NWX-OD DIRS

Moderator: Norm Augustine
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10:30 am CT

Coordinator: I would like to inform the parties that the conference is now being recorded. If you have any objections please disconnect. And you may begin.

Chair Augustine: All right good morning, this is Norm Augustine, I have the privilege of being the chair of the Scientific Management Review Board or the SMRB as it's known. This is the ninth meeting of the full board plus numerous meetings of our subcommittees. And we have a full agenda today so we will move forward.

But, before we do begin, I do want to take the opportunity for the board members to indicate who they are, to introduce themselves perhaps by stating your affiliation. And I think the easiest way to do that is for me to ask Dr. Patterson if she would read the list of members, the roster, and if you would answer with your affiliation.

And I do want to comment, please speak very clearly into the phone because we have a lot of people on this line and then press mute when you're not speaking. That's very important. And I do want to note that this is a public meeting so we have the members of the public here as well. Amy would you please read the roster?

Dr. Patterson: Certainly. Bill Brody?

Member Brody: Yes, the Salk Institute for Biological Sciences in California.

Dr. Patterson: Thanks Bill. Gail Cassell?

Member Cassell: Gail Cassell, recently retired from the Eli Lilly & Company and presently visiting professor at Harvard University School of Medicine.

Dr. Patterson: Dan Goldin? And Norm, I think Dan let us know that he was not able to participate in this meeting.

Chair Augustine: Okay.

Dr. Patterson: Tom Kelly? Tom Kelly?

Member Kelly: Sorry, I pressed my mute button by accident as instructed. Tom Kelly, Sloan-Kettering Cancer Institute, New York City.

Chair Augustine: Thanks Tom.

Dr. Patterson: Okay thank you Tom. Deborah Powell? Norm I - Deborah also let us know that she is not available for this meeting.

Chair Augustine: Thank you.

Dr. Patterson: Okay, Bill Roper? Bill Roper? Okay, Arthur Rubenstein?

Member Rubenstein: Yes, Arthur Rubenstein, University of Pennsylvania.

Dr. Patterson: Thank you Arthur. Sol Snyder?

Member Snyder: Sol Snyder, Johns Hopkins Medical School, Baltimore, Maryland.

Dr. Patterson: Thank you Sol. Huda Zoghbi? I believe Norm that Dr. Zoghbi also indicated she is not available for this meeting so if she shows up that will be good news, but we're not anticipating her. Josie Briggs?

Member Briggs: Here, NCCAM, NIH.

Dr. Patterson: Thank you. Tony Fauci? Eric Green? Norm I think both of them are unable to participate today. Richard Hodes?

Member Hodes: Here, National Institute on Aging.

Dr. Patterson: Thank you. Stephen Katz?

Member Katz: Here, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Dr. Patterson: Thank you Steve. Griff Rodgers?

Member Rodgers: Here, National Institute of Diabetes, Digestive, and Kidney Diseases.

Dr. Patterson: Thank you Griff. Susan Shurin? And Norm, Susan also is not available for today's call. Harold Varmus?

Member Varmus: The NCI.

Dr. Patterson: Thank you. And Francis Collins. Francis Collins.

Director Collins: Yes I'm here, sorry.

Dr. Patterson: Oh okay, good, thank you. Okay Norm that's the roster.

Chair Augustine: Okay thank you Amy and I do want to take note of the fact that Dr. Gene Washington has left the board so that he can focus his attention on his new responsibilities as Vice Chancellor for the UCLA Health Sciences as well as Dean of the UCLA School of Medicine. We're sorry to see Gene go. He has been a great contributor but we certainly all wish him well in his new responsibilities.

And we're also losing Dr. Jeremy Berg, Director of the National Institute of General Medical Sciences. He has accepted a position as Associate Vice Chancellor for Health Policy and Planning at the University of Pittsburgh. And he too has been a major contributor to our work and will certainly be missed but we're always happy to see our members move on to new and important things. We do Jeremy wish you the very best at Pitt.

And I would - since I'm on a cell phone as I suspect many others are, that has the dangers and the exigencies of modern science, and so should I disappear, which I don't plan to do, but since Dr. Tabak has most of the agenda anyway, Larry could I ask you if I do disappear to fill in until I reappear?

Dr. Tabak: I'd be happy to try and fill your shoes Norm.

Chair Augustine: Okay thank you, that shouldn't be hard. The purpose of the meeting today is to get an update from two of the groups at NIH that have been tasked with addressing the recommendations of our board on translational medicine and therapeutics or TMAT as it has come to be known. And as you probably all recall -- I know the members will and perhaps the public -- in December at our meeting the board issued some recommendations to the NIH Director, the more significant of which were the following three.

One was a new translational medicine and therapeutics center be created as was recommended in the TMAT working group report. And secondly, that the board endorse and support the NIH's commitment to undertake a more extensive and detailed analysis through a very transparent process to evaluate the impact of the new center on other relevant programs at NIH, including those at NCRR. And thirdly, that the NIH report their findings to the SMRB at its next meeting that will be scheduled to take place in about three months.

And the TMAT report was of course transmitted to the NIH Director and to the HHS Secretary right after our meeting in December, and for those of the public who have not had a chance to read it and wish to do so, you can find it on the SMRB's website.

The SMRB will be hearing about the subsequent steps from the agency officials during today's teleconference. These are steps to follow through on the recommendations of the board. And as we always do, we ask Dr. Collins to make any remarks he might wish to make before we begin the formal agenda so Francis, is there anything you would like to say?

Director Collins: Yes, thank you Norm and thanks to all the members of the board who have made time for this call which is going to have a lot of content and I think will be of great interest. And I'm glad also we have many public members who have called in to hear the discussion and also public comments that have been put forward that you'll hear from in a while.

I do want to say the SMRB has been a wonderful addition to NIH's ability to look at important issues as far as our scientific organizational structures and I really appreciate the time and effort this group has invested to produce no less than four thoughtful and comprehensive reports in 2010, which is a pretty

amazing record. The NIH has accepted all of those recommendations issued in those reports.

I just want to begin though, by updating the board on what NIH has been doing regarding the SMRB recommendations about advancing translational sciences and therapeutics development, which is the main topic today. After the last SMRB meeting on September 7, I transmitted your report and your recommendations to the Secretary and to the Congress.

In addition, I submitted a proposal to create this new center to be named the National Center for Advancing Translational Sciences or NCATS to Health and Human Services Secretary Kathleen Sebelius who is enthusiastic about the plans.

If all goes well, we expect to stand up this new center on October 1 of this year, just over 200 days from now, and this reflects the sense of urgency of getting this center up and running so that it can accelerate the important translational work that is ongoing at NIH, but it is intended then to catalyze a new approach to understanding the process and improving the potential for success.

Let me begin though by stating that NIH has been engaged in clinical and translational science for decades including development of diagnostics, therapeutics, and prevention strategies. Benefits to the health of a nation have been profound from our role in translation. Look at for instance the drop in coronary artery disease death as an example.

And NIH supported basic science has led to discovery of molecular pathways that could ultimately be targeted by drugs. Perhaps a famous example being

Brown & Goldstein identifying the LDL receptor, or Julius Axelrod identifying neurotransmitters that led to the development of SSRIs.

But perhaps less well known is that NIH has also been centrally involved in actual drug development, for instance, taxol or AZT. And I don't know if all of you saw, but it's very timely to point to a paper published in the New England Journal of Medicine just two weeks ago documenting that about 20% of drugs that receive priority review by the FDA from 1990 to 2007 were discovered by public sector research institutions. So this is a major contribution and these were public sector research institutions funded by NIH.

To that end, NIH intends to continue to support these kinds of vigorous efforts in translational science in each one of the 27 institutes and centers. The creation of NCATS is intended to serve as a catalyst for the discipline of translational science to advance. To ensure this new center can serve in this capacity, I have asked two different groups to help advise me on the creation of NCATS.

The first group, which you'll hear from shortly, from Tom Insel, is composed of senior leadership across the agency and is charged with issuing recommendations on the missions and functions of this new center. They were asked to deliver recommendations by March 1 and Tom will tell you about the findings.

The second group is actually a working group of the Advisory Committee to the Director. This is a working group chaired by Maria Freire, a member of that advisory committee, and is made up of external advisors. We have asked them to provide high-level findings on how this new center can best partner with the private sector.

So this group has a more extended timeline, just held its first all-day meeting on February 4, which was extremely interesting and I think further encouraged the idea that NIH has an important new role to play here and a new kind of partnership with the private sector. I anticipate this group will update you further in the future.

I should also mention the agency has formed a third group in accordance with the TMAT report's recommendation that we undertake a more extensive and detailed analysis using a transparent process to evaluate the impact of NCATS on other relevant extant programs at NIH including NCRR. This group is co-chaired by NIH Principal Deputy Director Larry Tabak and he will be talking more about this process in a few minutes.

So, it has been a very busy time since December 7 when the SMRB last met. This has involved virtually all of the institute directors at NIH in various conversations, but most importantly much outreach to stakeholders in the community about the standing up of NCATS and all the other associated changes that we expect to make at NIH to facilitate this.

Perhaps one might call this a disruptive innovation, but it is an innovation that we believe is timely indeed and I very much look forward to hearing SMRB's thoughts about this in the course of this two-hour conference call. So, I'll stop there and again look forward to hearing the discussion.

Chair Augustine: Francis, thanks very much and in particular thanks for your careful consideration of the board's recommendations. As you know, the members have devoted a good deal of effort and thought to them and it's nice to know that our thoughts are being considered and we appreciate that.

The first person on the agenda will be Dr. Larry Tabak who will give an update. He of course is the Principal Deputy Director of NIH and, as you've heard, is co-chair of the NCRR task force.

And after that we're going to hear from Dr. Tom Insel, who is the Director of the National Institute on Mental Health, and he co-chairs a committee that has an unpronounceable acronym, but he of course as you've just heard chairs one of the working groups dealing with the implementation of the National Center for the Advancement of Translational Sciences or the NCAT.

We're also going to hear today from individuals from the public who have signed up to make comments. And if there's time, we'll be able to accept additional comments from those who have not had an opportunity to sign up. We've had a number of just extremely thoughtful inputs from organizations as well as individuals and we appreciate them greatly, we take them seriously.

And I should note that all of this is not a formal stakeholder consultation that we're holding today. We do appreciate the public input that we look forward to receiving.

And in that regard to be fair to all the members who wish to make comments so that you can be doing last minute planning here, we are going to ask that you hold your remarks to five minutes per person and that if you wish to submit a longer statement in writing we certainly welcome such comments. When we receive them, those letters are always posted on the board's website.

Finally, we come to the last administrative item here and that is the minutes for the meeting on September 14 and 15. They have been completed, they are I think quite thorough. We've had a number of comments by members, we particularly thank Richard Hodes, Josie Briggs, Deborah Powell, and Gail

Cassell for reviewing them so thoroughly. Would any of the members care to make a motion to approve those minutes?

Member Rubenstein: So moved.

Member Shurin: Second.

Chair Augustine: Thank you. It's been moved and seconded, would all those in favor please say aye?

Members: Aye.

Chair Augustine: Those opposed, same sign? And the ayes have it, the minutes are approved. Well I guess there's one other important item, I started to say administrative item, it's a very important item and that is that we are required by law to review the NIH's conflict of interest rules before each meeting. We have all heard this, I think are very familiar with them, but we do want to follow the procedures here.

So I have asked Dr. Patterson, the Associate Director for Science Policy as well as the Executive Secretary of the SMRB if she would review the salient parts of those conflict of interest rules. So Amy could you do that?

Dr. Patterson: Certainly, thank you Norm and welcome everyone to the call. As members of this committee, we'd like to remind you that you are a special government employee and therefore subject to the rules of conduct that apply to government employees. These rules and regulations are explained in a report titled 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 and you were briefed on how to adhere to the principles outlined in that report.

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

As each of you know, before every meeting you provide us with lots of information -- information about your personal, professional, and financial interests. And 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 committee meetings.

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

But we also rely to a great degree on you to be attentive during the course of the meeting to the possibility that an issue would arise that could affect or at least appear to affect your interest in a specific way and if that happens we ask you to recuse yourself from the discussion. If you have any questions about the rules of conduct, of conflict of interest, we'd be happy to address them. Thanks Norm.

Chair Augustine: Does anybody have any questions you'd like to ask of Amy at this point? Hearing none we will proceed. You will recall our TMAT report recommended that the Clinical and Translational Science Award program also known as CTSAs be relocated from NCRR to the new Center on Translational Medicine. And that was done because of - in part because of the extreme importance that we assigned to the Translational Medicine Center and also because of the obvious association of CTSAs with that.

And having made that recommendation, we encouraged NIH to conduct a more detailed analysis of the specific issues that would result from these changes and that brings us to the first presentation which is from Dr. Tabak who as I said is a Principal Deputy Director of NIH and the co-chair of the NCRR task force. So Larry let me turn the floor to you and once you are finished we'll have an opportunity for questions.

Dr. Tabak: Thank you Norm and good morning to all of you on the phone. So the process that the task force used included first meeting with subject matter experts that had been selected by NCRR leadership to gain a better understanding of each NCRR program.

We then engaged in extensive consultation with multiple stakeholders through seven stakeholder teleconferences which had over 550 phone lines registered in aggregate, although there were obviously multiple persons on many of those phone lines.

We have met individually, in person, or by phone with multiple representatives of professional organizations, the leadership of a number of key programs from the NCRR including the National Primate Research Centers, leadership of comparative medicine programs, RCMI directors, the

leadership of the IDeA programs, and leaders of the SEPA programs among others.

All through this, we received continuous feedback from NCRR leadership, NCRR staff, the council of the NCRR, and other NIH staff including leadership of potentially affected other institutes and centers at the NIH. And so now, I will just summarize for you the final interim recommendations that the task force has made.

And so we concluded first that many NCRR programs would benefit from the scientific synergies that would result from their transfer into other entities at NIH. First, we concurred with the original recommendation of the Scientific Management and Review Board proposing the transfer of the Clinical Translation Science Awards, the CTSA program, into the proposed new center NCATS.

Second, the task force recommends placement of the Research Centers and Minority Institutions, the RCMI program, into the National Institute of Minority Health and Health Disparities, NIMHD.

Third, the task force recommended placement of the Science Education Partnership Awards program into the Office of the Director of NIH where it would be combined with the Office of Science Education, which is currently located within the Office of Science Policy in the Office of the Director for NIH.

Fourth, the task force recommended placement of the Institutional Development Award, the IDeA program, into the National Institute of General Medical Sciences, NIGMS.

Fifth, the task force recommended that Biomedical Technology Research Centers be transferred either to NIGMS or the National Institute of Biomedical Imaging and Bioengineering, NIBIB. Specifically those grants that are related to biomedical imaging and point of care diagnostic would be transferred to NIBIB with all other Biomedical Technology Research Centers being assigned to NIGMS.

Similarly, the task force proposed assignment of the majority of the research grants for technology research and development and the SBIR, STTR, and BIRN network grants to NIGMS with a subset of these related to biomedical imaging and point of care diagnostics to NIBIB.

Sixth, the task force recommends placement of the following programs in a permanent new infrastructure entity to be located within DPCPSI within the Office of the Director. These are clearly infrastructure in nature. First, the Extramural Construction program, next the Research and Animal Facilities Improvement program, third the Shared and High-End Instrumentation program, and then finally the Comparative Medicine program.

In this instance, there was a great deal of feedback focused on the value of keeping this particular program intact despite the rather large breadth of spanning both infrastructure, capacity building, and certain programmatic work. And so, it is proposed to keep this intact and in this permanent new infrastructure unit.

So with that Norm that would conclude the formal remarks and I will turn it back to you if there are specific questions.

Chair Augustine: Okay.

Dr. Patterson: Norm, excuse me for interrupting. I just wanted to acknowledge that another SMRB member Dr. Susan Shurin has joined the call. Susan are you there?

Member Shurin: Yes thank you very much.

Dr. Patterson: Okay and I just - if I could take the opportunity to ask if there are any additional SMRB members who joined the call that were not previously acknowledged, could you announce your name please. Okay thank you Norm.

Member Kelly: This is Tom Kelly.

Chair Augustine: Oh good.

Member Kelly: I've got a couple of points I'd like to ask you about and some of them raised for maybe general discussion and one relates to the fact that as I'm sure you are aware there is a fair bit of angst out there in the scientific community about the redistribution of all of the NCRR programs. And I gather this essentially amounts to the elimination of NCRR, which is of course a major structural change at the NIH.

And I guess I would raise for a potential point of discussion since this is such a major structural change for NIH, eliminating a center is a big a change as adding a new one, and I don't think the SMRB has had a really lengthy and deep discussion. I assume the working group really talked about this at some length. But, we certainly didn't give this the same sort of depth of analysis that we did for the NIDA and NIAAA question.

So, the question is whether it would be appropriate for the SMRB to undertake a real in-depth study of whether NCRR should be essentially eliminated. That's - so that's one sort of general question.

The other is the question of whether it was given the fact that the only thing that's required to be pulled out of NCRR for the new center are the CTSAs I gather. It seems that one possible simple and less disruptive approach would have been to leave all the other programs in place within NCRR rather than distributing them. And I was wondering whether that course of action had been contemplated.

Dr. Tabak: So Tom thank you for the question. So with regard to the latter part of your question, indeed that was the first thing that the task force considered. In other words, once we agreed to concur with the SMRB recommendation to propose moving the CTSA program from the NCRR into the proposed new center NCATS, we were left with the question would the remaining 60% budget wise of the NCRR be a unit that if given the opportunity to think this through, would that be the unit that we would recapitulate.

And it was the opinion of the task force that in fact the character and breadth of programs which some have likened to a coat of many colors was such that we would probably not recapitulate that in the same way. So for example, would you have support for the resources required for the Chimp Haven in juxtaposition scientifically to Biomedical Technology Research Centers trying to improve synchrotrons for structural biology.

And we concluded that we probably wouldn't recraft things that way and instead would take advantage of the possibility of creating new scientific opportunities by placing the various remaining 60% of the NCRR portfolio in a more optimal juxtaposition to programs that are, you know, within the various institutes and centers around NIH. So, for example, the Biotechnology Research Centers related to structural biology and NIGMS where so much structural biology of course is supported.

With regard to the former question, we basically took our lead from the SMRB, which asked us to consider what the potential impact of the formation of NCATS would be both specifically on the NCRR but other organizations as well and indeed went through a very deliberative process.

There were six formal meetings; many, many, many email debates and discussions; and extensive consultation with stakeholders framed by the so-called straw model that was issued in mid-January and that was just a planning document.

And as people who have been following this will note, changes were made from the original straw model to the current final interim recommendations based on the feedback that we received.

And so I would say that the group did do a very in-depth analysis of the various programs and believe that we have come up with recipient homes for these programs that will maximize the opportunity for new scientific programs to emerge, new scientific opportunities to emerge.

Finally, I would add that at no time was there ever an intention to eliminate any of the extant NCRR programs. At all times, and one of our guiding principles was that the programs were to be maintained but simply we were considering whether a potential move of the program could enhance the scientific opportunity based on adjacency. And so that is the tack that the task force proceeded with.

Chair Augustine: Larry thank you and Tom thank you as well. I might just add to the - Larry's comments who spoke to the working group's efforts that SMRB as a whole of

course met on this topic on five different occasions over a period of several months.

And our timing was of course driven by the fact that we thought the translational medicine issue was so important that while we wanted to consider it thoroughly we didn't want to miss another budget cycle, in fact, that be avoided, so we would have to wait another year before anything could be done in that regard.

We've had a number of comments on this very question you raised Tom, others have raised both with regard to process and with regard to the substance of handling the NCRR components and I think Larry you provided a sound answer to our considerations. Is there anybody else who would like to make a comment on this topic at this point before we go ahead?

Member Cassell: I'd like to ask a question Norm, this is Gail Cassell. And Larry, could you comment on the Division of Comparative Medicine in particular? This is the one area of concern that I personally have, just to be certain that it remains intact and optimal since it did go through - undergo a rather substantial change back in the 70s and 80 and I watched the impact of that.

I'm just real concerned that we made a very strong entity, as were a number of the people that commented from the public. So could you just comment on some of the discussions that you may have had in particular about the comparative medicine function?

Dr. Tabak: Thank you Gail and indeed as you report, we received many, many comments about this. Some members of the SMRB might know that we originally suggested dividing this Comparative Medicine Program.

But overwhelming feedback that we received from the leadership of this program and stakeholders around the country provided us with compelling reasons to keep this program intact which is the current plan, to put it into a permanent infrastructure unit to be located in DPCPSI.

And it was indeed because of that very compelling feedback that we received from stakeholders around the country that we changed from the original planning of dividing this program to keeping it intact for the reasons that you have articulated.

Chair Augustine: I should also note that among the many thoughtful inputs we had, one came from one of our former SMRB members, Dr. Jeremy Berg and that letter has been given consideration and will continue to be of course. Are there any other comments anyone wants to make at this point? Hearing none, I think we should move ahead, because I do want time for the public to make inputs.

And let's continue with the presentation from Dr. Insel and as you all know he is the director of the National Institute of Mental Health and co-chair of the working group that Dr. Collins described. And that group has been deliberating on the proper missions and the functions of the proposed new center on translation. So Tom if you would, this would be a good time for your presentation.

Dr. Insel: Very good. Norm, I want to make sure you can hear me.

Chair Augustine: I can hear fine. Is anybody not able to hear? It sounds like you're in good shape.

Dr. Insel: Okay, so as you said, we were convened by Francis back in the beginning of January on the 4th to take a look at this new entity. We were called the ICD-

NCATS working group and to provide some advice and recommendations regarding the mission, the functions, and the organization of what this would look like.

We - our group actually overlaps a little bit with the SMRB so the members were myself and Eric Green as co-chairs and then Josie Briggs, Tony Fauci, Alan Guttmacher, Story Landis, Griff Rodgers, and Harold Varmus were the members.

We also had a group of non-voting advisors who were senior staff from the Office of the Director who were also very helpful and provided a lot of insights about ways we should think about this particularly in terms of the organization of this new entity.

Altogether unbelievably there were actually seven meetings in the time since January 4 when we first met and the discussions largely focused on this question of what is this going to look like, what's it going to be.

Throughout most of the discussions, we kept in mind that the NIH institutes and centers have a longstanding history of conducting and supporting translational research just as Francis said in his opening comment and he pointed to some of the notable successes we've had.

So much of what we talked about and where we ended up was the sense that this new effort really needed to aim at advancing the discipline of translational science. And what it should really be about is enabling and enhancing the efforts from the various institutes and centers.

Most of the meetings were devoted to briefings about current programs. Some were about those that had been recommended for inclusion in the original

TMAT report that you referred back to that's from December. And we also had a chance to hear about some other potential elements that could be put in here from existing projects within the institutes and centers.

I should also note that as Francis mentioned, on the 4th of February, we had a joint meeting with this ACD, this Advisory Committee to the Director group which Francis had set up to get a different kind of input about NCATS. And that group actually was very, very helpful. You know, they're coming at this from the perspective of industry, academia, venture capital firms, and non-profits. And so we were very interested in their perception about both the benefits and the risks of doing this.

Overall, I'd say that they were very positive about the proposal. They did encourage us to think about this entity as a catalyst for translation. The term that they used is this was an opportunity to take NIH science of interest and make it science that was compelling for development of therapeutics.

They also said that this was an opportunity to actually study the process of treatment development, something that pharma actually doesn't do very well according to them and they stressed to us the need for a new generation of clinical pharmacologists, that we needed to think about the need for training and maybe this would be a place where we could do that.

So the group ended up in a very interesting place. We - after much discussion and hearing about lots of different potential programs that could go into this NCATS we pretty much ended up where the TMAT group ended up in December which was feeling that we needed to put the focus on the Molecular Libraries Program, the NIH RAID program, the Therapeutics for Rare and Neglected Diseases, and the CTSAs and then think about how to link those together would by itself be an important and considerable challenge.

There was a sense from the group that translation needed to focus on diagnostics and devices and biologics and vaccines but we felt that maybe this wasn't the time to do that at this point, that we needed to start small and to keep the focus on those elements most of which are coming from the Common Fund that we wanted to provide longer term support for and find a way to optimize them and get them to integrate very well with what's going on in the institute.

And we also saw that this NCATS could be a home for this developing FDA-NIH partnership and a chance to do something more in kind of the regulatory science arena. As the TMAT report had suggested originally, this could also be the home for the Cures Acceleration Network, for CAN, when that is ultimately appropriated.

So, that's about where we ended up. I'll just finish here by saying that the final mission for the - for NCATS which is something that we talked a lot about was to advance the discipline of translational science and catalyze the development of novel diagnostics across a wide range of human disease conditions.

So I'll say that again just so it's clear, to advance the discipline of translational science and catalyze the development of novel diagnostics and therapeutics across a wide range of human disease conditions recognizing actually at the beginning this would not be diagnostics as much as therapeutics.

And our (unintelligible) was that it was very much a kind of open access environment for experimenting with innovative approaches to developing therapeutics; to think about reengineering the pipeline in various ways;

collaborating with NIH institute and centers throughout and building really a kind of network to make sure that happens; and to promote and facilitate interactions with the FDA and other regulatory agencies to advance the field of regulatory science.

So that's a very quick rundown of what this committee ultimately decided to recommend back to Francis. We had a final meeting with him last Thursday and suggested that the elements be almost precisely what was originally recommended by the TMAT group back in December. And that at this point, we would focus on those pieces and get those integrated in a way that was likely to have the greatest impact on translation.

Chair Augustine: Tom thanks very much for that summary. It's obvious that those of you at NIH have been working very hard on our recommendations among the other things you have responsibilities for.

This is probably a good time to ask any of the members that would like to comment on any of the issues Tom has raised, any other issues you might have, or for that matter anything else you'd like to say with regard to Larry's presentation. So let me open the floor to members of the SMRB.

Member Snyder: This is Sol Snyder. One of the challenges for the new entity will be trying to figure out how to interface with the pharmaceutical industry and get over that big, big gap. I wasn't sure whether pharmaceutical industry people were involved in Maria Freire's advisory group or what other kinds of things we can start doing in this connection. I know that Foundation for the NIH has helped by bringing together industry and the NIH with the biomarkers effort.

Chair Augustine: Important point. Tom do you want to address that?

Dr. Insel: Sure, so that was part of the idea Sol for having this ACD group. And Maria brought together really an extraordinary cast of characters here from different sectors. So in terms of from pharma directly it was Moncef Saloui from GSK who is the chairman of R&D there; Marc Tessier-Lavigne who for another couple of days is still at Genentech.

From the - from Medicines 360 the CEO there is Victoria Hale, so that's not pharma itself but an advocacy group; Infinity Pharmaceuticals, Julian Adams is the president of R&D which is a big biotech effort. Let's see who else. We had Bill Chin who is no longer at Lilly but was able to give us a pretty good sense of what the world looks like from inside pharma.

And then of course a number of senior people from academia as well. There may be people like Stelios Papadopoulus from Exelisis who certainly could give us the biotech perspective. Bob Langer was on from MIT and Susan Desmond-Hellmann from UCSF, David Valle from Hopkins. So there were some academics there as well.

Chair Augustine: Are there other questions? Hearing no other questions at this point we should turn I think to the public comments and questions. And the SMRB was formed as many will recall in part on a recommendation that was made by the National Academies Committee that was studying the NIH and asked that a process be set up for public input to consider or when reorganization of NIH was being considered.

And that input has been an important part of what's been done in our deliberations while today's presentations are informational only and the NIH is in fact undertaking as you heard a very formal public consultation process. We do nevertheless want to afford another opportunity for the SMRB and

those present from the NIH to hear any public comments that one wishes to offer.

There have been a number of individuals who signed up in accordance with the notice in the Federal Register and I will call you to the phone in the order that you had signed up.

And again if you would limit your remarks to five minutes out of courtesy to your colleagues and fellow speakers. And again if you would like to submit a longer statement that would certainly be welcome if it were in writing and your written comments of course will become a part of the record that the board will consider.

So let me begin by calling on the public commentators, I believe there are eight that I'm aware of at this point. And the first of those is Dr. Bobbie Ann Austin who represents the Association for Research in Vision and Ophthalmology and Dr. Austin we will activate your phone now so you may speak.

Dr. Austin: Hello, thank you for the opportunity to comment today. NCRR benefited vision researchers in the past by placing critical programs within a single institute that has done an excellent job over the years of unifying diverse research areas.

The impact can be grossly underestimated, since each grant benefits more than one area and investigators who did not actually apply for their institution's funding for NCRR core facilities may not know the full extent of their support. However, in a recent survey 55% of the U.S. members indicated direct or indirect support from such programs.

I worked with five separate working groups composed of NCRR stakeholders who prepared recommendations for the NCRR task force. Overall we recommend that the SMRB carefully analyze the proposed changes and consequences to prevent introduction of conflicts of interest during grant reviews that can result from moving programs from a center with a diverse mission to ones with more defined missions.

In the interest of time I will mention the top two member concerns. First, NCRR core instruments and facilities are used by our members as much as 18 hours a day, 7 days a week by a large user base. If proposed changes reduced resources outside technologies for developing drugs and biologics it will be difficult for scientists to follow up on existing studies and collect preliminary data for grant applications.

Therefore, we recommend that existing programs be moved to the Office of the Director and that respective funds, resources, and staff be transferred with the programs.

Second, moving NCRR IDeA programs to an institute or center with a defined constituency will result in loss of funding. IDeA sites do not necessarily have backup core facilities. Often the closest major research center is many hours of driving distance away. Such programs effectively build infrastructure and are an important pipeline for junior investigators.

For example, promising junior investigators from Oklahoma as an example achieved remarkable funding success rates of 83% compared to national average success rate of 10%.

Prevent a backslide of more than a decade of progress, we recommend that IDeA programs be funded at the current level in a permanent NIH division

where they can be maintained for the purposes intended to expand the geographic distribution of NIH funding for biomedical research.

A full version of our recommendations is posted at www.arvo.org/advocacy. Also our animals in research committee prepared a statement about NCRR animal programs which is posted at www.arvo.org/animals. Thank you for the opportunity to comment and thank you for all the hard work that the NCRR task force has been doing.

Chair Augustine: Dr. Austin, thank you very much. And the next speaker will be Dr. Stuart Zola with the National Primate Research Centers. Dr. Zola?

Dr. Zola: Yes, thank you very much. I have just a short comment and that is that the National Primate Centers really believe that the placement in the Office of the Director maintains the Primate Center's commitment to both fundamental and translational sciences.

We really have quite a broad breadth of research and we have a good sense that within the Office of the Director we'll be able to take much more advantage of that broad breadth than if we were in an individual categorical center. So the research that we support and that is supported by us really spreads across many categorical institutes and accordingly we think this really is the right placement for us.

Additionally, we think this will allow us to more fully contribute to other NIH priorities like training and outreach. We really do a great deal on that in those areas, as well as in therapeutics. And so, in a sense, the time is really right and really ripe for us to be able to step out in those domains as well.

As I am hearing from Dr. Tabak, the framework of the straw plan has changed a bit now to include as, I'm looking on my chart here, it says other disease model resources. Presumably that means we're talking about comparative medicine altogether.

So, this could provide some additional possibilities for scientific adjacencies and even for infrastructure adjacencies. So the Primate Centers really are aimed at doing the best that we can for whatever is the best for science and we're glad to be part of this kind of new dynamic. Thanks very much for that opportunity.

Chair Augustine: Thank you Dr. Zola. And I call on Dr. Judith Van Houten of the IDeA Networks for Biological Research Excellence. She is the principal investigator of the University of Vermont and president of the IDeA Principle Investigator Association and I believe we actually have a letter from you as well. The phone is yours Dr. Houten - Van Houten.

Dr. Van Houten: Thank you very much and thank you for taking my call. Dr. Tabak, I would like to follow up on a recent conversation that you and Dr. Guttmacher and I had regarding the IDeA program. We talked about finding mechanisms by which the RCMI and IDeA programs could retain their synergies even though we are now in the new model going to be put into different institutes.

And the other topic that we talked about was the membership of various NIH committees and councils where there are relatively few if any members from IDeA states. And I wondered if you had some more thoughts or could follow up on those discussions.

Dr. Tabak: Norm, did you want to have a back-and-forth here or did you want to continue with the various comments from the stakeholders?

Chair Augustine: We should probably continue, but if you have a very short answer that would certainly be all right.

Dr. Tabak: So with regard to the first question, yes we will explore mechanisms to ensure continued collaboration between RCMI and IDeA programs. And certainly with regard to appropriate membership on councils, this is something that we do strive to do, but we'll keep in mind, you know, the comments that you made to Alan and to me during our conversation and have reiterated now.

Dr. Van Houten: Thank you and I would just like to add that the IDeA Association is very pleased that we are now assigned to a standing institute and we would like to work with Dr. Berg on the transition of IDeA moving into that institute so we thank you very much for hearing our concerns.

Chair Augustine: Well thank you Dr. Van Houten. And the next speaker is Dr. Richard Bucciarelli, representing the American Pediatric Society, Society for Pediatric Research, Association of Medical School Pediatric Department Chairs, and the American Academy of Pediatrics and the Academic Pediatric Association. And Dr. Bucciarelli, if I have mispronounced your name I hope you will correct it and accept my apologies.

Coordinator: Sir, I apologize, this is the operator. I do not see a line with his name, unless someone else called under a different name for him. His line is not on.

Chair Augustine: Okay, then we will proceed ahead and the next speaker who signed up in sequence was Ms. Amy Comstock Rick of the Parkinson's Action Network. Ms. Comstock Rick, the phone is yours.

Ms. Comstock Rick: Hello, thank you. Thank you to the SMRB for allowing me this time and for once again addressing the very important topic of the creation of NCATS. PAN is a very strong supporter of the creation of NCATS and has expressed these views in writing to the House and the Senate.

There are so many challenges that are faced in bringing promising discoveries through the proverbial Valley of Death that it's logical as the SMRB report put it to "create one home for knowledge regarding applicable resources, technology, program experts and partners at each phase of product development." This is especially true given the need for NCATS to include partnering with the private sector.

I have to tell you though we are concerned at the reaction that this new center is receiving from some sectors. The requests to slow down, to continue to analyze, and just wait are being made with all sincerity, but they do not represent the views of all the stakeholders.

I find it very telling that in all the objections to NCATS and the resulting closure of NCRR including in the recent letter from 14 senators that no one actually disputes the existence of the Valley of Death and the problem that it is causing for therapy development in this country.

It is undisputed that private sector money is disappearing and, in some cases, is just gone for at least some classes of therapy development. For these diseases and for these patients, nothing is moving through the pipeline.

Yet while arguments are being made to challenge the SMRB's recommendation to create NCATS to begin addressing the problem of the Valley of Death, no one is addressing the impact that inaction is having on the very desperate need to promote clinical and translational science.

For all the time that is being spent challenging the thoughtful recommendation that was put forth by a diverse board, the very real problem of research hurdles and a dried up therapy pipeline is going unaddressed. This is not acceptable to us.

I would suggest that while I realize the significance of this proposal that adequate analysis has already gone into it. It is designed to address some very real problems in this country and it's time to hurry up and do so.

From this stakeholder's perspective, I would also like to suggest what I see as another unfortunate consequence of these discussions about NCATS and NCRR. These are very trying financial times, that's not news to anyone, and we were all heartened to see in the president's 2012 budget that he put forth a more significant increase for NIH.

But, in order to achieve even that increase, there will have to be an all out united effort by all impacted parties to make the NIH budget and biomedical research a funding priority, but these arguments are keeping us from presenting that united front.

As so many of us know, the fastest way to have won funding priorities and requests rejected by the Hill is to show disunity. It seems pretty clear to me that rather than appearing to the world to be arguing about organizational matters, that we should all be united in arguing together about the very real needs for biomedical research -- basic, translational, and clinical.

I fear that if we don't do this, we will be missing an opportunity to make a strong case for more funding for everyone in order to solve some very real health problems. Thank you.

Chair Augustine: Thank you very much for those comments. The next speaker is Mr. James O'Leary with the Genetic Alliance. Mr. O'Leary?

Coordinator: One moment sir.

Chair Augustine: Thank you.

Coordinator: You may go ahead and speak sir.

Mr. O'Leary: Thank you. Thank you very much. Genetic Alliance supports the newly proposed National Center for Advancing Translational Sciences, NCATS, the National Institute of Health. We are a network of health organizations numbering more than 10,000 and we're committed to improving human health outcomes including accelerating the development of new therapeutic options for patients and consumers.

The Genetic Alliance Network includes more than 1200 disease specific advocacy organizations, representing the millions of Americans affected by disease. For them there is an urgent need to bring the promise of translation to fruition. Last year despite more than $100 billion in research spending, only 20 drugs came to market. This is much too slow and needs to be vastly improved.

Further, fewer than 200 of the 7000 rare diseases have any available therapy options. The current system of therapeutic development has been failing patients and consumers for far too long and the time to transform translational medicine is upon us.

Genetic Alliance believes that the National Institute of Health has both the potential and the responsibility to leverage its existing and emerging programs and resources to accelerate translational medicine. The passage of the Cures Acceleration Network highlights that both the American public and Congress share this expectation that NIH will play a leading role in improving human health outcomes through translational research.

Genetic Alliance supports the newly proposed NCATS because it offers an unparalleled opportunity to advance translational medicine and improve human health.

Currently there are a number of programs spread across NIH that are tailored to the goal of translating basic research into therapeutics including Molecular Libraries Program, Therapeutics for Rare or Neglected Diseases program, NIH Rapid Access to Interventional Development program, and the Clinical and Translational Science Awards and the NIH-FDA Regulatory Science initiative.

The opportunity to reorganize these programs into a single cohesive center promises to be a powerful catalyst for advancing translational research, one that we urge you to support.

In addition, even as NIH takes this critical focused approach to drive drug development, it is important that we remember the broad needs of translation including the meaningful involvement of individual families and communities in the process and the effective engagement of the public.

The excellent work done as part of the Clinical and Translational Science Awards in the arena of community engagement should not be lost and the

trans-NIH movement to increase a broad focus on translation should continue and be encouraged as part of the new center and beyond.

Genetic Alliance works with all the federal agencies charged with promoting the nation's health. We determined long ago that there are enormous silos preventing the coordination essential to developing timely and robust diagnostics and therapies. We identified steps to accelerate translational research and the NCATS is essential to this mission.

We thank you for your continued interest and support for translational medicine. The men, women, and children who live day in and day out with these diseases are depending on your leadership. It is incumbent upon us to make a difference and as a nation we have the tools to do so.

It is time for the NIH to claim responsibility for accelerating translation. Let's work together to realize that promise that lies before us and in the multitude of sciences that are ready to come to fruition in the form of solutions for those who suffer. Thank you.

Chair Augustine: Thank you Mr. O'Leary for your comments. And the next speaker is Dr. R. Balfour Sartor who is a distinguished professor of medicine, microbiology, and immunology director, UNC Mobile Disciplinary Center for IBD Research and Treatment, co-director of the Center for Gastrointestinal Biology and Disease. We will call on you now Dr. Sartor please.

Dr. Sartor: Yes thank you. That introduction was probably longer than my comments. But basically it's - my comments are redundant with those of Gail Cassell's and the comment on the Primate Center Director in which I completely endorse keeping the comparative medicine division intact.

I am - among the other things I do, I direct the National Gnotobiotic Rodent Resource Center which is an NCRR funded animal resource that is administered by the Division of Comparative Medicine.

And there are approximately 50 centers, probably the most recognizable are the Primate Centers and the Mutant Mouse Regional Resource Centers. But they also include individualized, specialized, highly specialized animal resources that are absolutely critical for a number of R01 funded investigators.

I've been incredibly impressed with the leadership of the Division for Comparative Medicine that brings both veterinary and bench science expertise so that the - this division can communicate with both the producers of the animals as well as the users. And they've done an excellent job in expanding and optimizing these resources in a very cost effective manner that individual investigators could not possibly do.

So keeping this group intact, I think is a very wise decision and I completely endorse it. And I am glad this is a redundant comment of agreement on a job well done, so thank you so much.

Chair Augustine: Well thank you for your comments as well and the next speaker is Dr. Adam Clark who represents FasterCures. Dr. Clark?

Dr. Clark: ...for the opportunity to comment and the work that SMRB has done. FasterCures is a non-profit, non-partisan center dedicated to accelerating the progress of discovery and the development of new medical solutions for deadly and debilitating diseases. As part of our mission we work across the disease spectrum with all the sectors in the medical system to improve both the effectiveness and the efficiency of biomedical research.

We want to comment to applaud the board's recommendations to create the National Center for Advancing Translational Sciences, which will expand NIH's investments and efforts to speed the translation of basic discoveries to clinical application. We view this as a significant development for the future of getting basic discoveries translated into much-needed and long-awaited treatments and cures.

NCATS has the potential to cut across the institutional boundaries and address fundamental scientific and biomedical challenges regardless of the disease type. This integration of efforts will produce synergy that will benefit Americans through improved health and more efficient and effective investment of their tax dollars. The transition from basic research to clinical application requires an interdisciplinary and multi-disciplinary expertise.

As we outlined in a FasterCures white paper recently entitled Crossing Over the Valley of Death, many new drugs drop out of the development pipeline for a variety of reasons, including lack of funding for critical translational studies and insufficient investment in the technical expertise needed for technology development and transfer.

These barriers stand in the way of both the scientists dedicated to improving health and the patients who ultimately need improved cures and care. We need to bridge the void between basic discoveries and better medicine.

The steps in between discovery and application like target validation, assay qualification, product refinement, and preclinical development are necessary investments to move promising new interventions to the patient. These areas of focus are often the bottleneck to moving drugs forward and exist across the drug development enterprise regardless of the disease.

FasterCures believes that the NIH is proposed new center will provide a significant stimulus to moving ideas out of the lab and into the clinic and we fully support NIH's willingness to disrupt its own paradigm in search of better solutions. Again, thank you for the opportunity to comment and we look forward to future meetings.

Chair Augustine: Thank you Dr. Clark. And that completes the remarks of those who signed up in advance. We do have a few minutes so that if one or two additional people from the public who did not sign up in advance would like to make any comments at this point following the rules we already set up, that would be most welcome. So let me ask the conference coordinator, has anyone else a wish to do so?

Coordinator: Sir, not at this time, but we do have Dr. Bucciarelli online. Would you like to take a comment from him then?

Chair Augustine: That would be fine.

Coordinator: Great, thank you.

Dr. Bucciarelli: Thank you and good afternoon. I'm sorry I missed my call. It would have been helpful if I took my phone off mute but I learned and I'm moving in the right direction I hope.

Yeay, my name is Rick Bucciarelli, I'm a pediatrician and chair of the Department of Pediatrics at the University of Florida. I appreciate the opportunity to speak to you today on behalf of the pediatric academic community consisting of the Academic Pediatric Association, the American Academy of Pediatrics, the American Pediatric Society, the Association of Medical School Pediatric Department Chairs, and the Society for Pediatric

Research. We are organizations dedicated to improving the health and wellbeing of children by furthering pediatric medical research.

The National Institutes of Health Scientific Management Review Board has the important task of guiding the integration of translational research at the NIH. With the advice of the SMRB, the NIH has proposed a plan to establish a National Center for Advancing Translational Sciences and abolish the National Center for Research Resources.

We applaud the NIH for its dedication to furthering the translation of basic scientific advances into meaningful therapeutics for patients and we urge the board to seriously consider the needs of children and their families as it provides guidance to the NIH on the reorganization.

We believe that investments in the health of our children are among the most valuable uses of public funds because they produce lifelong benefits of increased wellbeing and productivity. Biomedical and behavioral research are the origin of the pediatric medical advances that deserve our support.

Translational research is an essential piece of the process that brings the scientific developments into medical practice. This bench-to-bedside approach is especially important for children who are frequently left without the scope of quality of therapies that are available to adults.

Effective translational research for children however would not be possible without infrastructure that recognizes the unique nature of children and supports pediatric efforts from basic science through Phase 4 translational research.

Eunice Kennedy Shriver National Institute of Child Health and Human Development has been a critical partner in the effort to expand knowledge about the disease that affects children and their development. Along with the NICHD, the Clinical and Translational Science Awards Consortium has helped further the child health by advancing clinical and translational research through investments in infrastructure and training programs.

The CTSA Consortium Child Health Oversight Committee which was created as a result of determined legislative advocacy by the child health committee - community has been particularly valuable in ensuring that the CTSA program works for the benefit of children by supporting pediatric researchers and trainees.

The pediatric community supports NIH's effort to promote translational research and urges the board to affirm its commitment to child and family health by recommending that number one, the NCATS should specifically establish child health research as a key priority.

Number two, the NCATS should support the promotion of the important role of the NICHD and the CTSA Consortium child health oversight committee in advancing child health research.

Three, that NCATS should be cognizant of ongoing child health research conducted at the NICHD and other institutes and should work to facilitate translational research relevant to children across the institutes.

And four, in recognition of the clear need for training the next generation of clinical and translational research professionals with expertise in children, the reorganized translational research infrastructure should maintain its commitment to research, training, and career development programs.

Thank you for allowing me to speak to you today. The pediatric community looks forward to working with you to improve child health by maximizing opportunities to translate advances in pediatric care.

Dr. Tabak: Norm are you with us? Is anybody with us?

Member Shurin: Yes.

Member Rubenstein: Yes.

Dr. Tabak: Okay good. So let's see now if Norm is reconnected. If not I will transiently fill in for him. Operator could you let us know if there were any additional individuals who wish to speak?

Coordinator: And in order to do that please press star 1 at this time. One moment.

Dr. Tabak: Okay. Okay and is the silence meaning that we are not...

Coordinator: And at this - yes sir, at this time I am showing no one prompting up for any questions.

Dr. Tabak: Thank you so much. Now, Norm have you been able to rejoin us?

Chair Augustine: I just came back. Thank you for filling in Larry.

Dr. Tabak: Oh thank you for coming back. So the operator has informed us that there are no additional speakers and so I will turn it back to you Norm.

Chair Augustine: Okay fine, I'm sure you handled it very well and I'm sorry, I got lost somehow in cyberspace. Well first of all, I wanted to thank Dr. Bucciarelli for his comments and to thank each of the speakers for their comments.

And it's clear that people have strong interest, concerns, and some concerns that we may be moving too quickly and some we may be moving too slowly. And I'm sure that the leadership of NIH will carefully consider the comments that they heard and as will the members of SMRB when we have future deliberations on these and other subjects of related nature.

Let me say a little bit about - well before I do that, any of the members of SMRB want to make any comments at this point in time?

Member Rubenstein: Hey Norm, this is Arthur Rubenstein.

Chair Augustine: Yes, Arthur.

Member Rubenstein: Is there any way for us to go through the official representatives of all of the programs represented in NCRR, if the progress that has been made and detailed in the discussion today as well as on the website, if those are - if these plans are now acceptable to them?

I know there is a very diverse constituency, but there are some obvious leaders of many of these programs. So I just wonder how the or if NIH has been able to gauge whether the anxieties that were understandable and obvious have been allayed by the deliberative process since December.

Chair Augustine: Larry would you care to comment on that?

Dr. Tabak: Just so that I understand the question, are you asking if the NCRR staff has reached a point of acceptance or are you asking if grantees are being accepting of the recommendations?

Member Rubenstein: I was more focused on the grantees and whether the changes that are being recommended now in terms of where these various programs are going to be housed in the NIH, whether they feel more comfortable or accepting of those or if there's still, you know, a lot of anxiety that the plan is not acceptable to them. It was more the outside constituents who had a stake in the funding from the NCRR.

Dr. Tabak: So Arthur, it is a little early to gauge this. We just yesterday posted the final interim recommendations. As you heard today on the call, a number of folks spoke to the fact that they were in agreement and supportive of what the final recommendations look like and we have also on an ad hoc basis received comments in a similar vein. But, in fairness, we have just recently made this public and so it remains to be seen if this is, you know, general and widespread across all programs.

Member Rubenstein: Okay and that's helpful. Do you have a timetable for assessing people's response to what you posted yesterday and this discussion today and, you know, how you will evaluate the input? Because it does seem to me that with more information, more people are becoming comfortable. But, whether it's everybody or some of them is kind of my question of how you are going to gauge that as best as possible.

Dr. Tabak: Right so no thank you. So as you know, blogs are inherently interactive in their nature and so we are welcoming of additional input and comments, which was one of the reasons why we have been using that medium to communicate. And then, on March 14 there will be a stakeholder town hall

meeting, in which we assume folks will participate to share their views and hopefully the fact that they are, you know, in accord with the plans as they are now laid out.

Member Rubenstein: Okay that's helpful, thank you.

Chair Augustine: Do any other members have questions or comments? Hearing none, let me give a quick synopsis of sort of where we've been and where we're headed here that as everyone knows it's been a busy year. We've had six of the full board meetings in 2010 and a large number of working group meetings.

We've produced reports on four topics, deliberating organizational change and effectiveness; substance use, abuse, and addiction; translational medicine and therapeutics research; and the NIH clinical research center.

And the first two reports you will recall we approved in December and the last two in December and since then NIH leadership has been hard at work reviewing and implementing the appropriate recommendations as they deem proper. And that of course is an ongoing process with considerable public input as well.

Regarding upcoming activities of the board, we're in the process of scheduling meetings for this year and for next year, and we'll do that rather quickly here so that you can plan your calendars. The agency is in the early stages of considering several important functional and organizational issues and that they may be turning the SMRB with some additional tasking in the next few months and Dr. Collins and I have been in close conversation on that topic.

Let's see, as to meeting of the board that will be coming up this autumn. We anticipate that the NIH will be providing us with updates on the implementation of substance, use, abuse and addiction recommendations as well as obviously the additional translational medicine and therapeutics research recommendations.

And let me take one last opportunity for any member of the board that wants to say anything before we move ahead. Hearing none, Dr. Collins we always give you the opportunity for the last word. Francis do you have anything you'd like to say?

Director Collins: Well thanks Norm and again thanks for your skillful leadership of this SMRB with remarkable talent represented here and the complexity of the topics, but you are an absolute master at making the most of these opportunities and I really appreciate your very strong leadership.

I think the comments we've heard today from the public input and from the board have been extremely helpful. I want to really think Larry Tabak and Tom Insel for their leadership of these two groups that have worked extremely hard since December to get us to this point.

And I think the point raised by Arthur at the end here in terms of whether we are on the right trajectory towards an outcome where the grantees will feel as if science is well served, I think we are on that trajectory as evidenced by some of the comments made in this conference call. And clearly we will continue to work hard on that effort including the town hall meeting that was mentioned which is another chance for us to hear that feedback from many different important stakeholders.

I do think the SMRB is going to have other tasks in front of them. Norm and I have talked briefly about some possibilities, but aren't ready yet to define exactly what those might be.

Certainly, we will want in the fall meeting to talk about the topics that Norm just mentioned, namely what our plans are for this new institute on substance use, abuse, and addiction, as well as the status of where we're going with the translational medicine and therapeutics effort.

We will probably also want to tell you how we're doing in terms of our conversations about the Clinical Center, because of course that was another major recommendation of the SMRB is to have the Clinical Center open its doors to extramural involvement and we aim to have that transition also occur by a year from this coming October, so we are clearly going to need to address many specifics about how best to implement that recommendation.

So, you have done so much in the year 2010 that our plates here at NIH is quite full in terms of implementation. But, we're grateful to you for giving us such a great set of exhortations and recommendations to allow us to do so. It's a great time for science right now. Things are moving with great rapidity. The opportunity both in basic and clinical research seems to most of us to have never been better.

We obviously are facing a series of significant budget anxieties in the current circumstances but we I guess adhere to the principals that my predecessor Elias Zerhouni once put forward into words that is namely it's never the wrong time to do the right thing.

And it seems to me the right thing is for NIH to pursue its mission with boldness to try to make a difference in biomedical research applications for

the hundreds of millions of people who are afflicted or who might become afflicted in the future with diseases that our research could assist in prevention, in diagnostics, and in therapeutics and that is our goal.

And you've helped us a lot with that goal and we will ask you no doubt to continue to do so as other organizational issues arise when we could really use your help. So thank you all of the SMRB members, thank you especially Norm. And this has been a very helpful call. I appreciate everybody's time.

Chair Augustine: Well Francis thank you very much and Larry and Tom, thanks to you, thanks to the public commenters and I particularly want to say how much I appreciate all the hard work of my colleagues on the SMRB. I count it a privilege to work with such a group on so many important topics.

And I also should thank our conference coordinator for keeping things under control even when I accidentally hit the wrong button. So, with that we will declare the meeting adjourned and I hope everyone has a great day.

Member Brody: Thank you Norm.

Member Briggs: Thank you.

Coordinator: Thank you for participating. All lines will be disconnected. Have a good day.

END