NATIONAL INSTITUTES OF HEALTH

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SCIENTIFIC MANAGEMENT REVIEW BOARD

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Wednesday
March 10, 2010

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The Scientific Management Review Board met in Conference Room 6 in Building 31, C Wing, NIH Campus, Bethesda, Maryland, at 8:00 a.m., Norman Augustine, Chair, presiding.

BOARD MEMBERS PRESENT:
NORMAN R. AUGUSTINE, Chair
JEREMY BERG, PhD
JOSEPHINE P. BRIGGS, MD
ANTHONY S. FAUCI, MD
THE HONORABLE DANIEL S. GOLDIN
RICHARD J. HODES, MD
STEPHEN I. KATZ, MD, PhD
THOMAS J. KELLY, MD, PhD
DEBORAH E. POWELL, MD*
GRIFFIN P. RODGERS, MD, MACP
WILLIAM L. ROPER, MD, MPH*
ARTHUR H. RUBENSTEIN, MBBCh
SOLOMON H. SNYDER, MD
LAWRENCE A. TABAK, DDS, PhD
A. EUGENE WASHINGTON, MD, Msc

EX-OFFICO MEMBERS PRESENT:
FRANCIS S. COLLINS, MD, PhD

DESIGNATED FEDERAL OFFICIAL:
AMY P. PATTERSON, MD, Executive Secretary

*Present via telephone

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P-R-O-C-E-E-D-I-N-G-S

(8:08 a.m.)

CHAIR AUGUSTINE: First of all, thanks so much for the enormous amount of effort everybody has been putting in since our last gathering. In that regard, I also want to thank the staff at NIH for the terrific support we've given and Amy particularly, to call attention to your terrific help trying to keep things on the track here.

We've got a fairly busy day, but what I would suggest we do, since we've not met that many times, is go around the table once and reintroduce ourselves, and I'll start out. I'm Norm Augustine, and I have the privilege of chairing this happy clan. Bill, do you want to -- I got you with your mouth full. I'm sorry.

DR. BRODY: I'm Bill Brody with the Salk Institute.

DR. BERG: Jeremy Berg. I'm Director of the National Institute of General

Medical Sciences.

DR. RAINEY: I'm Hal Rainey. Now am I on the air?

CHAIR AUGUSTINE: You're on the air. Start again.

DR. RAINEY: I'm Hal Rainey. I'm from the School of Public and International Affairs at the University of Georgia. I'm here to talk about organizational change.

DR. COLLINS: I'm Francis Collins, Director of the National Institutes of Health. I want to express my gratitude to all of you for the hard work that's gotten us this far and appreciation for what yet is to come.

DR. SNYDER: I'm Sol Snyder from the Neuroscience Department at Johns Hopkins.

DR. TABAK: Good morning, Larry Tabak. I'm Director of the National Institute of Dental and Craniofacial Research.

DR. RODGERS: Good morning. I'm Griffin Rodgers, Director of the National Institute of Diabetes, Digestive and Kidney

Diseases.

DR. KELLY: I'm Tom Kelly, Director of Sloan Kettering Institute.

DR. KATZ: I'm Steve Katz, Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

DR. WASHINGTON: I'm Gene Washington, Vice Chancellor of Health Sciences, University of California, Los Angeles.

HON. GOLDIN: Dan Goldin, Chairman of the Intellisis Corporation.

DR. FAUCI: Tony Fauci, Director of the National Institute of Allergy and Infectious Diseases.

DR. HODES: Richard Hodes, Director of the National Institute on Aging.

DR. RUBENSTEIN: Arthur Rubenstein, Dean and Executive Vice President for the Health System at the University of Pennsylvania.

DR. PATTERSON: Amy Patterson, NIH.

Thank you.

CHAIR AUGUSTINE: Most important of all. Well, again, welcome, and we have three members who were not able to be here in person today, which, given the demands on all of the members of this Board, is sort of sensational in terms of attendance, I think. It shows a degree of commitment almost above and beyond.

Huda Zoghbi will not be able to be with us today. Deborah Powell will join us by telephone, and is Dr. Powell on the phone now? Or I guess that will come later. Where is the phone? I don't even see the phone here.

Oh, the voice of God. Okay. Right. Bill Roper will join us by phone, and Susan Shurin will join us by phone, so we're very close to perfect attendance if you include cyberspace.

Let's see. Just kind of as a reminder why we're all here and how we got here, particularly for those who joined us since the beginning, you will recall that the

Congress passed some legislation, rather specific legislation, in fact, to create an independent group to advise the Director of NIH on organizational issues and also ultimately to advise the Congress on anything that we might find that we think would improve the quality of the research, the efficiency of the organization, or any other matter that we might see dealing with basically the organization of the science that's pursued here.

And as you will recall we decided to pursue three issues. We set up task forces to do each of those three. One will be probably a rather continuing undertaking, and the good news to the chairs of each of those is when you get done with this immediate term, we'll rotate the chairs, and so that's a bit of incentive here.

You will recall we were taking the general look at organizational principles that could kind of underlie the work we do in the

future. That group we've also asked to help us identify some of the areas that we ought to look into in the future when we finish these two specific tasks that we've taken on, and I would ask also in support of that that you be thinking about areas that you believe do deserve further attention on our part.

Each of the groups I think has made a good deal of progress. Today we're not in a position to make decisions yet, both because we have not complied with the legislation in terms of what we have to do before making recommendations. On the other hand, we, I think, are beginning to converge on some ideas, and we'll hear about that as we go on.

We do have a task to get out of the way here. That is I hope you've all seen the minutes, which are about the finest set of minutes I think I've ever seen in my life, and they've been reviewed by Dr. Zoghbi, Dr. Hodes, and myself, and if anyone would care to

move approval of those minutes, that would be helpful.

PARTICIPANT: So moved.

PARTICIPANT: So moved.

CHAIR AUGUSTINE: Okay. I'll take one of those as a second. All those in favor?

(Chorus of ayes.)

CHAIR AUGUSTINE: Opposed? All right. Thank you. Let's see. One of the things that we are required to do at each meeting to keep ourselves out of the big house, so to speak, is get an update on conflicts of interest, and so, Amy, if you don't mind doing that for us.

DR. PATTERSON: As has become apparent by now, this is a ritual that we go through at every meeting, and so it's my duty and pleasure to remind you that as members of this Committee you are special government employees and, therefore, subject to the rules of conduct that apply to government employees. You are not, Mr. Rainey, but we are -- Dr.

Rainey. We're very glad to have you here, though.

These rules and regulations are explained in a report entitled "The Standards of Ethical Conduct for Employees of the Executive Branch," and you each received a copy of this document when you were appointed to the Committee, and I trust you've memorized it by now.

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

Before every meeting, you provide us with a lot of information about your personal, professional, and financial interests, and we use this information as the basis for determining whether you have any

real, potential, or even apparent conflict of interest that could compromise your ability to be objective in giving advice during the activities of this Board.

If such conflicts are identified, we either issue a waiver or recuse you from a particular part of the meeting, and we usually waive conflicts of interest for general matters because we believe that your interests will not impede your ability to be objective regarding those matters.

That said, we also rely to a great degree on you being attentive during the meetings and being aware of the possibility of an issue arising during the course of the discussion that may present an issue or appear to affect your interest in a specific way.

And, again, as always, we ask if this happens during the course of the meeting that you let me know, and we can talk about whether you need to be recused from the discussion, and I think that's it.

CHAIR AUGUSTINE: Okay. Does anybody have any questions they'd like to ask on the subject? I might just note that the NIH has certainly done a thorough review. It looks like we're all in good shape at this point.

Just as an aside for a bit of amusement to begin with, as evidence of the thoroughness of the review, not unique to NIH, but I do a lot of work with the government, and so when I left my position at Lockheed Martin I sold all my stocks so I just wouldn't have that hanging over my head except for one share, which is share number one of Lockheed Martin when the company was formed.

It's got my signature approving the issuance of it, and I'm not about to sell that. It's framed on the wall at home, and I can't tell you how much money it's cost government lawyers in the various departments because of this one share, which I will not sell, and it's a real problem.

My wife says the dividends are 72 cents a quarter, and Uncle Sam takes about a third of that, I guess, and it costs her, I think -- what is postage, 44 cents, to deposit it now, so it's a real loser all the way around. But, anyway, I cite that to show you the thoroughness of the work that's done by these reviews.

We do have -- as you heard from Dr. Rainey, we're going to have a presentation on some organizational change principles and experiences, and I understand that several members of one of the working groups have actually had the chance to visit with you, and they were extremely impressed and thought it would be good for us all to hear this, so that's something we'll be doing.

As you heard, Dr. Rainey is the Alumni Foundation Distinguished Professor at the Department of Public Administration and Policy in the School of Public and International Affairs -- that's a real title -

- at the University of Georgia. He is well known in the field, and I think it'll be to our benefit to get some of your review, so, Hal, thank you for coming.

Also during this meeting, as always, we'll seek views from stakeholders. If the first -- and we want to welcome those who are our guests this morning. We do want to hear from you, and there's a sign-up sheet outside, and we'll take people in the order that they signed up.

We have two periods during the day for the public to make comments. If you've not signed up or there's time available during the periods we've set aside, we'd certainly welcome your comments. If there is not time enough for everyone to speak, we do welcome written inputs, either on the -- electronically or by regular mail.

The -- I think that covers most of what I wanted to mention, and I guess I would just say that the -- as we do the briefings, I

think it'll be most efficient if we let the briefer go through the briefing and interrupt only if there is a matter of understanding. If there's something that you just don't understand, you can't benefit from the briefing without it, then by all means interrupt, but please keep a list of questions.

We've allowed a lot of time for questions and discussion, a lot of time, so if you'll have that list handy, that would be terrific. We'll try that, if that's okay. Does anybody prefer we not do that approach?

Okay, so before we go ahead, Francis, I wanted to give you a chance to elaborate anything else you might want to say on any topic.

DR. COLLINS: Well, thanks, Norm. I'm really happy to have a chance to spend the day with you all, and I will be here, except for one brief interval where I have to jump out for something at 1:00.

I have been getting regular briefings from the chairs of the sub-groups and from you, Norm, and it's been very instructive to learn all the way along about exactly the directions you're going in, and the level of communication has been extremely gratifying. I want to thank Amy again for being such a capable staff lead on this important enterprise.

I'm looking forward very much to hearing the status of where the three groups have gotten to today and hearing the discussion about their deliberations, recognizing that we are still not at the point of actually arriving at concrete conclusions, but that a lot of work has been done and that directions are being defined.

And, again, I want to thank the Institute Directors who have been working hard as part of this effort, as well, who are represented around the table. I think this has been a really effective collaborative

dynamic, and it's going to put us in a very good position, I think, for trying to make the right decisions about this extremely complex organization.

And it is an extremely complex organization, as I can vouch for now, having tried to get my head around all of the issues that are presently on the plate since I arrived in August, but I think by the end of today I hope we'll have a somewhat clearer sense of where we might want to go with these important issues.

Obviously, as we get through this phase and begin to think about where SMRB ought to go next, we should contemplate what other topics would be particularly appropriate. Now, I don't think we need to do that today, but pretty soon. As you are coming forward with this first set of recommendations, we might begin to imagine what might be some other things to take on.

So, again, thank you to everybody.

I really appreciate enormously the amount of time that's gone into this from busy people. Sol was saying this morning that he wasn't quite clear when he was first asked to do this exactly how much time was going to be involved with this requirement of having five meetings before you can decide anything.

That kind of has put a burden on all of you, but hopefully it will result in a very nuanced and sophisticated set of recommendations. With the talent represented around the table, I'm sure that will be the case.

CHAIR AUGUSTINE: Francis, thank you very much, and with regard to the five meetings, as we begin to converge on our findings, I'm told by counsel that those meetings -- we wouldn't want to overdo it, but if we wanted to, one of them could be done telephonically, but publicly, so the public could participate, or listen, I guess, is the way to put it, and we may want to do that.

We'll give you ample notice.

The only reason we would do that is somebody was really ready to float their findings. There's no sense leaving the organizations wondering what's going on in suspended animation while we wait for another meeting. So that's just an alert that we might have a telephonic meeting.

So why don't we turn to the first briefing. We've allowed 45 minutes for each of the reports to be made, plus 45 minutes for each of them for discussion, so, as I said, I think that will be ample time.

The first one on the agenda is "Deliberating Organizational Change and Effectiveness," that Bill has been heading, so, Bill, the floor is yours.

DR. BRODY: Thank you, Norm. I'm going to get mic'ed up, I think. Well, good morning. I will be making a presentation. In fact, some years ago I had the pleasure of introducing George Bush, Sr. when I was at

Johns Hopkins, who was in town to give a lecture, and it happened to be the last time the Orioles were in the playoffs, so it was obviously a long time ago.

And as we were going over to the auditorium I said, "President Bush." I said, "You can appreciate that normally I'm sure we would have a standing room only crowed, but as a former baseball person yourself, you probably understand that, with the Orioles in the playoffs, we might have a limited crowd." He said, "No problem."

So we got there, and the auditorium was packed. It was standing room only, and I introduced President Bush. Then he got up, and he said, "I asked Dr. Brody what to speak about, and Dr. Brody said speak about ten minutes. There's a playoff game on."

So I'm going to speak about a little bit longer than ten minutes, for which I apologize profusely, but our group has been

looking at trying to understand the parameters on which we might contemplate organizational change.

And the background for this, obviously, is if you ask ten people about the organizational -- organization of the NIH, they said, "Well, this is not the right organizational structure," and you would get ten different answers, completely different answers, about how the NIH ought to be reorganized, and I always use this phrase, coming from academic institutions where organizational change is an anathema.

People love innovation, but they hate change. Innovation is something that affects somebody else, but change is something that affects you. And so, as we go through this, we'll give you some background and, first of all, to introduce our committee members, all of whom participated with great effort to try to understand how to get our hands around what I think is a very difficult

problem and yet one, I think, that deserves a lot of thoughtful consideration.

So what we wanted to articulate is what are the circumstances for which the Agency might contemplate organizational change and the principles which would guide that change. And, obviously, this is a work in progress, and as we go through, our goal really is to try to help the Director, Dr. Collins, as he contemplates making different changes in the structure or function of the NIH and how this might occur.

I think that we got briefed by the NIH Director, by the former NIH Directors, and a number of distinguished scientific and public leaders representing different groups of the constituents of the NIH, and those people included the list that's shown here -- I won't go through all the different people -- including Hal Rainey, who will be speaking to us later this afternoon.

And I think what we got from that

was a, I think, a familiar set of themes which are no surprise to those of us who are familiar with the National Institutes of Health and biomedical research; resounding support for the NIH and what it does, and appreciation of the complexity of the mission going from basic science to health.

And I think really the overarching theme, no surprise again, is just the changing nature of science and the need for increased collaborations, not only within the NIH but across agencies and not only between agencies but intramural and extramural, as well as now internationally as science and technology and health become global issues.

And we did hear a lot of discussion about the need for balancing fundamental basic science and translational research and some discussion of the Valley of Death, the fact that there are probably things that are sitting on laboratory benches that maybe could see the light of day, but, for a

host of reasons, are not getting through there.

But it's not my purpose this morning to really talk about specifics except to say that I think people are viewing the rapid change in the process of discovery and innovation and the issues impacting healthcare as requiring some nimbleness on the part of the National Institutes of Health as it looks forward to this.

So, the context for our discussions really is that, as difficult as change is to effect in an academic organization, I think the National Institutes of Health is even more complicated because it has a much larger external constituency including the Congress, obviously, patient groups, and the general public, as well as the scientific, medical, and public health community which it serves, and winding your way through that in order to understand how to effect change is a rather complicated process.

If you look at the org chart of the NIH, it's alphabet soup. Please don't ask me to -- I wonder, Francis, if you know all -- you probably know all of the acronyms. I always ask for an LOA when we start, a list of acronyms.

And I think the NIH is organized both structurally in terms of the institutes which you see at the bottom, institutes and centers, and functionally by putting together various committees, working groups, and task forces.

And, as I understand it, most of these committees are not funded by a central mechanism, but they're funded by institutes or centers or laboratories getting together across institutes and agreeing to put support into a particular initiative that is cross-cutting. But, it is funding these cross-cutting initiatives that has been one of the more complicated tasks at a place like the National Institutes of Health with its

enormous decentralization.

And, I should comment that there was a report in 2003 by the National Research Council on the National Institutes of Health, which I won't read this. Did we hand out copies of the slides? Yes.

So, you can read this, but I think it just echoes the thing that I said earlier, that if you were redesigning the NIH for some new country that wanted to start an NIH, you might come up with a different organizational structure. On the other hand, if you want to change it, the one that you have, it's a much more complicated process.

And I think, again, there have been some alterations in the budgetary mechanism for the NIH, which I'll talk about very shortly and superficially, which have, I think, allowed the NIH Director to deal with some of the issues, particularly with cross-cutting scientific or health initiatives that fall within the purview of multiple institutes

and centers, but not enough within one to get the work done by one particular institute.

So, strategies for functional integration really is try to figure out what are the platforms for integrating staff. I recall when I was on the advisory committee to the Director seven years ago under Harold Varmus, the issue was how to fund bioinformatics, which was an important emerging field, which now, of course, is disseminated across all of biomedical science, but at that time it was complicated to figure out how to fund that cross-cutting initiative, because although each of the institutes would see a need for it, they were not necessarily willing to put up sufficient funds to make it happen.

And so it required, I guess, jaw boning mostly by the Director to convince people of the common good, which is not necessarily a bad thing, but in some cases it does require funds in order to get a certain

activation energy over the threshold for creating a new initiative.

And I think that you have within that several ways of providing integration, one of which has been to create new institutes, and the one that I'm most familiar with is biomedical engineering, biomedical imaging and bioengineering, again a cross-cutting scientific initiative that impacts multiple institutes and centers, but required through a variety of mechanisms support in and of itself for the technology.

And one could argue this could be done in a different way, but this is the way that it traditionally has occurred in the past, and I think as the National Research Council report looked at this and, again, our committee, it doesn't seem realistic to believe that the NIH can continue to grow by adding more institutes and centers. Not that it won't happen, but that that probably doesn't seem to be the ideal way to deal with

the new cross-cutting initiatives.

And, of course, underneath all of this, is testimony that we got from the former NIH Directors as to the complexity of the management task for the Director of the NIH when you have to deal with large numbers of entities. And, if you consider just recruiting new Institute Directors, on average, I don't know how many are open at any given time, but there are probably between three and half a dozen, at least, at any time.

So recruiting becomes an important and sometimes an all-consuming function for the NIH Director. So one of the questions to ponder as we go forward is how do we deal with new cross-cutting initiatives that either impact science or health and do that without necessarily forming new institutes.

So one of the things that has happened under the Reauthorization Bill of the NIH was creation of the NIH Common Fund, which did provide support, financial support, that

comes through the Office of the Director, which allows that person to coordinate with input from all of the constituents of the NIH, a series of these cross-cutting and trans-NIH programs.

And so, I won't comment further except to say that organizational change can also be encompassed or can be achieved -- rather, an organizational change can be achieved, rather than by structural reorganization, by functional change, and this is one, I think, excellent example.

And, a variety of these cross-cutting, integrative initiatives, again, these are the kinds of things where it requires a set of willing participants who step up and put together resources in order to make these things work, and the Obesity Research Task Force, for example, is one example. Another one is Neurosciences Initiative, again, very cross-cutting.

So, now what we looked at really

were the aspects of organizational change dealing with how one might do this and, again, talking about both structural change, where you change -- if you think about structural change, it's changing reporting relationships.

And I think in our society we have this view that if you have a problem, you reorganize, and I think if you look at, at least in the corporate world, sometimes that's successful, but oftentimes it's reorganizing the deck chairs but not necessarily changing the effectiveness of the organization.

And in the case of an academic institution, or, in this case, a governmental/academic institution, one can be entirely consumed by the process of organizational structural change and not then be able to keep your eye on the ball of achieving the mission for which you are tasked.

And I think that's an important thing to recognize, and I'm sure that the NIH

Director would not want to spend all of his or her time dealing with multiple constituents who are upset about a minor organizational change within the NIH, not that this doesn't happen every day, probably, Francis, but --

And so, the other -- the other opportunity is to do this in a functional way, which changes how people go about doing the work but doesn't necessarily require the same degree of energy and political maneuvering in order to effect the change.

I think a critical factor about change is the threshold for change, and I look at the threshold -- we looked at the threshold for change in really two ways.

One is if you are going to change something, there has got to be sufficient reason in order to make the change, and if it's not -- if there isn't sufficient reason, then it doesn't justify the time and energy for which one will have to devote in order to effect that change.

The second part of change, and maybe Hal will talk about this, is if you -- if you implement incremental change, once you do change process, whether you're changing jobs, buying a new house, moving into a -- moving houses or changing something in the workplace, things never go right when you start, and if you do incremental change, it's too easy for people to move back to where they were.

So think of it. You know, you want to -- you buy a house down the street, but you still have your old house, and when you see the new house, the roof leaks, so you move back into the old house. On the other hand, if you buy a house 3,000 miles away, it's kind of hard to move back to your old house when the roof leaks, so you've got to fix the roof.

So, the change really has to be sufficient. The need for change has to be sufficiently great to justify the energy to do

the change, but then the change itself has to be more than incremental change. Otherwise, the organization will shift back -- doing what it does into where it came back into the ground state.

So the activation energy and the magnitude of the change are important, and I sort of look at this. I talk about the Hurricane Katrina Effect. You know, Tulane was able to achieve substantial, substantive reorganization, both functional and structural, because it really had no choice. It had the so-called burning platform, and you hear people talking about that, and I think Hal will talk a little more about whether you need the burning platform and how that works.

Obviously, you need resources. Change is in some ways a revolution, and I say in a revolution you need three things. You need the banks, you need the police force, and then you need the schools.

So, you need the banks because you

have to put sufficient resources into funding the change. You need the police force in the sense that you have to have people who are driving the change and say, "This is something we really need to do." In this case, the police force is the power of persuasion, not the power of arms.

And education is because you have to really spend a lot of time bringing people up to speed as to why change is important, and so that says -- all of those things take an enormous amount of -- consume resources of one form or another.

So, what we looked at was what's the process for thinking about organizational change and effectiveness, and we started with a fundamental premise, which I hope is not that controversial, but basically the only defensible rationale for which we would contemplate organizational change at the NIH is to improve the Agency's ability to fulfill its mission.

And therein is a simple statement that is very complicated to interpret because how you measure the Agency's ability to fulfill its mission is a very complicated task. It's not like a business, where we can look at return on investment or profitability or market share.

We have many different metrics, and I know the NIH goes through a very elaborate process, which I have participated in the past, on evaluating its effectiveness across a variety of metrics, from scientific impact to health impact to economic return on investment, and more and more kinds of things, producing an educated workforce for health and science and so forth.

The NIH mission statement is science in the pursuit of fundamental knowledge about the nature and behavior of living systems, the application of that knowledge to extend healthy life and reduce the burdens of illness and disability, and I

think we understand the mission.

I think the people in the science community look at the NIH as the National Institutes of Science. They don't recognize that our mission is really to improve the health of the nation and the world, and so it's a much broader mission than one might want to look at necessarily, if you're based in a laboratory.

And it also has a mission to promote and enhance economic well being and ensure a high return on public investment in research, which also is important, somewhat more difficult to measure, and when you put all these things together and you say, "Okay, so we have to improve these things," it becomes a little bit complicated to translate that into a rationale for changing, as is being considered here, the organizational structure of two institutes, for example.

So, there are a set of guiding principles that we have thought about and

we'll talk about, and then steps and considerations into how you move about and sort of the underpinning attributes of the process. I hesitate to read this, but I guess I should have to at least summarize the guiding principles. Obviously, we want to strengthen the ability of the NIH to carry out its mission, and that mission is advancing science in the interest of improving public health.

We need to provide an environment that allows more effective collaboration, coordination, and interaction across disciplines, again to carry out the mission, to create synergies, to enhance the public understanding and the confidence and the support for science and the impact on public health, and to increase our operational efficiency and ensure a high return on public investment in biomedical research.

The three steps in the process are clearly to assess what is the need for change;

step two is what are the options for change, and then three is to navigate the complicated jungle of constituents, internal and external, political, sociological, and then to navigate the change and drive the change.

And I should say at the outset that irrespective of what this Board might want to do, any change that is going to be effectively implemented, whether it's structural or functional, needs the strong support and the full buy-in of the NIH Director and will require the time and effort of the NIH Director in order to implement that change.

Assessing the need for change, of course, are a whole different things. You can have a Hurricane Katrina Effect. It could be a budget crisis. It could be -- it could be an epidemic.

It could be a variety of different things that impact what is in the purview of the National Institutes of Health or the

country. It could be unaddressed scientific opportunities, changes in the landscape, and so forth.

All of these things drive the dynamism of institutes at the NIH and the organization, and some of these fall below the radar screen but are occurring on a daily basis, and some of them come periodically, as in the AIDS epidemic or the H1N1 pandemic.

Step two, then, is to evaluate what are your options for change, and really, I think most important, is to look at the risk-benefit. Is the benefit of affecting some kind of change worth the risk of taking it on? And, the risk could be reputational risk, scientific risk, organizational risk.

It could be just the time that's required to invest in that process, and again we talk about, unless -- there should be some risk-benefit. The reward should justify the investment in time and effort.

I always say that people only have

so many attention units to focus on things, and if you divert the attention of key people within the NIH on an issue which is not fundamental to its carrying out its mission, they can get so bogged down in it that it's hard to carry out the other parts of the mission. On the other hand, there may be things that come along that are really critically important and justify the full time and attention of the key leadership of the NIH.

And then, of course, you have to identify the broader implications of each option, and I think this is where an organization like the National Institutes of Health is complicated because we have many constituents with which to deal.

And then, there's the spectrum of options from merging selected scientific programs, creating blueprints that are cross-cutting, again, putting together functional groups. We could merge existing institutes or

centers to encompass a current mission, or we could merge existing institutes and centers to create a new institute or center which has a new mission that transcends the center, that transcends the mission of the individual institutes or centers.

So, there's a spectrum from functional organization which is loose, to functional organization which is tight, to a full merger or creation of an institute.

And across that, again, it just emphasizes that there is not -- there is not a broad demarcation between structural and functional change. It's really a dynamic -- a dynamic process and could start with functional initiatives, and it could end up with a structural or significant organizational change.

Nothing in this, of course, talks really about the interest or willingness of the Congress or the public to come in and sort of dictate new structural changes for the

National Institutes of Health, and I think there is a view from external constituents that the way to get their particular initiative funded is to go to the Congress and get a new institute created.

And I think our committee would say that those days, although constituents may still want to do that and Congress may be persuaded, that this is probably not something that our committee -- I'm speaking for the committee without actually having a frank discussion of this or a vote, but I think this is something the committee would not think is a particularly good idea to the NIH.

The large number of institutes and centers has sort of gotten to a point of vanishing returns, in terms of its ability to help the NIH carry out its mission, but I'm speaking for myself, not so much for the committee.

Step three, then, is to begin to implement, navigate, evaluate the change and

development, and implement these plans, the operational implementation, and, again, every change process requires a champion.

It requires supporters, so any change that's going to take place would have to have the support of the important constituents of the NIH, including this Board, and would have to be driven by a champion, either the Institute Director, the Director of the NIH, or one of the institute directors or somebody who is really charged with that, who has the authority and responsibility to carry out the change.

The ultimate success, of course, depends on transparency, communication, and accountability, easy words to write down, very difficult to effect, and I always go back to my experience in academia. When we were trying to implement something, people would say, "You haven't communicated with me," and what that meant was, "I heard what you said. I just didn't agree with it."

And so, rather than say, "I don't agree," you just say, "You never communicate. You're not communicating with me." It is -- it is a challenge because at any point in time you have constituent groups that can come in and say, you know, "We weren't consulted in this process," whether they were or weren't.

This is a very busy slide, which just kind of summarizes from starting from very high 30,000-foot principles to actually getting down at the bottom to the steps of change, assessing the need for change, evaluating the options for change, and implementing and evaluating change.

We are in the process of circulating a draft report, first to the full SMRB for review and feedback, and then we will discuss the report at the next meeting. At this point, I think I have been a little bit longer than I wanted to, but I think, Norm, we do have time for discussion.

CHAIR AUGUSTINE: We sure do, Bill.

Thank you and your group. I thought that was terrific. You pulled out some fundamentals that I think are in the back of a lot of people's minds that aren't always expressed as clearly. I thought it was helpful.

So let's open the floor to questions that people may have, and we have ample time, so feel free. Who wants to start out? Okay, please, Art.

DR. RUBENSTEIN: Thank you so much.

CHAIR AUGUSTINE: I'll tell you what. While -- okay.

DR. RUBENSTEIN: So I wanted to just say how much I appreciate your report, because I think many of us struggle with these issues, and I don't think I've seen it enunciated so clearly, and it would have implications, I think, for many of us. I appreciate that.

The question I have, when one talked about all these things from a theoretical and looking at the NIH in

specifics, I guess the question is, is there almost anything on the horizon, or have you thought about that, that would be worth all the effort to make a change, or should one just assume that things are working well enough, and the changes should be in the current structure and on the margin, rather than making fundamental structural change? It's a kind of a question I think comes to the heart of many of the things we're talking about, and I'd just be interested in your opinion about that.

DR. BRODY: Well, first of all, I think -- I won't -- I'll say a couple things, but probably some other members of the committee might want to chime in. I think we've had a discussion which ranges from complete optimism to complete pessimism.

One view is that if you can't -- if you really can't take on something like merging a couple of institutes, then the NIH, you know, will be kind of doomed to people

just adding more institutes and centers until some point it becomes overly top-heavy.

I do think that one of the things that we did not assess, but Norm has asked us to look at when we finish the initial report, is exactly what are the kinds of things that really need to be looked at in more detail for which some kind of significant change will be undertaken.

We, of course, look with great interest on the work of your subcommittee and also the one of Bill Roper's, to see how you get from 30,000 feet down to ground level. You know, as Yogi Berra, the famous baseball player, said, in theory, there's no difference between theory and practice. In practice, there is. You know, and I think that's where the rubber meets the road.

I think that absent -- and this is my view, but I know Dan -- in fact, Dan, you might want to comment, having been through this kind of change, significant change in a

government organization.

HON. GOLDIN: I was on the pessimistic side and just a general statement. When an organization exists too long with a fixed organizational structure, familiarity sets in, and a comfort sets in that takes the edge off pushing the boundaries, and at some point in time, one has to get out of their comfort zone and say, we need to do something.

And, my comment when I read this report was, as a report in and of itself, this is excellent. I didn't see a set of principles laid down this way, but what this doesn't deal with is this continuing level of comfort that takes the edge out, especially in an organization that does such critical research as the NIH, so you do need a changeover, and I was -- and there was the burning tree, burning bush. I can't remember, burning something.

Burning platform. Sometimes you need a burning platform, but sometimes one

might want to create a burning platform, not to take down the whole organization, but just cause a set of discussions to take place to kind of refresh.

You don't need revolution, but sometimes you need to at least turn over some issues to get that edge that makes an organization perform at its best, and it's very hard to figure out how to state that, and I'm going through the write-up that goes behind this to see if some words could be crafted to address that.

CHAIR AUGUSTINE: Jeremy?

DR. BERG: From my perspective, I think one of the implications of our discussion is that incremental change is relatively small changes, even if they are still substantial or likely to give you most of the pain and not necessarily all that much benefit.

So it's an urge to -- you know, if you're going to go through a significant

organizational change such as merging two institutes, it's worth taking the time to think bigger than that and think, you know, if we're going to do this, let's really do it at the broadest scope that will really change things significantly.

You're likely to get just about as much of moving people out of their comfort zone and push-back, but at the end of the day you will have accomplished something that will really make the NIH more well equipped to fulfill its mission.

HON. GOLDIN: I'd like to add another item that I thought was excellent in this, and when you go through change, you can't have organized confusion. You need guiding principles, and I'll give you the guiding principles that we used when I was at NASA.

There we really had some problems, and NASA had been trying to change, and I followed a prior Augustine report when I came

to NASA. Norm in, I think, 1990 asked for some changes at NASA.

But, I arrived at my confirmation hearing, and the senior senator from North Carolina looked at me, saying, you're going to go run this organization. Well, you have a few problems. And he started to list those.

The Hubble telescope is blind, and the Galileo spacecraft is deaf, and the shuttle is sitting on the launch pad with leaking hydrogen, helium, and the space station has gone for eight years, and the weather satellites are dead, and the hurricane season is coming, and the Ten Plagues are arriving, and they're slaying the first born, and it went on and on.

So, what we did at NASA is we underwent -- and I don't know if you have the stomach for this, Francis, but what we did was we set up a series of town hall meetings, rather than rushing in, and literally went to ten or 12 cities in America and invited

citizens to come in, and we got incredible feedback to build the public support that allowed us to do fundamental change that built an underpinning that the NASA leadership was able to go along with.

So, sometimes you can get the burning platform by generating it, and sometimes it happens to you, but it was very, very refreshing, and we brought in the people, the industry that supported it. We had a meeting with the CEOs, and people like Norm Augustine and his peers showed up. We had a lot of input and feedback.

So, you can change that and you can perform fundamental change, and the Congress could actually go along with it. So you don't need an outside force to cause it, and it really, in the end, Francis, comes from the Director. Feel the stress, but don't overreact.

So it can be done, and, by the way, what we ended up doing really helped, and

our measurement was we set up some guiding principles. We said failure shouldn't occur. If you had ten failures out of ten, you didn't succeed, and if you had ten successes out of ten, you didn't succeed, because you didn't try too hard.

So, we set a criteria that said one out of ten failures is acceptable. We also set some threshold criteria of how big things should be, because one of the problems we had at NASA is things got so big, it was hard to manage them. We broke it into smaller chunks, and at the bottom line we said, we're going to cut the cost of doing things.

So for 174 missions that we had, the average cost went from $600 million to $200 million, and out of 174 things, we had 11 failures. So it met one out of ten, and if you measure over a ten-year period and you just set simple criteria, you could actually get some feedback.

So you can, and the change itself

took three years to go implement from the time we started until the time we ended, but the key was things that Bill had on his charts that the committee prepared. You must have guiding principles, and you must have some metrics.

Otherwise, there is no feedback, and that has been one of the difficult dilemmas for the NIH. You could set guiding principles, but how do you set metrics? And, boy, I tell you, that's where the problem is going to occur in my mind for the NIH.

CHAIR AUGUSTINE: Very helpful comments. Were you going to add something?

DR. RUBENSTEIN: Yes, I just wanted to follow up, that it seems to me, that this issue of making a change in a crisis or where there is a burning platform is something that can happen relatively easily. Like you said with Katrina, of course, there is no options.

I think the problem is that with the NIH, most people think it's working pretty

well, and so I guess the whole question is when you start changing things that are working very well, you're always going to have the people resist it, because they think there is no reason to do this.

So my question is, is it worth any kind of energy and effort, or is there enough flexibility in the structure along the lines that you pointed out, Bill, that makes it reasonable just to continue under a strong Director with the tools that he has at this time?

DR. BRODY: I'm not going to answer that question directly. I think the answer to that question is that, ultimately, it's up to the NIH Director and working with the constituents. I think if you talk to the various constituents, you would hear, I think, broad support for the NIH except for, you know, if you talk to the scientists, they want more R01 funding, and if you talk to the disease groups, they want faster translation,

faster cures.

And so, everybody has some particular issues, but I think that there is not a sense, as there perhaps was with Congress and NASA, that this is an organization that's in trouble. I mean, I think this is held up with the great successes of the organization.

But, that said, I think the Director, and I'm not going to speak for Francis, but hearing from previous Directors have said, you know, there are continual issues that restrict the flexibility, and I think the Common Fund was one way around that, because money is a way to invest in programs if you have it coming through the Director's office that allows that flexibility.

You know, but one should always ask, are we getting the most effective utilization of our resources? Is the investment in XYZ the best way to make that investment? And if it isn't, and there is

substantial opportunities to do it better, then one ought to be continually looking at that. Continuous improvement is a good thing.

CHAIR AUGUSTINE: Francis?

DR. COLLINS: So, I think this is a very thoughtful presentation, Bill. My congratulations to you and your group for putting this together in such a comprehensive way, in terms of defining what the approach ought to be in a general sense.

I think your example of the Common Fund as a new entity at NIH that really has provided a lot of flexibilities is a good one, and I particularly have benefitted from Zerhouni's having championed that in order to make it possible to fund things that no single institute could sign up for and to avoid having to endlessly tin cup to try to achieve those kind of programs, which used to happen in a way that wasn't particularly enjoyable for anybody.

But, of course, the Common Fund

was also resistant. It became, and maybe still is, the most common reason for somebody whose grant didn't get funded to say, well, it's because of that thing. It used to be the Genome Project. It became the Common Fund, which was the source of all woes for R01 investigators.

And so, of course, any kind of organizational change requires this kind of stakeholder consultation, as you said, and communication, but there is always going to be feedback, no matter what the change is, no matter how sensible it is, no matter how much it's going to empower the organization, where people are going to say, no, don't do it.

So, in your general principles of consulting with stakeholders, did you sort of factor in some thinking about how much resistance should be considered as just so much that you really shouldn't go there? How do you -- how do you play that particular game so that you are consulting, but you're not

basically being paralyzed by the fact that there are always going to be objections to whatever you decide to try to do?

DR. BRODY: I think that's the art, the art of effecting change, and I think, again, I think Hal will have -- Hal Rainey will have some comments about examples of this.

I think it's -- you know, there are plenty of examples of people who tried to effect change and went up in smoke in the process, because they didn't assess the degree of resistance that would come about, or you effect change, and then the leader steps down, and the next person comes, and it's -- everything is reversed back.

So, again, I think it's a judgment call, and I think it goes back to this idea of a threshold. You don't have to have a burning platform, but you do have to have a sufficient reason to invest in change that you're willing to stake your reputation, your personal energy

and effort and that of the organization behind making the change, and it does require getting people out of their comfort zone.

You know, I think Norm Augustine can tell you lots of interesting stories in the Lockheed Martin merger and changes. I mean, it was a very tough time to go through, and then afterwards you ended up with a stronger organization.

It's an art. It's not a science, but I think that there is a sense that while people are happy with the NIH and things are going along well that there are always going to be opportunities, again, because of the changing nature of science or technology or health or political constraints, which will dictate really thinking about what things ought to be taken on, and I think this group can be an important sounding board to help and give you support for it, but if it's not something you in your heart believe needs to be done, it won't happen, I think.

CHAIR AUGUSTINE: Jeremy?

DR. BERG: Just to follow up on that, just from my own experiences with some changes within my institute. I think one very important ingredient is clarity of purpose. I mean, why are we doing this?

If you can't answer that question very crisply, then the push-back you will get will be paralyzing. If you can say, it's going to be challenging. There are going to be lots of changes, but at the end of the day, we'll get this -- you know, have new capabilities or get to a different place, then it's a different discussion.

CHAIR AUGUSTINE: Solomon?

DR. SNYDER: Yes, in continuation of that, did the committee go over specific problems at the NIH and relative importance of them to be changing? Like any organization they'll already discuss the issue -- that's the CEO -- the CEO for Johns Hopkins.

The CEO to Coke doesn't have any

of his own money. It's all spread out, so that's a key thing, but the other issues are, you know, like the CEO has too many different reports. Another issue I can think of is that so much money is wasted in the overhead for having 27 different institutes, and I can see we've done this via function.

So I was wondering whether the committee just took all these different kinds of things and tried to quantify them and just try and add them up and see if that, at the NIH, you know, warrants doing something.

DR. BRODY: We have not gotten to that level of granularity. I think at some point that might be something that our committee or another committee could look into. We were really charged with sort of the principles on which one would contemplate change.

I would like to get back to something you mentioned, Francis, with an example that has nothing to do with science,

but I was involved with an initiative in patient safety at my former my institution, and it turns out that hospitals are not particularly safe places, and yet, when we sat down with people to try to deal with either reducing infections or medication errors, we got enormous resistance, enormous resistance.

And, in the end, we adopted the mantra, what do patients expect? And patients expect zero infections. They expect zero medication errors, and it wasn't until we put that mantra out that we got alignment, and we didn't get a -- we didn't get willing participation all the time, but nobody could go against that thesis, and it allowed us to get infection rates from above average to near zero for indwelling catheters and allowed us to reduce medication errors substantially, but the process was dirty.

It was tough, but with that mantra, you know, you just -- nobody could mobilize resistance against you, and I think,

again, you know, when it comes to issues of the NIH, if we can frame them around public health and even -- we're doing the science in the interest of public health, and we need to change how we organize the science, or we need to do this.

I think you have a -- you have an imperative, perhaps, that gives you more credibility, but never assume that people want to change willingly, even when it's obvious that they should, and that goes back to this people love innovation, but they hate change.

CHAIR AUGUSTINE: I'd like -- did you want to come again, Art? You're good up here. Okay. I'd like to comment a little from my perspective, which obviously does not have to do with healthcare or health research, but as you talked, Bill, I was struck by how your principles just exactly fit the sort of things that I've lived through.

I've been struck -- I spent ten years in government and most of the rest of my

life in industry and in and out of academia on the edges here and there, and one of the things I've concluded is that the two toughest places to produce change are in government and academia, and if you think about it, that's what NIH combines. Francis, good luck.

So I think there is a great challenge there. I am also mindful of the studies that have been done, and in business it's easy to measure was change successful or not. You could look it up in the newspaper every morning.

The studies that have been done that I've seen show that about 80 percent of the mergers and acquisitions fail, not in the sense they all make things worse, but they either didn't make it better, which means they failed, or they did make it worse, which happens in a lot of cases, unfortunately, and, Hal, I suspect you'll talk about that.

I am also a believer that -- and, Art, you said this better than I can say it -

- but if it ain't broken, don't fix it, and that -- I think it's widely viewed that NIH ain't broken, but at the same time, it ain't perfect, either, and that's, I think, the narrow line. And, it may be that as you look going forward, you might have a much tougher set of requirements for creating new institutes than is your willingness to get rid of institutes that you already have.

One of the things, too, that I observed was that -- Dan, you spoke to this eloquently is that you do need a crisis to make really big change. It's very helpful, and in our case, the industry I was in, aerospace, the crisis was not of our own creating.

It was when the Soviet Union suddenly came to an end, and our industry lost 640,000 people in two-thirds of the companies in about five years. So the question was, who's going to survive? Even knowing that the odds were 80 percent against you, under those

circumstances, we combined 17 companies, I hope successfully, but it was a lot easier when you were looking up at the guillotine, and we were.

We also found that people who are positively impacted by change are much less vocal than people who are negatively impacted by change by orders of magnitude, so one has to weigh that when you listen to the rumbles. Sometimes you just have to work your way through it.

In that regard, we also found, at least in our business, we used to say there are three kind of people overall. We said there are bear catchers, there are bear skinners, and there are people who like to sit around the campfire and tell bear stories.

In this case, I think there are three kinds of people, one of whom thrive on change, new opportunity, exciting things to do. We were able to build a company we never could have built in normal times. It was a

fabulous opportunity.

And so, there are people that love that. Then there are the people who can tolerate it and say, this is the way it's going to be. Get with it. Then there are the people who just could never accept change, and the only solution I found with them is to encourage them to find some new position where there is no change, because they become a cancer in an organization.

You just can't keep people around like that. It's a sad conclusion, but I think it's in their interest as well as in the organization's interest. Those are a few of the things I've observed.

One of them that comes to mind, Bill, based on your talk, and I, too, am convinced that in various fields of science that cross-cutting science is going to be evermore important, and when you look at the total budget of NIH and you look at your budget for opportunities that you can

administer, is that --

I forgot what we call the fund. What is it? Common Fund. It's kind of minuscule in a world of cross-cutting technology in an organization this size. I guess, Bill, I'd like to get your view on that, maybe Francis's, as well. Maybe there is something that ought to be addressed.

But, lastly, I would certainly say from my perspective that if you were starting from a clean sheet of paper, I can't imagine an organization with 39 committees, 27 institutes and centers, and not much, with all due respect, authority at the central level to manage and allocate budget. I would guarantee you that organization would fail, which suggests maybe I shouldn't be sitting here.

I wouldn't think it would have a chance, and yet it's working so well. It's remarkable. Bill, would you want to comment on this notion that maybe the Common Fund deserves some mention?

DR. BRODY: Well, now, is the Common Fund, does it increase, Francis, or is it -- I thought it was going to go up.

DR. COLLINS: So, at the moment, as you point out, it's $568 million, so it's less than two percent of the overall NIH budget. It is authorized by the NIH Reauthorization Act to grow up to five percent, but the expectation has been that it would only grow faster than the rest of the NIH budget in years where the budget itself was better than the inflationary index, which has not been the case for a long time.

So, at the moment, the Common Fund pretty much travels in synch with the rest of the NIH budget, which means it stays at about that same percentage, 1.8 percent or thereabouts of the overall total. And I should say that there are certainly other cross-cutting initiatives, quite a lot of them that aren't paid for by the Common Fund, that are supported by other mechanisms.

The Neuroscience Blueprint was mentioned, for instance, as a place where 16 institutes have gotten together to support projects that no single one of them would have, and a variety of other programs that are voluntarily supported by institutes, the mouse knock-out project, for instance, where people just decided, this is important. We're going to pay for it.

Could you do more with the Common Fund if the funds were there? You bet. I mean, I've been this year -- because the churn in the Common Fund is pretty small. Even though it's $568 million, most of that goes for projects that are multi-year investments, some of them as much as ten years.

And so this year the amount of money that was actually available for new investments in the common fund was only about $20 million, so pretty modest, to say the least. That number will, by attrition of some of the existing projects, get larger.

Another thing that we're trying to do with the Common Fund is to support some of these high-risk, high-reward programs that encourage real out-of-the-box ideas and sort of be a counter to the concerns about the conservatism of peer reviews.

So the Pioneer Awards, for instance, the Transformative R01s, the New Innovators, those three programs are all paid for by the Common Fund and now occupy a third of the Common Fund dollars, and that seems to be a good investment, but, of course, that is a further limitation on other bold project-specific efforts that one might want to put into that part of what NIH is supporting.

People have suggested that maybe we should expand the Pioneers and the New Innovators and the Transformative R01s, and that would be very hard to go much further without basically consuming the entire Common Fund for that purpose, which would really limit the ability to do other kinds of bold

organized projects.

Again, I should say there's plenty of innovative efforts going on in the Institutes that support out-of-the-box ideas, and people should not assume that those three programs in the Common Fund are the only way that we're doing high-risk, high-reward research. That's certainly not true, but it is a delicate balance, obviously.

In the best of all worlds, we could certainly see the NIH budget overall arising substantially over where it was and the Common Fund, perhaps, rising disproportionately faster, but that's dependent up on the Congress, which in turn is dependent upon the economy, which is not a particularly lovely picture right now, to say the least.

CHAIR AUGUSTINE: Gene?

DR. WASHINGTON: Two comments. First, I'm a member of this group, and this report looks even more remarkable as you

present it than what it appeared to be as we engaged in the discussion, so as an academician --

DR. BRODY: I don't know if that's good or bad.

DR. WASHINGTON: That's good. That's good.

DR. BRODY: Thank you, Gene.

DR. WASHINGTON: And as an academician, I think about publication, so even though I'm sure to the expert this would be, you know, Change 101, I do think that the way this is laid out and framed will be helpful to many confronting this, particularly in the academic world, and Arthur alluded to that earlier.

But, my comment probably will be seen maybe as heretical in some ways, because there's this conclusion that the NIH is doing well, and so I raise the question based on what metric? There is a perception that it's doing well, but I haven't seen the

quantitative evidence that says, here are the goals, and here is the quantitative aspirational change in public status that we want as some outcome as a result of this investment that we're measuring ourselves against, whether it's in a year or in five years, to draw that conclusion.

If we were working in a decision analysis world where we're going to be making investments, there is something called qualities, where you could make comparisons, quality adjusted life years across different conditions where there is a common metric that allows you to day that you are investing the resources optimally. I haven't seen that done.

So, I would say there is a perception. It's certainly mine as a recipient, but also as a participant in the broader scientific community, that the NIH organizationally is doing well, but I think as leaders sitting around this table, we should

be asking the question.

Is it really doing well as it could be, going to the optimal use of resources, in its current environment, and given the environment that's on the horizons, getting to your point, Norm, are we making the right kind of investments for the future to ensure that it continues to succeed?

DR. FAUCI: Gene, is that an organizational change issue, or is that fundamental to other issues relating to the kind of science you fund and the balance between fundamental basic and applied and translational, et cetera? I mean, so I'm wondering, is that what you had in mind, because it goes well beyond any structural change.

DR. WASHINGTON: It's an organizational issue, which could drive functional, not necessarily structural change, but it is an organizational issue if the organization is about quote what some call

peak performance in terms of using its resources, and so, I mean, it starts with the high-level question of are we optimally achieving our mission?

And then that leads to other questions about what changes do we make organizationally or changes, and those can be structural or function or other changes that might not relate to the organization. Sometimes it just relates to people and leadership issues.

DR. FAUCI: So let me -- let me just stay with that just for a second, Gene, because we get asked that question all the time when we go before the Congress, and they say, should we be doing more to translate what your basic science findings are into something that's good for the American public? Or, "What have you done for us lately?", kinds of questions.

And that's the reason why, you know, if you look at Francis's five pillars,

one of them is translational research among all of the others, so, I mean, those are the kinds of things that I think we need to reexamine about are we optimizing our resources, because there are many people that think we should take a much more proactive role in taking a basic science observation to a fundamental product, which is a whole new series of discussions that I'm involved with in another whole arena about what role the NIH has in partnering with industry in developing products from the basic science observations. So, in that regard, I think we can think about can we be doing better or not.

CHAIR AUGUSTINE: I saw Art and then Dan.

DR. RUBENSTEIN: And that comes to the issue of metrics and expectations, and that's where I have the most difficulty by answering your question and translating also what Tony says. As an example, in the field I've been in, the biggest disappointment has

been a statement that both NIH and JDF, the Juvenile Diabetes Foundation, have said for 30 years now. Our mission is to cure diabetes, and we haven't done that, or we haven't cured cancer, right, or parts of cancer, whatever it is. So then the problem is all this money has been invested, and we haven't done that, and the question is, was that a reasonable metric to do, because we're not doing organizational change for a bottom line money.

We're trying to do something that, I think, we don't know how to do, and that metric is a vision, but it isn't a -- you know, it has no substance in my view, and, you know, the JDF asks me all the time, we've put in $200 million or $300 million, never mind the billions at the NIH, and you haven't done that. And I find that very troublesome, you know, because we promised them, in a sense, we would.

So that comes to the problem I see in organizational change to the NIH, is the

metrics are not reasonable in terms of saying, if we do this, it'll happen. It doesn't work that way.

CHAIR AUGUSTINE: Francis?

DR. COLLINS: Well, I think that's a very interesting discussion about metrics. It's certainly something I think about a lot in terms of how do we assess whether we are living up to the promise that NIH represents for the public, and you can look retrospectively and say, here are some metrics that demonstrate the effectiveness of the institution.

If you look at longevity, for instance, it goes up by a year every six years, and you could point directly to advances funded by NIH, particularly in cardiovascular disease, for instance, heart attack, and stroke, that undergird that in a way that you can draw not just a dotted line but a solid line from what we have learned through research and which has now become part

of the practice of medicine.

Likewise, disability, 20 years ago something like 27 percent of people over 65 were disabled in some major life function. That's now less than 20 percent, and again you can draw a solid line from our investments to show why that has come about, but those are long lead times to see those, because it's not just doing the research.

It's actually getting them implemented, the results implemented in the practice of medicine, which, as we know, especially now with the debate about healthcare reform, has many other factors beyond our control in terms of whether these insights actually get utilized or whether they lie on the shelf.

So probably to use those metrics to basically look at a change in the health of the nation, at least in the short-term, is not something that we could draw a tight plan around, because it would be, I think, very

difficult to assess whether we were achieving that in a sort of two- or three-year time line.

So, instead, I mean, you will probably not be surprised to know the government worries about this, too, and so there is a whole process which we at NIH deal with, sometimes not particularly with delight, called GPRA, the Government Performance and Results Act, where we are supposed to put ourselves on the line about what are we going to deliver in a certain timetable.

So, okay, we are going to deliver the, for instance, the major genetic causes of 20 common cancers by doing systematic cancer genomics in the next few years. We are going to promise that.

We will deliver with the new translational effort new molecular entities in some way that we collaborate with industry, which is still in the process of being developed, but I think it's a very exciting

time, but those are obviously considerably upstream from what you really want to have, which is public health benefit, and there's the challenge.

There's many steps after what we can put down in a promise as far as deliverables and what its impact is going to be on the health of the nation, but I think we should try in every way we can to hold ourselves accountable by identifying those intermediate end points and make sure that we are aggressively pursuing them, and if there is an organizational problem that's getting in the way of those, then that's the kind of thing we should be thinking about very seriously in this kind of a conversation.

CHAIR AUGUSTINE: Dan and then Jeremy.

HON. GOLDIN: I wanted to make comments about Art and Tony and Gene's and the Director's comments.

The NIH is one of the premiere

organizations, not just in our country, in the world, that does innovative research, basic research, basic science, and one must be very careful about imposing too many rules and too many metrics so you impact that science.

And there has been an enormous pressure on the part of the Congress that is -- they really have their hearts in the right place in asking for metrics, but if you press metrics too hard, you will quench the flame of that innovation taking place in a young researcher at a university in the middle of the country.

It is -- and I remember in the nineties there was move afoot to get to more applied research so the American people will know what the federal taxpayer dollar is doing, and as a result we've lost the funding that to this day is gone on the pioneering research that had to be done.

So, as we're looking at organizational change, this organization has

to be very careful that we don't impose so many controls on the system that we will quench this basic research, and NIH is the leader. You know, there are a lot of problems and issues, but you cannot lose that, and that's why the American craziness is what distinguishes us from others, and in our desire for order we will quench that basic research.

Let me give a little vignette. You know, you get to a certain point in life, you're allowed to tell stories, but I was an executive in the aerospace business, and I was concerned about the cost of doing business, and I said, aha, I've got a great metric.

In engineering, there's something called an EO, engineering order. Every time there's a problem with a drawing, you have to go fix it, and I wanted to keep track of the number of engineering orders per drawing, and people are very clever.

I saw within six months a factor

of two reduction in engineering orders per drawing. What did my geniuses do? They doubled the number of drawings, and I really ask this body -- and this -- and, Bill, I think we need some more thought on this.

In our desire for organization and order, we must help improve the innovative science, because that is at the very core, and if translation -- we keep talking translation. We're not going to have innovation, and the translation in 20 years is going to have nothing to work with, so that's my discussion about metrics. Beware of metrics.

CHAIR AUGUSTINE: Jeremy.

DR. BERG: Well, I wanted to respond to your -- the paradox that you raised of the structure of NIH and the small Common Fund, and, you know, I think there are two additional factors. One is there are a number of institutes that have missions that cut across diseases, NIGMS being one example, NIBIB, which Bill mentioned.

So there are already, in addition to the Common Fund, cross-cutting institutes, and there are also both collaborations between categorical institutes but also categorical institutes who fund highly interdisciplinary research. So it's not as if we're --

I mean, the reason NIH succeeds despite its structure is the structure is there, but it's not -- doesn't really -- we don't get constrained by it too much. You know, when science becomes more interdisciplinary, we find ways --

I mean, the scientists first off find ways to get it done, and then we find ways to try to help them when something reaches the level where we can identify a barrier, the multiple PI changes a few ago being one small example. So, I think one should not sort of ascribe the Common Fund as the only source of cross-cutting interdisciplinary research at NIH.

CHAIR AUGUSTINE: That's helpful.

DR. BERG: It's actually spread out very widely.

CHAIR AUGUSTINE: That's a really good point, and I was wondering if it would be helpful if the Pioneer Fund and the New Researchers Fund and so on was broken out from the Common Fund, funded separately. Those are all good purposes.

So, you really did have the Common Fund with some horsepower behind it. It seems to me that would be a good thing to do, and it's probably also a little above our pay grade but something worth thinking about.

DR. KATZ: So, Norm, just to underscore what Jeremy said, the clinical and translation science awards, which are big homes for clinical research that really transcend all of the institutes, constitute about $500 million from the National Center for Research Resources. There will be -- there currently are 46 of these centers around the country. There will be 60 at its full

inception.

CHAIR AUGUSTINE: Thanks, Steve.

DR. HODES: And just to elaborate, I know what Steve's referring to. This initiative, the CTSA, actually began as a part of Common Fund and with the realization, as Francis alluded to, that one needs churn and turnover. The system, functional, not structural, managed to arrange to transfer the program in evolution over a few years to NCRR and managed to provide the funding in part through an adjustment in appropriation as an example of the complexity by functional adaptation that can be made in a circumstance such as that.

CHAIR AUGUSTINE: Gene?

DR. WASHINGTON: Yes, just a related comment. I think my use of term may have been proven to be more of a lightning rod that I intended it to be, but the larger point that I was making, and you answered it, Francis, is that if we make statements like

that, we should have a way of defining what it is that we consider to be success.

I certainly strongly support the idea that there is going to be fundamental signs not connected to any kind of metric or outcome and that our major discoveries and advancements have often taken place as a result of that, but any institution has to have some measures of success that are, in fact, definable and made public and to some degree be held accountable for meeting them.

CHAIR AUGUSTINE: One thing we've not talked about that is in the back of my mind, and that is that a poor organization can be made to work with good people, and a good organization can't overcome poor people in the boxes.

And, I think that's one of the things, that NIH has been able to attract quality people, and that may be one reason why what looks like an unworkable organization works. Jeremy, as you say, you find a way to

work your way around it so that it does work.

Bill, we ought to give you the last couple of minutes to summarize or say anything that you'd like to add.

DR. BRODY: Okay, well, first of all, the discussion has been very insightful and hopefully helpful in framing our report. I would be remiss if, first of all, I didn't thank Dr. Amy Patterson and her staff for an enormous amount of work pulling together lots of disparate ideas into a more cohesive presentation.

Secondly, I would comment that there is a book. I read a lot of books on organizational change, and years ago I read one, and I think the name of it -- I'm not sure if it's in print. It's Managing at the Speed of Change, and the "Aha" moment in the book is that the writer makes the -- and he talks about what you mentioned.

He doesn't call them bear huggers or whatever, but, you know, there are -- in

any given change there are people who are for it and people who are against it and people who sit on the fence, but he draws the analogy in change in an organization between Elisabeth Kubler-Ross's book on death and dying.

And, at the beginning, people are in denial, and then they go through the anger phase, and then they kind of go through the resolution phase. And I think anybody who is contemplating significant change ought to sort of think about it in those terms, that you've got to drive through those phases.

I think that one thing that we didn't mention because it wasn't in our purview, per se, but something that is alluded to, the most important thing in an academic organization like the NIH is people. Everything else pales by comparison, and I think there is a subtext which we didn't really delve into but picked up in various conversations with people at the NIH is that there are some important issues around HR and

hiring and retention of people that probably will deserve some attention, if that's something that Francis sees is important for us to take up.

It's always an issue, and my concern is that in any academic organization that is the issue and probably deserves some of our attention, and with that, I think everything else that's been said has been really amplified and illuminated really by the discussion today. Thank you very much, and thanks to our committee members for their hard work.

CHAIR AUGUSTINE: Bill, thanks to you and your group. I think you've contributed a great deal, and I particularly like the idea that we may be able to offer something constructive in the question of attracting people, and certainly my experience in the government is that the government makes it very hard to attract really quality people and to keep them, and there may be some things

we can collectively say that might be helpful in that regard.

I understand that we don't have a lot of people signed up for comments, so we've got a little time. Maybe, if I can, I'll share a story on the people front that has always amused me.

It was an organization where -- well, I was Undersecretary of the Army at the time, and Jim Schlesinger was Secretary of Defense. Jim was not impressed with the people we had in a lot of the jobs in the Army, and I had only been there a few months, and I had put together a new organization for the research and development part of the Army.

I went in to show Jim my conclusions, and I had this big organization chart that you could roll out, all the boxes, you know, the tree you have, the organization tree. I rolled it out on his coffee table, and those of you who know Jim, he sat there puffing on his pipe. He didn't say a word.

I really hardly knew the man. I had only worked for him for a few weeks, and he didn't say anything. I could see my story wasn't going over, so I tried to make up for the lack of quality with enthusiasm. That didn't work, either.

Finally, I got done. Jim got up and walked -- we were in his office. I'm sitting at his coffee table on the couch, and he gets up. He walks out of the office, and so I'm sitting there. I think, "Well, what do I do now? Do I just sit here? Do I get up and leave or what?"

It was a painfully long period of time that I sat there. Finally, the door opened. Jim's head appeared in the door. He took a puff on his pipe, and he pointed at my tree, my chart. He said, "New tree, same monkeys," and he walked out the door, and I will never forget that.

So that's the reason I'm so pleased at the end that you mentioned the

quality of the people is -- if we can have an impact, it's probably a lot more important that what we can do for the government personnel system than we could by rearranging or, as I learned, the people in our company used to refer to it, re-disorganizing, we can probably make a contribution there.

We can turn now to public comment, and as it turns out, we don't have anybody signed up officially, but we have allotted a half-hour, so if there is anyone here from the public or guest that would like to make a comment, you would be most welcome to do so at this time. Anybody?

And seeing no one, I think what we will do, if it is acceptable to the group, is we'll take a 15-minute break, and then we'll come back and delve into our second topic, and I've got a quarter of ten. So why don't we come back at ten, and we'll begin promptly then? Thank you.

(Whereupon, the above-entitled

matter went off the record at 9:46 a.m. and resumed at 10:01 a.m.)

CHAIR AUGUSTINE: We're now going to the current working groups. This one was set up to address the Central Research Program. Art was kind enough to lead that, and we'll call on you, then, at this point in time.

DR. RUBENSTEIN: Thank you, Norm, and good morning, everybody. First, I, too, would like to thank Dr. Amy Patterson. We've had tremendous support from her and her colleagues, and we couldn't have got done what we did without their help.

So, thank you, and I would also be remiss if I didn't say we have a terrific subcommittee, very interesting discussions, great people, and it's such a good committee that I decided I wouldn't make the whole presentation. So, I've invited two other members of the committee, Tony Fauci and Steve Katz, to share it with me, and they are

intimately involved in just every part of what we're doing, so I thought that was appropriate, and they have agreed to that.

Finally, I'd also just like to thank Drs. Gallin and Gottesman. We peppered them with all kind of requests repeatedly, and I think, very good-naturedly, they answered all the things.

So, the charge to this subcommittee, if we could, is a broad one, to recommend where the organizational change could further optimize the Agency Intramural Research Program and thereby maximize human health and patient well-being.

So it's a microcosm of the whole NIH mission, but culling down to look at the Intramural Program, which I think is about ten percent of the total NIH budget, but still big and very important and a program with a tremendous history and so on, and I've kind of made jokes in the past. We have very visionary people on our committee, and I'm a

pragmatist, so I didn't know how to do the first bullet.

So, there seemed to be a more urgent issue that was kind of needing careful discussion and debate, and perhaps could be resolved in a shorter time frame, but it had an important role both intramurally and extramurally, as well, and that seemed to be the fiscal vitality, organization, vision, and so forth for the NIH Clinical Center.

And so, we, with the agreement- with the parent committee, chose to begin with this issue first, and that's the report I'm going to do. It's to talk about how we might think about, in a more creative way and with more careful thinking, the fiscal sustainability and utilization of the Clinical Center, and put it in the context of its vision and governance.

So with everyone's permission in the parent committee, that's what we're going to talk about today. We'll come back to the

other part of our mission at another time.

These are the members of the committee. Dr. Cassell is in China, and I think Dr. Shurin is not here today. Everyone else is here. As I mentioned, a terrific committee, and we've had very good discussion. So here is the issue about the Clinical Center. It's a important part of the NIH, a very important part.

It's also a very important part when we're talking about translational research, which is a key important imperative for all of us, in terms of how we fund it and how we are responsible to the public and Congress, of course, how we do this, and the Clinical Research Center stands kind of at the intersection of all that, so it is very, very important.

There are unresolved problems, and you'll see in terms of governance and budget, which I think by general agreement, if not quite at this time, but certainly in the

short-term future, are believed to be impediments to the fully realizing the potential of the Clinical Center, and so that was why we thought it was so important to try to deal with this at this time.

So we have consulted broadly, as is appropriate for our mandate, and we have had tremendous input from a whole variety of individuals, which have been extremely helpful. I won't go through all the details, but just to talk about we've talked extensively with people within the NIH, and you'll see some of the important leaders there.

And then, we talked about investigators who use the Clinical Center, and so they have firsthand knowledge of both the advantages and disadvantages and barriers and also have a view of what the bit opportunities might be if we could make some changes. And some of the briefings were really, really important, because these are investigators who

have made discoveries and contributions that surely have changed health and disease in a major way.

Again, I won't go through the details, but we may have time for discussion. We could talk about some of them, but these are international research stars who use the Clinical Center quite extensively, and we listen carefully to their views.

There is also an Advisory Board established at this time for the Clinical Center, and I'll come to that in a moment, and we consulted with those individuals who have had firsthand experience in terms of giving advice, overseeing, and also listening over a number of years to both the upside and also challenges in the Clinical Center.

So Dr. Ronald Evens is, at the moment, the chair of this Advisory Board for Clinical Research. It's called the ABCR if you're talking about acronyms, and these are a mixture, again, of outside and inside people,

so their views are very important, Dr. Benz, who came from the -- President of the Dana-Farber.

These are individuals who, if they're not on the Board now, have been on the Board in the past, and so they have firsthand experience. That hospital, of course, is a cancer-focused hospital, Dr. Finan, President and CEO of a community, but important community hospital, so we try to get a broad range of perspectives, and Dr. Ed Hall, who runs a major academic medical center at Virginia.

So, again, we try to think about, of course, the Clinical Center, both the operational hospital with all the challenges of dealing with patients and their families, including safety, as was pointed out earlier, and so forth, as well as creating a climate where studying these individuals would allow new advances to be made in terms of discovering things that could enhance their

health.

Then we also talked, and we have material which talks about if we were to advise some change, which we are leaning towards, as I'll come to or we'll come to at the end, there are always both inside and outside the government, but maybe within the government they may be more challenging, legal, administrative, and financial issues that when change occurs need to be taken into careful consideration, because nothing, as we know, is neutral in all of these issues.

And so, we were grateful for the opinions, and they will be ongoing if we go forward with some of the suggestions of McGarey, Bartrum, and Barros, so I think in your book some of this material will be there, as well.

And, finally, as I mentioned, this Advisory Committee currently functioning was having a meeting, and so we took the opportunity, several members of the

subcommittee, to interact with one of their regular meetings and talk to them, as is our mandate and their mandate, about some of the changes we were considering at that time, and then, finally, we had a meeting with some of the people here today.

So the point I want to make is we've tried to very carefully, before getting too far along in terms of recommendations, kind of test our theories and our thoughts and some of our suggestions with a large number of people who have a major stake in the success of the Clinical Center, because it's easy to talk about these things from a theoretical point of view.

But, we try to be more practical in terms of thinking about, if we did make some suggestions, how would they be impacted, and what are the various constituents who would have to be consulted and whose opinions we would value, and so I think we've done that, hopefully to a credible extent.

Let me get on to the substance, then, of the presentation. We have thought about the Clinical Center. There are a number of ways to think about it, but we've broken it down into three overlapping Venn diagram issues such as here.

First of all, the vision and role, and, second of all, if we were pretty clear about that, what would be the most efficient and optimal governance structure, and then how would that work through the key fundamental issue that may have begun the process, but we didn't want to just start with solving a financial problem except in the context of the vision and governance, and so they overlap, of course, quite extensively.

I'm going to talk a little bit about the vision and role, and then Steve and Tony are going to do the governance and budget, I think in tandem, so we'll see how they do that. So let's begin with the first. These are three well defined, but

overlapping, issues, and they all, of course, impact on each other.

So, when we think about the Clinical Research Center, and there have been a number of studies, there is enormous amount of background material to all of this, as there is with all important organizations, and I won't bore you with saying this has been the subject of a variety of internal and external committees, evaluation.

There's been a report, or maybe several, from the Institute of Medicine, and there have been a number of advisory boards that have commented on this. We've tried to be sensitive again to evaluating all that material without being bogged down by or being paralyzed by just so many details.

As you'll see, as we go down the structure, there is a feeling at the moment that there is a problem with prioritization and commitment to funding the Clinical Research Center. As these things overlap, the

funding comes from the Intramural Program and its institutes, and I won't preempt that, but it does seem that the current way that those decisions are made and where the budget comes from could be improved, and that's part of what we are trying to do.

There is also a really important issue in terms of how we view the Clinical Research Center, because I think it's pretty much true to say that, with some modest exceptions that I will highlight, if you had asked people around the country who had a big stake in the NIH, whether it's the public or the investigators themselves or administrators in university, they would say, I think, that the Clinical Center is very important, but it's mainly a tool of the Intramural Program. Or it's run by the NIH, and, you know, we like what they do, but we don't have much of a stake in it.

This is a reaction that is not entirely appropriate for how it's organized

now, because there is some input of extramural investigators and opportunities to use it, but it seems to be rather modest at the moment in terms of how it's utilized.

So one of our thoughts was, could this be changed so that the Clinical Center would be viewed on as a national opportunity, a national resource, both for inside and outside the government so that people would have a bigger state in its success and, of course, utilize it for bigger opportunities, and so that's a big part of our thinking.

And, as Norm and several people said, and I won't go through this in detail, because we didn't address it specifically, but this point about how important people are and what are some of the barriers to recruiting and retaining them in the NIH is really, really important, and that's changed over the years with the draft going away.

So some of the incentives for people to come and work in the Clinical

Research Center and the Intramural Program have changed, and although there have been modest advances in terms of making this a more successful recruitment and retention, there's still a lot of issues there, as everyone has pointed out. And I am, of course, a great believer that people are a very critical part, and we can do a lot of things, but if we were to improve that, too, it would have a big impact on what we're talking about here.

Then, in terms of governance that Tony and Steve will talk about, at the moment the way the Clinical Center is organized, and you'll hear about that, it's dependent a lot on a number of institutes, and it seems to not have very great central priority setting and so on. It's just difficult to do that, although, again, I want to give credit to Drs. Gallin and Gottesman.

Everything here is relative, and I don't want it to sound again like it's broken. These are things we think -- and I think they

agree -- could be improved and, like many of our organizations, and, of course, the government seems to be at the top of some of them, there is tremendous complexity in the overall organization and administrative setup.

And you'll see some of those pictures about how many boxes there are. Maybe Norm, that's what he would say about monkeys if he looked at some of these things, so you'll see some of that.

And then, of course, a key driving thing, because it's here with us now, and the projections for the next few years are not rosy in this regard, is the issue of how this Clinical Center is going to be optimally funded.

And part of the problem, which is not that different from other hospitals, and that's why we wanted to get their opinion, is that the costs of taking care of patients in any kind of hospital are increasing, and if the NIH budget goes up two or three percent or

less, these costs tend to go up more for all of us.

And so, how are we going to not have the Clinical Center consume a greater and greater part of the intramural budget in a way that people feel uncomfortable? And that reflects, as well, instability of funding for the Clinical Center, because the funding comes from the intramural institutes now in terms of a formula that you'll hear about.

And because of the growth of various parts of that budget, both fixed and flexible costs, it may have undesirable effects on other parts of the Intramural Program, because if it consumes a greater amount, that will be less money for research and so forth.

And, again, as I've pointed out, although there are mechanisms for external investigators to partner with and to use the Clinical Center, there's not really much money easily available and not an easy

administrative route to go to make this easily done. So, again, the budget just indicates in terms of a mission that it isn't really congruent with it in many ways.

Just a point about the Clinical Center. I've kind of mentioned it briefly, but we've tried to look at whether this is more expensive than other kind of hospitals, and, you know, it's a very, very difficult comparison.

You'll see some numbers in the book about this, but, overall, it's not unreasonable in terms of being so costly that we would say it's being run inefficiently. These are often very sick patients. They are on protocols, as you will see, and the size of the Clinical Center is restricted just because of how it was built and also the opportunity to do clinical research.

And so things can't just be changed in terms of scale and so on, and I think there are probably opportunities for it

to be more efficient and greater utilization, and they are things that we will talk about, but it isn't a simple answer that that would solve the budget problem.

So that's a kind of overall background. Let me talk just very briefly about this issue of the Clinical Center being a national resource. So, this was part of how we thought the vision and role of the Clinical Center could be enhanced and then how it might be done through governance and budget changes.

So the thought, of course, and this is not new, is the Clinical Center should serve as a state-of-the-art national resource with resources optimally managed to enable both internal and external investigators. As I say, it's not precluded at this time, but I think the opportunity is not taken care of with external investigators at the full potential of what is possible.

And part of the vision is, as translational research and clinical research

become a greater and greater imperative, and I think most of us at least buy into that view generally, and certainly the public I think have embraced that, and there are a number of ways it can be done, as Francis indicated.

Nevertheless, the possibility of clinical and translational research, nationally utilizing the Clinical Center to the benefit of patients and their families seem to be a really very positive outcome, and so we have spent a fair amount of time thinking about how to expand and make this possibility easier.

So, internally, the NIH Clinical Directors were recently queried about the Clinical Center by outside investigators. This was done not as part of our thing, but it's been thought about by the Intramural Program for a while, and many of the institutes actually do have training programs involving collaboration with outside institutions and use outside consultants

through a variety of federal mechanisms, which are listed.

So I want to put in context that the Clinical Center is utilized by the external research community to some extent. Our point was it probably could be expanded and enhanced in a number of ways.

Here are some examples. I won't go through them in detail, but particularly with rare diseases, which the NIH has been at the forefront internationally in terms of taking people with very rare diseases or undiagnosed ailments, that could be investigated with a whole variety of very sophisticated techniques, and, of course, if the diagnosis is made, it could then be promulgated and extended to people, of course, outside anywhere in the world.

There are a number of these programs that are extraordinarily successful and being done. I might say they're usually done with the key person being the NIH

investigator and him or her working with external colleagues, but I don't want to make that sound too rigid.

There are a number of partnerships that are being done, and there are a variety of ways to do it. Again, the point I'm going to make is it does exist at this time, but probably could be expanded and enhanced quite considerably.

Here are a number of examples, which is being done, and, again, they're all in your books. I won't go through them in detail. The point I want to make is that we wouldn't have to reinvent the wheel, but we may have to add to it in a significant way if we were to expand the national presence and use of the Clinical Center.

Here's some of the areas we thought, at least in a preliminary fashion, would really benefit from this change in the vision and organization of the Clinical Center to be more of a national resource than more

focused intramurally.

So, as part of also Francis's focus, collaborative research -- major league development of new therapies and phenotyping is apparently a big issue now. The NIH has certain unique capabilities in terms of technology and development that are very special that only a government agency could really do to the extent they are.

And we toured the facility and saw the new GMP facility, which is really magnificent and probably will have the capacity to have a lot of other people use it, so, again, this would be too expensive for many university centers to have their own GMP facility, and this I think could be a tremendous positive use across the country.

And then, in terms of clinical research training, some of this is very expensive, and many of our academic centers do it, but many smaller academic centers struggle with this. And as you heard, the CTSAs will

grow to 60 centers, but the funding of them is constrained, and opportunities for clinical research training more broadly for young investigators who could use this facility and be mentored here, as well as in their home institution, is a very attractive possibility.

Again, there are a whole variety of programs now where there are opportunities, we think, of bench-to-bedside programs that could work, and, again, some of it is more difficult than other things, but the point, I think, that the committee wanted to make is this is not just incremental change for the sake of incremental change. There could be a tremendous upside to opening up the Clinical Center to a national resource if it could be done effectively.

Not to bore you, of course, anything like this that would need to be changed would have to deal with a whole lot of important administrative, legal, and financial issues, and we were underway to looking at

that but not all the way along.

And, there are also unintended consequences with any of these changes that the previous reports have pointed out, but we're not discouraged at all. We think we could deal with this, and we're somewhere along towards assembling all the issues that we would need to evaluate with colleagues in the NIH to be able to assist this.

So, I think that's the first part of the report about vision, putting it into its context of governance and budget, thinking about opening the Clinical Center more broadly to investigators all around the country, and finding ways to make its role in clinical translational research even more important than it is now. So with that, I'm going to turn it over to Steve and Tony.

DR. KATZ: Thank you, Arthur, and thank you for your leadership of this -- of this group. I think we've moved quite along, and Tony and I are going to participate in

presenting the deliberations of the group with regard to governance and budget, me from this end, Tony from the kibitz end of the table.

We are anywhere but at a streamlined governance structure. This is the goal. Governance should have a simplified structure, capable of developing and overseeing a clear, coherent plan for clinical research, and you can see that that is not the way that this is depicted.

The colors here, I should say, this all means this is internal NIH. This is -- this is combined internal and external NIH. The potential -- we have three options with regard to potential new governance structure.

One is to retain this Advisory Board for Clinical Research that Arthur talked about and providing some input to a Clinical Center Governing Board that's made up of IC Directors and others who are knowledgeable in what the NIH current and future anticipated NIH budget will be to provide some reality to

deal with the recommendations of the Advisory Board, and this is one proposed model to go through this Governing Board.

Another proposed model is to leave that IC Director's Governing Board off, and just for the NIH Director to get input directly from the Advisory Board for Clinical Research. This has not been done in the past, but could be done in the past and, alternatively, as a -- as two separate inputs for the NIH Director to make an ultimate decision, however the budget is going to come out, whatever the budget options will be, to get advice not only from the Advisory Board for Clinical Research, which is, of course, made up, as Arthur said, of people who are knowledgeable in the organization of hospitals, et cetera, for them to provide input to the Director, for the internal group to provide information to the Director, and then the Director will ultimately make a decision in terms of the increments or

increases of the NIH -- in terms of the NIH budget.

So all of these, I think, any one of these options is a much simpler option than the current input and structure that is ongoing, and we can come back to this in the discussion.

Now, getting to budget, the budget should be stable, we think. It should be -- it should be underscored by priority setting, and it should be linked to a strong planning process, remain stable in source and equitable in distribution, be effective in attracting and supporting a high quality workforce and assure efficient use.

I think that one of the issues, if we come right down to it, one of the issues is that the costs of doing patient-related medical research have gone up to a far greater extent in the last years than has the NIH budget, and currently the budget formulation involves cross-cutting across all of the

central services, obviously, each of them very important, but as one of those central services, as opposed to being a national priority and a national treasure, where the priority setting with regard to the NIH budget would be kept -- would be separate from the others.

I'm going to be talking about fixed and variable costs in a few of the suggestions that we -- that we have, and basically you can see over the last five- or six-year period how these fixed and variable costs have gone up.

The fixed costs have gone up by about 17 percent, the variable costs by 19 percent, not much in the way of difference over these years, and what are the differences between the fixed costs? So the fixed costs are incurred regardless of the volume of services -- you're all familiar with this -- and the variable costs change with the output and saved if service is not provided.

So, with increased patient accrual, patient utilization of inpatient beds, as you'll see in a slide or two to come, these variable costs become markedly increased. So, the comparable level of increase, as I said, is about the same in both of these -- under both of these headings.

This shows -- and I can say that in the last few years we have made a -- we, all of the institutes that do patient-related research, have made a major effort to recruit people who are going to utilize this national resource. So many of our tenure track investigators are physician investigators who are actually writing protocols, and I think that translates into what we see as increased utilization of the -- of the Clinical Research Center.

This is the weekly inpatient census. You can see the three-year average. You can see what it was in fiscal year 2009, the increment, and even in fiscal year 2010 up

to the middle of March has shown an increase in utilization. We're all happy about this, because this is really the goal is to maximally utilize this national resource.

This is -- if one looks at bed occupancy in terms of what is the capacity that we have, and a question that Arthur raised -- and this is a new slide that was inserted. I'm not sure it's in everyone's packet, but it's an important slide, because it shows what the percent occupancy has been over the years.

So, despite the fact that we're up to about 70 percent, we still have a capacity that's well beyond that to utilize the Clinical Center by investigators who are not housed and who are not in our Intramural Research Program. So there is -- there is considerable capacity to utilize that.

Now, what are the potential funding models that we -- that our group has come up with? There are basically five.

There are two at this end and three at this end, and you'll see in a moment why we have this differentiation.

Basically, the two at this end continue doing what we've been doing, and that is that the Clinical Center costs compete with other Intramural Research Program resources in these two. In these two, the denominator becomes all of the NIH -- all of the NIH budget, as you'll see in a minute.

So there's an increase. There's an increasing degree of change in the budgeting mechanism from none to incremental to significant, and you'll see that in a moment.

So, these are the five options that we're talking about. The current school tax, which I'll explain in just a moment, the modified school tax, and then the Clinical Center line item either in the mechanism table of the institutes, in the mechanism table of the Office of the Director, or as a

congressional appropriation.

As we see, every institute gets an appropriation. This would be an appropriation in the same way, and these lines were drawn because the budget decision-making passes from the NIH to the Department at OMB and to the Congress as you move in this direction.

The congressional appropriation clearly is one that is -- that is made by the -- by the Congress, and, as well, the line -- this underscores what I said before. The Clinical Center competes for funding from within a larger pool of resources as we move to the Clinical Center line item.

Now, I show you this slide not so that you can read it. It's in your handbook. It's in your -- it's in what we sent you, but the important thing is to know that we have addressed the governance program and the budget implications of each of these different types of options that we've talked about, and you can look at that carefully.

I think this best depicts what the Pac-Man, that is, the Clinical Center portion of the budget is under the various scenarios. Under the first two scenarios, which are not unlike what we have now, the Clinical Center is a part of the Intramural Research Program budget.

As a -- if one takes the view that this is a national resource, and one can change this Pac-Man view or the Clinical Center view to be a part of the overall NIH budget, as opposed to eating into the Intramural Research Program budget.

Now, I'm going to go through five, the five options, and I hope that Tony will join in, in any one of these, if you want to expand on some of the pros and cons. I'm not going to go into tremendous detail in each of these, but just to start with, the school tax.

Now, I mentioned the school tax probably at our last meeting, and there were lots of glossy eyes. What are we talking

about with regard to the school tax?

Basically, the Clinical Center is funded by virtue of a percentage of everyone's Intramural Program. So the larger your Intramural Program, the larger the share that you have of the Clinical Center costs, and what does that mean?

Basically, it means not to disincentivize the utilization of the Clinical Research Center, because if you were just paying per bed and costs were -- and your budget line here were not increasing, you might decrease the number of beds that you would utilize so that your intramural costs would go down vis-a-vis the Clinical Center. Basically, it's a matter of the status quo just doesn't work, basically.

The problem has been that the Clinical Center costs have gone up to a much greater extent than the total NIH budget, particularly for the last six or seven years, and as a consequence, one of the slides that

Arthur showed was -- on the slide it talked about cost shifts, and basically the costs of the Clinical Center are being shifted to the institutes as a consequence of not being able to keep up with the patient care.

Now, the modified school tax -- tell me anything to add on that school tax.

DR. FAUCI: Yes, why don't you go through the modified, and then I'll make a couple of comments before you make the transition into the line item?

DR. KATZ: Good.

DR. FAUCI: I just want to amplify a couple things you said, but why don't you go through the modified?

DR. KATZ: Good. So the modified school tax is a -- is a modification using variable costs and fixed costs. So, variable costs are about 80 percent of -- excuse me. Fixed costs are about 80 percent of the total -- of the total NIH costs.

The modified school tax would

allow for funding the Clinical Center, supported by the Institutes, like it's done now, but we would internally reallocate funds, whether they are fixed costs or variable costs, and the funding actions and decision-making still remains at the NIH, and there is no Clinical Center-specific action for the Department or for the Congress.

So they are disassociated. The fixed and variable costs are dissociated, and the fixed costs are assessed by the school tax, so it would still be according to your Intramural Research Program.

That is 80 percent of the cost, about, and the other would be for initiatives that a particular institute has that they want to implement where perhaps the total budget couldn't absorb it, and the institute priority dictates the utilization of the Clinical Center. They would then pay for this -- for this -- for this increased cost.

So, let's just stop there, and let

me just say that the one con about this particular model is that, again, it tends to disincentivize the utilization of the Clinical Center, because the institute then pays for any increment of increased clinical research that they want to do in the Clinical Center. Tony?

DR. FAUCI: So let me -- thank you, Steve, very clear explanation of it, but let me just put a much more in-the-trenches type of explanation of what Steve means by disincentive.

So, if you -- you have to put it in the background that we have been encouraged, and I think appropriately so, by our constituencies, by our Congresses, you know, going back a couple of Institute Directors, from Harold Varmus through Elias Zerhouni and now with Francis, to really enhance the whole issue and execution of clinical research.

I mean, that's been something that

has been very well agreed upon, so that's not controversial. So, in order to do that, we've made a couple of moves of hiring and training more clinical investigator type people within our Intramural Program.

So, if you look at the Clinical Center and its relationship to the Intramural Program, if you have an Intramural Program, you will pay on a pro-rated basis, relative to the size of your Intramural Program, for the running of the Clinical Center. So, in essence, you're going to get tapped for the Clinical Center.

Now, if you are a Director of an Intramural Research Program, you have a couple of responsibilities. You have responsibility for the people at the bench who never, ever make use of the -- of the Clinical Center, fundamental basic scientists who have nothing to do with the clinical research protocol, as well as scientists whose fundamental mission or, at least, part of their mission is to do

clinical research.

That happened to be my career path from the very time I took a fellowship that I have always been doing clinical research together with fundamental bench research.

So, with that as the background scenario, if you look at the tensions that evolve when you have, as all of you know who are involved in medical centers, that the cost of doing clinical research and of running a clinical research facility, the inflationary increase of that exceeds the inflationary increase of the other things that go on in the Intramural Program.

So what the Directors of the Intramural Research Program see is that even if they don't do anything in the Clinical Center, the relative amount of their intramural budget gets progressively more eroded by a couple of percent, because we're talking about an inflationary increase of five and a half or so percent versus three percent.

So, there is an imbalance that over a period of time takes its toll.

Superimposed upon that is what Steve was saying about the variable costs. So if I'm responsible for an Intramural Research Program, I'm already, A, getting tapped, which is fine, because I'm going to use the Clinical Center. The increase of the cost of the tap is disproportionate to the increase of all of intramural research.

Superimposed upon that, I have investigators that come in to me and say, "I really want to do this clinical program, so can we put more money into the Clinical Center?" because those are the variable costs, because I can't just come in and start a brand new program that's going to essentially occupy Clinical Center resources, perhaps to the detriment of the other programs. So I'm going to have to put more money into that.

So if I look at this model here, and I say, "Now, wait a minute. I have an

increasing percentage of running the place," the incentive for me to do the things that the NIH Directors and the Institute Directors want us to do. I'm going to be very reluctant to say, "Okay, we're going to put even more money in now to do a clinical research program."

So we're faced with a very interesting paradox here of being encouraged and being enthusiastic about doing clinical research at the same time that the relative increased cost of it makes it a major disincentive to not then encroach upon the resources for the other aspects of the Intramural Program.

So, with that in mind, what we're talking about is --

DR. KATZ: I put up that slide now again with the --

DR. FAUCI: So if you look at what the denominator from what you're coming from, if you have an Intramural Research Program that's at ten percent of all of your

resources, and you start eroding a few percent out of that, that becomes painful in a very serious way.

If the denominator is the entire NIH budget, it is a fraction of it, and I see our extramural colleagues smiling, Tom, but that is the reason why, in order to justify the kinds of proposals in option three, four, and five that Steve is going to make, is that that would only be justifiable if the extramural community can have access to and can utilize the very special capabilities of the Clinical Center.

So, that's what Steve is going to talk about now. By making it a line item, a line item means instead of taking it out of just a fraction of the budget, you say it goes either into the institute, into the OD, or as a separate institute, making it a separate institute, and there are pros and cons to each of these, which Steve will get into.

Does anybody have any questions

about that?

DR. KELLY: Yes, I have a question.

DR. FAUCI: Yes.

DR. KELLY: So what's Pac-Man --

DR. KATZ: Speak up, Tom.

DR. KELLY: What's Pac-Man eating on the right side?

DR. FAUCI: No, Tom. That's the obvious thing that people get anxiety and neuroses about, but, no, but what it is, it's eating out of a $32 to $33 billion budget. It's the same amount of money as opposed to a $3 billion budget. That's --

DR. KELLY: It's still a dollar.

DR. FAUCI: No, no, you're right.

DR. KELLY: So it's an interesting argument.

DR. KATZ: But it is important, Tony, to say that the current -- this is not meant to be a total cost shift into this -- into the -- into the total NIH budget. What we currently have is going to actually go into

this to increase that denominator so that money that's currently allocated in taps, what Tony is talking about, that money is going to go into this.

It's not going to be a $362 million transfer. It's going to be -- or reallocation. It's going to be the increment above that $362 million that's going to be this Pac-Man. Tony, is that --

DR. FAUCI: Let me just -- it's a one-time cost shift, so if the intramural research budget is $300 million to $400 million, under the model that $300 million to $400 million would shift from the intramural budget to the extramural budget, and then any changes we're talking about are the one or so percent increase over that $300 million.

So it isn't as if you're now having all of a sudden the extramural program pay for the Clinical Center. You're shifting all of that money into the extramural line.

DR. RUBENSTEIN: Just to give it

some quantitative thing, because Kelly's point is, of course, what everybody will think about. So just let's say there's $400 million that goes up five percent, as opposed to three percent.

We're talking about $20-$25 million increments either out of the Intramural Program, which is 3 billion, or out of 34 billion. It's always the same amount of money. The issue is the impact on it that we have to assess.

So there is both philosophical issues, and if you take $30 million or $40 million out of the extramural budget, it is not inconsequential. The question is, is the trade-off worth it for the use of the Clinical Center in a collaborative way that will produce other kinds of value, and that's what needs to be assessed eventually in the pros and cons.

Why don't we go through the other things? Then there will obviously be

important discussions about these. Go ahead, Steve.

DR. KATZ: And just to add one word, a lot of this depends on whether -- the reality of viewing the Clinical Research Center as a national resource is something that can be embraced by the -- by the various communities.

So, as Tony mentioned, the next three are basically line items. They're line items in the mechanism table, and basically the mechanism table just tells us how much money each institute plans to spend for research project grants, for contracts, for centers, et cetera, and this would just be one of those line items.

It would be separated between fixed and variable costs. Variable costs would still remain in the Intramural Research Program or would be a part of an extramural grant, for example, if there was utilization of the Intramural Program.

So, the NIH would propose to Congress its intent to provide a specified amount to the Clinical Center from the total funds appropriated to the institutes. The funding for the fixed costs would be allocated to the Clinical Center, drawn from the entire Institute budget and not as a portion of the IRP budget.

Here we would be utilizing a school tax, I assume, to make that allocation, and each institute would carry its portion of the fixed cost payment in this new line item in its mechanism table. Basically, the way that would be done is the Director would make a determination as to what that fixed cost would be, and then the allocation would go to each of the institutes as a line item.

The amount will be requested as part of the appropriations process. It's visible to the Department, OMB, and to the Congressional submissions, and the amount will initially be subtracted from other appropriate

mechanisms where these costs are currently budgeted, presumably the IRP. This is what we were talking about with regard to the one-time cost adjustments.

Once funds are appropriated, they're transferred from the Institutes to the Clinical Center via Central Services, and the amounts listed establish a funding limitation, and Congress must be notified of the programming if we are going to reprogram with regard to fixed costs.

If we reprogram with regard to variable costs, then we have far more flexibility. Should an institute all of a sudden want to invest in doing a clinical project in the current year, that is doable.

Should additional funds be required for the fixed costs during the budget year, there would have to be a reprogramming and no reprogramming if it's in the variable cost line. The variable costs continue to be budgeted in each institute's IRP line. The

amount is not visible to the Congress, and the amounts -- this is all -- this is all in that blue area, which is the IRP area.

Basically, once budget levels are approved, the funds are transferred. If additional funds are needed, they will come out of the Intramural Research Program. That, basically, is included in the mechanism table of each of the institutes that does clinical research.

The next, which is the fourth suggestion, is a line item in the OD appropriation, not so dissimilar to the previous one, and basically all of these things are basically the same, except that the totality of the fixed costs would appear in the Office of the Director appropriation, as opposed to in each individual appropriation.

I think I don't have to go through this line, because that basically is -- Tony, would you agree? That's basically the difference.

DR. FAUCI: Yes, it's exactly the same thing. The benefit is that you don't have it broken up into 20, whatever it is, how many institutes that have Intramural Programs, and you have it as one issue under the auspices of the NIH Director, so the Director could have a direct impact on it, because that is in his office or her office.

DR. KATZ: So there's good news and bad news there. The good news is it increases the amount of money in the Office of the Director line. The bad news is it increases the amount of money in the -- in the Director's line, so input from Francis becomes very important in this -- in this regard, as well, and all the negatives are the same sorts of negatives.

Whenever one has variable costs, one has the negative of potentially disincentivizing the utilization of the Clinical Center for patient-related research, number one, and number two, something that I

haven't said is that I don't -- at this point, I'm not sure that the variable costs can really be truly assessed for each of the projects that are being done. I don't know that we have a process in place in the Clinical Center currently to make that assessment.

Finally, the congressional appropriation is something different, and that is that, just like each of the institutes gets an appropriation at the beginning of every year or, at least, close to the beginning of every year, the Clinical Center would get that appropriation, and in this way the NIH Director would propose funding levels to Congress, which are directly appropriated to the Clinical Center.

The amount will be requested as part of the appropriations process. The amount would be budgeted and developed by the NIH Director with input from the Governing Board or from whatever sources he wants to get

his information from, and the amount will initially be subtracted.

This is that one cost. This is that cost adjustment, and Congress in taking action on the budget required ultimately sets the funding level.

Once funds are appropriated, they're allocated, and then if there are any changes that have to be made, the Director would have to go to the Congress and make a plea for reprogramming. So I think that is the -- those are the five options that we've talked about, and, Arthur, let me turn this back over to you.

DR. FAUCI: Steve, before Arthur makes a comment, I just want to give the whole group a feel of some of the concern of the last option, the direct appropriation, which would essentially make the Clinical Center an institute, and there are a number of reasons why there is some concern about that.

One of them is it would make

itself more vulnerable to direct language in your appropriation that affects what you do. So as an individual institute, as the Director of NIAID, I would get X amount of money, somebody could say, and, yes, in the report language they may say, "And we strongly suggest you study this or this or that."

And I think that would leave the Clinical Center open to some vulnerability if they had a separate line item to which there would be report language associated. We would like to keep it as a completely driven by the science, as opposed to a constituency getting to a committee that would then say, "Spend it on this."

DR. KATZ: And the other point that I should make is that it then really dichotomizes clinical research from all the other types of research, and, as we know, it's really a part of a continuum, and that's the other -- that would be the other real downside.

DR. RUBENSTEIN: I just have one or two more slides. Then I hope we'll have some discussion.

Let me just say, in terms of the last option, Gail Cassell, who is not here, does favor it, or does believe it is something very important, and although acknowledging what Tony said that a lot of us are concerned about, I think she has a thought that because clinical and translational research is so important and that Congress is so responsive to it that the Clinical Center could get a disproportionate share of any increase in funding that may occur in the government.

Most of us are very pessimistic about that and think if the Clinical Research Center -- Clinical Center got more, it would come out of somewhere else, and so a lot of our discussion is predicated on the view that the NIH budget was going to go up, even if we're lucky, two or three percent a year and not more.

Of course, when there is more money in the budget, a lot of this becomes, who cares? There's more money. But, for the last ten, 12 years that just hasn't been the issues. I mean, we haven't had that thing except through the doubling period. So, I just wanted to give her view as something that you should all be aware of.

So, leaving aside the details, the first two really focus on the money coming out of the intramural budget. The last three, the pie is greater, but even so, if the NIH budget goes up by a certain amount, the money does come from somewhere in the budget.

And, as will become obvious when everyone looks at it, somewhat more money -- it seems to be a rather small amount, but somewhat more money will come out of the total NIH budget, and that includes the Extramural Program, which is two-thirds of the budget.

So it is a real change, but, as we've talked about money being in the Office

of the Director, the $560-odd million, this would add to it over time, maybe $20 million a year or 30. The number needs to be worked out, of course, but the basic funding would still come from its present source, and the incremental funding would come out of the total NIH budget.

So here are the issues that we think make this discussion an important and timely one, that these changes could position the clinical centers a national resource. We think at the moment it does play that role to some extent but not optimally.

It does prioritize clinical and translational research at the NIH, tries to remove some of the disincentives to doing clinical research. It does streamline governance, and we think that could be really quite helpful.

It ensures longer term fiscal sustainability in a stable, responsible budget. This every year is a problem for the

Intramural Directors, and this would give it some relief in that regard, and, most important, we believe it could really enhance programmatic planning for a major initiative that the country and we all believe in, in terms of direction.

And here we are. I think the committees had very vigorous debates. We thought about the possibility of just putting out all five of these options for you, but we thought that wasn't fair, because you have not had the opportunity to have all these debates.

So, we wanted for your thinking to tell you where we were coming out, at least in terms of preference, but, of course, ours is a subcommittee, and it will need all the kind of oversight by this committee and others.

But, nevertheless, the majority of the working group do prefer a line item, either in the IC mechanism table or the Office of the Director, and I think most feel the latter is more helpful and that if we were

able to do that, that's option three and four.

This would facilitate the use of the Clinical Center by external community. It would lead to a higher visibility of the Clinical Center, to external community, the Congress, all kind of people who would have a greater stake in it.

The funds would come from the overall NIH budget, at least the incremental funds, and the base funds would come from where they are now in the intramural budget. This will enhance the stability, and it will also encourage more people and more opportunities on a NIH-wide and also national basis to focus on clinical research by removing many of the disincentives that are not really important, because they seem to be modest budgetary issues, but they have a very big impact.

And here we are, last slide, the next steps. We're somewhere along in analyzing each of the options, but each of

them will need legal and administrative and then budgetary evaluation in a lot more detail, and we're somewhere along with that, as I pointed out in the table.

We will look at the governance, simple models and try to define how it would work in more practical terms so there are no unintended consequences. We will talk to all the people involved, and there are many of them that even though it's a relatively small amount of money, it's real important, and it's a shift in philosophy.

So we'll need to talk about all of that with the people inside the NIH and also constituents outside to get their support if we're going to go this way and, of course, the public, who we hope will weigh in on this, as well, and give us their opinion.

And I just mention there have been a variety of points. I mentioned a variety of reports. I mentioned that right in the beginning. One really important one was

Institute of Medicine recommendations concerning the clinical research across the NIH, and we're going to go back and extract some of those, but mostly they are consistent, not in the details that we mentioned, but in the vision for the Clinical Center.

They nearly all said this is what they would like the Clinical Center to do, but did not really operationalize how to effect that, and we've tried to come somewhere along to be able to do that. So I hope that wasn't all too much, but all of us would be happy to answer any questions.

DR. KATZ: One more slide on next steps, I guess.

DR. RUBENSTEIN: Okay, so this is what Norm mentioned in the beginning. We hope that by the May meeting we will have fleshed all of these out. We'll have a stakeholder meeting before the -- both during and the full Board meeting in May. Then we'll try to put all of this together and at the full Board

meeting come to some kind of agreement.

So we hope in the next three months -- here we are in the middle of March, but we do hope by the end of or middle of July -- so that's April, May, June, July, four months -- to actually make specific recommendations that could have been evaluated and passed on by this parent committee. Thanks.

CHAIR AUGUSTINE: Well, thank you very much and your group. Steve and Tony, that highlights just what a difficult issue this is, along with the others we're addressing. We've got time for, I think, full discussion here. Bill, you have something to add, I think.

DR. BRODY: Arthur, that was quite a comprehensive report. I had a question whether you considered a more radical approach, which would be outsourcing the operation of the hospital to, let's say, Georgetown or GW, where they could bring some

economies of scale and backfill patients as required.

DR. RUBENSTEIN: You know, we tentatively thought about it without giving it any kind of in-depth analysis. It comes to the issue of pragmatism and vision. I think it may be age. I'm a pragmatist.

If somebody wants to think of something radical like that, we'd have to really go back to the drawing board and do it. It's not unreasonable, but we didn't do it in any kind of depth.

I don't know if any other subcommittee would like to say. You know, we changed the whole philosophy of how this is run, and we try to do that without changing it so dramatically, but it's not unreasonable.

DR. FAUCI: No, it's not unreasonable. The only issue, Bill, that was -- that comes up when you talk about outsourcing, if this were a hospital that you would want to be run like a hospital in the

community, Georgetown, GW, whatever, then that would be reasonable, but this is a very different kind of hospital.

So, I can't imagine how outsourcing it to Georgetown is going to alleviate the issue that we have when we're dealing with fundamentally a research hospital that's not driven by the best economical use of beds but is driven by the research questions that are driving the protocols. So, I think that's an issue.

CHAIR AUGUSTINE: Sol?

DR. SNYDER: Actually, our little working group has been a lot of fun and has accomplished something that harks back to our discussion about organization and whether you should have changes, and here I think you have eminent justification for a substantial change in order to secure a really important mission.

My own element in this whole thing has been making the Clinical Center a national resource. The Clinical Center has facilities

that are extraordinary from the perspective of neuroscience, the imaging stuff, the PET scanning.

We have good PET scanning at Johns Hopkins, but it's dwarfed by what my former student, Bob Ennis, does with the PET scanning at NIH. It's just amazing what's available, and to say that's only to be used for scientific ideas coming from intramural scientists is really wrong.

There are so many great things that could be done all over the country that aren't being done, because facilities like that, facilities with the GMP approach, aren't available, and this reorganization of the funding would be critical to making the Clinical Center a national center, which I think could have a really important impact on the biomedical research enterprise altogether.

And, also, in terms of dealing with what's most important, which is called Tom Kelly's Sloan-Kettering budget, I

calculated that the -- that $20 million represents -- basically, it might affect, at best, 0.1 percent of Tom Kelly's research budget. But he would come out as a winner, because all of these great clinical research studies, instead of cutting that out of your hide, a lot more than 0.1 percent would go down to Bethesda, and so you'd be a net winner.

CHAIR AUGUSTINE: Tom, you will see why I accidentally overlooked you. It's your turn.

DR. KELLY: I'm glad that my budget is going to go up as a result of this process.

DR. BRODY: Let me -- I'd like to follow --

DR. KELLY: Can I?

CHAIR AUGUSTINE: No, Tom.

DR. BRODY: Sorry.

DR. KELLY: So, I don't want to sort of get hung up on the intramural/extramural part of this, but maybe

I'll make one comment, and then I have a couple of questions about the report. First, I think the report was really great, and you really are struggling with a lot of difficult, complex issues that I think the rest of the membership are going to have to think about a lot to get our heads around it.

But, in terms of the intramural/extramural discussion that we had in the middle of the report, I would only make one comment, and that is I think the denominary argument is sort of an interesting argument, that things should be driven by the size of the denominator.

But I'm not sure that I buy that argument, and I think really the decision of how to shift costs, and clearly this is a cost-shifting exercise, has to depend on whether it makes sense for the science as a whole.

If it's going to go to other parts of the NIH budget, then it has to compete with

the components that are already in those parts of the budget to ensure that as best we can we get the best science in the end coming out of that process. So that's all I'll say about that.

I had two questions, one Sol sort of began to deal with, and that is that I think, looking at the report as a whole, a lot depends on changing the view of the Clinical Center and making it a really viable national resource. Arthur pointed out that many of the institutions around the country don't feel much stake in the Clinical Center, and they also have big health centers of their own that provide many services.

So I guess my question would be whether the committee was able to convince itself that one can overcome those barriers, and does the Clinical Center really offer something that's efficient and unique to really engage the national community?

I think the idea is a really good

one, and I suspect that there are some unique features of the Clinical Center that would engage institutions around the country, but I'd be interested in your expanding on that a little bit.

And the second question I had, it seems to me one of the main issues when we first decided to take this particular issue on was the ability of the Clinical Center to attract the best people and to retain those people, and I wonder if the committee took up that issue, as well.

CHAIR AUGUSTINE: Art, let's let you answer that. Then we'll go to Bill.

DR. RUBENSTEIN: Sol, I could start, and then others could help me. So the second point I didn't mention, because it is so central to everything, and although we acknowledged it, we didn't spend a lot of time on it.

But if we did move ahead, like many things, you know, the retention and

recruitment of clinical investigators would be a really important thing, and I think it may be something we could do, but also the whole committee we talked about it in terms of keeping the best people functioning in a government milieu.

In terms of the first one, I think we really haven't gone through it in all the kind of detail, but I think all of us in our own areas really do believe that the Clinical Center could be an extraordinary resource that at the moment isn't known about, isn't acknowledged, and then, even if it is, isn't easy to use by external investigators.

I think we'd have to come up with a menu of some of the real big opportunities that may not be available at our places or that would be more efficiently run here or that the NIH community would welcome, partnership with.

And Sol mentioned a couple in the neuroscience, and, you know, he's obviously

thought about that a lot and could expand it, but we were impressed. There are enormous resources for pediatric investigation that many other places don't have, and the pediatric beds are pretty much -- John is here now -- that's oversubscribed a lot of the time, and it's difficult to do clinical research on children in many places, and the resources here are quite remarkable, I think.

And there are other areas that are expanding now in the GMP area, which a few of our places have, but they are modest facilities sometimes. And if we're going to do these partnerships with industry, it depends a lot on who's controlling what, but this GMP new facility is an enormous resource.

So there are a number, and we would need to be more specific in terms of delineating it, and then we'd have to see if extramural investigators would embrace it. This is not just something, as you know, we could impose.

We'd have to say, "Are you interested? Is this a resource that you could use? Would it save you some money at your institute?" We'd really have to go through that to satisfy the kind of questions you brought up, which are very real.

I wonder if others would like to add to that. Steve?

DR. KATZ: So I would -- I would underscore that point. If you look at the examples that are in your book and that Arthur made, they're really very -- it's very a small amount that's currently being utilized with regard to the Extramural Program.

So, as a part of our charge, we were going to actually get that sense from the community, because if there is this shift in terms of where the allocation is, Francis certainly would have to be able to back that up with what is going to be utilized, and we do need a reality test in that regard.

With regard to the second point,

and that is the retention of the best and the brightest, and the recruitment and the retention, particularly in terms of clinical research, we heard a lot from the intramural investigators that that is a challenge. That's a challenge that I know that Francis is dealing with now.

The prior Director, Elias, dealt with it. He did -- he did move -- he did move the line considerably, but the years are passing, and I know that Francis has heard about that in terms of top notch clinical investigators coming in under the current budget constraints and other constraints that we have as working in the Intramural Program. So that's something that really does have to be on a regular basis addressed, and I know that it's come to Francis's table.

CHAIR AUGUSTINE: Bill?

DR. BRODY: Well, I think most of what I wanted to say has been raised, and the idea of creating a facility that would be

embraced nationally is pretty complicated. It's complicated by virtue of the fact of medical licensure.

It's complicated by the fact that the investigators that are here have their own programs, and if you want to send a patient in with Parkinson's and it doesn't fit the protocol of the Parkinson's investigators here, they're probably not that interested in doing it.

That said, there are enormous resources here, as Sol indicated, and if there's a way to figure out how to capitalize on that and expand that base, it would be wonderful, a wonderful opportunity to do so, but I think it would take a lot of thought and planning to actually make it a reality.

DR. RUBENSTEIN: I think we agree. This is one of those things where we think it's worthwhile making the effort. You know, if it can't work, it seems like the goal is worth trying if there's enough support for it,

but there are a number of hurdles, as you correctly point out, and people are very cognizant of that. Never mind just the geography, you know, people have just got to come here. You know, it's not a simple matter. Tony?

DR. FAUCI: Tom, to get back to your argument, which is a reasonable argument, I mean, I don't think denominator size should drive anything if it's not linked to an advantage for that from a scientific standpoint, so that's really the reason why this model absolutely has to hinge on utilization by the extramural community.

In that regard, I think we need to be realistic that it is not going to transform extramural research in the United States by having accessibility. There will be things that we have here that may not be available to investigators who want to pursue a particular direction.

I mean, you're coming from a place

that has extraordinary resources, so I can't think off the top of my head right away something that would -- we would have here that your people would desperately need to get involved with, but I think there were other areas in other institutions in the country where you might need a metabolic unit that you have no access to that you could easily have access here.

Sol mentioned the whole issue of some of the imaging capabilities that we have that some other institutions may not have. I think institutions of the magnitude of Memorial Sloan-Kettering likely would not get significant benefit from that, so we'll exempt you from that tax, Tom.

CHAIR AUGUSTINE: Gene.

DR. WASHINGTON: I agree with the comments that have been made about the practical challenges of making this truly a national resource, but go back to the early discussions about the Clinical Center, and if

I recall, the real driver we should acknowledge was sort of finances and economics, and so much of that comes through in the presentation.

So I really have a suggestion for going forward, and that is taking a quick look at those same guiding principles, particularly the top three that talk about strength and ability of NIH to carry out its mission, provide an environment for collaboration, coordination, and interaction, and bringing together synergies, and think not just about the internal community or the extramural community, but then think of it, too, as this national resource.

Sort of build the case from that, because the case now is about why should this be a national priority for the whole NIH community, extramural and external, versus -- what you've been facing, really, is why it's been a priority for the extramural research community.

The points are here, but when I look at it, they sort of become secondary when some of the key points should be primary, and if you start with the vision, it's the right vision, but then it's not developed along the lines of what's already been proposed in the general framework.

I think it would be a more -- it would make a more compelling case, but more importantly, it will, I think, force us to be a little bit more rigorous about exactly what will we, you know, achieve and what's the real driver behind this.

DR. RUBENSTEIN: I think that's a fair comment. Most of what we spent time was seeing if there was a model that could do it, but I think if we were to sell it as everyone has said, the extramural community has to embrace it, not for the budget reasons, so I think your point is well taken. It's a work in progress, and we'll listen to that carefully.

CHAIR AUGUSTINE: Francis?

DR. COLLINS: This was a very useful discussion, and, Arthur, again, your group has done a yeoman's job here in sorting through a problem which clearly has been vexing at NIH for many years, and clearly we've reached the point where I think all of us who have lived within the current school tax system would say something has to be done in order to maintain the viability of this critical resource.

So, in this case the platform is burning, and that's going to force us into some form of change. The question is what's the right fit. I think what Gene just said is right, that what we ought to think of here is the driver, though, is not the financials but really the science, and the science opportunity does not limit the way in which this critical resource should be utilized just to the Intramural Program.

It is unique in ways that have

already been mentioned, and we've tried over the course of several years to try to figure out how to make it more accessible to the extramural community, but we've been kind of hamstrung by the fact that its budget line is coming from intramural.

And we have these limitations that are partly constraints placed upon us and partly constraints that are just traditional about not mixing the color of money, and the color of extramural and the color of intramural money are in general kept quite clearly separate for understandable reasons, and that has gotten in our way in terms of the best of intentions of trying to open up access in the past.

But as we look towards the future and see particularly the opportunities in translation that are coming out of the identification of large numbers of new drug targets for cancer, for heart disease, for diabetes that are pouring out of the basic

science enterprise, and as we have increasingly empowered academic investigators to follow up on those target identifications by teaching how to do assay development and providing high through-put screening facilities, now four of them through the Common Fund that have the capacity of mid-sized pharmaceutical companies, we have more and more lead compounds coming out of this that could move into the pre-clinical phase, and we even have a program now, the Therapeutics for Rare and Neglected Disease Program, that encourages pursuing those all the way to the point of an IND.

And so we are going to have, I think, an increasing opportunity for phase one and two trials for new molecular entities that may still be targeting conditions for which the economics are not sufficiently attractive for a company to pick up the project and run with it, although if they would, we would love for them to.

And the Clinical Center, because of its capabilities in terms of looking at response, whether it's by imaging or other kinds of biomarkers, and because of its GNP facility ought to be a place where some of that really exciting science could go forward, and a lot of it will not be coming from intramural researchers, although I hope a lot will.

It's certainly true that's only ten percent of where the effort is going on for biomedical research, so the notion of having this capability more broadly accessible, seems to me that's the driving force behind the conversation we should be having is how do we set up an environment where that is possible.

One of the things, though, I wanted to ask, Arthur, in terms of your group's discussion is exactly how have you thought about this in terms of the variable costs that would be associated with the

protocols? Coming from the extramural community, we in the outline here certainly identified the fact that variable costs from Intramural Program efforts would have to be coming from those intramural budgets, presumably in a symmetric way.

Extramural utilization of the Clinical Center would not be entirely free, either. There would be some mechanism of determining what the cost of a protocol was, and those would then have to be covered in some fashion, and I'm sure the extramural community's interest in using the Clinical Center will be tied to what that formula looks like.

If it's not free, well, that's probably going to discourage some applications, but maybe you want to discourage ones that people aren't willing to put up some kind of support for. So have you wrestled it all with how that part of the formula would work in terms of costs that would be shared by

extramural utilization?

DR. RUBENSTEIN: Honestly, we wanted to see the reaction of the Committee. There was that whole slide that I went through very quickly, like in ten seconds, because I didn't want to bore you with it, but I couldn't bore you, because we didn't have the answers to most of it.

It's in your book. There was a whole list of things that would have to be done legally, administratively, and financially, and this is just a key part of one of them. It would also come to the heart of what Tom said, you know, how would we share these costs and so on, and what would have to be paid, and what are the incentives of using it.

So if there is general support for going forward with those, it's -- here you are. You know, you asked a few of these questions, and I would just say we're cognizant of it, and we started to explore it

in the context of the -- how the rules and regulations work now, but we really need a lot of work to see what would be feasible, what the barriers would be.

You know, to make a thing like this work, just like the governance, we've got to make it relatively easy, because if there are going to be a hundred forms to fill in, nobody will want to do it. So you're right, and we would need --

If there is support of the parent committee to go ahead, we'll start fleshing out some of these things, as well as looking at specific areas, a number of which have been mentioned, which we might engage the external community early on, because there would be special opportunities. So, we have a fair amount of work still to be done. Steve?

CHAIR AUGUSTINE: Steve.

DR. KATZ: So it just should be mentioned that although the committee has not gone into great detail on the governance, it

seems to me that those governance models can be considered and are not tied to any one of these particular funding lines so that they are -- they can go forward, and they can be -- something can be implemented after recommendations without necessarily coming to terms with the whole picture. Governance is one issue that exists, no matter what the funding line is.

CHAIR AUGUSTINE: Francis?

DR. COLLINS: So, Arthur, at the very end you also suggested your group might go back and look at the IOM report from 2003 --

DR. RUBENSTEIN: Yes.

DR. COLLINS: -- as another possible sort of source of thinking about this, and, of course, what they did recommend was that the Clinical Center would be perhaps moved into a completely new entity, which I think they called the NCCRRR, standing for a merge of Clinical Center of some of the

activities that are currently in the NCRR, including the CTSAs and some other as activities, as well.

That would be a much more dramatic kind of step to take, and, obviously, consequences there could be quite significant in terms of who would be excited about it and who would be upset about it. But I did wonder if you were going to maybe take another look at that as one more option, because basically, at the moment, you have these three, moving the Clinical Center budget on the right side of your diagram there either into the institutes -- all 26 or however many have a clinical component -- into the OD or into its own line. There would be this other possibility of moving it into some other unit of the NIH, not by itself.

DR. RUBENSTEIN: Yes, we'll need to evaluate that after today. I would say we wanted to try to focus on things we thought could happen in a reasonable time, because

leaving aside Gene's admonition, which I think is right, there are budget things that we thought for five years wouldn't be a good idea to keep talking about it.

On the other hand, these are important reports, and we'll go back and look at that and see. I think the subcommittee will look at it and evaluate it.

CHAIR AUGUSTINE: I come away from the discussion with less confidence than I had when I got here on this question of if you build it, will they come, to borrow the baseball movie analogy.

I had the impression that if a reasonable cost model were built, that there would be enormous demand, and I gather that maybe some of the inhibitants, ranging from governance to intellectual property to differences in protocols to geography --

We've heard a lot of things mentioned. It may be a lot more serious than I had imagined, so I guess, Art, to you and

your colleagues that does sound like it needs some further meat on the bones before we can make a recommendation.

I'm also struck from both our current discussions and in my prior lives associated with NIH that nobody is terribly satisfied with the status quo, so hopefully we can find something that's better.

I also would want to suggest to the committee Bill's comment about outsourcing is sufficiently different that I would not want to leave the impression we hadn't considered it, but I don't think we have to beat it to death, either, and I would hope that maybe in your report that we could at least make clear that that was thought of.

I thought Tony gave a pretty good answer to that. I mean, it fundamentally changes the whole concept, and we just didn't think that was worth taking on if indeed that's the way the committee feels, but I think it should be mentioned.

Does anybody else want to -- anything? Bill, please.

DR. BRODY: Yes, you know, my comments should be taken in context. I did spend in the seventies two years at the Clinical Center, and I don't think much has changed from my impression then, which is it's a tremendously under-utilized resource, and we might be able to think about doing this in a two-step fashion. One is to move --

It sounds like the budget and the governance is an issue that's got to be solved, and one could think about moving that to the OD line or a comparable line but then studying the issue of how do we make it a true national resource, including the possibility of perhaps merging it with other parts of the NIH to create what would be, I think, a very -- potentially a very exciting entity.

And I do think that if you could figure out how to make it available as a resource for testing new molecular entities,

many places do not have the capability, including my own organization now, to test out these things, and so it could be very attractive, but there are lots of factors including legal and regulatory issues to overcome, but, I mean, I would encourage you to continue, our comments notwithstanding, to make progress in this area.

DR. RUBENSTEIN: If I could just comment, Norm. So I agree with that. You know, I think there is really a compelling vision here.

There are lots of barriers to getting there, but just walking around the Clinical Center, if any of you haven't done that, and many have, you know, the resources are extraordinary, I mean, government resources that are doing unbelievably wonderful things and discoveries being made and so on.

And I think there are just a lot of places around the country. I mean, Tony

made a point about Memorial, and you can say with Hopkins and Penn, but there are many, many places that just don't have these capacities to do it, and they -- good ideas, good investigators.

I'd also mention the CTSA funding is pretty much going down from expectation, leaving aside what level it would be, so many people seem to have lots of ideas even at the very best institutions that can't get funded now.

And maybe there would be efficiencies when we really analyzed it and thought about where it should be done, rather than just, "We have this amount," and, you know, "We have that amount," and there are national examples of cooperative efforts that have been very successful.

So I would just say I think we're excited by the possibility while acknowledging the difficulties, and we just have to get on and look at all these things and see what's

possible.

CHAIR AUGUSTINE: Dan?

HON. GOLDIN: I really caution, having lived through a lot of national facilities over decades, one of the things you might want to consider, Arthur, is working with the people who you believe might have use of it. It's very hard to get people to go from their own internal world.

There is a bureaucratic barrier that you've got to get through, very, very difficult, and I think doing some test marketing with people who were the primary targets without making commitments may be very helpful in guiding where we're going to go. As I say, I've tried this on many, perhaps ten, 12 times, and it's been very difficult, and that's my advice.

DR. RUBENSTEIN: I think that's fair. We really need to look at a group of really unique opportunities to see who would be interested, so I agree with that.

CHAIR AUGUSTINE: Tom.

DR. KELLY: Yes, following up on that comment and also on Bill's, I think there is sort of an intermediate model between outsourcing to American University or GW and trying to build this national resource as one investigator at a time, and that might be to think about partnering with one or two or three, a small number of research-intensive institutions around the country, maybe making some kind of formal relationship with a relatively small number of organizations that might be able to generate a large body of collaborative research that might use the Clinical Center more effectively.

CHAIR AUGUSTINE: Okay. I think we've fairly well covered that. Art, thank you again and your group and the presenters. Is there -- I'd mention two things based on what we've said here that we ought to do in follow-up.

Is there anything else in follow-

up that anybody wants to raise so that when we next meet we'll be able to have a fulsome conversation? If there is, and you don't think of it right now, please mention it to Art, and he could pick up on that.

We're a little ahead of schedule. I think that's good news, because, Hal, that way we won't have to have you talk while we're munching sandwiches, and so I think --

I'm told that those of us who have ordered lunch, it is now out there, and for those who did not order lunch in advance, probably including our guests, there is a restaurant, cafeteria, I guess, on the first floor, and you can find it by following the crowd, probably, but it is fairly easy to get to.

And what I would suggest is that we get together at five after 12, and then we won't try to have a working lunch. We'll -- will that work for you, Hall, all right, schedule-wise? So at five after 12 we'll meet

here and be able to listen to what Hal has to say.

So does anyone have anything else you want to say before we break? Okay, we'll meet at five after 12. Thank you.

(Whereupon, the foregoing matter went off the record at 11:36 a.m. and resumed at 12:17 a.m.)

CHAIR AUGUSTINE: If everybody can gather around, we'll reconvene. I introduced Hal this morning, so I won't take time to do it now other than to comment that his reputation precedes him as somebody who has thought a lot about the subjects of change and organizational management and so on, and we're really honored you'd be with us. We thank you, and we'll give you the floor.

DR. RAINEY: Okay, thank you. Thank you. I am honored to be here. I hope I can contribute to the very important work you're doing, and I'm already impressed with that work. In fact, I knew this before I

came.

There is obviously a fund of experience and insight in this room, and so many of the comments being exchanged were comments that I wanted to respond to that I regret I don't have the facility and flexibility to respond to them all in the remarks I'm going to offer, but it has me thinking, the wheels turning.

I can hear the rust up there working off the wheels about some points that I am not covering well in this presentation and that I may try to do some more about and have some thoughts about.

I'm concerned, given what I've said, with how I avoid being redundant with matters you've already covered, what can I add of value, since you're already made a lot of progress and have covered a lot of the beginning issues and challenges in considering organizational change.

Some of what I say will be

redundant or echo what you've said, but I think other points I'll cover suggest additional challenges you probably already know you face but that can bring them on to the agenda.

I also hope to flesh out the discussion with some examples from experiences I've had in research on large-scale organizational change, and these can trigger your own thinking about how much these examples are applicable to you.

In some cases, they might not be applicable, but as you're seeing in your own discussion, these discussions about topics like this and management and organizing tend to be a dance of generalizations at the general level.

We have very general generalizations about what we need to do to make organizational change, but then those have to become mixed with the experience of the people with real decisions and real-world

actions to be taken to be fleshed out using your intuition and your experience. Ultimately, it becomes a people problem.

Pardon me if I use first names when I'm trying to respond to things people said. I do that for collegiality, and I assure Amy this has no implications for conflicts of interest.

We're not really friends. We don't have anything going, but Dan was talking about some of the problems of trying to bring experience into the consideration of what we do, or at least he was illustrating that.

What I'm going to do is to summarize for you an article that's apparently been provided to you. I know how busy you are, and I didn't assume that you were going to pack this article in your briefcase and take it home for your leisure reading, so I want to summarize the main points.

The article was published in *Public Administration Review*. My co-author I

decided to make a co-author on the presentation here. He's Sergio Fernandez from the School of Public and International Affairs at Indiana University. That's one of the major programs in our -- in my particular field, and we're very proud of Sergio.

He's one of my doctoral students, and he won the top three dissertation awards that are awarded in our field for his dissertation a few years back. He's doing very well, and I'm building him up here now and using him as co-author so that if you find fault in this, I'm going to blame it on Sergio. He's the first author.

What we did in this article was to go back through literature on large-scale organizational change and looked for consensus among researchers and expert observers, and I can go into more detail later if you want about the nature of this body of research and expert observation. I'll omit that now.

What you find is that the research

consists mainly of case studies and expert observations. It's hard to assign -- to do experimental research on large-scale organization change. You can hardly assign at random an experimental group of large federal agencies who are to implement an identical organizational change and compare them to a randomly assigned control group.

So, what this consists of generally is a body of research or knowledge, comes from expert observers, or I and some others have been involved in studies of organizational changes involving extensive interviews and observations of various sorts. And it produces very general generalizations, as I said and as you will see, and one issue is do these amount to anything more than Zen-like aphorisms? Are they not common sense?

But, I defend them on the basis of the point that they are easier said than done. They point to major challenges that change agents and change leaders have to face, and

part of this literature is based on observations of failed organizational changes, and, as some of you have indicated, you know of many of them where people did not do these things, or they did not do them well.

Let me try to move through this and stick to the knitting here. I'm trying to avoid reacting to some of your comments with stories and incidents that I can remember, but, number one, ensure the need.

You're already into that issue with trying to decide how you justify the need for a change in an organization that is not in crisis. How do you justify the expenditure of resources and time when time of your people and you is so valuable and such a precious commodity?

In the larger sorts of change processes I have observed, they typically involve what is called, in this literature these days, transformational change. That is, large-scale changes in large organizations

that involve changes in multiple dimensions of the organizations, new strategy, new product or service lines, new structures, new performance assessment processes.

And, in such large-scale changes, there is an emphatic message from this literature that top-down fiats don't work. It will not work to have the people at the top simply to announce a change. "We're going to do this, and this is exactly what we're doing to do."

They have to -- there has to be sustained, stable leadership with a commitment to change. That can take various forms that I'll get back to in a minute, but there is an actual salesmanship and political problem of building support for the change to make the change accepted and effected.

It's -- there is going to be resistance to the change, as you know. There are ways to resist change, and so the problem is how leadership of the change process

develops a compelling vision for the change, and this often will involve -- inevitably will involve a lot of written and oral communication, active participation, and the successful patterns tend always to involve these processes.

This is one of the reasons that the burning platform issue comes up. With a large-scale, multi-faceted organizational change, why do we need to do this, and how do we build the momentum to do it and deal with resistance to do it? And sometimes the resistance, as you're implying in some of your discussions, is well justified.

I didn't bring with me a Dilbert cartoon that -- I was trying to save time -- that ridicules large-scale change processes in organizations by depicting the higher level executives planning a change for self-serving reasons, and when the change plan hits the operating level, one of the little characters is running out of the cartoon to get his

reorganization boots on, because there is a certain substance that he says is going to get deep when we reorganize once again.

There are good reasons sometimes to resist change, and the burning platform justification is part of the advantage a change agent can have if there is a major crisis or a problem that provides a rationale for major commitment to a change process.

Now, this is a bit of a departure I don't want to take too much time with. In reacting to some of what you're talking about here, changes that are not initiated by a crisis, it occurred to me we want to avoid burning platforms, don't we?

I was chuckling, because in the biographical sketch that is in the notebook there, it mentions that I was an officer in the U.S. Navy years ago. I don't know why I even include that anymore, because I chuckle about it because Horatio Hornblower and I followed a very different career trajectory.

I had a very glamorous job. I was an officer on a fleet oiler, and my job was to be the damage control officer and the fuel cargo officer. I was in charge of the oil, and, as I understand it, the burning platform analogy originated --

It was used a lot by the CEO of IBM when they were undergoing a major transformation and really challenged with what they needed to do to right the ship once they -- when they were in deep trouble, and he talked about the burning platform.

Please correct me if you know better, but as I understand it, it was based on the analogy of an oil platform out in the ocean and a burn of the -- when there was a fire on the platform and there was oil present, that justifies emergency action and response.

Well, from my job in the Navy, we didn't like burning platforms with oil involved. There were upsides some of the

sailors would point out. They increase your visibility.

The emergency response people will never have any trouble finding us, but we all agreed an oil fire on a ship at sea will ruin your entire day, so you want to avoid that, and I'm thinking more about there are other patterns of bottom-up changes that can happen in organizations and that might be applicable to you.

A friend and colleague, Steven Kelman, who is at the Kennedy School at Harvard, has written a book called *Unleashing Change* based on his experiences in leading major reforms of the procurement system in the federal government, especially the Defense Department.

And, he actually found through survey research and other means, that within the organization, within the system, there was support for change. There were a lot of people who agreed, "We need to do something.

We're not in an intense, overwhelming crisis, but we'd like to look for better ways to do things."

I'm going to try to think more about that and do more research on it, and I'd like to try to submit some written responses to this problem to the group here when I get a chance, but the examples I know about are examples of, in effect, crisis situations leading to major changes. And, I'm going to mention -- I can't get as deeply into the detail as I'd like to -- refer to several examples I am familiar with, I did research on.

Several decades back, not reflecting on anybody in the Social Security Administration now, the Social Security Administration experienced a very large claims backlog. A claim was a request by a citizen for their Social Security payments or for certain other services.

They had a million case backlog.

In a sense, this change was driven by a metric. The cases were overdue. There was a certain period of time when a case was supposed to be opened and then closed, and the client should get their response within a certain period of time, but there was a huge backlog.

If you were a retiree and you have time on your hands, and you're not receiving your Social Security check, what do you do with some of that time you have on your hands? We don't have to guess.

Congress was getting a lot of comments and complaints from the recipients who were not receiving. They were transmitting the complaints to the Social Security Administration. "Do something. Get this fixed."

They had some antiquated methods within their case processing, claims processing procedure that they ended up fixing. They had different units of the

organization handling different parts of the claim. One unit would authorize the claim. Another unit would decide how much to be paid on the claim.

They actually ended up creating modules, and it was a very painful process creating these modules that would be teams that would process a case from beginning to end. All the specialists were in the team that would handle the case, and with that and other changes, they were able to resolve the problem of the -- of the backlog, and it was a successful change.

It was very well institutionalized, as I'll mention again in a minute, but it was very painful at the outset. They were -- these modules involved changing the pattern of management in the organization and many other changes. There were early retirements. There were dislocations of various sorts.

I was involved in a pretty

extensive study of major changes at the Internal Revenue Service beginning in the late 1990s due to a firestorm of criticism of the Agency, hearings in Congress that dramatized abuses by IRS agents against taxpayers, widely publicized breakdowns in their information technology system, complaints from taxpayers about inadequate processing of their tax payments and their tax returns.

So, there was a firestorm of criticism and actually led to a reform commission that, in turn, led to reform legislation, and Charles Rosati came in as a new Commissioner and let large-scale changes that I'll refer back to in certain ways.

I was involved in a study at the Brookhaven National Labs where, due to intense criticism by environmental activists including major celebrities, they made internal management changes and structural changes and changes in processes and procedures.

These were driven by a firestorm

of criticism there, including a major movie actor or famous movie actor appearing on television in the area and introducing a young boy who claimed that he had gotten cancer due to the pollution of the Brookhaven Lab.

Well, these -- according to the scientists in the lab, these allegations were completely unfounded scientifically, but things got out of hand, and the organization fell under pressure from elected officials and higher levels in the Department of Energy to do something about this, calm down this firestorm, and they made changes.

So, a lot of what I'm talking about here really is crisis response change in organizations, and just how applicable it is to the case of some of the changes here is a matter for discussion.

Leadership has to provide a plan, obviously. It sounds obvious, but devising that strategy for what we're going to do and how we're going to do it becomes a challenge.

Often, the successful leadership patterns in these organizations involved success at doing this, at devising, at least at the outset, a general vision, if you will, or plan for the change. "Here is an idea about what we ought to do." Mr. Rosati, when he took over at the IRS, wrote a white paper, if you will, a vision piece about the new IRS, the transformation that had to happen involving, among other things, new operating divisions.

Now, I've taken out of this part of this table a statement about the plan needing to be clear and specific, and so please don't tell Sergio I took that out without consulting him first. I'll tell him when I get a chance, but there is an issue as to how clear and specific this original idea has to be, and it appears the indication is it should not at the outset be that clear and specific.

For example, Mr. Rosati rolled out

this plan and ultimately appointed 26 design teams representing people from all areas of the organization, all levels of the organization, and they worked on the refinement of this broader plan and this broader vision. And this was obviously a very expensive and time-consuming process aimed at generating participation in the -- in the change process for obvious reasons to people like you.

You build support. You get input. You try to get good ideas. You also finesse the union. Mr. Rosati let the union leader appoint members, some members of the design teams, and the union member, the head of the National Treasury Employees Union, was delighted with this, and the union bought into the change process.

So, the original idea need not be that specific but should provide guidance for later refinement. In the Social Security Administration, the idea of the modules that I

mentioned was developed after extensive deliberation, research, consultation with industry, and other developmental processes of that sort.

Build internal support and overcome resistance. There is a pattern, again, of widespread participation, involvement of multiple interests and levels of the organization in considering the plan, in hearing about the plan, and the successful leaders invested very heavily in this.

You know, Dan mentioned the town hall meetings he conducted in the IRS. Rosati disseminated films of himself and others explaining the change process. He appointed these design teams. He conducted town meetings with employees around the country, some of which -- at some of which he was actively insulted and berated by the employees for these changes he was making, which they would claim were making things soft on the tax cheaters.

He held a meeting in Atlanta of all the middle managers in the IRS. It's pretty expensive to fly every middle manager in the U.S. Internal Revenue Service to Atlanta for a meeting and put them up and feed them and so on, but there was a major commitment to this change process.

Interestingly, in relation to this part of the process of -- part of the process of publishing this article involved having the editor of this series in the journal put the article up on the web and inviting several other researchers to critique the article, and these actually were our friends and colleagues from other universities.

But, they were helpful in trying to help us see the error of our ways, and they objected strongly to this idea of overcoming resistance, as if we were adopting the perspective of organizational consultants who come in subservient to management and seek to squelch resistance to the change.

Well, we didn't really mean that, but one of them in -- there is a fairly idealized commitment to organizational democracy in our field, and this is one form of it, but one of the critics said, "You need to involve everyone in the organization in the change process."

Well, at the time, there were 120,000 employees in IRS. That's a lot of people to invite to the Commissioner's office for a round table discussion, but they felt that this was too top-down. This was -- and we didn't really mean it that way, but in the successful patterns there is a major effort, as I have tried to indicate here, to represent people.

There is a real problem in these patterns of participation that is like the problem of representation in political science. Who gets to come to the table? Who gets to participate? Part of the idea of the design teams was bring as many people into the

consideration as you can.

I'll try to hurry on up now. There has to be top management support and commitment, and this can take different forms. Somewhere there has to be sufficient authority and resources to sponsor and drive the change. There are a couple of different models in these or different patterns in the experiences I'm talking about.

In the Social Security Administration, a very effective or, at least, long-term, well established Director of the Administration served as sponsor to a long-term, well respected career civil servant who was appointed to lead the change process. The top person did not do the change, did not micro manage the change, but rather became the sponsor for the change champion or the change leader.

One issue that, I guess, your group will face, as some of these proposals for change move out of the committee here,

what's the launch momentum? Are you going to try to assess and conduct these change processes yourselves, or are they going to be turned over to people in those units that are proposed for change, or are --

Who's going to lead the change? You may have been through that, but that as an outsider occurs to me to be a challenge to be decided. Where do you go from here?

In the IRS, obviously, Commissioner Rosati played a major role as head of the Agency, but at the same time he had a very strong, long-term insider as his major Deputy Commissioner who was instrumental in the change process, and he very carefully partnered outside people coming into the IRS from the outside -- I'll mention that again -- with long-term IRS experience.

External support is obviously very important. I don't need to tell you that, but relationships with the elected officials, the Congress, can become very essential. There

are certain federal agencies that are insulated from political interference in various ways, but the insulation is often very leaky, and sometimes the Congress --

There are many examples of Congress intervening and vetoing a change. "You will not do this." "Why not?" "Well, we're not going to tell you, but certain interest groups have told you -- told us that we're not going to make the change."

In the IRS situation, there was an interesting mixture of relationships with the Congress that were very antagonistic and on the other hand relationships that were very cooperative, and the reform legislation written by the Congress actually wrote into the legislation some proposals that the leaders of the organization had for the reforms.

For example, they gave Rosati a five-year fixed term to give him the staying power to see through the changes so that

people couldn't wait the changes out for a new political appointee to come in.

They gave the IRS a number of new pay, I mean, personnel flexibilities, including one I studied for the IBM Center for the Business Government, in which they gave them 40 positions that were critical pay positions where they could expedite the hiring of external people, professionals and executives, going around the complex federal personnel process and getting external people they needed, and then Rosati very skillfully partnered these people with long-term IRS insiders.

But part of the point here is getting those changes, including the structural change, into the mandates from Congress, the people in the organization said that was infinitely helpful in getting them implementing and accepted within the organization.

I'll move on quickly, because I

want to give you plenty of time to talk. Obviously, all this takes resources. It took major commitments of resources in these changes processes. The changes, to be effective, have to be institutionalized. They have to be made permanent. A lot of changes evaporate and disappear, as you know.

How do you do that? You reward new behaviors. You set up new reward structures, new organizational structures and processes, effectively implemented and monitored over time and made flexible over time, reformed as necessary institutionalized changes.

When we went back 30 years after the adoption of the modules in the Social Security Administration, that was a very painful change they made originally. When we started talking to them about some of the obsolescence of the modules, given advances in information technology and other developments, they thought coming out of those modules was

unthinkable. They had become institutionalized as part of the process.

In this IRS, the structural changes, the new operating divisions that Commissioner Rosati put in, are still there ten days later, as are may of the other institution changes that he made. So they made the changes reasonably permanent, and, of course, changes have to be, typically in this domain, comprehensive.

They need to be coordinated with each other. There are bad examples of change processes where we were changing one system, and that change wasn't consistent with the change in another system, so coordinating all of this becomes an issue.

Okay, I'm not going to drag you through the rest of these slides. I have talked more than I should already, but there are some other items here not from our article but tend to reflect the kind of generalizations emanating from this

literature.

So I will go ahead and let that be it, and I will be glad to hear your comments. They don't have to come at me, obviously. I'd like to hear you talk to each other.

CHAIR AUGUSTINE: Thank you. We do have time for some questions if there are questions. While you're thinking, I'll start with one. I think the most important thing I learned about change was counterintuitive.

I had always been told don't try to make change too fast, because people can't deal with change too quickly. They've got to get used to it, and I found out that was just exactly wrong in my own experience.

If you've got to make major change, do it and get it over with, and get on with life. Does that fit your experience at all, or was that an anomaly?

DR. RAINEY: Well, both things have to happen. It sounds like a funny answer, but there has to be a momentum from change.

CHAIR AUGUSTINE: We need the microphone.

DR. RAINEY: I'm sorry. I said both things need to happen, in a sense, and that's not a wise guy answer. There has to be momentum. Long-term, slow, incremental change is not a response to major crisis or major impetus, a major impetus to change for a lot of obvious reasons.

But, what is built into some of these changes processes is the launching of a major initiative. "We are going to make big changes. Here are the ideas. We're going to flesh these out," sometimes coupled with experimentation and incremental change within that broader framework.

For example, in the Social Security Administration, they developed this modular concept, and instead of saying, "All the public service centers are going to do this," they went to the Philadelphia public service center, and they bargained with them

and said, "Don't you want to try this brand new way of doing things?"

Early on, the module system had real problems. They worked those out and showed that the module system could process the claims a lot more efficiently and effectively. Then, they sold the change to the rest of the public service centers. "Look how well it's working in Philadelphia. Why don't you improve that much by doing this?"

So, there was a major momentum for change. The top leaders were pressing for change. They were supporting the change process. They were working on ideas. They came up with this model, but it was mixed with sort of a flexible experimental approach to change.

So that doesn't obviate what you're saying. The overall point is that some -- if you really want to make big changes, a slow, incremental process is not in order, but at the same time, to the extent that you can

build in flexibility, experimentation, you try something and see if it works.

That appears to be part of a successful model often. Obviously, that's a luxury. One of the problems in the public sector, as you know, is the short-term nature of high-level political appointees, and that's why people can wait out the changes.

So the short-term nature of top leadership is not necessarily a justification for rapid change, because that's part of the -- what can get a political appointee in trouble in trying to make a change in a year when a lot of the changes you're talking about, big changes, take three and four years.

So, simple, incremental, slow-moving change processes do not bring big change, but there has to be momentum. There has to be a big push and initiative, heavily supported with resources and authority, but at the same time the extent that you can build in experimentation and trying different things

and seeing what works, that seems to be part of a successful model, as well. I don't know if that --

CHAIR AUGUSTINE: Thank you. Thank you. Let me get Steve and then Dan.

DR. KATZ: So, thanks, Dr. Rainey. In your Rosati example of the -- at the IRS, you talked about there being a lot of criticism. Would you put that in the category of the burning platform, and where was the criticism coming from that motivated this change, which seems to me that he was -- he integrated all levels of management in terms of implementing that big change?

DR. RAINEY: Well, the two sources of criticism, the driver -- the driving force behind the change was external criticism. As I said, there were some well publicized breakdowns in their processes.

There was a meltdown in one of their public service centers where political officials were visiting and touring the

center, and they happened to find tax returns, including taxpayers' checks, stuffed in the trash cans and stuffed in the overhead of the bathroom.

The information technology, the technological processes they tried to adopt to expedite tax processing weren't working, and getting back to what Dan said about the often dysfunctional nature of metrics, they were evaluating people on how fast they processed tax returns, among other things, and so what they were doing was deep-sixing the tax returns.

That was -- so there were a lot of criticisms --

DR. KATZ: That's a good way to get rid of them.

DR. RAINEY: I'm sorry?

DR. KATZ: That's a good way to get rid of them.

DR. RAINEY: Well, there are stories about that in the Social Security

Administration, too, but there were major hearings in the Senate that were publicized internationally where they brought forward people behind partitions to report on abuses they received at the hands of IRS agents, agents raiding their houses in the middle of the night and brutalizing their children and so on.

Many of those turned out to be exaggerated and were discredited later. There were widely acknowledged problems in the information technology system that were causing disservice to taxpayers. The taxpayer would receive a letter that said, "You owe us more taxes." They'd send in a check.

Three weeks later, they'd send another letter threatening them, "You'd better send in the check." The problem was the information technology system was moving too slowly to take in the information and store and retrieve the information that the person sent their check in.

So they had huge information technology challenges. That was an external -- the external --

DR. KATZ: So he was brought in from the outside to --

DR. RAINEY: Yes, I'm sorry. As I mentioned, these are pretty complicated cases, and I'm giving the most thumbnail of sketches, and it's hard to fill you in on all the details. I'm sorry about that, but he was brought in from the outside. He had had experience in government earlier in his career.

He had been one of McNamara's whiz kids, but he'd gone out and become very successful in the private sector leading a consulting firm, made a lot of money, apparently. That's his business, not mine, but came back to government in part because he was challenged to come back and make a contribution but was selected in part because of the background in the private sector.

Now, internally, the opposition that he encountered was, in part, because he sought to change -- he didn't use the term "culture," but the culture of the IRS to more heavily emphasize taxpayer services.

He was drawing on a theory of -- a new theory of regulation by an author named Malcolm Sparrow, who wrote about the need to move to new forms of regulation that depart from the detection and punishment version of regulation to forms of regulation that encourage cooperation with the regulatory process.

And, he was convinced that a lot of people have trouble with their taxes because they don't understand the tax laws, and one of his messages that he delivered in his book was that it's imperative that we try to simplify the tax code, which isn't going to happen, by the way. He's right, but it's not going to happen. He thought that there should be more -- better customer service. They

should take care of the taxpayers better.

Well, there's a strong body of opinion within IRS that their job is to defend the rest of us from the tax cheaters, and our job is to stop those tax cheaters, and they felt that Rosati was diminishing the emphasis on detection and enforcement of the tax laws with this orientation to service. So, there were strong opponents within the organization on that count.

CHAIR AUGUSTINE: Dan?

HON. GOLDIN: Yes, I'd like to comment on the interchange you had with Dr. Rainey and say I agree with you both, but you had talked about the need sometimes for rapid change, but there are two aspects to change.

There's the change that the leadership brings about. That's what I'll call phase one of the change, and that you could do rapidly, but phase two of the change is overcoming the resistance in the understanding of the change, because there is

a comfort with existing systems, however bad they are.

So people would like to stick with what they know versus the fear of what they don't know, so there's a time lag in the -- in phase two until a large complex organization with, you know, 100,000 people comes along.

So phase one you could do rapidly, perhaps, in a good fraction of a year or in months, but phase two is generally going to take a couple of years and involves -- and phase one needs to have planning for the implementation of the education and the building of the acceptance.

An example, you did a magnificent job in bringing together I don't know how many dozens of companies when Lockheed Martin was formed, and that process took place fast, but the grumbling stopped about two years after you did it.

And one of the things that people miss in planning for change is they generally

focus on those first three to six months, which gets the blood pumping and is exciting, but it is doing a real good plan for bringing along those tens of thousands of people, and you have to say that that's going to take a couple of years. You cannot do that fast. I don't know whether you agree or disagree with that.

CHAIR AUGUSTINE: I think I partially agree, Dan. I am convinced -- we had 180,000 people that were affected, and we did do some very careful planning, but once we said what was going to happen, boy, it happened, and one of the things I found was that people could stand bad news. They can't stand uncertainty, and your point is a very good one.

I think there's balance of these things, but the arguments I always heard were, "Go slow. Let people get used to the idea," and the fellow who used to run Penney's, the department store, he went through some major

change. His comment to me was, "Don't cut the cat's tail off an inch at a time," pretty good advice, but your point is well taken

Why don't we --

DR. RAINEY: I would just mention that's a useful clarification I think I didn't make clear enough, and I was talking too long, anyway, but part of the process of institutionalizing the change, of implementing the change, they took multiple years in these processes.

There may be a distinction between the public and the private sectors here. I didn't even get into it, but a major issue in the IRS changes was the role of the consulting firm. There was a major consulting firm involved.

That person was -- we spent a lot of the time with interviewing this person about the process of facilitation by the consultants, and I think he wanted us to hear his side of the story, because it was very

expensive.

But, he said that he was actually invited to compete for the consulting contract, because he was representing consultation with large-scale corporate changes, not government changes, corporate changes.

And he mentioned to us on several occasions he thought that industry, I mean, private sector firms are better able to roll out a change than government organizations are, because the -- because of what's going on here. It's a lot more public.

There are a lot more -- there is a lot more openness to the decisions, but what Dan is pointing out is consistent with what we observed in these cases, and I didn't make it clear enough that the original idea may roll out fairly rapidly and soon, "Here's the idea," but all these processes of having town meetings, training sessions, bringing all the middle managers to Atlanta, doing all those

things, that took quite a while.

This same consultant, they were trying to monitor and track the change at the IRS with large-scale customer surveys, because they put in a new evaluation system that's a variant of the balance score card system with which some of you may be familiar that was developed Professor Kaplan at Harvard, which basically argues you study not only the business processes but your consumer responses, your customer responses, and your employee development.

So, they were doing employee surveys and, among other things, trying to assess employee acceptance and support for the change, and at one point, when you'd go into the Deputy Commissioner's office, he would have these survey results open in front of him, and he would be really interested in what we were finding in our interviews out there, because this was a very far-flung organization.

At one point, about two years after the change or three years, when we were in doing the interviews, the survey came back and showed something like 40 percent of the employees supported the change, and the consultant said, "Boy, that's a lot more progress than we made when we were working with this corporation and that corporation. You're really getting along pretty well here," because three years after the change at such-and-such a large firm, about 25 percent had bought in.

The rest didn't think it was such a great idea, but his attitude was it's a little easier to roll out things more rapidly in the private sector. I'm not sure of that.

CHAIR AUGUSTINE: Yes, I would absolutely agree with that. Well, Hal, thank you very much. We appreciate your sharing your thoughts with us. I hope you can stay around, because as other things come up, we can incorporate Hal in the discussion, if

that's all right.

DR. RAINEY: Sure.

CHAIR AUGUSTINE: Just as an aside, for a little break, I happen to know Charlie Rosati, and during the period that Hal is describing I was giving a speech. I knew that Rosati was in the audience, and I commented. I worked it in my speech that I had had a problem with my income tax and that I was told there was a Mr. Jones who was the expert at the IRS.

So, I called Mr. Jones's office on the phone. Somebody else answered the phone and said, "Mr. Jones is on vacation. Do you want to wait -- or do you want to hold?" He didn't think that was funny.

Okay, moving ahead quickly, we turn to our final group that's underway, and hopefully Dr. Roper is on the phone. Do we know that? We're a little -- we're a little ahead of time, I think.

Okay. Hey, Bill, are you on? We

need to scramble a little bit here. Okay.

DR. ROPER: Hello?

CHAIR AUGUSTINE: Yes, Bill, is that you?

DR. ROPER: Yes, hello?

CHAIR AUGUSTINE: Hey, that's -- that's terrific. Can you hear me at all?

DR. ROPER: Hello?

CHAIR AUGUSTINE: No?

DR. ROPER: Can you hear me? Hello?

CHAIR AUGUSTINE: Yes, Bill, can you hear me?

DR. ROPER: I can hear you. Can you hear me?

CHAIR AUGUSTINE: We got you pretty clearly now. Bill, am I clear at this point?

DR. ROPER: Norm?

CHAIR AUGUSTINE: Yes, I've got you here. Are you clear at this --

DR. ROPER: I've been on for a couple of hours, but until just a moment ago

all I could hear was music through the phone, but I've been watching you online, and it's come through quite well.

CHAIR AUGUSTINE: It's a good thing you couldn't see what was going along with the music. Bill, I'm assuming you can hear me all right at this point. There's a huge amount of feedback from somewhere. We've got feedback.

DR. ROPER: Yes, I can hear you. I think the way this is going to have to work is when I'm talking, you all need to have muted your microphone. Otherwise, it cycles through the system and echoes.

CHAIR AUGUSTINE: Terrific. We needed an engineer to tell us that. Good.

DR. ROPER: Yes. I'm ready to start whenever I get the word from you, Norm.

CHAIR AUGUSTINE: Okay, we're all ready. We're sitting here. We've had a briefing, as you know, on the other two groups, and we've set aside 45 minutes for you to talk, but we'll let you go probably without

interruption, and then we'll have plenty of time for a discussion when you're done. So please proceed, and thank you for all your good work.

DR. ROPER: Thank you, sir. I am pleased to have the chance to present to you on behalf of the Substance Use, Abuse, and Addiction Working Group. I regret that I'm not there with you in person, but like I was just saying, I've been viewing it online. I'm in California for another meeting.

Some of the members of our working group are there, and I'm sure they will be able to add some additional points after I finish my presentation. We've taken care as a group, and I've taken care personally to reflect our collective views, including in a meeting that we had just yesterday, and then draft talking points that we all worked on overnight last night.

So, I'll just plunge in. I assume my slides are up there, and I'll be drawing

your attention to the slides.

This working group has had 13 sessions, some of them in person, some of them electronic, and as I said, we had a meeting yesterday, an hour-long session, and all members of our working group participated in it, and we had a very vigorous and good discussion. We understand that the substance use, abuse, and addiction discussion is surely related to the overall work of the SMRB, including the work deliberating organizational change and effectiveness.

Some people, I'm sure, view the work that we are looking at as a prototype for other activities that the SMRB, indeed that the NIH might take on, and in that regard we are anxious to learn from what our other working group on deliberating organizational change and effectiveness is producing. Dr. Washington is a member of both working groups, and Gene has been particularly helpful in making that cross-connection.

At the same time that we are seeing this as a prototype for larger or other activities, we are anxious to pay particular attention to the issues in this sector, substance use, abuse, and addiction and to be sure people in that research community want us to see them as unique and not be casual in the way we view this particular effort, and so we are trying very hard to do both of those things at the same time. So let me plunge ahead.

Slide two shows what I'm going to be talking about, and slide three shows the members of our working group, and some of them are there with you, as I said, but Deborah Powell and Huda Zoghbi, I believe, are not able to be there. Federal members we appreciate, as well, and it's been a very useful process having some outsiders, some insiders in this discussion.

Slide five begins the content of my presentation, and that is for some time

neuroscience research has shown that addictive substances, including drugs and alcohol, have some things in common with each other and some difference from each other, and so the question that's been posed to us is, considering both the differences and the similarities, does the current organizational structure at the NIH with separate institutes on drug and alcohol provide the optimal infrastructure for supporting these areas of scientific research?

There is a context, a wider context to this discussion, of course. The NIH Reform Act that established the SMRB in `06 was interested in these broader issues, but the particular questions of alcohol and addiction have been looked at before, including in `03.

The National Academies recommended considering merger of the two institutes, and an earlier report from the Lewin Group more than 20 years ago raised the option of a

combined institute of addition, and also almost ten years ago the Drug Abuse Act of 2001 required the HHS Secretary to request that the IOM study whether combining the two institutes would be worthwhile, and, unfortunately, that study has never been done.

So, in effect, our deliberation as a working group and, ultimately, the SMRB follows in the tradition, the train of those earlier efforts. Our charge is shown on slide seven, to recommend whether organizational change with NIH could optimize further research into substance use, abuse, and addiction and maximize human health and/or patient well being.

We've had, as I said, 13 sessions. Most of them -- most of them involved hearing from others as their views on this subject, and we began with hearing from the two Institute Directors, Dr. Warren from NIAAA, Dr. Volkow from NIDA, and we've heard from -- slide ten shows, beginning -- a large number

of distinguished Americans who come from a variety of sectors, prevention specialists, treatment providers, patient advocates, policy specialists.

On slide 11, we heard perspectives on the science of the research in this area. Slide 12 continues listing the experts that we've heard from. Slide 13, we heard from a number of people about alternative models for organizing substance use, abuse, and addiction research and people from the judicial system, from academia, from industry.

And slide 14, we heard from former NIAAA Directors and NIDA Directors, people who have been in leadership positions in these two institutes, and then, finally, on February 3 I met with the NIAAA and the NIDA Advisory Council and heard from them.

A couple of weeks ago, I had the chance to brief Dr. Collins and Mr. Augustine to inform them on our work to date, much as I'm describing it for you right now, and we

had a good discussion that day.

So let me describe what we have learned from the briefings to date, and that begins on slide 17. I think it's fair to summarize that we have heard from some people who very much favor reorganization, and we've heard from people, some people who are very much against reorganization.

First, those who advocate for reorg, they say that the science would benefit from synergy, that there are commonalities across these areas, and they point to the fact that emerging scientific research indicates similar pathways and that alcohol and drug abuse often begins in adolescence with similar early risk factors.

They point to the high prevalence of drug users who also use alcohol, and they say that having separate disciplines and separate institutes creates public health gaps that are not in the public's interest. They further say that reorganization and

particularly merging the two institutes would create synergy for advancing the science and would increase the flexibility in cross-training new investigators for the combined field.

Slide 19 begins a layout of what the advocates against reorganization say. They point to the fact that they are concerned that such a merger would create research gaps in understanding. They describe the fact that alcohol in particular has many effects on the body well beyond the addiction issues, and they fear that those would be lost or research in those areas would be lost under such a merger.

They also point to the different contextual and social-cultural environment, meaning alcohol is legal in most parts of our society, and that has many implications. And, advocates against reorganization suggest that they don't see compelling evidence to suggest that such a reorganization would actually

improve things.

They would say that this is largely theoretical and unproven, and they say that the current organizational structure mirrors the separate professional and scientific associations in the alcohol community and in the drug community. Of course, it's obviously arguable which came first, the chicken or the egg, on that one.

And, they further say that reorganization would decrease the emphasis on the effects of alcohol on multiple target organs. In particular, we've heard that they fear that research on alcohol's effects on the liver would be lost in such a combined institute on addictions.

And, the alcohol advocates fear that they would lose out in the budget process that a combined institute in which the previous NIDA forces were two-thirds of the new institute. They fear that they would see their particular area of research compromised,

and, in general, they are strongly opposed to such a merger.

In the discussion that we had -- I'm now at slide 21 -- a number of other issues came up that I just want to briefly highlight for you. One that's come up many times is, "What about other areas of research, in particular, other areas of addiction research across the NIH?"

Tobacco addiction is done in the National Cancer Institute, and so people have suggested, "Well, if you're going to do this, you might as well do that, as well, and have a pan-NIH focus on addiction research. Don't just constrain it to these two institutes."

Another point that's been made is that there is codified in statute a particular role for the Office of National Drug Control Policy at the White House in overseeing the NIDA budget, and the question has been posed what would happen to that role if such an institute were created, a combined institute.

People have asked what's the comment, if any of the beer, alcohol, and spirits industry in all of this.

Some have said quite straightforwardly, "Our patients seem to have no difficulty in using multiple substances. Why does the government seem to have such a difficulty in combining the work done across substances?" and some have asked are we going to, as a working group, recommend a single solution or multiple options.

There are some broader issues that people have pointed to -- I'm on slide 22 -- including the fact that they believe that both institutes are under-funded, and combining the two runs the risk of short-changing research topics across both areas.

I mentioned already, but would say again, we've heard repeatedly that the public health message for alcohol is different from that related to drugs in that moderate alcohol usage may be healthy. Immoderate usage is

not. People worry about a single research dogma crowding out other possibilities in researching this.

Folks have mentioned that we ought not to restrict this just to alcohol or drug abuse. I mentioned already tobacco addiction, but there are other addictive practices in American society, and also the mental health-behavioral health aspects of this are looked at through the National Institute on Mental Health, and so where do you draw the circle of the Venn diagram is the question.

And others have said if we are to talk about a merger, surely this ought to be a genuine merger, not just a creation of a holding company institute with separate divisions within it that are pretty much the current institutes as they are now constituted. I'm at slide 23.

I mentioned that, on February 3, I met with the NIAAA Advisory Council and summarized this pretty much as I have given it

to you so far and then responded to the Council's questions and comments. That day, they passed the resolution that's on the slide before you, which I leave to you to read for yourself, but they said they are against any reorg that would eliminate NIAAA as an independent institute.

That same day, I also met with the NIDA Advisory Council, and I similarly presented our work to date and then heard from them, interacted with them, and later they passed a resolution, again unanimously, saying that they are in favor of such a merger, and I think those two resolutions typify what we have heard from a variety of quarters on this subject.

So, slide 25 begins to describe where we are as a working group on this subject. It lays out step one in the process for assessing the need for change and poses the question, "Is current substance use, abuse, and addiction research at the NIH

capitalizing on opportunities and meeting needs, or could reorganization better do this work?"

And, on slide 26 we lay out a number of considerations that we believe ought to be undertaken in answering those questions. We borrow heavily in these five considerations from our colleagues in the Deliberating Organizational Change and Effectiveness Work Group.

That's an intentional crosswalk between the two groups. I won't read all the points on this slide, but would just say these are the things that we have tried to pay attention to as we've heard from these individuals and organizations and their strongly held views.

Slide 27, in assessing the need for organizational change we've asked for some additional information. That is, including, we've asked the Directors of the two institutes what the major challenges are

facing the advancement of research in these areas.

We've asked to look at the funding history of the two institutes and grant success rates across those institutes, support for early investigators, the rest of the NIH portfolio, and then some population demographics in this area, and I'll show you results to date from those areas.

Slide 29 is the NIAAA answer to the question, "What research and public health needs are not yet currently addressed?" Again, I won't read the words, but it lays out Dr. Warren's answer to our question of what's being lost or missed in the current arrangement, and then on slide 30, what Dr. Volkow said to the same question, what is being missed or lost because of the way things currently are organized.

Slide 31 shows what happened over the last decade or so in funding for the two institutes, a similar growth rate, but NIAAA

is the smaller of the two institutes, and that has ramifications that I alluded to earlier. I'll just pause for a minute and let you look at those numbers. And then, on slide 32, it shows what the support for young investigators, training support and K-awards looks like in the two areas.

And then, the next slide shows funding for substance use, abuse, and addiction research across the NIH. This slide is multi-colored and shows funding that is in institutes and centers across the NIH for work in the areas down at the bottom of each of the bars.

I would draw your attention, please, to the point made at the bottom of the slide that these estimates were provided by individual institutes and centers and don't reflect the official NIH budget numbers, but I think they are notionally close and are helpful to answer the question, "What's the rest of the NIH look like?"

I assume your colors are about the same as mine, but the dark blue is the NIAAA. The bright red is the National Cancer Institute, and the purple is NIDA, and what you see is there's a lot of addiction research across the NIH, and not all of it is in these two institutes, as we've noted already.

And then, on Slide 34, some information about the population involved with use and addiction, first, a dominantly younger population, and it shows the use of multiple agents, alcohol, drugs, and both.

The next slide continues that same point and then makes the additional point that there is an intersection between substance abuse and mental health problems, and that theme is carried forward on the next slide, 36, that shows there is a high percentage interrelationship there.

So, I am now at slide 37, and I want to present to you the preliminary findings of our working group, and I say

again, that we met yesterday electronically, all of us, and discussed this thoroughly and vigorously, if I can put it that way.

We've come to agreement that the status quo is not ideal for fulfilling the NIH's mission and optimizing research into substance use, abuse, and addiction, and we are eager to improve how the NIH manages research in this area.

Slide 38 begins to lay out the spectrum of options that one might undertake to improve the current situation, evaluating options for change, and that is portrayed on slide 39 that shows at the far left the status quo with two institutes entirely separate, at the far right a new institute, and then in between several what we are calling functional strategy options that shows -- each of which shows things that might be done in common, including, for example, a single advisory council for the two institutes or some shared functions, joint ventures, if you will, or a

blueprint for research in some areas across the institutes, so a variety of functional strategy options.

As it begins to say on slide 40, to date the working group disagrees on how best to proceed, whether structural, that is, merger or other organizational change, versus functional integration across these areas.

There is a minority of our working group who have a view that structural reorganization is needed involving a merger of NIDA and NIAAA into a single institute focused on alcohol and drug abuse and addiction.

They would say that, given the scientific landscape, research opportunities, and needs in these areas that surely we ought to have a vision for doing more and doing it better, and mergers, however difficult it is, we ought to take on that task, or Dr. Collins and the NIH ought to take on that task to press ahead.

On slide 42, I begin to lay out

another view held by a majority of the working group that would say that the best way to proceed is a functional reorganization of research programs in these areas.

This part of our working group would say that given the science and the research opportunity and the public health needs clearly provides a rationale for considering change. But, this majority isn't convinced that structural changes would benefit the science behind what functional integration would do.

They see substantial room for improving the science across the NIH, and there is some evidence that in other areas, not all, but other areas where this has been attempted there has been some improvement, and people have pointed to the Neurosciences Blue Print and the NIH Common Fund and which say that that should be done or attempted in this area before pressing ahead to structural change.

We will be continuing this effort and look carefully at the pros and cons of each option. We plan to present our working group recommendation at the next SMRB meeting. Whether it will be a single unanimous recommendation or a majority/minority set of recommendations remains yet to be seen.

My final slide, number 44, lays out the calendar that's before us. One of the things that I've learned, speaking just for myself, is that this long and rather arduous task that the statute setting up the SMRB requires of us seemed at the outset to be overkill to me.

But, I have come to the conclusion that this thorough process is warranted in this instance, and as I said, at the outset, if this is a prototype of what is to be undertaken in other areas, I think this is a useful, careful, I hope, thoughtful process.

So, Norm, let me stop there, and I'd be happy to answer questions, or I'm sure

others from the working group who are there with you in the room might have other things to add.

CHAIR AUGUSTINE: Bill, thank you so much. That was a thorough update. I guess no one said this would be easy, and it's certainly proven to not be easy, but the number of people you've spoken with and the number of meetings you've held speaks to the complexity of the challenge.

Why don't we, before we take questions, let the other members of the working group that are here, if you have any comments you'd like to make or anything, this would be a good time to do it.

Bill, I think we need to put you on mute. Bill, I think we need to put you on mute there.

DR. ROPER: I just did. Sorry.

CHAIR AUGUSTINE: Okay. Fine.

DR. TABAK: Hi, Bill. Larry Tabak. So just to underscore one of the points that

Bill made, really circling back to the discussion we had at the beginning of the day, I think it may have been Jeremy who pointed out that change just for change's sake -- and I'm paraphrasing. I'm not quoting Jeremy now -- is probably not worth the aggravation, so if you're going to have change, it needs to be substantive to be worth the effort.

One of the side bars that the group has had, and Bill alluded to, that I just want to underscore, is this notion of if you truly believe that you will improve the science of addictive behavior research by merging things, why not include all addictive behaviors in your design for change?

And, again, not wanting to misrepresent anybody's views, on the one hand it was expressed that, "Well, you should not try and bite off more than you can chew," no pun intended, versus, "We just haven't had enough time to deliberate that, but at least some people were open to considering it," to,

"Oh, my goodness, that's the NCI," and, you know, the political issues surrounding that.

So, I think that that also needs to at least be on the table. My own personal view, and I said this to several people, is that we have to be consistent.

We either believe that a change can improve the science, in which case, I don't know how you parse out one type of addictive behavior over others, and if we say we shouldn't allow political issues to get in the way, then we shouldn't allow political issues to get in the way.

That all said, we've got to be really sure that, in fact, the science will be improved, okay, and I hope I haven't misspoken about anybody's position during the discussions, but I'm sure my colleagues will be quick to correct me if I have.

CHAIR AUGUSTINE: Thanks, Larry. Who else? I saw other hands. Griffin.

DR. RODGERS: I think Bill really

captured the essence of the discussion, actually, quite well. I think that we still are in a position in which there is, you know, areas in which we can sort of continue to consider our interests and the general interests of the science of substance abuse.

And so what I think Bill has, if I'm -- if I'm not overstating his comments, is giving you our position at the moment, just the interest that needs to be clarified, perhaps, through additional data analysis that Larry is suggesting, but we've really heard over this course of meetings, individual meetings, phone conversations really passionate views on both sides of this issue.

And while, as Larry suggested, you know, we really have to sort of view this primarily as what's going to improve the science for all to improve public health, one can't escape, you know, some of the major other non-scientific considerations to the point that, you know, they can lead to really

a lot of effort being involved in trying to manage, you know, the downstream consequences of those changes just for the sake of change.

I want to point out I think that Deborah Powell may be on the line, so I just wouldn't want to ignore her.

CHAIR AUGUSTINE: Deborah, are you on the line?

DR. POWELL: Yes, I am on the line, Norm.

CHAIR AUGUSTINE: Deborah, terrific. This would be a good opportunity if you wanted to add anything at this point.

DR. POWELL: I would. Thank you very much for the opportunity, and I want to just make the point that I think the minority group really believes that there is more sustainability in structural change than functional change and are certainly -- and have expressed our interest in broadening the mission of a new institute to include addiction in its broadest sense, including

addictive behaviors and other addictive substances, in addition to simply alcohol and drugs of abuse.

However, I think the point that one of us made, that we have not really seriously invested that yet, is the kind of thing that Larry Tabak was referring to, but we, in essence, feel that this is something that has been discussed for many, many years, as Bill correctly pointed out, and this time we feel that we are in support of a structural change in order to sustain something going forward.

CHAIR AUGUSTINE: Well, thank you very much for those comments, and we'll continue around the table. I saw other hands. Tony?

DR. FAUCI: It's a question for Larry and your comment about the criteria that would move you to make a structural change, is the science going to benefit from it, which is obviously very important, but what I didn't

hear mentioned in any of the discussions was just the strict administrative issue.

If you have two institutes, and if you put them together or kept them apart, the science wouldn't be hurt, and it wouldn't be helped. It would stay about the same.

Isn't the advantage of then having two separate structures with two budgetary, two personnel, two this, two that, isn't it an advantage to put them together if it's going to be a wash on the science?

If the science is going to be still good in both, don't you consider the fact that you have two separate entities that you've now made one as an advantage or not? I'm not coming down on either side. I'm just asking if that was discussed.

DR. TABAK: So, to respond to that, it has been discussed. I think the group, in general, felt that there is little dollars to be saved. You know, so you'll save the salary of an IC Director, you know, top five kinds of

things, but in the trenches, particularly in a government system, you're not going to save money.

With regard to efficiency, we had that discussion, and it's a question of how many -- in my mind. Now, I'll only speak for myself, and I'll let others comment, as well. In my mind, it comes down to how many loci of decision-making you have.

It's been argued, rightly or wrongly, that all of NIAAA is not about addictive behavior and that there is a subset that's very much involved with end organ pathobiology, and the concern that's been expressed is if you go from two loci of decision-making to one, the possibility of that piece of the pie getting short-changed becomes more possible.

Now, the other piece, and, again, if I misrepresent what somebody else said, please correct me, other members of the committee, is that, in fact, it's not the top-

down advantages that you're looking for, but rather it's the bottom-up.

The argument was made that the research community would somehow benefit from having a single budget, single program, and so forth, and to that, at least personally, I argue that functional change can achieve that, as we have seen with the neuroscience blueprint, for example, but others, I'm sure, can add or --

DR. BRIGGS: You know, I just want to amplify on that issue of the impact on the scientific communities. What I found most convincing in what we were hearing is the extent to which these two scientific communities, that have a lot of commonalities may not have had a lot of crosstalk and a lot of people who look at common issues.

And whether that is best addressed by true structural change here or could, in fact, be adequately effected by more, for example, solicitations that require that kind

of thought about both kinds of problems is where -- what I found convincing.

CHAIR AUGUSTINE: Steve?

DR. KATZ: So, I have a question of Larry. You mentioned that more data was needed. What sort of data is needed in terms of these deliberations?

DR. TABAK: What I was speaking to, Steve, was the suggestion made by one of the members of the committee that it would be premature for the group to consider whether or not all addictive behavior research would be included in a new entity should one be formed, because we simply haven't looked at it sufficiently to have that discussion. That would be the additional data that I was referring to.

DR. KATZ: So the data would be to look into each of the institutes to look at addiction across the board, whether it's sexual, whether it's tobacco, whether it's gambling.

CHAIR AUGUSTINE: Bill, we should probably let you break in here. You've been listening to the discussion. Do you want to - -

DR. ROPER: Yes, Norm, I've been listening to it. Larry especially is doing a very great job of reflecting what I would say. It avoids the problem with feedback through the electronics, but I really don't have any more to add at the moment in this conversation. I'm going to stay on the line, though.

CHAIR AUGUSTINE: Terrific. Let's see. I saw Bill. Bill next and then Tom.

DR. BRODY: You know, the idea of functional integration is great, but only if you have allocated dollars for it, and, you know, within the NIH system it's very hard to get dollars allocated, and here you have two institutes that say, you know, what they do is completely different, and, you know, getting them to ante up money for a functional program

is going to be, at best, complicated.

DR. TABAK: There was a famous dinner that preceded the formation of the Neurosciences Blueprint where the former NIH Director made us an offer we couldn't refuse, and that's how the Neuroscience Blueprint was born. So there are ways of, you know, assuring that there is allocation of resources for this purpose.

DR. ROPER: Yes, there are carrots, and there are sticks.

CHAIR AUGUSTINE: Tom.

DR. KELLY: I was going to go to the same point. I'd be curious if Larry or somebody else can sort of flesh out a little bit more what kind of functional reorganization you all are thinking about and how that would -- and how it would prevent people from just continuing to do what they're doing now as separate entities and whether you're talking about a particular model. I'd like to hear a little bit more about that

model or any other models for functional integration across NIH.

DR. TABAK: Bill, did you want to handle that?

DR. ROPER: Yes, let me just try it. Let's see if the electronics work. It's a thoughtful question.

If whoever is operating the slides could put up the one that shows the horizontal range of options, what we have been talking about is, and I think I said this in my opening comments, a range of possibilities that look at things that could be done to have a shared common program -- I'm getting to the slide here on my computer -- including, as I said, a single council or a joint venture. I think that's the business term for what is here represented as a clustered function.

Clearly, I don't think this would work with the two institutes left entirely on their own to miraculously see the wisdom in some shared functions. I believe that the NIH

Director and the people around him would need to have the kind of dinner discussion that Larry referred to in an earlier analogous situation to say that this is just the way it's going to be, and you're going to have to allocate and pick up the right percentage of the budget of each of the institutes for this shared function.

That kind of top-down push would have to be exerted, I believe, for this notion of functional strategy to have any real chance of success. Ultimately, the answer to this question that is before us, before the working group and before the SMRB and before the NIH, is which is the greater likelihood of success, this thing that I was just then trying to describe or outright merging the two institutes.

And, as I said to you in my opening comments, we are debating that central question right now, but it should not be seen as leaving things the way they are and hoping

that people will on their own wish to do business together versus an outright merger. That is not what we're suggesting.

CHAIR AUGUSTINE: Let's see. I saw Gene and then Sol.

DR. WASHINGTON: My comments basically have been covered in response to Bill Brody's question about how do we achieve this, but it's my assumption that this group has some influence through its recommendations.

And so, if we recommend some combination of measures, including a single council and a push from the leadership and others for some set of initiatives that draw on current development that's taking place in science that foster the kind of collaborative environment we want to see across the discipline, then that becomes at least a driver for making those kinds of changes happen.

And I see that that would be the

next phase of our discussion is first deciding that as a group, in fact, we are going to recommend functional versus structural, and the majority of that favor that right now, but then making a recommendation about what do we mean by function and driving it, I think the sense of the group is, as close to structural without delineating or pushing for a merger as possible.

CHAIR AUGUSTINE: Sol?

DR. SNYDER: I thought I might give a little historical perspective that might inform this issue, because I've been involved almost 40 years. My interest happened when President Nixon declared war on drug abuse and appointed Jerry Jaffe as the first drug abuse czar, who was a psychiatrist who started methadone clinics and who was a good friend, and I was trying to push Jerry to put money.

While I was worrying about getting money, I became interested in what were the issues, because he was pushing me back.

"Well, why aren't you doing anything about heroin addiction?" and I said, "I don't know morphine from marijuana. I started reading about it, and that led to the work on the opiate receptor.

Now, I'm a psychiatrist fully supported by NIMH. Had I been part of the drug abuse, and there was a whole -- literally called the Narcotic Club. Had I been part of the community and been involved with opiate research, I would have -- the work on the opiate receptor would have never happened, because I would have known that it was impossible.

And then, it became a hot area and endorphins, and then Marshall Neurenberg, the great Nobel laureate, got very interested and developed a neural blastoma cell line, our first major insights into molecular mechanisms of addiction. Had Marshall had a background in the opiate community, he wouldn't have done that work, because he would know that that

can't be done, and that's wrong.

And, meanwhile, all of this, all our work was done through NIMH, and there was a drug abuse division of NIMH, and then, of course, they created NIDA and then the Alcohol Institute, and there was a -- and then, about that time, there was lots of community mental health centers, and they decided to take the community mental health centers and the methadone clinics and NIMH, NIDA, and Alcohol and put them together into something completely separate from the NIH, the Alcohol, Drug Abuse, Mental Health Administration or ADAMHA, and so that's where our checks came from.

And what became an annoying problem was that the people in the NIH said, "That's not real science. Those three institutes are just second-class science," and the people in the institutes were feeling sort of like second-class citizens. And then, because the clinical enterprise was dwarfing

the research enterprise, there was a movement to move it all back into NIH.

And then there was a big political brouhaha, because the institutes, including NIMH, thought that, "Well, we're going to be -- if we go back into the regular NIH," which is now at this point -- God had invented molecular biology, and here we're just measuring neurons, and we're second-class science. We're not going to get any money.

And, actually, already within ADAMHA the NIDA and the Alcohol Institute said, "Well, we're not getting money, either, because NIMH has the better neuroscientists, and we're considered second-class citizens. We're being pushed out, too, so we should be even separate yet."

And, of course, the reintegration of those institutes into NIH was the best thing that ever happened in the history of the field and putting people together. So I'm not making any recommendations, just letting you

know.

CHAIR AUGUSTINE: That's very sobering, no pun intended. Let's see. Dan, I saw your hand there.

HON. GOLDIN: I don't have all the scientific input, but I believe that the NIH is at a very crucial turning point, and I'm not sure how many more institutes it could stand.

There's going to be -- and from what I heard, the reason for not going all the way -- I'll make my own interpretation, because I wasn't there -- is there's bad socialization. Group A says, "Hell, no, we won't go." Group B says "We'd really like to do it."

If this institution cannot bring together two organizations with scientific merit, Katie, bar the doors as to all the new organizations that are going to start, and it'll end up going from 27 -- you're going to have a trend. We'll keep going up.

If anything, this organization needs a little bit more consolidation. I think the way to go at this is to take a look at the sociology and understand how to address the legitimate concerns of Group A, which says, "Hell, no, we won't go."

It's very simple to address the non-addiction work and build a branch or something else, but I think it will be a gross, bad signal to send if this merger cannot be made to happen after all the years, and I see all the angst and all the science. We ought to grow up and get big about this. End of statement.

DR. ROPER: Norm, can I respond to that, please?

CHAIR AUGUSTINE: Absolutely.

DR. ROPER: This is Bill Roper. The point that Dan just made is one that we have talked about across the work of this working group, and I think I alluded to that in my opening comments when I said that we are

trying to take account for the larger context and view this as a prototype for what might be done in other areas while at the same time looking at the merits of this particular case. That issue surely is there, no question about it, and I think it is one that we need to debate and discuss as the larger SMRB.

Speaking just for myself, not for the working group, I would just say if that is what we're about, that is, discussing a roadmap, no pun intended, but a roadmap for the NIH Director on how to consolidate down from 30 some-odd institutes and centers to a much more manageable number, I would say ten or 12, then, fine, I'm game for this, but as long as it's just viewed in isolation, it's a different question, and to date we've been asked to view -- to debate this in relative isolation.

DR. HODES: Just to amplify that, it was a basis for a lot of discussion, and we decided we needed to be careful, first of all,

not to make the decision between science and the courage based on science to consolidate versus, if you will, cowardice, the unwillingness to take on the administrative burdens. We think it's not that.

On the other side, we decided we weren't going to make this a symbolic stalking horse and merge if we were not convinced it was scientifically meritorious, because it was a broader principle. Now, either of those can be debated, but I think our real emphasis was in this case to identify which solution was best for the science of these two institutes and for addiction, and the game changes completely.

As we just said, if the imperative is to make this the first case to prove in principle that we can merge, that's very different from making what we think is the best decision for science in this case.

CHAIR AUGUSTINE: Let's see. Dan?

HON. GOLDIN: I'd like to press

back a little bit. I find it hard to believe with all the evidence that I've seen that you won't get outstanding science if you merge.

I think it's on the margin, perhaps, measured in percentage points, and I really do believe it's the issue that is the bigger issue, and I agree with that. It is the bigger issue.

We've been asked by the Congress to address organizational change at the NIH, and if we don't consider the bigger issue, we will not have dealt with one of the reasons that this panel was asked to be formed, and if we make small, minor changes, I don't think we meet the intend.

At least we ought to answer the big question, and perhaps we ought to have a discussion, "Should we answer the big question?" And if the discussion says, "Well, you should answer the big question," that should go first. I agree with that.

CHAIR AUGUSTINE: Seeing no lights,

I'll take a crack. What I was going to say, and much of it's been said, the -- let me say that my comments aren't intended to either endorse or not endorse the premise of my questions here.

One thing that comes to mind, we haven't talked a lot about it, or maybe we have, but it's the opportunity cost associated with the kinds of things we're discussing. Francis is only going to have a certain lifetime here, and he can have a major --

Sorry, but I don't know anything that you don't know, but he is obviously a very talented individual who can contribute a lot, and he's got to decide how he's going to spend his hours, because he doesn't -- there's only so many a day you have, and he could have a major positive impact here. One thing he could do is tackle this issue, and he could tackle other issues.

I am struck -- supposing you do go from 27 to 26, what have you accomplished?

Twenty-six is still a pretty big number. If we could get to 12, I'd say we had accomplished something, but if the difficulty of getting from 27 to 26 is anything like getting from 26 to 12, it'll introduce chaos. So I'm not adding a lot, but these are sort of the thoughts that are going through my mind that there is an opportunity cost here that has to be weighed.

The other thing that I guess I wanted to mention was that there are different kinds of change. There is organizational change. There's functional change. There are other changes. Organizational change, one of the nice things about it is when you draw a new organization chart and put names in it, it's pretty clear what you've done.

When you talk about functional change, it's very fuzzy, and so should we end up in the functional change camp, I hope that we can be very, very specific about what functional changes we're talking about. What

do you have to go do so that if we do go that way, you can hand to whoever is in charge, and they'll know exactly what it is we want them to do, and this is kind of --

DR. ROPER: Norm, this is Bill, Norm.

CHAIR AUGUSTINE: Yes, Bill, sure.

DR. ROPER: Just to reassure you, that's exactly what we plan to do next after today is shape that option so that it's not some fuzzy abstraction but rather a very precise possibility.

CHAIR AUGUSTINE: Terrific.

DR. BERG: A scientific question. One thing that I've been struck in reading through the materials and hearing the discussions is the sense that the alcohol research community and the drug abuse research community are much more separate than one might have imagined there would -- they would be.

And one possibility for that is

that investigators are, even though they're working on overlapping issues in terms of alcohol abuse and other substance abuse, that they are intentionally targeting their research applications so that they fit neatly into NIAAA if they're alcohol-related and NIDA if they're not, and they avoid writing applications that cut across the two areas.

And, that would seem to me to be a case where the organizational structure could be hurting science, because you're distorting it based on fundability or perceived fundability rather than on scientific issues. Is there a sense that that's a straw man that's real, or is it --

DR. HODES: I think it's real, but, again, the question is which solution, structural or functional, is most appropriate at this time, and another perspective, I don't know if the subcommittee or even the whole group would agree, but in real sincerity we, those of us at NIH and Institute Directors,

are used to a dynamic in which we get together and invest very serious intellectual effort and then make a recommendation.

And in some cases the recommendation is to the NIH Director, and the choice about which of the options he or she wants to undertake as the most effective way to accomplish solution does depend heavily on the person, as you've been pointing out, who is going to have to invest the capital and deal with it.

And it may be in the end, from the perspective of our working group, that we'll have still minority and majority opinions, and I think a part of the sense of that is that we respect mutually these two positions and think it reasonable that in the end -- and further informed by this whole committee that part of the decision may appropriately rest with the NIH Director in determining which strategy in this case he wants to undertake to accomplish this.

DR. ROPER: I would just say, Amen, to what Richard just said.

CHAIR AUGUSTINE: Very good point.

DR. SNYDER: Just to address Jeremy's point about the scientific basis, what the bottom line of what I said earlier was, of course, that alcohol, drug abuse is all -- the key questions are all in the brain.

Obviously, hepatologists can go study alcohol, because it's an easier place to get money, but the key thing is it's all in the brain, and the best way of solving the problems is to not say, "My whole life I just study morphine. I just study -- get more insights from morphine from doing something very, very different but probably in the brain."

And so, scientifically, putting them all together would make the best sense, but I think Norm's point about opportunity cost is such that, I mean, if I were the Director of the NIH, I would never dream of

eliminating the Alcohol Institute, because that would be 90 percent of my time going to Congress and fighting people who say, "You don't care about alcoholism."

DR. RUBENSTEIN: I mean, this issue of reducing the number of institutes goes back decades, right. Every report that somebody did said that that would be a good idea, and I guess the question I have, and I think I know the answer, is we've never, ever reduced any number of an institute ever, have we? Is that a question that has an answer? I mean we've changed the names. So binary fission is a rather simple process, right, but merging -- so I think there is a historic thing here, just to say to what Norm did.

Maybe the opportunity cost to go from 26 to whatever, 25, is a huge opportunity cost. There is no precedent for having done it, and the question is is it really worthwhile, and the case has to be compelling, I think, scientifically to spend the energy to

do that.

And, having read through this report, I think there's mixed views about it, and when you listen to Sol, who is the world expert on it, you know, maybe the answer is coming somewhere else, anywhere, so we'll spend all this -- or could. You know, so we'll spend all this time, and then somebody in, I don't know, Aging -- somebody in Aging will say --

So the real question I have is, you know, where do you want to spend your chips, and if it isn't so big, the noise is so great that it's distracting, so my view of all these changes are, I think, like many said. If you're going to tackle the big picture again, that's worth the effort even if the chances of getting there are low.

If you're going to do little things on -- not little things. If you're going to do something that will make a modest difference, there better be a compelling case

for spending the energy doing it, and I hope the subcommittee will address that as they -- you know, as a reason they'll come out one way or another in the end. I think you are, so I'm just saying the obvious.

DR. ROPER: Arthur, if I could just add, what you said is exactly my view, and that's what we're going to be debating.

CHAIR AUGUSTINE: Tony?

DR. RUBENSTEIN: Sorry. Just to add one last thing, the reason I also say that is the IOM and, I guess, the National Academy do debate these things enormously and do write very compelling reports, but it is kind of instructive that many of these reports have no impact, despite the fact that they are populated by really important and thoughtful and very capable people.

So, there has to be a lesson learned why, even with all that effort and the belief in the quality of the effort, of the report and the people involved, in the end

nothing happens to some of it, I mean, not all of it. So, it just is a historic thing that's worthwhile evaluating, because we're not here reinventing the wheel. It's around.

DR. COLLINS: Unless Norm is in charge. Then it has a new --

CHAIR AUGUSTINE: -- Tony and then Dan.

DR. FAUCI: So I just want to make a comment related to what you said, Dan, about proliferation of institutes. With the Reform Act, if you read the total language of the Reform Act, it argues strongly that you have to jump through some serious hoops if you're going to try and get yet again another institute, so I think there are some safeguards against the proliferation of institutes. That's one point.

The other point that I was struck by was what you said, Norman, about how does Francis want to expend his energy. So, as a good friend of Francis for many years, I would

look at it from my perspective where I don't have a horse in the race at all whether to merge or not these two institutes.

But, as I look at it from someone not in the field, if you're going to go from 27 to 26, that's nothing. If you're really serious, and I am -- I will state that I would be against this going from 26 to 12 or 13.

I think that would create havoc, but observing what we're seeing now, that from my somewhat objective perspective, if there was ever a rationale for merging two institutes that in my mind would be a slam dunk that everybody would say, "Do it," it would be merging these two institutes.

And, if you see this kind of dichotomy on that, could you imagine what you'd have to go through if you wanted to do something other than this and do institute -- you would consume all of your time. So, my recommendation as your friend is don't go there.

CHAIR AUGUSTINE: Dan.

HON. GOLDIN: First, let me say, Norm, I agree with you. It's not up to this panel to expend this nice man's energy and that there is an opportunity cost. However, I think, and the point I was trying to make, I think it is worth for this panel to have that discussion at the higher level and not burden the subcommittee with that issue.

I think it would be very important, no matter how it came out, and hopefully whatever discussion we have would come out before the final recommendation. I feel that that's a very important issue, but again I want to emphasize, Francis, I don't think it's our position to expend your energy.

CHAIR AUGUSTINE: Dan, I'm very sympathetic to your point of view, and you remember our first meeting. I had suggested we do a zero base, lay out -- if you were starting NIH from scratch, what would it look like? And, I was not suggesting for a moment

that you would go do that, implement that, but I thought it would be very instructive to see what would it look like.

Where are the big differences? What can we learn? And, that turned out to create so much terror in the halls that even that seemed pretty overwhelming, but I think your point is right.

You know, several have made it around the table that if it's this hard to get from 27 to 26, to do anything real, it boggles the -- well, it's going to take Francis's whole life to do it, but on the other hand of that, if you -- if you can't do the easiest one of all, what are you going to do?

The point was made, though, it's going to be hard to add them, add new institutes, I think, but it's going to be harder to get rid of them. Your point was good. Gene?

DR. WASHINGTON: I was just going to say we may be underestimating the impact

that functional change can actually have. I mean, many of us in academic institutions that are more ossified than any other organism you might imagine, where we have departments with two faculty members, and you can't change them, and you leave them there.

But, you create centers, and you create multi-disciplinary programs that work across them, and you slowly starve the others to some degree, but you change the asset allocation. There are some very powerful instruments for driving the kinds of change that we want related to improving the science, fostering better collaboration and integration across disciplines.

So I just -- I just want to underscore of amplify the point that's been made is that this is not a dichotomy where it's a win or a lose. I think we could still win-win while minimizing opportunity cost.

DR. HODES: I agree with that strongly, but also I would point out there is

not -- it's not an easy option for the NIH Director in this case, so if he -- we talked about the effort that would be involved in defending a merger. We shouldn't underestimate what would be required to make a substantial functional change. So either way, Francis --

CHAIR AUGUSTINE: Griff, you've been very quiet. We haven't given you a chance to say anything. Do you want to weigh in here?

DR. RODGERS: No, I think much that has -- that I was going to say and I have said already, you know, I have. I think, you know, again we still have work before us. This isn't sort of the final solution, but I think we will have to sort of write the important sub-notes and talking points to defend any of these changes that are shown on this.

I think this is a nice way of looking at it. Some people are sort of visual learners, and I think sort of we had Pac-Man

before, but this is -- I think Amy has done a good job of sort of putting this together.

This doesn't mean any one of these. The final solution and the optimal solution might be several of these taken together, or it could be staggered in a way that you start with one and then add on to others, so I think we still have work in front of us.

DR. BERG: Just a quick comment to Arthur's comment. I think, you know, the existence of this Board in some sense is, from my perspective talking to Elias, was to provide a clear pathway for doing these sorts of reorganizations.

I think his concern with IOM reports and so on is you get a thoughtful report, but there is no existing structure for dealing with it, so you have to create all these ad hoc structures, and every step of the way you've got potential political impediments. Here the intent was to create a

process where it can be done in a more regular way to make it as easy as possible while still building an up-barrier, so it's not so easy that you do things without thought.

DR. RUBENSTEIN: Yes, I do -- I do agree with that.

CHAIR AUGUSTINE: Let me -- I saw -- excuse me. I saw Dan and then Francis and then Art.

DR. RUBENSTEIN: Oh, sorry.

CHAIR AUGUSTINE: No problem.

HON. GOLDIN: I want to come back one more time and try it. I think it would -- I want to come back to the comment I made about the sociology that we have. It's a very difficult sociology.

I think it would be worthwhile -- and this may be extra work for you, Bill and the panel. I think you ought to consider taking a look at a model of what are the consequences that might happen if you cause this merger to occur and what steps could be

taken to try and minimize the impact.

Just like the exercise could be worked with the functional change, what steps could be taken to manage the functional change? One could build two models, and I think it's worth building these social models to see how to deal with it, to how to ease the possibilities, and then when you --

Once you have these two models put together, you could do a quantitative analysis and say, "Hey, Approach A or Approach B looks better," and, again, it's information for the -- for the Director to make a decision on. I think it would be helpful.

DR. ROPER: I agree, Dan, that that would be helpful, and a point that I would make is it'll be particularly important for our working group that the federal members, those of you there at the NIH, help us articulate what those two alternatives might look like, again, especially as we frame what is the functional reorganization model,

because you all live with this day in and day out, and so we need your help.

CHAIR AUGUSTINE: Francis?

DR. COLLINS: Well, I had the weight of the world on my shoulders this morning, and now it seems to have increased in its magnitude with all of these important and, obviously, not easy decisions looming.

I think it's fair to say that the situation here is different than what we talked about earlier today in terms of the Clinical Center, where I think the general conclusion was we have to do something about the clinical structure -- center structure -- because we have an unworkable model. So that one is going to be a driver of change of some sort, and it's a question of what the change should be.

Here, there's a lot of debate about whether the change requires that structural merger, but I think there is also a pretty good case here that the status quo is

not as good as we would want to see it in terms of the integration of addiction research across different substances.

So, I like what Dan said, sort of what I was going to say, as well, to this sub-group. If you can really try to think through what the models would look like of the merger of the institutes versus a functional approach and enumerate the pros and cons as best you can, that would probably be the next, most useful step.

And, I would say -- and I heard Bill asking, "Well, what would the functional model look like?" It would probably be one of these blueprint kinds of approaches where you do try to tap into interests in addiction research that occur in NIAAA that occur in NIDA but also occur in other parts of the NIH.

You don't want to miss the chance if you're going down that road to pull in other areas that haven't been very well connected, either, or not as well as they

could be, tobacco, particularly, but also probably you could talk about food addiction, sexual addiction, gambling, and so on, and that means bringing in some of the behavioral and social science research that maybe hasn't been as tightly connected, as well.

And in that regard, maybe something the group could look at is the neuroscience blueprint as an experiment in science management that's been around now for three or four years. One of the reasons that was pulled together by that famous dinner was that there was a lot of noise out there about, "Why do we have all of these neurology-focused institutes? We have NINDS. We have NIMH and so on. Why don't they work together better?"

Okay, so now we are trying that model of a functional connection. Harold Varmus, before he got criticized for his six-institute model, was certainly suggesting cram all of these things together under one roof. We didn't do that.

Is the blueprint actually accomplishing the goal? Because there is an experiment that's already been underway where there is some data. You could assess whether that has done it, and I would think that would be pretty valuable in this instance in trying to size up in the real world what would likely be the benefits of a functional solution.

CHAIR AUGUSTINE: Well --

DR. RUBENSTEIN: My comment --

CHAIR AUGUSTINE: Oh, I'm sorry.

DR. RUBENSTEIN: I just want to say what Jeremy said. I do actually believe this oversight board has much more opportunity because of its composition, so I actually agree with you. It's so much involved and rooted in the NIH and its advisors that I think we do have a shot at things IM could not do, so I agree.

CHAIR AUGUSTINE: Everyone, I think, has said what they had to say. Hal, having heard all of this, I know you don't

have the background that some of the folks around the table do, but do you want to make any comment, observation?

DR. RAINEY: No, I don't, because it's going to sound presumptuous, but I really don't know. But in reacting to some of what I'm hearing as an outsider asking dumb questions, one of the fundamental premises was that there are these interdisciplinary needs in scientific research now.

We need to bring people together, but I read the report, the earlier report on restructuring the NIH that came to the conclusion back in 2003 or so that there needs to be no change in the general structure of the institutes and centers, and now I hear that it's very difficult to bring these two together. Well, what happens to this premise that there are these interdisciplinary needs? Where are they going? I don't see it.

Another reaction I have trying to look at what the committee did, obviously

there's a lot of really impressive work going on here, but I as an outsider couldn't see how deep down into the membership of these units they went.

It looked as if a lot of the testimony was from experts from around places, and then there were the votes of the councils. Now, if the councils represent the scientists, that's one thing, but are the scientists interested in working together?

Have people talked to them? Because it's a much smaller problem that I dealt with, but I dealt with advising an institute on our campus, and when you went in there were people saying, "One of our problems is we're too Balkanized. We want to work with these people, and we're in silos, so change the silos."

So, as I said about my talk, it's easier said than done, but what's happening to this premise that there is supposed to be -- there's a need for interdisciplinary research?

Has there been a broader identification of the manifestation of that premise at NIH that there are scientists who really need to be working together and want to work together?

So, please forgive me for being presumptuous if you've taken that into account in the discussion of the zero base analysis, but I don't see it. I just -- you know, I'm not trying to be a wise guy, but how is that -- how are you assessing those?

Are you identifying those patterns of synergy through talking with scientists and the people who are going to do the research and the -- that's just one reaction, sorry.

CHAIR AUGUSTINE: Thank you very much for sharing those thoughts. You know, as we were talking, and, Dan, you'll relate to this, the world in which I've lived, the technology I've lived with and the science, it's become very commonplace to have this functional organization but on a very rigorous, formal fashion. We call it a matrix

organization that we've probably both lived with all our lives.

It's not easy to make work, but that's standard in the world I live in that you have your institutes, so to speak, here. In our case, you had various sciences and technologies that cut across, and they were very formal.

There were people who ran these, and there were people who ran these, and it took a very delicate balance. I'll say that, but that's the other extreme that is out there.

Well, I think we've said what there is to be said at this point. Bill, you've got clear instructions how to proceed now.

DR. ROPER: Thank you. Yes, we do. We just need about an extended period of time, but, seriously, we'll get it done. Thank you.

CHAIR AUGUSTINE: Well, thank you,

Bill. Is there anything you want to say yourself?

DR. ROPER: No.

CHAIR AUGUSTINE: Okay. Yes, Gene.

DR. WASHINGTON: My comments as we wrap up the conclusion of these three reports, and that is, is that I've worked on many NIH committees, many IOM committees, foundation committees, and I've never worked with a staff that was this exceptional in terms of the quality of work that they produce and their responsiveness, so I want to compliment publicly Amy and Lyric and the others who work with them.

CHAIR AUGUSTINE: Gene, I'm glad you said that, because we all share that view very strongly, and I --

DR. ROPER: Yes, indeed. Amen.

CHAIR AUGUSTINE: Let me just thank everyone. I particularly appreciate the ability of this group to talk about tough issues and disagree with each other and do it

so constructively. It makes it a pleasure, in fact, and so with that we'll turn to the public comment portion of the meeting.

We have one person signed up. We'll ask that person to limit their time to five minutes if they would, and when they're done, if there are others who would like to speak for no more than five minutes, we have a little bit of time to do that. So, the first person is Carson Fox with the National Association of Drug Court Professionals.

MR. FOX: Is that better? All right. Good afternoon, Mr. Director, Mr. Chairman, members of the working group. My name is Carson Fox. I am the Director of Operations for the National Association of Drug Court Professionals.

The National Association of Drug Court Professionals represents over 25,000 individuals working in drug -- in over 2,400 drug courts across the nation. Many of you know of our work.

I'm here today to say that NADCP strongly supports the merger of NIDA and NIAAA. We all know that it takes science, innovation, and teamwork to work within individuals that find themselves in the criminal justice system, because they have addiction and abuse issues with alcohol and drugs.

I'm a former prosecutor, and I've worked at that level, and I've worked in training drug court professionals for over a decade, and with all my years of working with the individuals who have these addictions, you all know better than I do these people don't differentiate their addictions between licit and elicit drugs.

The drug and alcohol dependencies that bring tens of thousands and hundreds of thousands of individuals before the court system in the United -- court systems in the United States these individuals don't differentiate. They don't split out what's

elicit and what's licit.

For the -- in the National Drug Court movement, what we've seen is a small program that started in Miami, Florida, 21 years ago blossom into 2,400 programs that now treat well over 120,000 individuals across the country who not only are in the system because of criminal issues. There's also juveniles who find themselves in the system, and there are parents who are at risk of losing custody of their children because of abuse and neglect issues.

It's our hope as a field that merging the two institutes together would benefit all those individuals, that having the research merged would actually bring the field to the next level and would really assist in that effort, and so I wanted to come here, and while I'm saying how much we support that, and I'm here on behalf of the 27,000 folks who work in drug courts, I also want to thank you.

Thank you for your service. I

have certainly worked on my share of state and local committees, and I can't imagine what you've bitten off here, so I want to thank you for what you're doing for the citizens of the country in doing this. I know it's a lot of work, and I want to thank you for giving me the opportunity to speak to you this afternoon.

CHAIR AUGUSTINE: Well, thank you very much. Your perspective is an important one to us, and we appreciate that. If you would want to elaborate at all in written form, we would -- we would welcome that.

MR. FOX: Thank you.

CHAIR AUGUSTINE: Thank you. Is there anybody else who are guests today who would like -- please.

MS. AUSTIN: I'm Bobbie --

CHAIR AUGUSTINE: If you could introduce yourself.

MS. AUSTIN: I'm Bobbie Austin from the Association for Research and Vision in

Ophthalmology. Today I've heard a lot of talk about structure and function, but the question at the end of today, that I have in my mind -- and I'll use an intramural example, because I did my training at the National Eye Institute as a fellow.

We have almost an N of 30 for institutes and centers, and all of these institutes and centers have similar functions, but among those functions some institutes do the functions more efficiently than others. I'll use purchasing as an example.

When I talk to other fellows from other institutes, some institutes can get orders in three days. Others it was taking three weeks, so if we looked at functions and analyzed which institutes are carrying out particular functions most efficiently and apply that to the other institutes, I think that could improve the efficiency a lot.

Taking an extramural example, our members actually get funding from a variety of

different institutes, but a large number of them get funding from the National Eye Institute. Historically, eye was combined with brain, but our members have concerns in how grants were reviewed at that time and that when vision scientists weren't reviewing the grants, they didn't have a favorable outcome in the scoring of the grants. Those are just two things I want you to consider.

CHAIR AUGUSTINE: Well, thank you very much for those points. We appreciate your sharing that with us, and is there anyone else who would like to comment? Seeing none, the -- I think we are approaching the end of our meeting, if I'm not mistaken.

Kind of the plan from here forward is to continue with out three groups, start preparing written reports. We've still got a lot of work to do. I'm not going to try to review the action items I picked up, because I'm sure, Amy, you got them, and we'll be sure each of the groups get them.

We will meet again in May 17 through 19, and depending on progress, we may have a conference call before that or shortly after, whatever proves to be the best. Again, my appreciation to everyone. I enjoy working with you. I hope we can make a contribution. Francis, I want to give you the last word.

DR. COLLINS: Well, again, I think I can't express enough my gratitude to all of you, and I appreciate that these are thorny issues and that you probably feel like this is somewhat of an interminable task. It all brings to mind a quote from my favorite source of quotes, which is Winston Churchill, and Winston Churchill once said, "When you're going through hell, keep going."

So, yes, consider the alternative of staying where you are, so I guess that's my exhortation, and I don't doubt that you're going to follow up on it. Thank you all very much.

CHAIR AUGUSTINE: To close the

meeting with another Winston Churchill quote, I hope we didn't close the last meeting with it. Do you recall it? He said you could always count on the Americans to do the right thing after they've tried everything else. Let's beat that. Thank you all. Have a safe trip.

(Whereupon, the foregoing matter was adjourned at 2:33 p.m.)