guess you're all in agreement with what Sol has described as their approach. And we will watch with great interest as you proceed.

That brings us then to the public comment portion of the meeting. We have time for a couple of public comments if there are any. Again we'd ask that you limit the time to five minutes.

And Operator, I guess you have a way to queue people if there are comments. And so to those who do have a comment if you would indicate to the operator at this time you do and we'll stand by here waiting, Operator, your guidance.

Coordinator: Okay, once again if you have a question or a comment it's star 1. Once again, if you have a question or comment it's star 1. And please stand by.

Chair Augustine: Operator, I think we're clear here. Do you have anyone there on the line?

Coordinator: We have no questions or comments at this time.

Chair Augustine: Okay that's fine. And let me then proceed just for kind of some wrap up observations. The next steps for our group, of course we will be meeting face-to- face in July here on the NIH campus. And at that time we'll as I said be going through the stakeholder consultation for the SBIR/STTR program.

We've got other items on the agenda including further updates of past recommendations. We also are in the process of polling your offices for a following meeting to the July meeting here on the NIH campus which will probably be in October.

Then finally we'll end the year in November early December with a teleconference to pick up on those items that need attention before the end of the year. And as I mentioned in the letter that was sent to the Board in April that Francis has asked that we give some thought to a new topic that I think is a particularly important and exciting one and relates to the charge that we were given by the Congress.

And it has to do with the assessment of the value of investments of biomedical research. There's of course a general sentiment that this is a good investment. But when it comes to try to defend that investment in terms of specific dollars before the Office of Management and Budget or before the Congress or indeed before the public it would be helpful if we had some more analytical methods of conducting that evaluation.

And we've been giving some informal thought here to the topic of just how do you assess the value of these investments in biomedical research or the appropriate metrics and what sort of conclusion might one draw? This could obviously have a great impact on NIH and it is something that's important that we do well.

It touches on some of the subjects that other members raised at prior meetings. Also, Sol, you touched on it in one of your charts with regard to your specific issue. So it would be very helpful if everyone would give some thought to the question of, how do you measure value hopefully analytically and quantitatively. And at the next meeting we'll have an opportunity to discuss that.

One of the questions that came up and in fact I guess I was the one that raised it when we first addressed this was how this fits in with our portfolio. And indeed the statute that created our group has in it the notion that one of our responsibilities is and I quote, "to review the research portfolios of the NIH in order to determine the progress and effectiveness and value of the portfolio and the allocation among the portfolio activities and the resources of NIH."

And that was in the NIH Reform Act. So it's a responsibility we do have and from efforts I've been involved in in other departments along this line it could be extremely informative. If any of you are particularly interested in serving on this group I hope you'll shoot an email to either Amy or myself and we will sign you up. And to complete the group and assure its balance I will volunteer others at the appropriate time. And I hope that will be acceptable.

I should also note that our meeting in July really corresponds to some changes in our membership where we have people, I will avoid the use of the word expiring so I'll say leaving our group. And we will be taking some new people aboard at that meeting. And we're in the process of getting cleared at this point in time. So when they are cleared I will be prepared to announce who they are.

Let me give each of you a last chance to comment before we adjourn the meeting. Are there any comments, further comments that anybody would like to make?

Member Brody: Norm, how do we know if we're about to expire?

Dr. Patterson: You're not.

Chair Augustine: We have good news for you. Very good news there in San Diego so.

Member Cassell: Well but Norm, how about the rest of us? How do we know?

Chair Augustine: I will ask Amy to check the list and send out the list so everybody will know everyone's standing.

Dr. Patterson: Yes.

Chair Augustine: That would be good.

Dr. Patterson: We'll send an updated roster. But those of you who are rotating off, and I will remind you that none of you are ever off SMRB entirely. We will count you as treasured alumni of SMRB and hope that we can at least call you up for some insight and wisdom even if you aren't formerly on the Board in the future.

Chair Augustine: Well put. And so we will inform you of that. And then there's as always, Francis, you get the last word.

Member Collins: Oh, well Norm, let me thank you again for leading us very effectively through this particular discussion. And I will really want to thank Sol Snyder who's

graciously agreed to serve as Chair of this SBIR/STTR Working Group and has already made substantial progress in digging into this topic.

And I appreciate, Sol, your initial concern about whether there was enough here to justify a Working Group. And I also appreciate your conclusion that the answer is yes. There is an actually I think a great opportunity here when you consider something like $1 billion a year are going into this combined set of enterprises. And that we have not really drilled down at the level that you are now doing in terms of ways to make this even better.

And we are at a circumstance where in addition to a boost in the overall dollars there's also an opening up of opportunities to companies that have venture capital support which has not previously been possible. So we're going to have a broader and I think actually quite exciting new list of potential applicants to the program and we want to be sure we make the most of that.

So I really appreciate the work that you and your group have already done and will be doing in the next few months to try to come forward with some recommendations.

I appreciate what you said about the cycle time for getting support because I hear about that a lot from small businesses where as you said a year may be the difference between being able to go forward or just not existing anymore.

And I would encourage your Working Group to think creatively about ways to substantially shorten that time for review even if it means going away from sort of the standard way that we do things. This is a program that I think could perhaps benefit from some piloting of bolder approaches to cut back that amount of time substantially. And I'm sure you'll have some thoughts about that.

I also appreciate Norm's forecasting for you the opportunity here for SMRB to tackle an additional project here on the economic benefits of biomedical research. I'm very enthusiastic about having your considerable expertise brought to bear on this question especially at this time where you can't assume that anything the Federal government is doing is just a good thing because it sounds good.

We really do have to consider very seriously what the return on investment is of every taxpayer dollar.

If you haven't seen the report that came out ten days ago from ITIF, The Information Technology Innovation Foundation, done jointly with UMR, United for Medical Research, it takes a crack at this from the perspective of American competitiveness.

And Amy, did that go to all the members?

Dr. Patterson: No.

Member Collins: We can send that out to all the Board Members. You might want to have a look at it as an example of the kind of analyses that's going on. But it's clear that this is a landscape where there's a lot of opportunity and it would be very helpful I think to get your thoughts on this.

So I will plan when you meet in July to present you with this new charge. And I appreciate the opportunity to work with you on that and for people to volunteer to take part in what I think is going to be a very interesting study. So we have lots of things that we're asking you to do, you know, lots of things you're asking us to do. I think we make a pretty good team.

And again let me say what I said at the beginning, how much we appreciate all of you busy people taking the time that it takes to drill down into these issues and make really substantive, thoughtful recommendations which we take with great seriousness. So many thanks.

Chair Augustine: Francis, thank you very much. Sol, thank you for your leadership. Amy, for putting together your team, for putting together the meeting. And I also wanted to thank the operator for handling all the calls so effectively.

So with that we will adjourn. We'll look forward to seeing you in July here at the campus of NIH and wish you all a good day.

Member Collins: Thank you, Norm

Coordinator: This concludes today’s conference call. You may disconnect at this time.

END