Transcripts of July 26 Public Teleconference: Translational Medicine and Therapeutics

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

NATIONAL INSTITUTES OF HEALTH (NIH)

SCIENTIFIC MANAGEMENT REVIEW BOARD (SMRB)

PUBLIC CONFERENCE: TRANSLATIONAL MEDICINE AND THERAPEUTICS (TMAT)

MONDAY, JULY 26, 2010

The Board convened via teleconference at 10:30 a.m., Norman R. Augustine, Chair, presiding.

MEMBERS PRESENT:

NORMAN R. AUGUSTINE, Chair

JOSEPHINE BRIGGS, M.D.

ANTHONY FAUCI, M.D.

RICHARD HODES, M.D.

STEPHEN KATZ, M.D., Ph.D.

THOMAS KELLY, M.D., Ph.D.

GRIFFIN RODGERS, M.D., M.A.C.P.

WILLIAM ROPER, M.D.

ARTHUR RUBENSTEIN, M.D.

SUSAN SHURIN, M.D.

SOLOMON H. SNYDER, M.D.

LAWRENCE TABAK, D.D.S., Ph.D.

HAROLD VARMUS, M.D.

EUGENE WASHINGTON, M.D.

EX OFFICIO MEMBERS PRESENT:

FRANCIS COLLINS, M.D., Ph.D.

STAFF PRESENT:

AMY PATTERSON, M.D., Executive Secretary

PROCEEDINGS

10:38 a.m.

CHAIR AUGUSTINE: Thank you everyone, and thank you for joining in this call. I know there are a number of members who will be calling in that are apparently having difficulty, due to the power situation in the Washington, D.C. area where many of us live. We'll continue in any event, and others can join us as they're available.

This is of course a public call and we particularly welcome the members of the public that are listening in. And you will have an opportunity for brief questions in about thirty minutes.

Just in the way of background, we of course have three working groups underway as part of the Scientific Management Review Board, or the SMRB as it's better known.

One of those groups has finished its initial undertaking. That will be a continuing effort. That of course is the group that Dr. Brody has been leading.

The other two groups are nearing the completion of their assigned tasks, and we should have firm recommendations before the board is — before too long.

Today, the purpose of the discussion is to talk about a new task that we've been asked to undertake by Dr. Collins, and it relates to translational medicine and therapeutics.

The reason for undertaking this, of course, is it — not only has there been a reasonable amount of public attention, public media attention to what some consider to be the relatively slow translation of scientific breakthroughs into practice in some instances.

And it's also been pointed out that in spite of tight budgets and shortages of venture capital, science has been offering a number of new opportunities that one would like to be able to benefit from.

So, the purpose of this group is to try to search for means where NIH could be even more effective, in terms of translational medicine.

The — I think we need to do a roll call, and so before I continue, let me call on Dr. Patterson to do that, please.

(No response.)

Have we lost Dr. Patterson?

DR. PATTERSON: No. Norm, are you ready for the conflict of interest?

CHAIR AUGUSTINE: Oh, I'm ready for the roll call.

DR. PATTERSON: Oh, roll call. Okay. When I say your name, if you could just say "present". William Brody.

(No response.)

William Brody? Bill?

THE OPERATOR: Will these be parties listed as speakers or individuals that have dialed in to listen?

DR. PATTERSON: As a speaker.

THE OPERATOR: Okay, I'm —

DR. PATTERSON: All speakers.

THE OPERATOR: Okay. I don't show a Mr. Brody dialed in as a speaker.

DR. PATTERSON: Okay. All right. Tom Kelly?

DR. KELLY: Present.

DR. PATTERSON: Bill Roper?

DR. ROPER: Present.

DR. PATTERSON: Arthur Rubenstein?

DR. RUBENSTEIN: Present.

DR. PATTERSON: Sol Snyder?

DR. SNYDER: Present.

DR. PATTERSON: Gene Washington?

DR. WASHINGTON: Present.

DR. PATTERSON: Jeremy Berg?

(No response.)

Tony Fauci?

DR. FAUCI: Present.

DR. PATTERSON: Richard Hodes?

DR. HODES: Present.

DR. PATTERSON: Stephen Katz?

DR. KATZ: Present.

DR. PATTERSON: Griff Rodgers?

DR. RODGERS: Present.

DR. PATTERSON: Susan Shurin?

DR. SHURIN: Present.

DR. PATTERSON: Larry Tabak?

DR. TABAK: Present.

DR. PATTERSON: Harold Varmus?

DR. VARMUS: Here.

DR. PATTERSON: And I skipped over, because I think she's calling in late, but I'll call anyway and see if she's joined us, Gail Cassell?

(No response.)

Okay. Norm, Gail is anticipated to dial in a bit later.

CHAIR AUGUSTINE: Right.

DR. PATTERSON: And we know that Bill Brody, Dan Goldin and Huda Zoghbi, and Deborah Powell will not be joining us. And Jeremy Berg is recused from this meeting.

CHAIR AUGUSTINE: All right. So, we do have a quorum, I think. Am I correct?

DR. PATTERSON: Yes, we do.

CHAIR AUGUSTINE: All right. And of course Dr. Collins is with us.

DR. COLLINS: Yes, I am.

CHAIR AUGUSTINE: Good. All right. Let's see, thank you Amy for doing that. And while I'm thanking you, let me say to the group and the public at large how much we appreciate Dr. Patterson's work on behalf of this committee. She's done a truly spectacular job and made a huge difference, and we thank you.

The next item on the agenda is to review the NIH conflict of interest policy, as we are required to do at each meeting. And so, for that, I'll again call on Dr. Patterson.

DR. PATTERSON: Thank you, Norm. Just a brief, but nonetheless important, reminder about the rules of conduct and conflict of interest.

As a member of this committee, you are a special government employee, and therefore subject to the rules of conduct that apply to government employees.

The rules and regulations are explained in the report entitled Standards of Ethical Conduct for Employees of the Executive Branch. And you each received this document when you were appointed to the committee.

And at every moment, we take a few minutes in the beginning of each meeting to remind you about the importance of following those ethic rules. And we always like to review the steps we take and ask you to ensure that any conflicts of interest are addressed.

Before each meeting you provide us with a great deal of information about your personal, professional, and financial interests.

And we use this information for assessing whether you have any real, potential, or even apparent conflicts of interest that could compromise your ability to be objective in giving advice during committee meetings, or appear to compromise that ability.

And we waive conflicts of interest on general matters because we believe your ability to be objective will not be affected by your particular interest in such matters.

We also rely, to a great degree, on you being attentive during the meetings to the possibility that an issue could crop up that could affect, or at least appear to affect, your interests in a specific way.

And if this happens during the course of the meeting, we ask you to recuse yourself from the discussion, and please let me know as well after the call.

And if you have any questions about the rules of conduct or conflict of interest, I'd be pleased to address them after the call. Thank you, Norm.

CHAIR AUGUSTINE: Thank you very much. And does anyone have any questions for Dr. Patterson?

(No response.)

If not, we'll proceed. This meeting was advertised in a Federal Register according to the regulations, and we can proceed.

I think each of the members has seen a copy of the charge of the new Translational Medicine and Therapeutics committee, or working group I should say. And that will be available on the web for the general public, if it's not already there.

I think what I'll do is call upon the person who kindly has volunteered to chair that, and that's Dr. Rubenstein.

And he has done that, I think, in part not only because of his personal interest and background, but this task relates so closely to the work of the committee that he chaired, or is chairing right now, that it seemed logical to build that bridge by having him chair this new committee. And he has agreed to do that.

You'll note also that we've overlapped the members of the committee he has been chairing with the new committee for that same reason.

And he will be discussing the membership, the schedule, the charge and the operating procedures. And at the end of his comments, we will have time for a general discussion among the members of the SMRB. So with that, let me turn it over to you, Art.

DR. RUBENSTEIN: Thanks, Norm. This is Arthur. Just one correction. Volunteer is a strong word, yet here I am.

But, we can discuss that in detail another time.

CHAIR AUGUSTINE: That means you only twist one arm as volunteer.

DR. RUBENSTEIN: Yes, I guess. Anyway, I do view this as very important. And I also want to thank Dr. Patterson, and of course Francis, who is committed to this program.

So in the ten or fifteen minutes of my presentation, we have a lot of material, which I hope you've been able to go through ahead of time because it wouldn't be useful to go through all the details, and particularly the excellent slide deck that you have.

And so, I'm going to highlight some of them. And hopefully we'll have enough time for questions, which would be the most important.

So the background of this, of course, is the general feeling in the country, I think, that despite tremendous advancements in science, there's less therapeutic outcomes of that benefitting directly patients and their families at this stage, and the view that we could do better in that regard.

And this is embodied in the Patient Protection and Affordability Act, which authorized a Cures Acceleration Network.

Now, much of this material — all of this material has been sent to you by Amy. I think under tab seven, if I've got it right, Amy, is some of the details of the Act, which is actually quite straightforward to read and very informative. Am I right, Amy, that's under tab seven?

DR. PATTERSON: That's correct, Arthur.

DR. RUBENSTEIN: And then derived from that is a charge to both the SMRB and its work group, and that is under, I believe, tab five.

DR. PATTERSON: That's correct, Arthur.

DR. RUBENSTEIN: Those are worth reading in detail and I hope that you've been able to do that. And if not, if you would just take ten or fifteen minutes sometime later and go through that. Of course, it's pretty straightforward the way it is spelled out.

With that, I thought I would just highlight some of the slides from the slide deck, just to draw your attention to them, although all of them are important, but some of them are just maybe more valuable today to highlight. And then, again, they will also inform any questions you may have.

So if we could start with slide five. That's the very high-level summary to the work group answering to the full SMRB group. And it's called TMAT, Translational Medicine and Therapeutics, charge. And one can distill it into two main functions, or two main charges.

The first is attributes, activities, and functional capabilities of a translational medicine program for advancing therapeutics and development. And of course, the NIH has been charged to lead this activity, look at it from a high-level NIH point of view as to how we might organize and function to optimize this kind of plan.

So those are the two things, what are the characteristics of the organization, and then in a practical sense, how should we organize, or recommend to the NIH that they organize such a group to effect this charge.

And again, I'm sure Francis when I'm done, we'll — if we can go from there, I think what I'd like to highlight is particularly starting on page — slide twelve.

And if there are any questions amongst — about the things in between, just make a note and ask us about it afterwards.

Given the responsibility for doing this, at least leading this effort, of course it will involve many other agencies and the private sector as well, particularly of course the FDA. And we'll come back to that perhaps at the end.

And then moving to the slide deck 13 through 18, there is some detail there about why NIH should be charged or be given, or has been given the responsibility to lead this effort.

There's a lot of progress already being made, as you can see on 13, with high-throughput technologies. There's an emphasis on basic science discoveries being translated into better treatment. The CTSAs are integrally involved in this, but many other things as well.

And so, there are already organizations and efforts and focus at the NIH to do this, and so it was appropriate as the lead agency to do that, and to be authorized to do that.

Page 14 will give you some of the issues that are already present at the NIH. And of course some of the issues that a variety of people have worried about needed to be changed in order to move translational medicine and therapeutics forward.

I won't go through it in detail, but there's been a lot written about this, including, as has been referenced, an important article by Dr. Paul about some of the problems in industry and pharmaceutical companies, biotech companies, as well as academia, about why this process seems to be less fast and efficient than it might be.

Fifteen just talks about the role of NIH and the healthcare reform act, which I mentioned, the Patient Protection and Affordability Act, which establishes this Cures Acceleration Network. And we can come back to that in a little detail after awhile.

This Act, or this part of the Act, really does very specifically authorize money, I guess it still has to be appropriated, and really to talk about, if you look at sixteen, the advances in basic research and the need to translate them into advantages to patients and their families as quickly as possible. And it does outline some of the mechanisms in which this may be actualized.

Seventeen goes on to the role that the NIH may talk about. And there are pretty straightforward statements about how it may involve the private sector, how to overcome some of the barriers, and particularly the importance that the FDA should and will play in such an effort. And so the relationship with other government agencies is critical for this success.

And then 18 talks about — we're not talking only about drugs but also devices, other biological products, things to do, earlier diagnosis, cell markers, biomarkers and so on.

So there's a broad mandate across a variety of areas that advantage patients in a more efficient and quicker way.

And there are opportunities for collaboration between a whole variety of people involved in this from pharmaceutical companies, to academia, to biotech companies and not-for-profit organizations and so on. So it's a very broad mandate to do this as efficiently as possible.

So those are a high-level summary of what this working group has been charged, and the background for bringing it into being and what some of the challenges might be.

If one starts at 19 and 20, it's the challenge that the work group and the SMRB has because there's a very tight time frame. Hopefully, this can all get done by the end of December, which we're really talking about only five months.

And there are a lot of important steps that need to be taken to get this done, they start on slide deck 20, where the group will present to the full SMRB.

And again, I won't read through the wording of it all, but it reflects accurately the details in the charge. That is under tab five.

So it talks about the attributes of such an organization, the recommendations of organizing the agency's existing components, and, of course, as well how it may relate to other organizations.

And then the metrics for evaluating success, and we'll say any untoward consequences, of course, of doing such a thing, seeing as there's a very broad mandate and will involve many aspects of NIH and other government agencies, as well as the private sector.

So that is a very important charge to the work group that we'll have to look at. And 21 just talks about that in more detail.

Twenty-two is important. In executing a charge consider — and you can see there just a further elaboration of some of the high-level outline that I gave you.

Again, that's worth looking at to try to see how we will try to be able to get this done in the next several months.

And finally, on 23, there is a timetable which tells you, at least in theory, it's all doable. And now we'll have to see in the practical sense, you know, if we can follow that time frame and get everything in place.

So I guess my summary of all of this is the Patient Protection, Affordability Act has authorized the establishment of a Cures Accelerating Network.

The focus is very important and of course could produce tremendous value for the country in terms of moving — embodying translational medicine and therapeutics, and moving your basic science tremendous advances to the benefit of patients and their families.

And then the charge really is how do we recommend, through the SMRB to the NIH, that this gets operationalized, and what are the kind of upsides and pitfalls that we need to be aware of in getting this done.

And hopefully this can all get done and debated and agreed upon by the SMRB sometime towards the end of the year.

So, Norm, I think that's my high-level summary. And I guess I wanted to keep it short in the hope that there would be questions of clarification. So, thank you.

CHAIR AUGUSTINE: Arthur, thank you very much. And again, thank you for agreeing to take on this task. I think we would all agree it's a very important subject. And it's also an area that I think that it's possible probably to make some very constructive recommendations.

One thing I neglected to do at the beginning, that I intended to do, was to welcome Dr. Harold Varmus to our group. And Harold, we're awfully happy to have you here and participating and we thank you.

DR. VARMUS: Thank you, Norm.

CHAIR AUGUSTINE: Let's see, at this point I would just observe that the task of this new working group — I'd just like to emphasize, I guess, what Arthur said about the importance of tying together the work of

industry, academia and government, particularly the NIH and the FDA in the latter category. Certainly the group will want to focus on that.

Before we turn to the general discussion where those of you who are members would like to make comments, I do want to ask Dr. Collins, although he's told us before at our last meeting generally what he has hoped to see here, Francis, if there's anything though that you would like to say, I would invite you to do that.

DR. COLLINS: Thanks, Norm. I think Arthur has nicely summarized the opportunity here. And I think it really is an opportunity.

We are in a circumstance of where the potential for expanding NIH's role in therapeutic development is coming along in interesting ways that relates to the discovery of a much longer list of potential drug targets than we have known about in the past.

And we also have a number of resources that have come into being in the last few years that could contribute quite usefully to this, such as the molecular library facilities that put in the hands of academic investigators high-throughput screening capabilities that didn't use to be acceptable.

And we have other programs that are more involved in the pre-clinical phase, such as the TRND program and the RAID program, and now the Cures Acceleration Network, which the House of Representatives in their mark-up of our appropriations bill for FY11 did include appropriation, up to $50,000,000 in FY11 for CAN.

So we don't know yet what the Senate may decide to do. They're supposedly going to do something this week, but it does look as if it's quite possible there will be funds made available for this new and rather flexible grant mechanism that is in the Affordability Act.

So we are excited about that potential but wanted to be sure we do it right, and wanting to be sure that we also tie this in together effectively with the clinical trial capabilities that exist in the CTSAs, and in, of course, that wonderful clinical center that this SMRB has been debating about for the last few months, in terms of how to make best use of its resources.

So as you've heard, and as you can see in the charge, what I'm hoping is the SMRB, at a high level, not going into very much of the nitty gritty details, but a high level to give any advice about how NIH could best organize these various components of a therapeutic development program, not in competition with the private sector, but in partnership, figuring out where the gaps are in that pipeline that NIH could potentially

fill, both for rare diseases and neglected diseases, and for neglected targets, maybe even for common diseases, one of the intentions of the CAN bill.

So I do appreciate Arthur, especially, your willingness to, as euphemistically was described, volunteer, to take on the leadership of this group.

I think you did a beautiful job with the clinical center discussion, which I know is not quite complete yet, but it does intersect with this in a very obvious way. And so it's helpful to have that continuity.

And I personally want to thank you for your willingness to do this, even though I know this is a pretty tight timetable. That's all I want to say.

CHAIR AUGUSTINE: Okay, well thank you for those comments. And you used the word opportunity, and that was the word that came to my mind too when I read the charter, or the task statement.

Let's open the discussion to the members of the committee. There are quite a few of us, so we'll just sort of let whoever happens to be speak first proceed and we'll try not to overlap too badly here. So the floor is open.

DR. VARMUS: Francis, this is Harold.

DR. COLLINS: Yes.

DR. VARMUS: Since this is a management board, I'd like to know what your thoughts are at the moment about two issues.

One is how we distinguish activities undertaken under CAN from things that are already being done in therapeutic development, which, as you know, a pretty broad spectrum of things being done. This is not a novel activity at the NIH.

Secondly, how do you foresee managing the tasks carried out under CAN with respect to the institutes. That is, obviously, we have strong scientific staff that manage programs of this kind already. The OD is not characterized by that kind of strength. So at what point will there be assignments of tasks and delegations of efforts that you believe are appropriate to undertake to the institutes.

DR. COLLINS: Well, a very appropriate question. And obviously, this has some similarities to things that have been done within the Common Fund, where much of the scientific expertise has existed and continues to

exist in the institutes. But having a function, an OD to try to pull that together, which was the intention of the Common Fund, turns out to be pretty useful.

I certainly agree with you. There is a fair amount of expertise, particularly in the larger institutes like NCI, like NHLBI, particularly like NIAID.

But some of the smaller institutes really have not had the capacity to get very engaged in the therapeutic arena. And part of the goal here is to try to make that possible because many of them are also responsible for investigating therapeutics for diseases that are otherwise not going to get much attention.

I think probably, Harold, there's a parallel pathway here that needs to be getting underway, now that it looks like CAN actually is going to happen. And I'm not sure the SMRB needs to get down into that level of granularity about how we make the most of the staff expertise that exists in the institutes. But it will need to happen.

We had a retreat before you arrived, back on April 29th, of all the institute directors, one of our leadership forum. And we spent the whole day talking about this very topic and out of that came some pretty good suggestions.

And I'm glad to sit down with you and go through, in terms of the ways in which we might try to make the most of the institute capabilities here.

And of course, CAN offers some new grant-making mechanisms, including some DARPA flexibilities, that NIH has not previously had. And that's going to be a useful part of it.

But, obviously, this has to be done in a fashion where there's the competition and there's peer review, and we figure out which particular therapeutic development projects have the greatest merit before we decide which ones are going to get funded.

DR. KELLY: Francis, Tom Kelly. Related to Harold's question, I noticed in the packet that Amy sent me that in the legislation that established CAN, there's a twenty-four-member board that's supposed to be appointed to advise you about CAN.

And I'm curious as to how — I know you want all the advice you can possibly get, but how will that — is that going to be established, and how will that relate to the SMRB's effort?

DR. COLLINS: So it is required to be established, but obviously will take some time to do so.

I am, by the way, attempting to identify someone with deep experience in pharmaceutical development to bring on to help get this program up and going, from a sort of NIH corporate fashion.

And one of the first tasks will be to try to identify the appropriate board members for this CAN board.

But, I doubt that that board will come into place until next spring some time, because of course we're now talking about things that the Senate and the House are potentially going to do.

But until we have a budget for FY 11, which is not going to happen until after the election, it will be difficult to actually do anything.

So I think this will actually dovetail reasonably well. But the SMRB's charge is to try at a high level to give advice about how to pull these components together by the end of this year.

And presumably, at least for the CAN part of what happens next, this board will then begin to step in.

But I also want to make it clear that, and I know this gives Arthur some heartburn, what I'm asking you all to do in this working group is not simply to look at the CAN part of this, but also to see how that intersects with other components like the high-throughput screening capabilities, like the clinical center and the CTSAs, like the relationship with the FDA, like the TRND program.

I think we have a lot of potential here, but the pieces aren't necessarily hooked together. And you could imagine there could be real impediments, mismatches that make the whole thing not function as efficiently as you would like.

DR. FAUCI: Francis, this is Tony. Just for clarity for the group, if you go to slide 18, and on the role of the NIH, a high-need cure is defined and they give the definition. `A' is pretty clear, the priority to diagnose, mitigate, prevent, et cetera.

The thing that might be a little bit blurry in the eyes of a lot of people, it says, for which the incentives of the commercial market are unlikely to result in as adequate or timely development.

It would seem that that would almost, you know, relate it a bit to what Harold brought up. Veer towards what you mentioned, that maybe there are things that are really important but coming out of, well, for a better word, small institutes, where they haven't had the resources to jumpstart the road towards a product.

I mean, if you look at some of the things that some of the bigger institutes that are involved in, like for myself, vaccine for HIV, I mean, that certainly is a high-need, quote, cure prevention. But there's a lot of activity going on there.

I would see maybe less of that being one of the objects, and more of something that really has been neglected, or do you think it's going to over — it's going to encompass both?

To what level would neglected efforts be addressed, as opposed to efforts that are major, that there's a lot of input from the institutes, from the industry, but still it's a very high-need objective?

DR. COLLINS: So I certainly would say whatever we decide to do here should not interfere with effective translational work that's already going on within the institutes, whether it's HIV vaccine, or whether it's things that NCI is doing in their experimental therapeutics program called NExT.

The idea here is to put together a pipeline, which will provide capacity for those that don't currently have it, or aren't happy with what they have.

This is not supposed to become some monolithic enterprise that swallows up all of the other excellent therapeutic work that's going on.

In terms of the need here, it is going to be therefore a couple kinds of needs. One is, is it something that the private sector is already doing effectively. Well, then probably NIH wouldn't necessarily be plunging in on that anyway, unless there was a call for a partnership.

And then if the private sector is not working on something, but one of the other NIH institutes is already poised to do that, more power to them. We would not want to get in the way of that.

I'm really thinking of this more as filling in what I think is a very long list of other needs that are not currently being met by some of the smaller institutes or the private sector, but where new drug targets have been identified, new possibilities are there, and everything is being rate limited by the absence of a coordinated pipeline.

DR. SNYDER: This is Sol. In slide 18, one of the bullets says two things for which the economic incentives in private industry aren't present, which suggests that we're dealing only with infectious diseases.

But I suspect also another big need for big disease is for when big pharma isn't willing to take risk, and little biotech companies also don't take risk because in the present economic environment — and venture

capitalists won't even fund a start-up company for a really innovative idea because they want to be able to cash out in a couple of years.

So I think that should, through CAN, be interested also in big diseases like schizophrenia and depression, but dealing with targets that could be very transformative, but for which the current private sector is just too risk averse.

DR. COLLINS: So, Sol, I agree with that. And I think basically that is incorporated in the lack of economic incentive, because at least from the company's perspective, despite the fact these are diseases that affect very large numbers of people, the economic practice, that is drugs available and you know as well as I do how hard that is to (Telephone interference.) is apparently insufficient to motivate the type of therapeutic efforts that we're hoping to see.

And so I think in assessing the NIH work (Telephone interference.)

CHAIR AUGUSTINE: Are there any other questions or comments by the members?

DR. RUBENSTEIN: Norm, this is Arthur.

CHAIR AUGUSTINE: Yes.

DR. RUBENSTEIN: One of the key issues seems to me the intersection with the FDA. And I'd just like to, for the benefit of the whole group, get Francis or yes, mainly Francis, I think would help us, how this may play out because it seems that it's thought about carefully in the thing, but not how we would do that practically, seeing they're not involved in the work group.

DR. COLLINS: So we have a newly formed FDA NIH Leadership Council that Commissioner Hamburg and I co-chair, which is about to organize its first face to face meeting, and which will include leadership of a senior sort from both organizations.

(Telephone interference.)

CHAIR AUGUSTINE: Francis, you're breaking up. Is anyone else hearing him all right?

DR. RUBENSTEIN: No, I don't think we can hear —

DR. PATTERSON: I think everybody's getting the same thing.

DR. SNYDER: Yes, I can't hear anything he says actually.

CHAIR AUGUSTINE: Francis started strong, but then it petered out. Dr. Collins are you there? I think we've lost him.

It's a good question. And it, certainly, the NIH and FDA has started some additional initiatives, as he started to describe, that are getting underway that we'll want to recognize.

But what I think we'll have to do is save his answer to that question to another session.

DR. RUBENSTEIN: Okay.

CHAIR AUGUSTINE: But does anybody else have a question for Arthur in particular, or for anybody?

(No response.)

And hearing none, what I think we should do, since we're right on schedule here, is turn to the public comment part of our meeting.

We've allotted fifteen minutes for pubic comment, which means that there won't be an awful lot of people who are able to participate, so we would ask you to hold your comments to like two to three minutes, if you would.

We welcome correspondence either by the web, e-mail, snail mail, or whatever, as long as you would like to make. And the comments we've received on other issues upon which we've worked have been most helpful.

So for those that we do have time this morning, let me ask the operator here to start that section of the discussion.

(Pause.)

Let's see, have we lost our operator?

THE OPERATOR: Sorry, sir. Were you ready to take questions over the phone?

CHAIR AUGUSTINE: We are, please.

THE OPERATOR: Thank you. If you would like to ask a question, please press star 1. If you have muted your phone line, please unmute and record your first and last name, as it is required to introduce your question. To withdraw your request, press star 2.

Once again, if you would like to ask a question, please press star 1. One moment please.

(Pause.)

Once again, if you would like to ask a question, please press star one. One moment.

(Pause.)

At this time there are no questions.

CHAIR AUGUSTINE: All right, then we can move ahead. Dr. Collins, are you back?

(No response.)

I guess not. Has anyone joined this call, any of the members joined the call that were not present for the roll call?

DR. BRIGGS: This is Josie Briggs. I was a little late, sorry.

CHAIR AUGUSTINE: We're glad to have you here. Thank you.

CHAIR AUGUSTINE: Gail, are you here now?

(No response.)

Okay. Then she's either not able to respond, or she's not there. Did any of the members on the phone have any additional business they would like to raise at this point?

DR. ROPER: Norm, this is Bill Roper. I just would ask Arthur perhaps, or Amy to say one more time what the next steps are and how we're going to proceed with this working group, please.

DR. RUBENSTEIN: Amy — it's actually described in the last tab. So it's —

DR. ROPER: Yes, I see the chart. It's page —

DR. RUBENSTEIN: Twenty-three. So if you turn to that, maybe we could ask Amy to kind of outline, seeing she's done all this work in a beautiful way, you know, how she thinks we'll be able to accomplish our goals. Amy?

DR. PATTERSON: Okay, thanks, Art, thank you. So Bill, if you have the charts in front of you, just had the fifth full SMRB call today.

We're having, after this, a thirty minute call with the TMAT work group members. So we'll ask those of you who are still available to call in on a separate call-in number just to talk in further detail about our next step.

But the main milestones are we are planning for a roundtable consultation that will include academic health centers that have started to engage more deeply in drug development efforts, and will also include industry and venture capital at a September roundtable that will be part of the regularly scheduled full SMRB meeting. That will be on September 15th. The full board meets September 14th through 15th.

And we'll probably have one teleconference, we're trying to schedule that now, between this meeting and the September meeting to flesh out that agenda.

We have a draft agenda developed that we'll be sharing with you, and welcome input, most of which will probably be done via e-mail, given the difficulties of scheduling calls in August. But we'll do our best.

Then we envision a couple of teleconference work group calls and some panel discussions or briefings that would be done by telephone. As you know, Bill, we've done some of those with the various SMRB work groups and those have worked pretty well.

And then you're out for a full board meeting in November. And that will be convened again by teleconference to give the full board an update on the group's progress, and an opportunity to ask questions.

We'll be developing the written report for the TMAT group in parallel with this ongoing process.

And then between November and December we'll have a couple of teleconferences of the work group, and then wrap up in mid-December with a draft report for the full board.

CHAIR AUGUSTINE: I might just — Amy, were you done?

DR. PATTERSON: Yes, Norm.

CHAIR AUGUSTINE: Okay. I might just note that Dr. Patterson's comments that the schedule has been set up partly in recognition of the urgency of providing some guidance in a report, but partly to be sure that we comply with the law that set up the SMRB. And as she's described, it does that.

Does anyone else have any comments they would like to make?

DR. KELLY: Amy, if we have some suggestions for speakers for the work group or consultants for the work group, I guess we can just forward those to you.

DR. PATTERSON: Yes, absolutely.

DR. RUBENSTEIN: And I would encourage anyone who has any thoughts or comments or suggestions to send them to Amy because the more we can get in a early phase of time would be very helpful. So any thoughts after this meeting and comments would be welcomed.

CHAIR AUGUSTINE: Any other comments?

(No response.)

Hearing none, I think we've completed the agenda as planned. Let me thank you again, Arthur, for agreeing to take on this additional assignment here, and thank Dr. Patterson for her terrific work on putting everything together here in such an orderly fashion, and appreciate each of the member's involvement and your participation today. Once again, Harold, we're glad to have you aboard.

And with that, I think we can adjourn the meeting —

DR. RUBENSTEIN: And Norm, do you want just Amy to kind of just say again about the work group half hour, if you would just stress that Amy, what we're going to next.

DR. PATTERSON: Sure. So the TMAT work group members, if you could, we've provided a different call-in number. If you could, when we adjourn this call, hang up and just call in. We'll have a few moments to collect your thoughts and talk in some more detail about next steps for the work group activities.

Also, Norm, I just wanted to remind the group that at the September full board meeting on the 14th and 15th, not only will we have a roundtable consultation on the TMAT topic, but we have the group that's deliberating the potential merger, the substance use abuse and addiction work group, as well as Arthur's group looking at the clinical center will be presenting their final recommendations to the full board.

And we will be sending out in mid-August their full written report for the group to look at. So those are two important agenda items for the September meeting.

CHAIR AUGUSTINE: Thank you for that summary. Anything else anybody?

(No response.)

All right. Hearing none, again, the meeting is adjourned. We look forward to seeing you in September. And the members of the TMAT committee will continue on a separate call.

I hope everyone has a very good day. And those of you who are sitting without air conditioning, I hope you get that back in the next day or two anyway.

DR. FAUCI: But there — TMAT will start at 11:30? So, right after this, in other words. Just hang up and call in, is that what we're saying?

DR. PATTERSON: Right.

DR. FAUCI: Okay. Let's do that.

DR. PATTERSON: Okay.

DR. FAUCI: All right. Thanks, Norm.

CHAIR AUGUSTINE: Okay. You bet. You all take care.

(Whereupon, the above-entitled matter went off the record at 11:24 a.m.)