Transcripts of November 10 Public Teleconference

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS)

NATIONAL INSTITUTES OF HEALTH (NIH)

SCIENTIFIC MANAGEMENT REVIEW BOARD (SMRB)

WEDNESDAY, NOVEMBER 10, 2010

The Board convened via teleconference at 1:00 p.m., Norman R. Augustine, Chair, presiding.

BOARD MEMBERS PRESENT VIA TELECONFERENCE:

- Norman Augustine, Chair
- Jeremy Berg, Ph.D.
- Anthony Fauci, M.D.
- The Honorable Daniel Goldin
- Eric Green, M.D., Ph.D.
- Richard Hodes, M.D.
- Stephen Katz, M.D., Ph.D.
- Thomas Kelly, M.D., Ph.D.
- Deborah Powell, M.D.
- William Roper, M.D., M.P.H.
- Harold Varmus, M.D.
- Huda Zoghbi, M.D.

EX-OFFICIO MEMBERS PRESENT:

Lawrence Tabak, D.D.S., Ph.D.

STAFF PRESENT:

Amy Patterson, M.D., Executive Secretary

Coordinator: Welcome, and thank you for standing by. All lines will be in a listen-only mode until the presentation is completed for today's conference call. Today's call is being recorded; if anyone has any objections, you may disconnect at this time.

I would like to introduce your host for today's call, Amy Patterson. You may begin.

Dr. Patterson: Thank you, operator, and I would like to turn the proceedings over to the SMRB Chair Mr. Norman Augustine.

Chair Augustine: Thank you, Amy. Good morning, everybody, and welcome to this meeting of the Scientific Management Review Board. This is the seventh meeting of our group.

The meeting is being broadcast to the public, so I'd ask that everybody be sure to speak clearly and also when you're not speaking if you'll press the mute we'll be able to hear better.

I'd also want to welcome Eric Green to the Board, and he will be replacing Larry Tabak. Larry has descended into top management here on us.

Probably a good thing to do would be to call a roll to begin with, and Amy — if you would do that.

Dr. Patterson: Yes, Norm. We have Norm Augustine on the line, and for the other members, when I call your name if you could just indicate that you're here. Jeremy Berg?

Member Berg: Here, present.

Dr. Patterson: Tony Fauci?

Member Fauci: Here.

Dr. Patterson: Richard Hodes?

Member Hodes: Here.

Dr. Patterson: Steven Katz?

Member Katz: Here.

Dr. Patterson: Deborah Powell?

Member Powell: Here.

Dr. Patterson: William Roper?

Member Roper: Here.

Dr. Patterson: Harold Varmus?

Member Varmus: Here.

Dr. Patterson: Huda Zoghbi?

Member Zoghbi: Here.

Dr. Patterson: And Larry Tabak in ex officio capacity on behalf of Dr. Collins?

Dr. Tabak: I'm here, thank you.

Dr. Patterson: Okay and Norm, Dan Goldin will be joining us, we expect him in ten minutes. We also have a couple of other members who I think have dialed in but were initially uncertain whether they could participate, and I'll call their names now.

Gail Cassell?

Member Cassell: Here.

Dr. Patterson: Thank you. Bill Brody? So Bill has not joined us yet. Arthur Rubenstein? I know that Arthur was going to be a bit late for this call and may not be able to make it.

Eugene Washington and Eric Green, I thought I heard your voice earlier.

Member Green: I'm here.

Dr. Patterson: Thank you. And Norm, not attending although it would be a pleasant surprise if they were able to dial in, I'll call their names anyway. Josie Briggs? Griff Rodgers, Susan Shurin, Sol Snyder, and Francis Collins? Okay. All right, that's...

Member Kelly: Amy, this is Tom Kelly. Am I still a member of this committee?

Dr. Patterson: Yes you are, Tom. Yes you are. You don't get off that easily, thank you.

Chair Augustine: You're a much respected member in fact, Tom, we're glad you're here. We won't be adding any votes today but - on any actions, however we do want to be briefed on the Translational Medicine and Therapeutic Work Group efforts of the past couple months.

As you'll recall, at the last meeting we discussed the plan whereby we would have this conference call so that we could sort of get a mid course update of where they stand.

This will be our opportunity to make suggestions for the work as they approach their final phase. Arthur will be providing us with an update of the group's activities when he gets on the line here. And if not, we will call on a pinch hitter, and we will have an opportunity to discuss these when the briefing is done.

And we've also reserved some time for the public to make any comments that members might want to make. And we've had a sign up system in place for that.

First of all, let me kind of give a quick summary of the status of our various working groups.

Member Goldin: Norm, this is Dan Goldin. I'm on the line.

Chair Augustine: Good, Dan. Welcome.

In the attachment you got — it's Attachment 8 that I'll do a fast summary here for the public that doesn't have that hand out.

The report that you recall we acted on regarding substance use, abuse, and addiction research has, in fact, been revised to reflect the vote that took place in September, and that revised version of the report has now been approved by all the members of our Board. And the plan is to transmit that to Francis this week.

Also, with regard to the TMAT Working Group, after our meeting today that group will take the results of our deliberations, also the comments from the public, and prepare its final report — hopefully, the final report — to the SMRB when we meet in Bethesda on December 7 and 8.

And at that time, the full Board will have the opportunity to vote on the findings of the TMAT Working Group report. That's only about a month from now, so what that means is that we're going to need to get all our comments in hopefully today or very quickly thereafter if we've got any correspondence that's necessary. And the - we attempt to transmit the TMAT report to Francis virtually immediately after that meeting, assuming that it's in condition we can or as soon as we can make whatever changes are in order.

The reason for this urgency is that the FY12 budget cycle has a cutoff that comes up, as it happens, right after our meeting. And if we don't make that schedule, we lose a year in implementation.

Let's see, the Intramural Research Program report will also be voted on at the December meeting, and you remember we reviewed that report at the last meeting and tabled it. And the reason we tabled it was so that we could get the results of the TMAT Working Group before we had to act on it, because the two are closely connected.

Also, I note that we will revise it if we need to, depending on what the TMAT recommendations turn out to be in early December as acted on by the entire Board.

So that's the sort of the status report on where we are. And let me ask Dr. Patterson to give us the usual conflict of interest policy rules here so that we abide by the regulations.

Dr. Patterson: Okay, thank you, Norm. A quick but important reminder to the members of the committee that as members of the committee you're special government employees and therefore subject to rules of conduct that apply to government employees.

And at every meeting, this meeting being no exception, in addition to reminding you about the importance of following the ethics rules, we also want to remind you to keep in mind during the course of the discussion if there are any issues that arise in the discussion that may present a real or apparent conflict of interest between your public responsibilities as members of this and your private interests and activities, that you make us aware of that.

In preparation for this meeting, you provided us with a lot of material regarding your private interest and activities. Those were reviewed and a determination made that you do not have conflicts of interest that would prohibit your participation in this particular discussion.

So again, just be mindful of any issues that might come up, and thank you, Norm.

Chair Augustine: Okay, thank you. Does anybody have any questions on that? Hearing none, we'll proceed. If Arthur is here we will begin, if not Bill Roper has been kind enough to offer to pinch hit.

So, Arthur, do I hear you? Bill, I think you win the prize.

Member Roper: Thank you, Norm. And good afternoon, everybody. I'm substituting for Arthur, and I'll do my best. What I'm going to be doing is going through the slides that I trust the members of the SMRB have already reviewed. There are 30 some odd slides.

I'm going to do this quickly. Speak up if you need clarification, otherwise we'll cluster the comments at the discussion period at the end.

I'm just now going to proceed. Slide 2 has the roster of the Translational Medicine and Therapeutics Working Group.

Charge is on the third slide, which is that we should identify the attributes, activities, and functional capabilities of a translational medicine and therapeutics program at NIH.

And let me pause there to make a point that I'm sure will come up later in our discussion, and that is, what do we mean by program? And at this stage I would just for discussion have it mean the same thing as an initiative or an activity or a set of activities, not necessarily an organizational unit.

Because that's the fundamental issue we have to grapple with is, what is the organizational structure? But for the initial part of this conversation, when I say the word program I'm talking about a set of activities, not an organizational unit.

So, furthermore, the charge is to broadly assess at a high level which programs, networks, centers, etcetera should be included in this set of activities and how should they be organized and how can it be leveraged across the NIH, including the new Cures Acceleration Network given to the NIH by the health reform legislation.

Slide 4 says that we should consider the current NIH "as is" structure and activities and how to create additional synergies and avoid competition with resources in the private sector.

We should hear previous recommendations from the IOM and others and lessons learned from industry and beyond. And then focus on how to measure changes that are brought about after these recommendations are implemented, if they are.

Slide 5 says that we are to deliver the attributes, activities, and functions of such a program, recommendations for how to organize it at the NIH, and measures for assessing success.

Slide 6 shows our time table, and Norm has already outlined this. I would just draw your attention to the middle line under November full SMRB teleconference review findings and draft recommendations. That's today's teleconference, that's what we're doing and we're headed towards an in-person meeting in December where all this will be brought before the SMRB for a vote.

Slide 7 begins to say we are drawing on the organizational construct given us by our colleagues in Deliberating Organizational Change and Effectiveness.

Slide 8 begins to lay that out, saying that our guiding principles are to proceed with reorganizations that strengthen NIH's ability to carry out its mission; increase collaboration and coordination; bring together synergies; enhance public understanding, confidence, and support; and increase operational efficiency.

There's three steps to the deliberative process: assessing the need for change, evaluating options for change, and then implementing and evaluating change. And across all of this we want to have transparency, communication, and accountability.

Slide 9 speaks for itself. Again it's the three steps of the so-called DOCE process.

And Slide 10 lays this out with asking the first question, is current TMAT research at the NIH capitalizing on scientific opportunities, meeting the needs of the public, or could reorganization better optimize that?

Slide 11 begins to supply the answers to that question, those questions just posed. Scientific discoveries have generated a large inventory of potential targets, there are advances in technology.

There's interest and expertise in therapeutics development growing at academic institutions. There's an evolving landscape in the therapeutics development area. And NIH should take account for this and be positioned to be a leader in this field.

Slide 12 talks about an opportunity to get the most of the resources across the NIH and how they ought to be brought together.

And then I've already mentioned but it's on Slide 12, health reform law of seven months ago, gives an additional responsibility to the NIH, the creation of the so-called Cures Acceleration Network.

Slide 13 says that there are opportunities to improve things. That's what this whole conversation is about, of course.

Slide 14 begins to tackle the - or identification of what sorts of functional capabilities and activities are necessary. Bridging gaps in therapeutic development pipeline, recruiting project managers, funding research in areas where little interest has been shown by the private sector such as rare and neglected diseases.

Slide 15, other essential activities include developing and providing scientific resources, coordinating TMAT activities across the NIH…NIH-wide.

Slide 16 says another role for the new TMAT activity — again, I'm stressing it's not necessarily a program — is to serve as a hub for information on and access to resources, tools, expertise, etcetera. It should help investigators navigate the processes and develop and support a data-sharing infrastructure.

Slide 17 emphasizes the point of serving as a catalyst and convener for collaborative interactions and partnerships.

We heard a lot in earlier session from industry, academia, and the nonprofit world that the barriers between them must be lowered and that NIH can be an honest broker in facilitating these kinds of joint activities.

Slide 18 talks about NIH help expanding the pre-competitive space by promoting the sharing of information, incentivizing the publication of research failures and lessons learned, promoting the use of informatics infrastructure, supporting research in pre-competitive areas.

Slide 19 brings a point that we heard before from those who came and spoke with us, that is, the NIH has the opportunity to play a pivotal role in the supporting and training workforce for this emerging discipline of translational research, and a variety of other things in this area.

Slide 20, the new TMAT should enhance communication with and among stakeholders, including within the NIH, identify opportunities to engage traditional NIH grant recipients, foster communication across the government, especially with the FDA, and give more outreach to the public, to patient advocacy groups, to congress, and others.

Now, Slide 21 begins to lay this out in a framework with what are the options for organizational change.

Slide 22 says any TMAT reorganization should expand and augment the agency's efforts. We want to leverage existing efforts, and that's a point that has come up before and I'm sure will come up more again. That is, how to improve things from here and not necessarily supplant what's underway already.

Slide 23, the TMAT Working Group proposes that a new institute or center be established at the NIH to be the coordinating body for this activity, translational medicine and therapeutics, to serve as a catalyst or resource, convener for collaborative interactions.

Slide 24 makes a point that I've alluded to several times already: any new institute or center should not duplicate consume or undermine the successful activities already underway within the NIH ICs.

Once the appropriate infrastructure has been established, NIH can determine what additional resources are needed to fill the gaps. And it's important as the NIH goes about establishing this new unit that it learn from what's been done in the past, both successes and failures.

Slide 25, the bulk of the new IC's activity should focus on providing and supporting resources, training, and tools. Should house some targeted activities to perform its functions, for example to implement the Cures Acceleration Network.

Slide 26, the new institute or center should have sufficient infrastructure, should amplify the connection between basic discovery and translation, employ new models for issuing funding opportunities and reviewing applications.

Lots of communication is important across the NIH and with other government agencies, again, especially the FDA.

Slide 27 begins to lay out a schematic drawing to illustrate the options that the Working Group saw putting this together.

In all four of these options that are laid out here, we envision the Molecular Libraries Program, RAID, TRND, and CAN being housed within this new unit.

And then the variations are what to do with the Clinical Center and the CTSAs. If I can just describe the four parts of Slide 27, option one in the upper left hand corner, has it all put in this new unit, including the Clinical Center and the CTSAs.

Option 2 has structural and functional reorganization with both the Clinical Center and the CTSAs remaining outside the new organizational unit.

Two B has the Clinical Center inside but the CTSA's outside and slide - the bottom right hand corner, option 2C has the Clinical Center outside and the CTSAs inside.

Slide 28 is the recommendation of the TMAT Working Group. It is option 2C as I just described it, where the CTSAs are housed within the new unit. The Clinical Center remains outside with strong functional ties to the new organizational unit.

Our group also consulted John Gallin, Director of the Clinical Center, and Barbara Alving, Director of the National Center for Research Resources, and we believe that the CTSAs would be a very good fit within the new unit.

On Slide 29, it describes the rationale for why we would recommend the Clinical Center not in this new unit. Those strong ties are to be desired, and it boils down to the Clinical Center does a number of things beyond translational medicine, and our recommendation is for the reasons elaborated on 29. It not being within the unit.

Slide 30 describes what at the previous full Board meeting we agreed to table the vote on recommendations for the Clinical Center until our December meeting, which is now upcoming.

And recall Arthur chaired that group as well, the Clinical Center discussion. And so this will all come together at our meeting in December.

Slide 31 lays out the recommendations regarding the Clinical Center, and recommendation number one would be seen as it is, a national resource, recommendation two is a streamlined governance structure, and then recommendation three, stable, responsive budget process, which is depicted on Slide 32 as a line item in the Office of the Director budget for the Clinical Center.

And so Slide 33, my last slide, members of the TMAT Working Group continue to support this earlier recommendation about the Clinical Center. We think this fits nicely with these more recent now TMAT recommendations.

Strong functional ties to this new unit for translational medicine, we think, will also strengthen the role of the Clinical Center as a national resource.

Norm, that's the end of my presentation. I believe it's time for discussion. I'd welcome, as others would, comments and questions.

Chairn Augustine: Bill, thank you very much, and thanks to Arthur and your entire group for the effort you've put in here. I thought that was a very clear presentation.

So, if you'd like to just continue to lead the discussion, that would be fine.

Member Roper: Sure. Anyone?

Member Kelly: Yep, Bill, this is Tom. I wanted to ask you a little bit about — first of all, looks like a terrific report, shaping up really well, and it does seem like some kind of a new organization is really necessary to implement this.

But I was wondering about whether you could expand a bit on the relationship of such a new institute or center would have to the existing programs at NIH.

I mean, there was one bullet that said it wouldn't duplicate, consume, or undermine successful activities already underway within the NIH. And I'm curious though, I mean, that suggests that there may be — that the new entity wouldn't bring together all of the relevant components of NIH.

Is it your vision that this would really become the center for therapeutic development across NIH, or will there still be separate entities doing that?

Member Roper: Tom, there are others, I'm sure, who can respond as well. The slide I'd direct us all to for this discussion is Slide 28 — if you can do that — which lays out schematically our recommendation.

The way I would describe what this Working Group is recommending is that several units that are doing things that are directly tied to translational medicine and therapeutics — TNRD, RAID, I've mentioned the CTSAs, etcetera — would be a part of this new unit.

But we're not suggesting that, for example, all of the translational medicine therapeutics activities of the National Cancer Institute or of Allergy and Infectious Disease or any of the other institutes be wholly pulled out of those institutes and transferred into this new unit.

I'd welcome others elaborating on that. I know Harold and Tony have thought a lot about this.

Member Fauci: Bill, this is Tony. Let me - I might just jump in first because I have to run to give a talk in a few minutes.

I had sent an email to Amy and to Lyric with some copies to other members to just underscore A, the point you made when you first started presenting and the very important point that was just brought up — and that Tom just brought up — and that is that if you look at Slide 23, we really need to — and we will — make sure that it's perfectly clear what we mean by the word program.

Because if you read the first bullet, Slide 23, it says it is proposed that a new TMAT program be established at NIH in the form of a new institute or center.

Now, the issue there is that if you consider all of the other things that you alluded to, not only things that are going on at the Clinical Center, at the CTSA, but that other institutes are supporting in the arena of translational medicine and therapeutics.

There's a lot of that stuff going on, so are we going to consider that as a broader TMAT program that has multi-faceted multi-components to it and that the new program is going to be housed in the institute?

Because the way the first bullet reads in Slide 23, it says that a TMAT program be established in the form of a new institute.

And we have a program in the loose sense of a program without walls that is huge and that does translational research. So, I think the issue is that we have to be clear when we talk about program, what do we mean by program?

Because we already have a program. It's a loose program, and it involves multiple institutes. And I think that's the question you were asking, and I think that was a caveat that Bill mentioned when he said we really have to be, you know, sure that we understand what we — we know what we mean when we say program.

Member Roper: Yes, thank you Tony. Others of you want to join in?

Member Varmus: This is Harold, I'm happy to have Tony speak for me; we've discussed this, I agree with what he has just said. I think it's important to emphasize that the kinds of programs and translational research and therapeutics that Tony and I and a few other institutes are overseeing will have interactions with this new entity we're talking about.

But I think we all feel pretty strongly that we are not ready to be subsumed and — or consumed and that you know we have much to offer this new entity and vice versa.

But we don't want to feel that the integrity of our own programs is in any way going to be challenged by this - by the new things that we're doing. Which we applaud, we think this is a good way to pull together a number of disparate activities to create some new facilities for promoting NIH science in an important area.

And then I think that there is the potential for giving to some of the smaller institutes that haven't been able to engage in translational research and therapeutics or other complicated things, including clinical trials, the opportunity to do so.

So we definitely applaud all that. The other issue that's not really out on the table, of course, is how is this all going to get paid for at a time when people are being threatened with very considerable cuts.

While I don't think this is the role of the SMRB to talk about that, I think it has to be on our minds as we contemplate what may lie ahead of us in the very near future.

Member Kelly: You know, I think what both Tony and Harold said makes a lot of sense, but I would - I think one aspect of that, I think this goes back to Tony's point, is I think I would urge the committee to sort of flesh out a little clearer way what the new entity is going to be doing relative to the entities that are already established.

Member Cassell: I think another - this is Gail Cassell - another way to potentially look at what is being proposed by the TMAT subgroup is not unlike what exists in most large companies today.

And that is that you have your specific therapeutic areas, i.e. institutes that are very disease focused with unique areas of research that need to be developed, targeted, and validated, etcetera.

But then what you might be looking at is, with the new entity, an entity that would be a space where you can reduce redundancy, synergize, and house those activities that are common to each of quote the therapeutics areas where say, for example, the offerings of RAID and even some, Tony, that NAID offers in terms of access to contract research organizations.

By having those under one entity and being able to bargain with outside contractors with a single voice as opposed to multiple institutes, you might be able to achieve much better arrangements, both price-wise and delivery-wise and quality-wise.

So I actually think that you know this great structure, and I do agree with what Tom has suggested about fleshing out more details about what specific entities one might actually see being housed.

I think one piece that has not occurred and that we haven't really discussed —and I don't know that it's the time to do so — but there are a lot of activities as we all know in other countries where large sums of money have been invested and are being invested both in government agencies and universities to facilitate translational research and drug development.

So we just want to be sure that this new entity also perhaps could serve as the face of primary interactions with those international activities to capitalize on them and bring in the knowledge and new technology, etcetera as well as help disseminate them.

Member Katz: This is Steve Katz. I would agree with everything that's been said. I would just address you all to Slide 3, because the last bullet on Slide 3 seems to imply that all of this is dependent upon an appropriation of funds to the CAN.

And I think that probably that should be taken out, because this is going to happen whether or not there are funds to the CAN.

Member Cassell: I agree.

Chair Augustine: Bill, do you want to comment on that?

Member Roper: That's pretty much an internal NIH issue, and I don't have an opinion, but I see the wisdom of what Steve is saying, yeah. Other comments?

Chair Augustine: Bill, this is Norm. Let me try to just reiterate what I think I've heard here. That the intent is that for those institutes that have the capability to do the translational work that there's no intent to take any of that away but rather use the new entity in a supporting role as needed.

For those institutes that don't have the capability to handle translational work that they — that work could be done by this new entity, and hopefully the two working together could produce synergy.

Member Roper: And there's the additional point that Gail made just a moment ago, Norm, that there are some things that will be more efficiently done in a central unit for all of them simply because they are shared functions that can be officially done one time rather than separately by a number of different units.

Chair Augustine: Right. That's what I meant by my comment on synergy which I didn't state very well, but if that generally reflects the understanding it surely sounds reasonable.

Member Roper: Yes, it does.

Chair Augustine: Okay, Bill. Is there anybody else that has any other comments here? If not, I'll assume we could go ahead. Once again, Bill, thank you.

And I would like to make not - have not a question but a request, and it goes back to the National Academy's concern that was expressed in their report a couple years ago over what they termed fragmentation of NIH into so many different institutes and centers. And if you could be rather explicit in the presentation in December on the relationship of the action that's proposed here, how it relates to the National Academy's findings of their report, that would be helpful.

Member Roper: Yes sir.

Member Katz: So just to further Norm's point and to flesh out this thing that Tony and Gail were talking about, I think it is important to really articulate how much enabling this new entity will be.

Because that really is what it's meant to be is to enable the other entities to do their work that much better in collaboration with this new entity.

So I would underscore the operational aspect and the enabling aspect of bringing all of these entities together.

Member Cassell: I think also, Steve, in order to do that well that one would need a very good inventory of those activities that are being contracted out separately and the different institutes to see, you know, what might best could be done.

And that I don't think would necessarily need to be done by our committee, but rather we could make that recommendation, because I think until you have that inventory it's not possible to realize all of the redundancies and the discrepancies in terms of pricing and efficiency.

Turn around times, we heard a little bit when we heard from some of the presenters at our last meeting about, you know, some dissatisfaction with CRO activities, which end up being very costly for everyone, including patients in the end.

So I think these are the areas that could be dramatically improved as well as, you know, tox and ADME studies and PK studies that everyone wants access to but has difficulty with from a research standpoint, from an investigator's standpoint.

Chair Augustine: Well, hearing no further comments… Thanks again, Bill, to you and Arthur and the group. And we will assume that you'll be prepared with a product that we'll be able to vote in December…

Member Roper: If I could just add, we are having another meeting of the workgroup next week, and we'll push ahead with the refinements that you all have asked for.

Chair Augustine: That's terrific. And at this point let me ask if there's anybody who's joined, any members who have joined the call that haven't had a chance to identify themselves either during the role call or subsequently.

Okay, so the next thing on the agenda is the public comments, which we always welcome. And those members of the public who are listening or to other members if you would like to submit in writing, there are a number of ways to do that, indicated in the Federal Register, but we would more than welcome any input you'd like to make to the discussion or the proposal that's been made.

And at this point, let me ask Amy — has anybody signed up in accordance with the Federal Register notice?

Dr. Patterson: No, Norm. No one has been signed up in advance to make comments.

Chair Augustine: Fine. Well, then there's no need for me to go through the rules, then. And I think that that basically brings us to the conclusion, other than for me to remind everybody once again of December 7 and 8 in Bethesda when we're going to have a number of items to deal with that are very important.

Does anybody have any further business they'd like to raise? Hearing none, let me thank everybody so much, thank the members of the public who are listening today, and we will look forward to assembling again in December.

Have a very good day, take care.

The meeting is adjourned.

Coordinator: Thank you for your participation. Your call has concluded; you may disconnect at this time.

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