

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

2 (8:08 a.m.)

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

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

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

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

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1 Medical Sciences.

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

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

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

10 DR. COLLINS: I'm Francis Collins,
11 Director of the National Institutes of Health.

12 I want to express my gratitude to all of you
13 for the hard work that's gotten us this far
14 and appreciation for what yet is to come.

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

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

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

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1 Diseases.

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

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

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

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

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

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

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

22 DR. PATTERSON: Amy Patterson, NIH.

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1 Thank you.

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

9 Huda Zoghbi will not be able to be
10 with us today. Deborah Powell will join us by
11 telephone, and is Dr. Powell on the phone now?

12 Or I guess that will come later. Where is
13 the phone? I don't even see the phone here.

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

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

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

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

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

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

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

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

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1 move approval of those minutes, that would be
2 helpful.

3 PARTICIPANT: So moved.

4 PARTICIPANT: So moved.

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

7 (Chorus of ayes.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So, again, thank you to everybody.

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

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

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

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1 We'll give you ample notice.

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

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

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

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

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

5 And as we were going over to the
6 auditorium I said, "President Bush." I said,
7 "You can appreciate that normally I'm sure we
8 would have a standing room only crowd, but as
9 a former baseball person yourself, you
10 probably understand that, with the Orioles in
11 the playoffs, we might have a limited crowd."

12 He said, "No problem."

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

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

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

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

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

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

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

13 I think that we got briefed by the
14 NIH Director, by the former NIH Directors, and
15 a number of distinguished scientific and
16 public leaders representing different groups
17 of the constituents of the NIH, and those
18 people included the list that's shown here --

19 I won't go through all the different people -
20 - including Hal Rainey, who will be speaking
21 to us later this afternoon.

22 And I think what we got from that

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

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

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

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1 host of reasons, are not getting through
2 there.

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

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

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

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

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

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1 enormous decentralization.

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

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

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

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

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

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

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1 activation energy over the threshold for
2 creating a new initiative.

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

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

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1 the new cross-cutting initiatives.

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

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

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

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

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

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

22 So, now what we looked at really

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 So, you need the banks because you

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

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

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

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

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

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

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1 think we understand the mission.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 I always say that people only have

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 CHAIR AUGUSTINE: We sure do, Bill.

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

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

10 DR. RUBENSTEIN: Thank you so much.

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

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

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

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

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

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

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

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

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

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

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1 government organization.

2 HON. GOLDIN: I was on the
3 pessimistic side and just a general statement.

4 When an organization exists too long with a
5 fixed organizational structure, familiarity
6 sets in, and a comfort sets in that takes the
7 edge off pushing the boundaries, and at some
8 point in time, one has to get out of their
9 comfort zone and say, we need to do something.

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

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

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

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

13 CHAIR AUGUSTINE: Jeremy?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 our measurement was we set up some guiding
2 principles. We said failure shouldn't occur.

3 If you had ten failures out of ten, you
4 didn't succeed, and if you had ten successes
5 out of ten, you didn't succeed, because you
6 didn't try too hard.

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

15 So for 174 missions that we had,
16 the average cost went from \$600 million to
17 \$200 million, and out of 174 things, we had 11
18 failures. So it met one out of ten, and if
19 you measure over a ten-year period and you
20 just set simple criteria, you could actually
21 get some feedback.

22 So you can, and the change itself

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

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

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

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

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

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

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

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

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1 faster cures.

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

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

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

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

4 CHAIR AUGUSTINE: Francis?

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

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

22 But, of course, the Common Fund

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

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

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

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

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

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

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

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

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

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

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1 CHAIR AUGUSTINE: Jeremy?

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

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

15 CHAIR AUGUSTINE: Solomon?

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

22 The CEO to Coke doesn't have any

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 It was when the Soviet Union
18 suddenly came to an end, and our industry lost
19 640,000 people in two-thirds of the companies
20 in about five years. So the question was,
21 who's going to survive? Even knowing that the
22 odds were 80 percent against you, under those

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

5 We also found that people who are
6 positively impacted by change are much less
7 vocal than people who are negatively impacted
8 by change by orders of magnitude, so one has
9 to weigh that when you listen to the rumbles.

10 Sometimes you just have to work your way
11 through it.

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

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

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1 fabulous opportunity.

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

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

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

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1 administer, is that --

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

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

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

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

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

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

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

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

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

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

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

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

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1 organized projects.

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

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

19 CHAIR AUGUSTINE: Gene?

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

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

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

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

8 DR. BRODY: Thank you, Gene.

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

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

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

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

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

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1 be asking the question.

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

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

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

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

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

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

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

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1 one of them is translational research among
2 all of the others, so, I mean, those are the
3 kinds of things that I think we need to
4 reexamine about are we optimizing our
5 resources, because there are many people that
6 think we should take a much more proactive
7 role in taking a basic science observation to
8 a fundamental product, which is a whole new
9 series of discussions that I'm involved with
10 in another whole arena about what role the NIH
11 has in partnering with industry in developing
12 products from the basic science observations.

13 So, in that regard, I think we can think
14 about can we be doing better or not.

15 CHAIR AUGUSTINE: I saw Art and
16 then Dan.

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

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

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

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

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

4 CHAIR AUGUSTINE: Francis?

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

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

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1 of the practice of medicine.

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

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

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

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

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

13 So, okay, we are going to deliver
14 the, for instance, the major genetic causes of
15 20 common cancers by doing systematic cancer
16 genomics in the next few years. We are going
17 to promise that.

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

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

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

17 CHAIR AUGUSTINE: Dan and then
18 Jeremy.

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

22 The NIH is one of the premiere

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

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

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

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

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

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

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

22 I saw within six months a factor

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

6 In our desire for organization and
7 order, we must help improve the innovative
8 science, because that is at the very core, and
9 if translation -- we keep talking translation.

10 We're not going to have innovation, and the
11 translation in 20 years is going to have
12 nothing to work with, so that's my discussion
13 about metrics. Beware of metrics.

14 CHAIR AUGUSTINE: Jeremy.

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

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

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

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

22 CHAIR AUGUSTINE: That's helpful.

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

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

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

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

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1 inception.

2 CHAIR AUGUSTINE: Thanks, Steve.

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

16 CHAIR AUGUSTINE: Gene?

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

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

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

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

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

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1 work your way around it so that it does work.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (Whereupon, the above-entitled

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

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

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

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

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

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

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

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

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

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

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

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

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1 other part of our mission at another time.

2 These are the members of the
3 committee. Dr. Cassell is in China, and I
4 think Dr. Shurin is not here today. Everyone
5 else is here. As I mentioned, a terrific
6 committee, and we've had very good discussion.

7 So here is the issue about the Clinical
8 Center. It's a important part of the NIH, a
9 very important part.

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

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

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

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

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

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

4 Again, I won't go through the
5 details, but we may have time for discussion.

6 We could talk about some of them, but these
7 are international research stars who use the
8 Clinical Center quite extensively, and we
9 listen carefully to their views.

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

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

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

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

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

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1 health.

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

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

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

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

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

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

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

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

17 I'm going to talk a little bit
18 about the vision and role, and then Steve and
19 Tony are going to do the governance and
20 budget, I think in tandem, so we'll see how
21 they do that. So let's begin with the first.

22 These are three well defined, but

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

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

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

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

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

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

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

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

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

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

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

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

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

20 Everything here is relative, and I
21 don't want it to sound again like it's broken.

22 These are things we think -- and I think they

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 through a variety of federal mechanisms, which
2 are listed.

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

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

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

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

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

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

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

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1 focused intramurally.

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

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

18 And then, in terms of clinical
19 research training, some of this is very
20 expensive, and many of our academic centers do
21 it, but many smaller academic centers struggle
22 with this. And as you heard, the CTSA's will

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

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

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

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1 that but not all the way along.

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

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

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

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

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

11 The colors here, I should say,
12 this all means this is internal NIH. This is
13 -- this is combined internal and external NIH.

14 The potential -- we have three options with
15 regard to potential new governance structure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 congressional appropriation.

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

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

15 Now, I show you this slide not so
16 that you can read it. It's in your handbook.

17 It's in your -- it's in what we sent you, but
18 the important thing is to know that we have
19 addressed the governance program and the
20 budget implications of each of these different
21 types of options that we've talked about, and
22 you can look at that carefully.

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1 I think this best depicts what the
2 Pac-Man, that is, the Clinical Center portion
3 of the budget is under the various scenarios.

4 Under the first two scenarios, which are not
5 unlike what we have now, the Clinical Center
6 is a part of the Intramural Research Program
7 budget.

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

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

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

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1 about with regard to the school tax?

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

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

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

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

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

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

12 DR. KATZ: Good.

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

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

22 The modified school tax would

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

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

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

22 So, let's just stop there, and let

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

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

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

22 I mean, that's been something that

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

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

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

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1 clinical research.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Does anybody have any questions

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1 about that?

2 DR. KELLY: Yes, I have a question.

3 DR. FAUCI: Yes.

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

5 DR. KATZ: Speak up, Tom.

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

8 DR. FAUCI: No, Tom. That's the
9 obvious thing that people get anxiety and
10 neuroses about, but, no, but what it is, it's
11 eating out of a \$32 to \$33 billion budget.
12 It's the same amount of money as opposed to a
13 \$3 billion budget. That's --

14 DR. KELLY: It's still a dollar.

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

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

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

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

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

10 DR. FAUCI: Let me just -- it's a
11 one-time cost shift, so if the intramural
12 research budget is \$300 million to \$400
13 million, under the model that \$300 million to
14 \$400 million would shift from the intramural
15 budget to the extramural budget, and then any
16 changes we're talking about are the one or so
17 percent increase over that \$300 million.

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

22 DR. RUBENSTEIN: Just to give it

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

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

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

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

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1 important discussions about these. Go ahead,
2 Steve.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 One of them is it would make

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 meeting come to some kind of agreement.

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

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

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

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1 economies of scale and backfill patients as
2 required.

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

8 If somebody wants to think of
9 something radical like that, we'd have to
10 really go back to the drawing board and do it.

11 It's not unreasonable, but we didn't do it in
12 any kind of depth.

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

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

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

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

12 CHAIR AUGUSTINE: Sol?

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

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

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

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

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

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

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

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

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

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

17 DR. KELLY: Can I?

18 CHAIR AUGUSTINE: No, Tom.

19 DR. BRODY: Sorry.

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

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

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

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

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

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

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

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

22 I think the idea is a really good

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 With regard to the second point,

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

8 The prior Director, Elias, dealt
9 with it. He did -- he did move -- he did move
10 the line considerably, but the years are
11 passing, and I know that Francis has heard
12 about that in terms of top notch clinical
13 investigators coming in under the current
14 budget constraints and other constraints that
15 we have as working in the Intramural Program.

16 So that's something that really does have to
17 be on a regular basis addressed, and I know
18 that it's come to Francis's table.

19 CHAIR AUGUSTINE: Bill?

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

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

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

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

18 DR. RUBENSTEIN: I think we agree.

19 This is one of those things where we think
20 it's worthwhile making the effort. You know,
21 if it can't work, it seems like the goal is
22 worth trying if there's enough support for it,

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

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

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

22 I mean, you're coming from a place

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

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

17 CHAIR AUGUSTINE: Gene.

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

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

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

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

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

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

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

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1 CHAIR AUGUSTINE: Francis?

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

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

22 It is unique in ways that have

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

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

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

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

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

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

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

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

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

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

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

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1 extramural utilization?

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

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

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

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

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

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

19 CHAIR AUGUSTINE: Steve.

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

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

10 CHAIR AUGUSTINE: Francis?

11 DR. COLLINS: So, Arthur, at the
12 very end you also suggested your group might
13 go back and look at the IOM report from 2003 -
14 -

15 DR. RUBENSTEIN: Yes.

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

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1 activities that are currently in the NCCR,
2 including the CTSA's and some other as
3 activities, as well.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 possible.

2 CHAIR AUGUSTINE: Dan?

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

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

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

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1 CHAIR AUGUSTINE: Tom.

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

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

22 Is there anything else in follow-

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

6 We're a little ahead of schedule.

7 I think that's good news, because, Hal, that
8 way we won't have to have you talk while we're
9 munching sandwiches, and so I think --

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

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

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

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

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

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

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

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1 came.

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

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

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

22 Some of what I say will be

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

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

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

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

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

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

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

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

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

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

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

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

22 What you find is that the research

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

9 So, what this consists of
10 generally is a body of research or knowledge,
11 comes from expert observers, or I and some
12 others have been involved in studies of
13 organizational changes involving extensive
14 interviews and observations of various sorts.

15 And it produces very general generalizations,
16 as I said and as you will see, and one issue
17 is do these amount to anything more than Zen-
18 like aphorisms? Are they not common sense?

19 But, I defend them on the basis of
20 the point that they are easier said than done.

21 They point to major challenges that change
22 agents and change leaders have to face, and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 sailors would point out. They increase your
2 visibility.

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

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

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

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

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

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

22 They had a million case backlog.

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

8 If you were a retiree and you have
9 time on your hands, and you're not receiving
10 your Social Security check, what do you do
11 with some of that time you have on your hands?

12 We don't have to guess.

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

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

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

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

14 It was very well
15 institutionalized, as I'll mention again in a
16 minute, but it was very painful at the outset.

17 They were -- these modules involved changing
18 the pattern of management in the organization
19 and many other changes. There were early
20 retirements. There were dislocations of
21 various sorts.

22 I was involved in a pretty

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1 extensive study of major changes at the
2 Internal Revenue Service beginning in the late
3 1990s due to a firestorm of criticism of the
4 Agency, hearings in Congress that dramatized
5 abuses by IRS agents against taxpayers, widely
6 publicized breakdowns in their information
7 technology system, complaints from taxpayers
8 about inadequate processing of their tax
9 payments and their tax returns.

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

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

22 These were driven by a firestorm

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

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

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

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

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

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

22 For example, Mr. Rosati rolled out

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

11 You build support. You get input.

12 You try to get good ideas. You also finesse
13 the union. Mr. Rosati let the union leader
14 appoint members, some members of the design
15 teams, and the union member, the head of the
16 National Treasury Employees Union, was
17 delighted with this, and the union bought into
18 the change process.

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

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

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

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

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

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

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

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

8 Well, at the time, there were
9 120,000 employees in IRS. That's a lot of
10 people to invite to the Commissioner's office
11 for a round table discussion, but they felt
12 that this was too top-down. This was -- and
13 we didn't really mean it that way, but in the
14 successful patterns there is a major effort,
15 as I have tried to indicate here, to represent
16 people.

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

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1 consideration as you can.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 I'll move on quickly, because I

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

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

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

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

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

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

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

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1 literature.

2 So I will go ahead and let that be
3 it, and I will be glad to hear your comments.

4 They don't have to come at me, obviously.
5 I'd like to hear you talk to each other.

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

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

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

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

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1 CHAIR AUGUSTINE: We need the
2 microphone.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 DR. RAINEY: I'm sorry?

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

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

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

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

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

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

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

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

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

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

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

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

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1 should take care of the taxpayers better.

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

11 CHAIR AUGUSTINE: Dan?

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

17 There's the change that the
18 leadership brings about. That's what I'll
19 call phase one of the change, and that you
20 could do rapidly, but phase two of the change
21 is overcoming the resistance in the
22 understanding of the change, because there is

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1 a comfort with existing systems, however bad
2 they are.

3 So people would like to stick with
4 what they know versus the fear of what they
5 don't know, so there's a time lag in the -- in
6 phase two until a large complex organization
7 with, you know, 100,000 people comes along.

8 So phase one you could do rapidly,
9 perhaps, in a good fraction of a year or in
10 months, but phase two is generally going to
11 take a couple of years and involves -- and
12 phase one needs to have planning for the
13 implementation of the education and the
14 building of the acceptance.

15 An example, you did a magnificent
16 job in bringing together I don't know how many
17 dozens of companies when Lockheed Martin was
18 formed, and that process took place fast, but
19 the grumbling stopped about two years after
20 you did it.

21 And one of the things that people
22 miss in planning for change is they generally

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1 focus on those first three to six months,
2 which gets the blood pumping and is exciting,
3 but it is doing a real good plan for bringing
4 along those tens of thousands of people, and
5 you have to say that that's going to take a
6 couple of years. You cannot do that fast. I
7 don't know whether you agree or disagree with
8 that.

9 CHAIR AUGUSTINE: I think I
10 partially agree, Dan. I am convinced -- we
11 had 180,000 people that were affected, and we
12 did do some very careful planning, but once we
13 said what was going to happen, boy, it
14 happened, and one of the things I found was
15 that people could stand bad news. They can't
16 stand uncertainty, and your point is a very
17 good one.

18 I think there's balance of these
19 things, but the arguments I always heard were,
20 "Go slow. Let people get used to the idea,"
21 and the fellow who used to run Penney's, the
22 department store, he went through some major

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1 change. His comment to me was, "Don't cut the
2 cat's tail off an inch at a time," pretty good
3 advice, but your point is well taken

4 Why don't we --

5 DR. RAINEY: I would just mention
6 that's a useful clarification I think I didn't
7 make clear enough, and I was talking too long,
8 anyway, but part of the process of
9 institutionalizing the change, of implementing
10 the change, they took multiple years in these
11 processes.

12 There may be a distinction between
13 the public and the private sectors here. I
14 didn't even get into it, but a major issue in
15 the IRS changes was the role of the consulting
16 firm. There was a major consulting firm
17 involved.

18 That person was -- we spent a lot
19 of the time with interviewing this person
20 about the process of facilitation by the
21 consultants, and I think he wanted us to hear
22 his side of the story, because it was very

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1 expensive.

2 But, he said that he was actually
3 invited to compete for the consulting
4 contract, because he was representing
5 consultation with large-scale corporate
6 changes, not government changes, corporate
7 changes.

8 And he mentioned to us on several
9 occasions he thought that industry, I mean,
10 private sector firms are better able to roll
11 out a change than government organizations
12 are, because the -- because of what's going on
13 here. It's a lot more public.

14 There are a lot more -- there is a
15 lot more openness to the decisions, but what
16 Dan is pointing out is consistent with what we
17 observed in these cases, and I didn't make it
18 clear enough that the original idea may roll
19 out fairly rapidly and soon, "Here's the
20 idea," but all these processes of having town
21 meetings, training sessions, bringing all the
22 middle managers to Atlanta, doing all those

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1 things, that took quite a while.

2 This same consultant, they were
3 trying to monitor and track the change at the
4 IRS with large-scale customer surveys, because
5 they put in a new evaluation system that's a
6 variant of the balance score card system with
7 which some of you may be familiar that was
8 developed Professor Kaplan at Harvard, which
9 basically argues you study not only the
10 business processes but your consumer
11 responses, your customer responses, and your
12 employee development.

13 So, they were doing employee
14 surveys and, among other things, trying to
15 assess employee acceptance and support for the
16 change, and at one point, when you'd go into
17 the Deputy Commissioner's office, he would
18 have these survey results open in front of
19 him, and he would be really interested in what
20 we were finding in our interviews out there,
21 because this was a very far-flung
22 organization.

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1 At one point, about two years
2 after the change or three years, when we were
3 in doing the interviews, the survey came back
4 and showed something like 40 percent of the
5 employees supported the change, and the
6 consultant said, "Boy, that's a lot more
7 progress than we made when we were working
8 with this corporation and that corporation.
9 You're really getting along pretty well here,"
10 because three years after the change at such-
11 and-such a large firm, about 25 percent had
12 bought in.

13 The rest didn't think it was such
14 a great idea, but his attitude was it's a
15 little easier to roll out things more rapidly
16 in the private sector. I'm not sure of that.

17 CHAIR AUGUSTINE: Yes, I would
18 absolutely agree with that. Well, Hal, thank
19 you very much. We appreciate your sharing
20 your thoughts with us. I hope you can stay
21 around, because as other things come up, we
22 can incorporate Hal in the discussion, if

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1 that's all right.

2 DR. RAINEY: Sure.

3 CHAIR AUGUSTINE: Just as an aside,
4 for a little break, I happen to know Charlie
5 Rosati, and during the period that Hal is
6 describing I was giving a speech. I knew that
7 Rosati was in the audience, and I commented. I
8 worked it in my speech that I had had a
9 problem with my income tax and that I was told
10 there was a Mr. Jones who was the expert at
11 the IRS.

12 So, I called Mr. Jones's office on
13 the phone. Somebody else answered the phone
14 and said, "Mr. Jones is on vacation. Do you
15 want to wait -- or do you want to hold?" He
16 didn't think that was funny.

17 Okay, moving ahead quickly, we
18 turn to our final group that's underway, and
19 hopefully Dr. Roper is on the phone. Do we
20 know that? We're a little -- we're a little
21 ahead of time, I think.

22 Okay. Hey, Bill, are you on? We

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1 need to scramble a little bit here. Okay.

2 DR. ROPER: Hello?

3 CHAIR AUGUSTINE: Yes, Bill, is
4 that you?

5 DR. ROPER: Yes, hello?

6 CHAIR AUGUSTINE: Hey, that's --
7 that's terrific. Can you hear me at all?

8 DR. ROPER: Hello?

9 CHAIR AUGUSTINE: No?

10 DR. ROPER: Can you hear me?
11 Hello?

12 CHAIR AUGUSTINE: Yes, Bill, can
13 you hear me?

14 DR. ROPER: I can hear you. Can
15 you hear me?

16 CHAIR AUGUSTINE: We got you pretty
17 clearly now. Bill, am I clear at this point?

18 DR. ROPER: Norm?

19 CHAIR AUGUSTINE: Yes, I've got you
20 here. Are you clear at this --

21 DR. ROPER: I've been on for a
22 couple of hours, but until just a moment ago

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1 all I could hear was music through the phone,
2 but I've been watching you online, and it's
3 come through quite well.

4 CHAIR AUGUSTINE: It's a good thing
5 you couldn't see what was going along with the
6 music. Bill, I'm assuming you can hear me all
7 right at this point. There's a huge amount of
8 feedback from somewhere. We've got feedback.

9 DR. ROPER: Yes, I can hear you. I
10 think the way this is going to have to work is
11 when I'm talking, you all need to have muted
12 your microphone. Otherwise, it cycles through
13 the system and echoes.

14 CHAIR AUGUSTINE: Terrific. We
15 needed an engineer to tell us that. Good.

16 DR. ROPER: Yes. I'm ready to
17 start whenever I get the word from you, Norm.

18 CHAIR AUGUSTINE: Okay, we're all
19 ready. We're sitting here. We've had a
20 briefing, as you know, on the other two
21 groups, and we've set aside 45 minutes for you
22 to talk, but we'll let you go probably without

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1 interruption, and then we'll have plenty of
2 time for a discussion when you're done. So
3 please proceed, and thank you for all your
4 good work.

5 DR. ROPER: Thank you, sir. I am
6 pleased to have the chance to present to you
7 on behalf of the Substance Use, Abuse, and
8 Addiction Working Group. I regret that I'm
9 not there with you in person, but like I was
10 just saying, I've been viewing it online. I'm
11 in California for another meeting.

12 Some of the members of our working
13 group are there, and I'm sure they will be
14 able to add some additional points after I
15 finish my presentation. We've taken care as a
16 group, and I've taken care personally to
17 reflect our collective views, including in a
18 meeting that we had just yesterday, and then
19 draft talking points that we all worked on
20 overnight last night.

21 So, I'll just plunge in. I assume
22 my slides are up there, and I'll be drawing

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1 your attention to the slides.

2 This working group has had 13
3 sessions, some of them in person, some of them
4 electronic, and as I said, we had a meeting
5 yesterday, an hour-long session, and all
6 members of our working group participated in
7 it, and we had a very vigorous and good
8 discussion. We understand that the substance
9 use, abuse, and addiction discussion is surely
10 related to the overall work of the SMRB,
11 including the work deliberating organizational
12 change and effectiveness.

13 Some people, I'm sure, view the
14 work that we are looking at as a prototype for
15 other activities that the SMRB, indeed that
16 the NIH might take on, and in that regard we
17 are anxious to learn from what our other
18 working group on deliberating organizational
19 change and effectiveness is producing. Dr.
20 Washington is a member of both working groups,
21 and Gene has been particularly helpful in
22 making that cross-connection.

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1 At the same time that we are
2 seeing this as a prototype for larger or other
3 activities, we are anxious to pay particular
4 attention to the issues in this sector,
5 substance use, abuse, and addiction and to be
6 sure people in that research community want us
7 to see them as unique and not be casual in the
8 way we view this particular effort, and so we
9 are trying very hard to do both of those
10 things at the same time. So let me plunge
11 ahead.

12 Slide two shows what I'm going to
13 be talking about, and slide three shows the
14 members of our working group, and some of them
15 are there with you, as I said, but Deborah
16 Powell and Huda Zoghbi, I believe, are not
17 able to be there. Federal members we
18 appreciate, as well, and it's been a very
19 useful process having some outsiders, some
20 insiders in this discussion.

21 Slide five begins the content of
22 my presentation, and that is for some time

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1 neuroscience research has shown that addictive
2 substances, including drugs and alcohol, have
3 some things in common with each other and some
4 difference from each other, and so the
5 question that's been posed to us is,
6 considering both the differences and the
7 similarities, does the current organizational
8 structure at the NIH with separate institutes
9 on drug and alcohol provide the optimal
10 infrastructure for supporting these areas of
11 scientific research?

12 There is a context, a wider
13 context to this discussion, of course. The
14 NIH Reform Act that established the SMRB in
15 '06 was interested in these broader issues,
16 but the particular questions of alcohol and
17 addiction have been looked at before,
18 including in '03.

19 The National Academies recommended
20 considering merger of the two institutes, and
21 an earlier report from the Lewin Group more
22 than 20 years ago raised the option of a

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1 combined institute of addition, and also
2 almost ten years ago the Drug Abuse Act of
3 2001 required the HHS Secretary to request
4 that the IOM study whether combining the two
5 institutes would be worthwhile, and,
6 unfortunately, that study has never been done.

7 So, in effect, our deliberation as
8 a working group and, ultimately, the SMRB
9 follows in the tradition, the train of those
10 earlier efforts. Our charge is shown on slide
11 seven, to recommend whether organizational
12 change with NIH could optimize further
13 research into substance use, abuse, and
14 addiction and maximize human health and/or
15 patient well being.

16 We've had, as I said, 13 sessions.

17 Most of them -- most of them involved hearing
18 from others as their views on this subject,
19 and we began with hearing from the two
20 Institute Directors, Dr. Warren from NIAAA,
21 Dr. Volkow from NIDA, and we've heard from --
22 slide ten shows, beginning -- a large number

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1 of distinguished Americans who come from a
2 variety of sectors, prevention specialists,
3 treatment providers, patient advocates, policy
4 specialists.

5 On slide 11, we heard perspectives
6 on the science of the research in this area.
7 Slide 12 continues listing the experts that
8 we've heard from. Slide 13, we heard from a
9 number of people about alternative models for
10 organizing substance use, abuse, and addiction
11 research and people from the judicial system,
12 from academia, from industry.

13 And slide 14, we heard from former
14 NIAAA Directors and NIDA Directors, people who
15 have been in leadership positions in these two
16 institutes, and then, finally, on February 3 I
17 met with the NIAAA and the NIDA Advisory
18 Council and heard from them.

19 A couple of weeks ago, I had the
20 chance to brief Dr. Collins and Mr. Augustine
21 to inform them on our work to date, much as
22 I'm describing it for you right now, and we

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1 had a good discussion that day.

2 So let me describe what we have
3 learned from the briefings to date, and that
4 begins on slide 17. I think it's fair to
5 summarize that we have heard from some people
6 who very much favor reorganization, and we've
7 heard from people, some people who are very
8 much against reorganization.

9 First, those who advocate for
10 reorg, they say that the science would benefit
11 from synergy, that there are commonalities
12 across these areas, and they point to the fact
13 that emerging scientific research indicates
14 similar pathways and that alcohol and drug
15 abuse often begins in adolescence with similar
16 early risk factors.

17 They point to the high prevalence
18 of drug users who also use alcohol, and they
19 say that having separate disciplines and
20 separate institutes creates public health gaps
21 that are not in the public's interest. They
22 further say that reorganization and

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1 particularly merging the two institutes would
2 create synergy for advancing the science and
3 would increase the flexibility in cross-
4 training new investigators for the combined
5 field.

6 Slide 19 begins a layout of what
7 the advocates against reorganization say.
8 They point to the fact that they are concerned
9 that such a merger would create research gaps
10 in understanding. They describe the fact that
11 alcohol in particular has many effects on the
12 body well beyond the addiction issues, and
13 they fear that those would be lost or research
14 in those areas would be lost under such a
15 merger.

16 They also point to the different
17 contextual and social-cultural environment,
18 meaning alcohol is legal in most parts of our
19 society, and that has many implications. And,
20 advocates against reorganization suggest that
21 they don't see compelling evidence to suggest
22 that such a reorganization would actually

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1 improve things.

2 They would say that this is
3 largely theoretical and unproven, and they say
4 that the current organizational structure
5 mirrors the separate professional and
6 scientific associations in the alcohol
7 community and in the drug community. Of
8 course, it's obviously arguable which came
9 first, the chicken or the egg, on that one.

10 And, they further say that
11 reorganization would decrease the emphasis on
12 the effects of alcohol on multiple target
13 organs. In particular, we've heard that they
14 fear that research on alcohol's effects on the
15 liver would be lost in such a combined
16 institute on addictions.

17 And, the alcohol advocates fear
18 that they would lose out in the budget process
19 that a combined institute in which the
20 previous NIDA forces were two-thirds of the
21 new institute. They fear that they would see
22 their particular area of research compromised,

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1 and, in general, they are strongly opposed to
2 such a merger.

3 In the discussion that we had --
4 I'm now at slide 21 -- a number of other
5 issues came up that I just want to briefly
6 highlight for you. One that's come up many
7 times is, "What about other areas of research,
8 in particular, other areas of addiction
9 research across the NIH?"

10 Tobacco addiction is done in the
11 National Cancer Institute, and so people have
12 suggested, "Well, if you're going to do this,
13 you might as well do that, as well, and have a
14 pan-NIH focus on addiction research. Don't
15 just constrain it to these two institutes."

16 Another point that's been made is
17 that there is codified in statute a particular
18 role for the Office of National Drug Control
19 Policy at the White House in overseeing the
20 NIDA budget, and the question has been posed
21 what would happen to that role if such an
22 institute were created, a combined institute.

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1 People have asked what's the comment, if any
2 of the beer, alcohol, and spirits industry in
3 all of this.

4 Some have said quite
5 straightforwardly, "Our patients seem to have
6 no difficulty in using multiple substances.
7 Why does the government seem to have such a
8 difficulty in combining the work done across
9 substances?" and some have asked are we going
10 to, as a working group, recommend a single
11 solution or multiple options.

12 There are some broader issues that
13 people have pointed to -- I'm on slide 22 --
14 including the fact that they believe that both
15 institutes are under-funded, and combining the
16 two runs the risk of short-changing research
17 topics across both areas.

18 I mentioned already, but would say
19 again, we've heard repeatedly that the public
20 health message for alcohol is different from
21 that related to drugs in that moderate alcohol
22 usage may be healthy. Immoderate usage is

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1 not. People worry about a single research
2 dogma crowding out other possibilities in
3 researching this.

4 Folks have mentioned that we ought
5 not to restrict this just to alcohol or drug
6 abuse. I mentioned already tobacco addiction,
7 but there are other addictive practices in
8 American society, and also the mental health-
9 behavioral health aspects of this are looked
10 at through the National Institute on Mental
11 Health, and so where do you draw the circle of
12 the Venn diagram is the question.

13 And others have said if we are to
14 talk about a merger, surely this ought to be a
15 genuine merger, not just a creation of a
16 holding company institute with separate
17 divisions within it that are pretty much the
18 current institutes as they are now
19 constituted. I'm at slide 23.

20 I mentioned that, on February 3, I
21 met with the NIAAA Advisory Council and
22 summarized this pretty much as I have given it

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1 to you so far and then responded to the
2 Council's questions and comments. That day,
3 they passed the resolution that's on the slide
4 before you, which I leave to you to read for
5 yourself, but they said they are against any
6 reorg that would eliminate NIAAA as an
7 independent institute.

8 That same day, I also met with the
9 NIDA Advisory Council, and I similarly
10 presented our work to date and then heard from
11 them, interacted with them, and later they
12 passed a resolution, again unanimously, saying
13 that they are in favor of such a merger, and I
14 think those two resolutions typify what we
15 have heard from a variety of quarters on this
16 subject.

17 So, slide 25 begins to describe
18 where we are as a working group on this
19 subject. It lays out step one in the process
20 for assessing the need for change and poses
21 the question, "Is current substance use,
22 abuse, and addiction research at the NIH

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1 capitalizing on opportunities and meeting
2 needs, or could reorganization better do this
3 work?"

4 And, on slide 26 we lay out a
5 number of considerations that we believe ought
6 to be undertaken in answering those questions.

7 We borrow heavily in these five
8 considerations from our colleagues in the
9 Deliberating Organizational Change and
10 Effectiveness Work Group.

11 That's an intentional crosswalk
12 between the two groups. I won't read all the
13 points on this slide, but would just say these
14 are the things that we have tried to pay
15 attention to as we've heard from these
16 individuals and organizations and their
17 strongly held views.

18 Slide 27, in assessing the need
19 for organizational change we've asked for some
20 additional information. That is, including,
21 we've asked the Directors of the two
22 institutes what the major challenges are

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1 facing the advancement of research in these
2 areas.

3 We've asked to look at the funding
4 history of the two institutes and grant
5 success rates across those institutes, support
6 for early investigators, the rest of the NIH
7 portfolio, and then some population
8 demographics in this area, and I'll show you
9 results to date from those areas.

10 Slide 29 is the NIAAA answer to
11 the question, "What research and public health
12 needs are not yet currently addressed?"
13 Again, I won't read the words, but it lays out
14 Dr. Warren's answer to our question of what's
15 being lost or missed in the current
16 arrangement, and then on slide 30, what Dr.
17 Volkow said to the same question, what is
18 being missed or lost because of the way things
19 currently are organized.

20 Slide 31 shows what happened over
21 the last decade or so in funding for the two
22 institutes, a similar growth rate, but NIAAA

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1 is the smaller of the two institutes, and that
2 has ramifications that I alluded to earlier.
3 I'll just pause for a minute and let you look
4 at those numbers. And then, on slide 32, it
5 shows what the support for young
6 investigators, training support and K-awards
7 looks like in the two areas.

8 And then, the next slide shows
9 funding for substance use, abuse, and
10 addiction research across the NIH. This slide
11 is multi-colored and shows funding that is in
12 institutes and centers across the NIH for work
13 in the areas down at the bottom of each of the
14 bars.

15 I would draw your attention,
16 please, to the point made at the bottom of the
17 slide that these estimates were provided by
18 individual institutes and centers and don't
19 reflect the official NIH budget numbers, but I
20 think they are notionally close and are
21 helpful to answer the question, "What's the
22 rest of the NIH look like?"

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1 I assume your colors are about the
2 same as mine, but the dark blue is the NIAAA.

3 The bright red is the National Cancer
4 Institute, and the purple is NIDA, and what
5 you see is there's a lot of addiction research
6 across the NIH, and not all of it is in these
7 two institutes, as we've noted already.

8 And then, on Slide 34, some
9 information about the population involved with
10 use and addiction, first, a dominantly younger
11 population, and it shows the use of multiple
12 agents, alcohol, drugs, and both.

13 The next slide continues that same
14 point and then makes the additional point that
15 there is an intersection between substance
16 abuse and mental health problems, and that
17 theme is carried forward on the next slide,
18 36, that shows there is a high percentage
19 interrelationship there.

20 So, I am now at slide 37, and I
21 want to present to you the preliminary
22 findings of our working group, and I say

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1 again, that we met yesterday electronically,
2 all of us, and discussed this thoroughly and
3 vigorously, if I can put it that way.

4 We've come to agreement that the
5 status quo is not ideal for fulfilling the
6 NIH's mission and optimizing research into
7 substance use, abuse, and addiction, and we
8 are eager to improve how the NIH manages
9 research in this area.

10 Slide 38 begins to lay out the
11 spectrum of options that one might undertake
12 to improve the current situation, evaluating
13 options for change, and that is portrayed on
14 slide 39 that shows at the far left the status
15 quo with two institutes entirely separate, at
16 the far right a new institute, and then in
17 between several what we are calling functional
18 strategy options that shows -- each of which
19 shows things that might be done in common,
20 including, for example, a single advisory
21 council for the two institutes or some shared
22 functions, joint ventures, if you will, or a

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1 blueprint for research in some areas across
2 the institutes, so a variety of functional
3 strategy options.

4 As it begins to say on slide 40,
5 to date the working group disagrees on how
6 best to proceed, whether structural, that is,
7 merger or other organizational change, versus
8 functional integration across these areas.

9 There is a minority of our working
10 group who have a view that structural
11 reorganization is needed involving a merger of
12 NIDA and NIAAA into a single institute focused
13 on alcohol and drug abuse and addiction.

14 They would say that, given the
15 scientific landscape, research opportunities,
16 and needs in these areas that surely we ought
17 to have a vision for doing more and doing it
18 better, and mergers, however difficult it is,
19 we ought to take on that task, or Dr. Collins
20 and the NIH ought to take on that task to
21 press ahead.

22 On slide 42, I begin to lay out

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1 another view held by a majority of the working
2 group that would say that the best way to
3 proceed is a functional reorganization of
4 research programs in these areas.

5 This part of our working group
6 would say that given the science and the
7 research opportunity and the public health
8 needs clearly provides a rationale for
9 considering change. But, this majority isn't
10 convinced that structural changes would
11 benefit the science behind what functional
12 integration would do.

13 They see substantial room for
14 improving the science across the NIH, and
15 there is some evidence that in other areas,
16 not all, but other areas where this has been
17 attempted there has been some improvement, and
18 people have pointed to the Neurosciences Blue
19 Print and the NIH Common Fund and which say
20 that that should be done or attempted in this
21 area before pressing ahead to structural
22 change.

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1 We will be continuing this effort
2 and look carefully at the pros and cons of
3 each option. We plan to present our working
4 group recommendation at the next SMRB meeting.

5 Whether it will be a single unanimous
6 recommendation or a majority/minority set of
7 recommendations remains yet to be seen.

8 My final slide, number 44, lays
9 out the calendar that's before us. One of the
10 things that I've learned, speaking just for
11 myself, is that this long and rather arduous
12 task that the statute setting up the SMRB
13 requires of us seemed at the outset to be
14 overkill to me.

15 But, I have come to the conclusion
16 that this thorough process is warranted in
17 this instance, and as I said, at the outset,
18 if this is a prototype of what is to be
19 undertaken in other areas, I think this is a
20 useful, careful, I hope, thoughtful process.

21 So, Norm, let me stop there, and
22 I'd be happy to answer questions, or I'm sure

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1 others from the working group who are there
2 with you in the room might have other things
3 to add.

4 CHAIR AUGUSTINE: Bill, thank you
5 so much. That was a thorough update. I guess
6 no one said this would be easy, and it's
7 certainly proven to not be easy, but the
8 number of people you've spoken with and the
9 number of meetings you've held speaks to the
10 complexity of the challenge.

11 Why don't we, before we take
12 questions, let the other members of the
13 working group that are here, if you have any
14 comments you'd like to make or anything, this
15 would be a good time to do it.

16 Bill, I think we need to put you
17 on mute. Bill, I think we need to put you on
18 mute there.

19 DR. ROPER: I just did. Sorry.

20 CHAIR AUGUSTINE: Okay. Fine.

21 DR. TABAK: Hi, Bill. Larry Tabak.

22 So just to underscore one of the points that

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1 Bill made, really circling back to the
2 discussion we had at the beginning of the day,
3 I think it may have been Jeremy who pointed
4 out that change just for change's sake -- and
5 I'm paraphrasing. I'm not quoting Jeremy now
6 -- is probably not worth the aggravation, so
7 if you're going to have change, it needs to be
8 substantive to be worth the effort.

9 One of the side bars that the
10 group has had, and Bill alluded to, that I
11 just want to underscore, is this notion of if
12 you truly believe that you will improve the
13 science of addictive behavior research by
14 merging things, why not include all addictive
15 behaviors in your design for change?

16 And, again, not wanting to
17 misrepresent anybody's views, on the one hand
18 it was expressed that, "Well, you should not
19 try and bite off more than you can chew," no
20 pun intended, versus, "We just haven't had
21 enough time to deliberate that, but at least
22 some people were open to considering it," to,

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1 "Oh, my goodness, that's the NCI," and, you
2 know, the political issues surrounding that.

3 So, I think that that also needs
4 to at least be on the table. My own personal
5 view, and I said this to several people, is
6 that we have to be consistent.

7 We either believe that a change
8 can improve the science, in which case, I
9 don't know how you parse out one type of
10 addictive behavior over others, and if we say
11 we shouldn't allow political issues to get in
12 the way, then we shouldn't allow political
13 issues to get in the way.

14 That all said, we've got to be
15 really sure that, in fact, the science will be
16 improved, okay, and I hope I haven't misspoken
17 about anybody's position during the
18 discussions, but I'm sure my colleagues will
19 be quick to correct me if I have.

20 CHAIR AUGUSTINE: Thanks, Larry.
21 Who else? I saw other hands. Griffin.

22 DR. RODGERS: I think Bill really

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1 captured the essence of the discussion,
2 actually, quite well. I think that we still
3 are in a position in which there is, you know,
4 areas in which we can sort of continue to
5 consider our interests and the general
6 interests of the science of substance abuse.

7 And so what I think Bill has, if
8 I'm -- if I'm not overstating his comments, is
9 giving you our position at the moment, just
10 the interest that needs to be clarified,
11 perhaps, through additional data analysis that
12 Larry is suggesting, but we've really heard
13 over this course of meetings, individual
14 meetings, phone conversations really
15 passionate views on both sides of this issue.

16 And while, as Larry suggested, you
17 know, we really have to sort of view this
18 primarily as what's going to improve the
19 science for all to improve public health, one
20 can't escape, you know, some of the major
21 other non-scientific considerations to the
22 point that, you know, they can lead to really

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1 a lot of effort being involved in trying to
2 manage, you know, the downstream consequences
3 of those changes just for the sake of change.

4 I want to point out I think that
5 Deborah Powell may be on the line, so I just
6 wouldn't want to ignore her.

7 CHAIR AUGUSTINE: Deborah, are you
8 on the line?

9 DR. POWELL: Yes, I am on the line,
10 Norm.

11 CHAIR AUGUSTINE: Deborah,
12 terrific. This would be a good opportunity if
13 you wanted to add anything at this point.

14 DR. POWELL: I would. Thank you
15 very much for the opportunity, and I want to
16 just make the point that I think the minority
17 group really believes that there is more
18 sustainability in structural change than
19 functional change and are certainly -- and
20 have expressed our interest in broadening the
21 mission of a new institute to include
22 addiction in its broadest sense, including

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1 addictive behaviors and other addictive
2 substances, in addition to simply alcohol and
3 drugs of abuse.

4 However, I think the point that
5 one of us made, that we have not really
6 seriously invested that yet, is the kind of
7 thing that Larry Tabak was referring to, but
8 we, in essence, feel that this is something
9 that has been discussed for many, many years,
10 as Bill correctly pointed out, and this time
11 we feel that we are in support of a structural
12 change in order to sustain something going
13 forward.

14 CHAIR AUGUSTINE: Well, thank you
15 very much for those comments, and we'll
16 continue around the table. I saw other hands.
17 Tony?

18 DR. FAUCI: It's a question for
19 Larry and your comment about the criteria that
20 would move you to make a structural change, is
21 the science going to benefit from it, which is
22 obviously very important, but what I didn't

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1 hear mentioned in any of the discussions was
2 just the strict administrative issue.

3 If you have two institutes, and if
4 you put them together or kept them apart, the
5 science wouldn't be hurt, and it wouldn't be
6 helped. It would stay about the same.

7 Isn't the advantage of then having
8 two separate structures with two budgetary,
9 two personnel, two this, two that, isn't it an
10 advantage to put them together if it's going
11 to be a wash on the science?

12 If the science is going to be
13 still good in both, don't you consider the
14 fact that you have two separate entities that
15 you've now made one as an advantage or not?
16 I'm not coming down on either side. I'm just
17 asking if that was discussed.

18 DR. TABAK: So, to respond to that,
19 it has been discussed. I think the group, in
20 general, felt that there is little dollars to
21 be saved. You know, so you'll save the salary
22 of an IC Director, you know, top five kinds of

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1 things, but in the trenches, particularly in a
2 government system, you're not going to save
3 money.

4 With regard to efficiency, we had
5 that discussion, and it's a question of how
6 many -- in my mind. Now, I'll only speak for
7 myself, and I'll let others comment, as well.

8 In my mind, it comes down to how many loci of
9 decision-making you have.

10 It's been argued, rightly or
11 wrongly, that all of NIAAA is not about
12 addictive behavior and that there is a subset
13 that's very much involved with end organ
14 pathobiology, and the concern that's been
15 expressed is if you go from two loci of
16 decision-making to one, the possibility of
17 that piece of the pie getting short-changed
18 becomes more possible.

19 Now, the other piece, and, again,
20 if I misrepresent what somebody else said,
21 please correct me, other members of the
22 committee, is that, in fact, it's not the top-

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1 down advantages that you're looking for, but
2 rather it's the bottom-up.

3 The argument was made that the
4 research community would somehow benefit from
5 having a single budget, single program, and so
6 forth, and to that, at least personally, I
7 argue that functional change can achieve that,
8 as we have seen with the neuroscience
9 blueprint, for example, but others, I'm sure,
10 can add or --

11 DR. BRIGGS: You know, I just want
12 to amplify on that issue of the impact on the
13 scientific communities. What I found most
14 convincing in what we were hearing is the
15 extent to which these two scientific
16 communities, that have a lot of commonalities
17 may not have had a lot of crosstalk and a lot
18 of people who look at common issues.

19 And whether that is best addressed
20 by true structural change here or could, in
21 fact, be adequately effected by more, for
22 example, solicitations that require that kind

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1 of thought about both kinds of problems is
2 where -- what I found convincing.

3 CHAIR AUGUSTINE: Steve?

4 DR. KATZ: So, I have a question of
5 Larry. You mentioned that more data was
6 needed. What sort of data is needed in terms
7 of these deliberations?

8 DR. TABAK: What I was speaking
9 to, Steve, was the suggestion made by one of
10 the members of the committee that it would be
11 premature for the group to consider whether or
12 not all addictive behavior research would be
13 included in a new entity should one be formed,
14 because we simply haven't looked at it
15 sufficiently to have that discussion. That
16 would be the additional data that I was
17 referring to.

18 DR. KATZ: So the data would be to
19 look into each of the institutes to look at
20 addiction across the board, whether it's
21 sexual, whether it's tobacco, whether it's
22 gambling.

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1 CHAIR AUGUSTINE: Bill, we should
2 probably let you break in here. You've been
3 listening to the discussion. Do you want to -
4 -

5 DR. ROPER: Yes, Norm, I've been
6 listening to it. Larry especially is doing a
7 very great job of reflecting what I would say.
8 It avoids the problem with feedback through
9 the electronics, but I really don't have any
10 more to add at the moment in this
11 conversation. I'm going to stay on the line,
12 though.

13 CHAIR AUGUSTINE: Terrific. Let's
14 see. I saw Bill. Bill next and then Tom.

15 DR. BRODY: You know, the idea of
16 functional integration is great, but only if
17 you have allocated dollars for it, and, you
18 know, within the NIH system it's very hard to
19 get dollars allocated, and here you have two
20 institutes that say, you know, what they do is
21 completely different, and, you know, getting
22 them to ante up money for a functional program

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1 is going to be, at best, complicated.

2 DR. TABAK: There was a famous
3 dinner that preceded the formation of the
4 Neurosciences Blueprint where the former NIH
5 Director made us an offer we couldn't refuse,
6 and that's how the Neuroscience Blueprint was
7 born. So there are ways of, you know,
8 assuring that there is allocation of resources
9 for this purpose.

10 DR. ROPER: Yes, there are carrots,
11 and there are sticks.

12 CHAIR AUGUSTINE: Tom.

13 DR. KELLY: I was going to go to
14 the same point. I'd be curious if Larry or
15 somebody else can sort of flesh out a little
16 bit more what kind of functional
17 reorganization you all are thinking about and
18 how that would -- and how it would prevent
19 people from just continuing to do what they're
20 doing now as separate entities and whether
21 you're talking about a particular model. I'd
22 like to hear a little bit more about that

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1 model or any other models for functional
2 integration across NIH.

3 DR. TABAK: Bill, did you want to
4 handle that?

5 DR. ROPER: Yes, let me just try
6 it. Let's see if the electronics work. It's
7 a thoughtful question.

8 If whoever is operating the slides
9 could put up the one that shows the horizontal
10 range of options, what we have been talking
11 about is, and I think I said this in my
12 opening comments, a range of possibilities
13 that look at things that could be done to have
14 a shared common program -- I'm getting to the
15 slide here on my computer -- including, as I
16 said, a single council or a joint venture. I
17 think that's the business term for what is
18 here represented as a clustered function.

19 Clearly, I don't think this would
20 work with the two institutes left entirely on
21 their own to miraculously see the wisdom in
22 some shared functions. I believe that the NIH

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1 Director and the people around him would need
2 to have the kind of dinner discussion that
3 Larry referred to in an earlier analogous
4 situation to say that this is just the way
5 it's going to be, and you're going to have to
6 allocate and pick up the right percentage of
7 the budget of each of the institutes for this
8 shared function.

9 That kind of top-down push would
10 have to be exerted, I believe, for this notion
11 of functional strategy to have any real chance
12 of success. Ultimately, the answer to this
13 question that is before us, before the working
14 group and before the SMRB and before the NIH,
15 is which is the greater likelihood of success,
16 this thing that I was just then trying to
17 describe or outright merging the two
18 institutes.

19 And, as I said to you in my
20 opening comments, we are debating that central
21 question right now, but it should not be seen
22 as leaving things the way they are and hoping

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1 that people will on their own wish to do
2 business together versus an outright merger.
3 That is not what we're suggesting.

4 CHAIR AUGUSTINE: Let's see. I saw
5 Gene and then Sol.

6 DR. WASHINGTON: My comments
7 basically have been covered in response to
8 Bill Brody's question about how do we achieve
9 this, but it's my assumption that this group
10 has some influence through its
11 recommendations.

12 And so, if we recommend some
13 combination of measures, including a single
14 council and a push from the leadership and
15 others for some set of initiatives that draw
16 on current development that's taking place in
17 science that foster the kind of collaborative
18 environment we want to see across the
19 discipline, then that becomes at least a
20 driver for making those kinds of changes
21 happen.

22 And I see that that would be the

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1 next phase of our discussion is first deciding
2 that as a group, in fact, we are going to
3 recommend functional versus structural, and
4 the majority of that favor that right now, but
5 then making a recommendation about what do we
6 mean by function and driving it, I think the
7 sense of the group is, as close to structural
8 without delineating or pushing for a merger as
9 possible.

10 CHAIR AUGUSTINE: Sol?

11 DR. SNYDER: I thought I might give
12 a little historical perspective that might
13 inform this issue, because I've been involved
14 almost 40 years. My interest happened when
15 President Nixon declared war on drug abuse and
16 appointed Jerry Jaffe as the first drug abuse
17 czar, who was a psychiatrist who started
18 methadone clinics and who was a good friend,
19 and I was trying to push Jerry to put money.

20 While I was worrying about getting
21 money, I became interested in what were the
22 issues, because he was pushing me back.

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1 "Well, why aren't you doing anything about
2 heroin addiction?" and I said, "I don't know
3 morphine from marijuana. I started reading
4 about it, and that led to the work on the
5 opiate receptor.

6 Now, I'm a psychiatrist fully
7 supported by NIMH. Had I been part of the
8 drug abuse, and there was a whole -- literally
9 called the Narcotic Club. Had I been part of
10 the community and been involved with opiate
11 research, I would have -- the work on the
12 opiate receptor would have never happened,
13 because I would have known that it was
14 impossible.

15 And then, it became a hot area and
16 endorphins, and then Marshall Neurenberg, the
17 great Nobel laureate, got very interested and
18 developed a neural blastoma cell line, our
19 first major insights into molecular mechanisms
20 of addiction. Had Marshall had a background
21 in the opiate community, he wouldn't have done
22 that work, because he would know that that

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1 can't be done, and that's wrong.

2 And, meanwhile, all of this, all
3 our work was done through NIMH, and there was
4 a drug abuse division of NIMH, and then, of
5 course, they created NIDA and then the Alcohol
6 Institute, and there was a -- and then, about
7 that time, there was lots of community mental
8 health centers, and they decided to take the
9 community mental health centers and the
10 methadone clinics and NIMH, NIDA, and Alcohol
11 and put them together into something
12 completely separate from the NIH, the Alcohol,
13 Drug Abuse, Mental Health Administration or
14 ADAMHA, and so that's where our checks came
15 from.

16 And what became an annoying
17 problem was that the people in the NIH said,
18 "That's not real science. Those three
19 institutes are just second-class science," and
20 the people in the institutes were feeling sort
21 of like second-class citizens. And then,
22 because the clinical enterprise was dwarfing

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1 the research enterprise, there was a movement
2 to move it all back into NIH.

3 And then there was a big political
4 brouhaha, because the institutes, including
5 NIMH, thought that, "Well, we're going to be -
6 - if we go back into the regular NIH," which
7 is now at this point -- God had invented
8 molecular biology, and here we're just
9 measuring neurons, and we're second-class
10 science. We're not going to get any money.

11 And, actually, already within
12 ADAMHA the NIDA and the Alcohol Institute
13 said, "Well, we're not getting money, either,
14 because NIMH has the better neuroscientists,
15 and we're considered second-class citizens.
16 We're being pushed out, too, so we should be
17 even separate yet."

18 And, of course, the reintegration
19 of those institutes into NIH was the best
20 thing that ever happened in the history of the
21 field and putting people together. So I'm not
22 making any recommendations, just letting you

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1 know.

2 CHAIR AUGUSTINE: That's very
3 sobering, no pun intended. Let's see. Dan, I
4 saw your hand there.

5 HON. GOLDIN: I don't have all the
6 scientific input, but I believe that the NIH
7 is at a very crucial turning point, and I'm
8 not sure how many more institutes it could
9 stand.

10 There's going to be -- and from
11 what I heard, the reason for not going all the
12 way -- I'll make my own interpretation,
13 because I wasn't there -- is there's bad
14 socialization. Group A says, "Hell, no, we
15 won't go." Group B says "We'd really like to
16 do it."

17 If this institution cannot bring
18 together two organizations with scientific
19 merit, Katie, bar the doors as to all the new
20 organizations that are going to start, and
21 it'll end up going from 27 -- you're going to
22 have a trend. We'll keep going up.

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1 If anything, this organization
2 needs a little bit more consolidation. I
3 think the way to go at this is to take a look
4 at the sociology and understand how to address
5 the legitimate concerns of Group A, which
6 says, "Hell, no, we won't go."

7 It's very simple to address the
8 non-addiction work and build a branch or
9 something else, but I think it will be a
10 gross, bad signal to send if this merger
11 cannot be made to happen after all the years,
12 and I see all the angst and all the science.
13 We ought to grow up and get big about this.
14 End of statement.

15 DR. ROPER: Norm, can I respond to
16 that, please?

17 CHAIR AUGUSTINE: Absolutely.

18 DR. ROPER: This is Bill Roper.
19 The point that Dan just made is one that we
20 have talked about across the work of this
21 working group, and I think I alluded to that
22 in my opening comments when I said that we are

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1 trying to take account for the larger context
2 and view this as a prototype for what might be
3 done in other areas while at the same time
4 looking at the merits of this particular case.

5 That issue surely is there, no question about
6 it, and I think it is one that we need to
7 debate and discuss as the larger SMRB.

8 Speaking just for myself, not for
9 the working group, I would just say if that is
10 what we're about, that is, discussing a
11 roadmap, no pun intended, but a roadmap for
12 the NIH Director on how to consolidate down
13 from 30 some-odd institutes and centers to a
14 much more manageable number, I would say ten
15 or 12, then, fine, I'm game for this, but as
16 long as it's just viewed in isolation, it's a
17 different question, and to date we've been
18 asked to view -- to debate this in relative
19 isolation.

20 DR. HODES: Just to amplify that,
21 it was a basis for a lot of discussion, and we
22 decided we needed to be careful, first of all,

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1 not to make the decision between science and
2 the courage based on science to consolidate
3 versus, if you will, cowardice, the
4 unwillingness to take on the administrative
5 burdens. We think it's not that.

6 On the other side, we decided we
7 weren't going to make this a symbolic stalking
8 horse and merge if we were not convinced it
9 was scientifically meritorious, because it was
10 a broader principle. Now, either of those can
11 be debated, but I think our real emphasis was
12 in this case to identify which solution was
13 best for the science of these two institutes
14 and for addiction, and the game changes
15 completely.

16 As we just said, if the imperative
17 is to make this the first case to prove in
18 principle that we can merge, that's very
19 different from making what we think is the
20 best decision for science in this case.

21 CHAIR AUGUSTINE: Let's see. Dan?

22 HON. GOLDIN: I'd like to press

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1 back a little bit. I find it hard to believe
2 with all the evidence that I've seen that you
3 won't get outstanding science if you merge.

4 I think it's on the margin,
5 perhaps, measured in percentage points, and I
6 really do believe it's the issue that is the
7 bigger issue, and I agree with that. It is
8 the bigger issue.

9 We've been asked by the Congress
10 to address organizational change at the NIH,
11 and if we don't consider the bigger issue, we
12 will not have dealt with one of the reasons
13 that this panel was asked to be formed, and if
14 we make small, minor changes, I don't think we
15 meet the intend.

16 At least we ought to answer the
17 big question, and perhaps we ought to have a
18 discussion, "Should we answer the big
19 question?" And if the discussion says, "Well,
20 you should answer the big question," that
21 should go first. I agree with that.

22 CHAIR AUGUSTINE: Seeing no lights,

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1 I'll take a crack. What I was going to say,
2 and much of it's been said, the -- let me say
3 that my comments aren't intended to either
4 endorse or not endorse the premise of my
5 questions here.

6 One thing that comes to mind, we
7 haven't talked a lot about it, or maybe we
8 have, but it's the opportunity cost associated
9 with the kinds of things we're discussing.
10 Francis is only going to have a certain
11 lifetime here, and he can have a major --

12 Sorry, but I don't know anything
13 that you don't know, but he is obviously a
14 very talented individual who can contribute a
15 lot, and he's got to decide how he's going to
16 spend his hours, because he doesn't -- there's
17 only so many a day you have, and he could have
18 a major positive impact here. One thing he
19 could do is tackle this issue, and he could
20 tackle other issues.

21 I am struck -- supposing you do go
22 from 27 to 26, what have you accomplished?

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1 Twenty-six is still a pretty big number. If
2 we could get to 12, I'd say we had
3 accomplished something, but if the difficulty
4 of getting from 27 to 26 is anything like
5 getting from 26 to 12, it'll introduce chaos.

6 So I'm not adding a lot, but these are sort
7 of the thoughts that are going through my mind
8 that there is an opportunity cost here that
9 has to be weighed.

10 The other thing that I guess I
11 wanted to mention was that there are different
12 kinds of change. There is organizational
13 change. There's functional change. There are
14 other changes. Organizational change, one of
15 the nice things about it is when you draw a
16 new organization chart and put names in it,
17 it's pretty clear what you've done.

18 When you talk about functional
19 change, it's very fuzzy, and so should we end
20 up in the functional change camp, I hope that
21 we can be very, very specific about what
22 functional changes we're talking about. What

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1 do you have to go do so that if we do go that
2 way, you can hand to whoever is in charge, and
3 they'll know exactly what it is we want them
4 to do, and this is kind of --

5 DR. ROPER: Norm, this is Bill,
6 Norm.

7 CHAIR AUGUSTINE: Yes, Bill, sure.

8 DR. ROPER: Just to reassure you,
9 that's exactly what we plan to do next after
10 today is shape that option so that it's not
11 some fuzzy abstraction but rather a very
12 precise possibility.

13 CHAIR AUGUSTINE: Terrific.

14 DR. BERG: A scientific question.
15 One thing that I've been struck in reading
16 through the materials and hearing the
17 discussions is the sense that the alcohol
18 research community and the drug abuse research
19 community are much more separate than one
20 might have imagined there would -- they would
21 be.

22 And one possibility for that is

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1 that investigators are, even though they're
2 working on overlapping issues in terms of
3 alcohol abuse and other substance abuse, that
4 they are intentionally targeting their
5 research applications so that they fit neatly
6 into NIAAA if they're alcohol-related and NIDA
7 if they're not, and they avoid writing
8 applications that cut across the two areas.

9 And, that would seem to me to be a
10 case where the organizational structure could
11 be hurting science, because you're distorting
12 it based on fundability or perceived
13 fundability rather than on scientific issues.

14 Is there a sense that that's a straw man
15 that's real, or is it --

16 DR. HODES: I think it's real, but,
17 again, the question is which solution,
18 structural or functional, is most appropriate
19 at this time, and another perspective, I don't
20 know if the subcommittee or even the whole
21 group would agree, but in real sincerity we,
22 those of us at NIH and Institute Directors,

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1 are used to a dynamic in which we get together
2 and invest very serious intellectual effort
3 and then make a recommendation.

4 And in some cases the
5 recommendation is to the NIH Director, and the
6 choice about which of the options he or she
7 wants to undertake as the most effective way
8 to accomplish solution does depend heavily on
9 the person, as you've been pointing out, who
10 is going to have to invest the capital and
11 deal with it.

12 And it may be in the end, from the
13 perspective of our working group, that we'll
14 have still minority and majority opinions, and
15 I think a part of the sense of that is that we
16 respect mutually these two positions and think
17 it reasonable that in the end -- and further
18 informed by this whole committee that part of
19 the decision may appropriately rest with the
20 NIH Director in determining which strategy in
21 this case he wants to undertake to accomplish
22 this.

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1 DR. ROPER: I would just say, Amen,
2 to what Richard just said.

3 CHAIR AUGUSTINE: Very good point.

4 DR. SNYDER: Just to address
5 Jeremy's point about the scientific basis,
6 what the bottom line of what I said earlier
7 was, of course, that alcohol, drug abuse is
8 all -- the key questions are all in the brain.

9 Obviously, hepatologists can go
10 study alcohol, because it's an easier place to
11 get money, but the key thing is it's all in
12 the brain, and the best way of solving the
13 problems is to not say, "My whole life I just
14 study morphine. I just study -- get more
15 insights from morphine from doing something
16 very, very different but probably in the
17 brain."

18 And so, scientifically, putting
19 them all together would make the best sense,
20 but I think Norm's point about opportunity
21 cost is such that, I mean, if I were the
22 Director of the NIH, I would never dream of

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1 eliminating the Alcohol Institute, because
2 that would be 90 percent of my time going to
3 Congress and fighting people who say, "You
4 don't care about alcoholism."

5 DR. RUBENSTEIN: I mean, this issue
6 of reducing the number of institutes goes back
7 decades, right. Every report that somebody
8 did said that that would be a good idea, and I
9 guess the question I have, and I think I know
10 the answer, is we've never, ever reduced any
11 number of an institute ever, have we? Is that
12 a question that has an answer? I mean we've
13 changed the names. So binary fission is a
14 rather simple process, right, but merging --
15 so I think there is a historic thing here,
16 just to say to what Norm did.

17 Maybe the opportunity cost to go
18 from 26 to whatever, 25, is a huge opportunity
19 cost. There is no precedent for having done
20 it, and the question is is it really
21 worthwhile, and the case has to be compelling,
22 I think, scientifically to spend the energy to

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1 do that.

2 And, having read through this
3 report, I think there's mixed views about it,
4 and when you listen to Sol, who is the world
5 expert on it, you know, maybe the answer is
6 coming somewhere else, anywhere, so we'll
7 spend all this -- or could. You know, so
8 we'll spend all this time, and then somebody
9 in, I don't know, Aging -- somebody in Aging
10 will say --

11 So the real question I have is,
12 you know, where do you want to spend your
13 chips, and if it isn't so big, the noise is so
14 great that it's distracting, so my view of all
15 these changes are, I think, like many said.
16 If you're going to tackle the big picture
17 again, that's worth the effort even if the
18 chances of getting there are low.

19 If you're going to do little
20 things on -- not little things. If you're
21 going to do something that will make a modest
22 difference, there better be a compelling case

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1 for spending the energy doing it, and I hope
2 the subcommittee will address that as they --
3 you know, as a reason they'll come out one way
4 or another in the end. I think you are, so
5 I'm just saying the obvious.

6 DR. ROPER: Arthur, if I could just
7 add, what you said is exactly my view, and
8 that's what we're going to be debating.

9 CHAIR AUGUSTINE: Tony?

10 DR. RUBENSTEIN: Sorry. Just to
11 add one last thing, the reason I also say that
12 is the IOM and, I guess, the National Academy
13 do debate these things enormously and do write
14 very compelling reports, but it is kind of
15 instructive that many of these reports have no
16 impact, despite the fact that they are
17 populated by really important and thoughtful
18 and very capable people.

19 So, there has to be a lesson
20 learned why, even with all that effort and the
21 belief in the quality of the effort, of the
22 report and the people involved, in the end

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1 nothing happens to some of it, I mean, not all
2 of it. So, it just is a historic thing that's
3 worthwhile evaluating, because we're not here
4 reinventing the wheel. It's around.

5 DR. COLLINS: Unless Norm is in
6 charge. Then it has a new --

7 CHAIR AUGUSTINE: -- Tony and then
8 Dan.

9 DR. FAUCI: So I just want to make
10 a comment related to what you said, Dan, about
11 proliferation of institutes. With the Reform
12 Act, if you read the total language of the
13 Reform Act, it argues strongly that you have
14 to jump through some serious hoops if you're
15 going to try and get yet again another
16 institute, so I think there are some
17 safeguards against the proliferation of
18 institutes. That's one point.

19 The other point that I was struck
20 by was what you said, Norman, about how does
21 Francis want to expend his energy. So, as a
22 good friend of Francis for many years, I would

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1 look at it from my perspective where I don't
2 have a horse in the race at all whether to
3 merge or not these two institutes.

4 But, as I look at it from someone
5 not in the field, if you're going to go from
6 27 to 26, that's nothing. If you're really
7 serious, and I am -- I will state that I would
8 be against this going from 26 to 12 or 13.

9 I think that would create havoc,
10 but observing what we're seeing now, that from
11 my somewhat objective perspective, if there
12 was ever a rationale for merging two
13 institutes that in my mind would be a slam
14 dunk that everybody would say, "Do it," it
15 would be merging these two institutes.

16 And, if you see this kind of
17 dichotomy on that, could you imagine what
18 you'd have to go through if you wanted to do
19 something other than this and do institute --
20 you would consume all of your time. So, my
21 recommendation as your friend is don't go
22 there.

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1 CHAIR AUGUSTINE: Dan.

2 HON. GOLDIN: First, let me say,
3 Norm, I agree with you. It's not up to this
4 panel to expend this nice man's energy and
5 that there is an opportunity cost. However, I
6 think, and the point I was trying to make, I
7 think it is worth for this panel to have that
8 discussion at the higher level and not burden
9 the subcommittee with that issue.

10 I think it would be very
11 important, no matter how it came out, and
12 hopefully whatever discussion we have would
13 come out before the final recommendation. I
14 feel that that's a very important issue, but
15 again I want to emphasize, Francis, I don't
16 think it's our position to expend your energy.

17 CHAIR AUGUSTINE: Dan, I'm very
18 sympathetic to your point of view, and you
19 remember our first meeting. I had suggested
20 we do a zero base, lay out -- if you were
21 starting NIH from scratch, what would it look
22 like? And, I was not suggesting for a moment

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1 that you would go do that, implement that, but
2 I thought it would be very instructive to see
3 what would it look like.

4 Where are the big differences?
5 What can we learn? And, that turned out to
6 create so much terror in the halls that even
7 that seemed pretty overwhelming, but I think
8 your point is right.

9 You know, several have made it
10 around the table that if it's this hard to get
11 from 27 to 26, to do anything real, it boggles
12 the -- well, it's going to take Francis's
13 whole life to do it, but on the other hand of
14 that, if you -- if you can't do the easiest
15 one of all, what are you going to do?

16 The point was made, though, it's
17 going to be hard to add them, add new
18 institutes, I think, but it's going to be
19 harder to get rid of them. Your point was
20 good. Gene?

21 DR. WASHINGTON: I was just going
22 to say we may be underestimating the impact

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1 that functional change can actually have. I
2 mean, many of us in academic institutions that
3 are more ossified than any other organism you
4 might imagine, where we have departments with
5 two faculty members, and you can't change
6 them, and you leave them there.

7 But, you create centers, and you
8 create multi-disciplinary programs that work
9 across them, and you slowly starve the others
10 to some degree, but you change the asset
11 allocation. There are some very powerful
12 instruments for driving the kinds of change
13 that we want related to improving the science,
14 fostering better collaboration and integration
15 across disciplines.

16 So I just -- I just want to
17 underscore of amplify the point that's been
18 made is that this is not a dichotomy where
19 it's a win or a lose. I think we could still
20 win-win while minimizing opportunity cost.

21 DR. HODES: I agree with that
22 strongly, but also I would point out there is

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1 not -- it's not an easy option for the NIH
2 Director in this case, so if he -- we talked
3 about the effort that would be involved in
4 defending a merger. We shouldn't
5 underestimate what would be required to make a
6 substantial functional change. So either way,
7 Francis --

8 CHAIR AUGUSTINE: Griff, you've
9 been very quiet. We haven't given you a
10 chance to say anything. Do you want to weigh
11 in here?

12 DR. RODGERS: No, I think much that
13 has -- that I was going to say and I have said
14 already, you know, I have. I think, you know,
15 again we still have work before us. This
16 isn't sort of the final solution, but I think
17 we will have to sort of write the important
18 sub-notes and talking points to defend any of
19 these changes that are shown on this.

20 I think this is a nice way of
21 looking at it. Some people are sort of visual
22 learners, and I think sort of we had Pac-Man

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1 before, but this is -- I think Amy has done a
2 good job of sort of putting this together.

3 This doesn't mean any one of
4 these. The final solution and the optimal
5 solution might be several of these taken
6 together, or it could be staggered in a way
7 that you start with one and then add on to
8 others, so I think we still have work in front
9 of us.

10 DR. BERG: Just a quick comment to
11 Arthur's comment. I think, you know, the
12 existence of this Board in some sense is, from
13 my perspective talking to Elias, was to
14 provide a clear pathway for doing these sorts
15 of reorganizations.

16 I think his concern with IOM
17 reports and so on is you get a thoughtful
18 report, but there is no existing structure for
19 dealing with it, so you have to create all
20 these ad hoc structures, and every step of the
21 way you've got potential political
22 impediments. Here the intent was to create a

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1 process where it can be done in a more regular
2 way to make it as easy as possible while still
3 building an up-barrier, so it's not so easy
4 that you do things without thought.

5 DR. RUBENSTEIN: Yes, I do -- I do
6 agree with that.

7 CHAIR AUGUSTINE: Let me -- I saw -
8 - excuse me. I saw Dan and then Francis and
9 then Art.

10 DR. RUBENSTEIN: Oh, sorry.

11 CHAIR AUGUSTINE: No problem.

12 HON. GOLDIN: I want to come back
13 one more time and try it. I think it would --
14 I want to come back to the comment I made
15 about the sociology that we have. It's a very
16 difficult sociology.

17 I think it would be worthwhile --
18 and this may be extra work for you, Bill and
19 the panel. I think you ought to consider
20 taking a look at a model of what are the
21 consequences that might happen if you cause
22 this merger to occur and what steps could be

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1 taken to try and minimize the impact.

2 Just like the exercise could be
3 worked with the functional change, what steps
4 could be taken to manage the functional
5 change? One could build two models, and I
6 think it's worth building these social models
7 to see how to deal with it, to how to ease the
8 possibilities, and then when you --

9 Once you have these two models put
10 together, you could do a quantitative analysis
11 and say, "Hey, Approach A or Approach B looks
12 better," and, again, it's information for the
13 -- for the Director to make a decision on. I
14 think it would be helpful.

15 DR. ROPER: I agree, Dan, that that
16 would be helpful, and a point that I would
17 make is it'll be particularly important for
18 our working group that the federal members,
19 those of you there at the NIH, help us
20 articulate what those two alternatives might
21 look like, again, especially as we frame what
22 is the functional reorganization model,

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1 because you all live with this day in and day
2 out, and so we need your help.

3 CHAIR AUGUSTINE: Francis?

4 DR. COLLINS: Well, I had the
5 weight of the world on my shoulders this
6 morning, and now it seems to have increased in
7 its magnitude with all of these important and,
8 obviously, not easy decisions looming.

9 I think it's fair to say that the
10 situation here is different than what we
11 talked about earlier today in terms of the
12 Clinical Center, where I think the general
13 conclusion was we have to do something about
14 the clinical structure -- center structure --
15 because we have an unworkable model. So that
16 one is going to be a driver of change of some
17 sort, and it's a question of what the change
18 should be.

19 Here, there's a lot of debate
20 about whether the change requires that
21 structural merger, but I think there is also a
22 pretty good case here that the status quo is

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1 not as good as we would want to see it in
2 terms of the integration of addiction research
3 across different substances.

4 So, I like what Dan said, sort of
5 what I was going to say, as well, to this sub-
6 group. If you can really try to think through
7 what the models would look like of the merger
8 of the institutes versus a functional approach
9 and enumerate the pros and cons as best you
10 can, that would probably be the next, most
11 useful step.

12 And, I would say -- and I heard
13 Bill asking, "Well, what would the functional
14 model look like?" It would probably be one of
15 these blueprint kinds of approaches where you
16 do try to tap into interests in addiction
17 research that occur in NIAAA that occur in
18 NIDA but also occur in other parts of the NIH.

19 You don't want to miss the chance
20 if you're going down that road to pull in
21 other areas that haven't been very well
22 connected, either, or not as well as they

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1 could be, tobacco, particularly, but also
2 probably you could talk about food addiction,
3 sexual addiction, gambling, and so on, and
4 that means bringing in some of the behavioral
5 and social science research that maybe hasn't
6 been as tightly connected, as well.

7 And in that regard, maybe
8 something the group could look at is the
9 neuroscience blueprint as an experiment in
10 science management that's been around now for
11 three or four years. One of the reasons that
12 was pulled together by that famous dinner was
13 that there was a lot of noise out there about,
14 "Why do we have all of these neurology-focused
15 institutes? We have NINDS. We have NIMH and
16 so on. Why don't they work together better?"

17 Okay, so now we are trying that
18 model of a functional connection. Harold
19 Varmus, before he got criticized for his six-
20 institute model, was certainly suggesting cram
21 all of these things together under one roof.
22 We didn't do that.

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1 Is the blueprint actually
2 accomplishing the goal? Because there is an
3 experiment that's already been underway where
4 there is some data. You could assess whether
5 that has done it, and I would think that would
6 be pretty valuable in this instance in trying
7 to size up in the real world what would likely
8 be the benefits of a functional solution.

9 CHAIR AUGUSTINE: Well --

10 DR. RUBENSTEIN: My comment --

11 CHAIR AUGUSTINE: Oh, I'm sorry.

12 DR. RUBENSTEIN: I just want to say
13 what Jeremy said. I do actually believe this
14 oversight board has much more opportunity
15 because of its composition, so I actually
16 agree with you. It's so much involved and
17 rooted in the NIH and its advisors that I
18 think we do have a shot at things IM could not
19 do, so I agree.

20 CHAIR AUGUSTINE: Everyone, I
21 think, has said what they had to say. Hal,
22 having heard all of this, I know you don't

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1 have the background that some of the folks
2 around the table do, but do you want to make
3 any comment, observation?

4 DR. RAINEY: No, I don't, because
5 it's going to sound presumptuous, but I really
6 don't know. But in reacting to some of what
7 I'm hearing as an outsider asking dumb
8 questions, one of the fundamental premises was
9 that there are these interdisciplinary needs
10 in scientific research now.

11 We need to bring people together,
12 but I read the report, the earlier report on
13 restructuring the NIH that came to the
14 conclusion back in 2003 or so that there needs
15 to be no change in the general structure of
16 the institutes and centers, and now I hear
17 that it's very difficult to bring these two
18 together. Well, what happens to this premise
19 that there are these interdisciplinary needs?
20 Where are they going? I don't see it.

21 Another reaction I have trying to
22 look at what the committee did, obviously

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1 there's a lot of really impressive work going
2 on here, but I as an outsider couldn't see how
3 deep down into the membership of these units
4 they went.

5 It looked as if a lot of the
6 testimony was from experts from around places,
7 and then there were the votes of the councils.

8 Now, if the councils represent the
9 scientists, that's one thing, but are the
10 scientists interested in working together?

11 Have people talked to them?
12 Because it's a much smaller problem that I
13 dealt with, but I dealt with advising an
14 institute on our campus, and when you went in
15 there were people saying, "One of our problems
16 is we're too Balkanized. We want to work with
17 these people, and we're in silos, so change
18 the silos."

19 So, as I said about my talk, it's
20 easier said than done, but what's happening to
21 this premise that there is supposed to be --
22 there's a need for interdisciplinary research?

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1 Has there been a broader identification of
2 the manifestation of that premise at NIH that
3 there are scientists who really need to be
4 working together and want to work together?

5 So, please forgive me for being
6 presumptuous if you've taken that into account
7 in the discussion of the zero base analysis,
8 but I don't see it. I just -- you know, I'm
9 not trying to be a wise guy, but how is that -
10 - how are you assessing those?

11 Are you identifying those patterns
12 of synergy through talking with scientists and
13 the people who are going to do the research
14 and the -- that's just one reaction, sorry.

15 CHAIR AUGUSTINE: Thank you very
16 much for sharing those thoughts. You know, as
17 we were talking, and, Dan, you'll relate to
18 this, the world in which I've lived, the
19 technology I've lived with and the science,
20 it's become very commonplace to have this
21 functional organization but on a very
22 rigorous, formal fashion. We call it a matrix

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1 organization that we've probably both lived
2 with all our lives.

3 It's not easy to make work, but
4 that's standard in the world I live in that
5 you have your institutes, so to speak, here.
6 In our case, you had various sciences and
7 technologies that cut across, and they were
8 very formal.

9 There were people who ran these,
10 and there were people who ran these, and it
11 took a very delicate balance. I'll say that,
12 but that's the other extreme that is out
13 there.

14 Well, I think we've said what
15 there is to be said at this point. Bill,
16 you've got clear instructions how to proceed
17 now.

18 DR. ROPER: Thank you. Yes, we do.
19 We just need about an extended period of
20 time, but, seriously, we'll get it done.
21 Thank you.

22 CHAIR AUGUSTINE: Well, thank you,

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1 Bill. Is there anything you want to say
2 yourself?

3 DR. ROPER: No.

4 CHAIR AUGUSTINE: Okay. Yes, Gene.

5 DR. WASHINGTON: My comments as we
6 wrap up the conclusion of these three reports,
7 and that is, is that I've worked on many NIH
8 committees, many IOM committees, foundation
9 committees, and I've never worked with a staff
10 that was this exceptional in terms of the
11 quality of work that they produce and their
12 responsiveness, so I want to compliment
13 publicly Amy and Lyric and the others who work
14 with them.

15 CHAIR AUGUSTINE: Gene, I'm glad
16 you said that, because we all share that view
17 very strongly, and I --

18 DR. ROPER: Yes, indeed. Amen.

19 CHAIR AUGUSTINE: Let me just thank
20 everyone. I particularly appreciate the
21 ability of this group to talk about tough
22 issues and disagree with each other and do it

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1 so constructively. It makes it a pleasure, in
2 fact, and so with that we'll turn to the
3 public comment portion of the meeting.

4 We have one person signed up.
5 We'll ask that person to limit their time to
6 five minutes if they would, and when they're
7 done, if there are others who would like to
8 speak for no more than five minutes, we have a
9 little bit of time to do that. So, the first
10 person is Carson Fox with the National
11 Association of Drug Court Professionals.

12 MR. FOX: Is that better? All
13 right. Good afternoon, Mr. Director, Mr.
14 Chairman, members of the working group. My
15 name is Carson Fox. I am the Director of
16 Operations for the National Association of
17 Drug Court Professionals.

18 The National Association of Drug
19 Court Professionals represents over 25,000
20 individuals working in drug -- in over 2,400
21 drug courts across the nation. Many of you
22 know of our work.

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1 I'm here today to say that NADCP
2 strongly supports the merger of NIDA and
3 NIAAA. We all know that it takes science,
4 innovation, and teamwork to work within
5 individuals that find themselves in the
6 criminal justice system, because they have
7 addiction and abuse issues with alcohol and
8 drugs.

9 I'm a former prosecutor, and I've
10 worked at that level, and I've worked in
11 training drug court professionals for over a
12 decade, and with all my years of working with
13 the individuals who have these addictions, you
14 all know better than I do these people don't
15 differentiate their addictions between licit
16 and illicit drugs.

17 The drug and alcohol dependencies
18 that bring tens of thousands and hundreds of
19 thousands of individuals before the court
20 system in the United -- court systems in the
21 United States these individuals don't
22 differentiate. They don't split out what's

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1 elicit and what's licit.

2 For the -- in the National Drug
3 Court movement, what we've seen is a small
4 program that started in Miami, Florida, 21
5 years ago blossom into 2,400 programs that now
6 treat well over 120,000 individuals across the
7 country who not only are in the system because
8 of criminal issues. There's also juveniles
9 who find themselves in the system, and there
10 are parents who are at risk of losing custody
11 of their children because of abuse and neglect
12 issues.

13 It's our hope as a field that
14 merging the two institutes together would
15 benefit all those individuals, that having the
16 research merged would actually bring the field
17 to the next level and would really assist in
18 that effort, and so I wanted to come here, and
19 while I'm saying how much we support that, and
20 I'm here on behalf of the 27,000 folks who
21 work in drug courts, I also want to thank you.

22 Thank you for your service. I

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1 have certainly worked on my share of state and
2 local committees, and I can't imagine what
3 you've bitten off here, so I want to thank you
4 for what you're doing for the citizens of the
5 country in doing this. I know it's a lot of
6 work, and I want to thank you for giving me
7 the opportunity to speak to you this
8 afternoon.

9 CHAIR AUGUSTINE: Well, thank you
10 very much. Your perspective is an important
11 one to us, and we appreciate that. If you
12 would want to elaborate at all in written
13 form, we would -- we would welcome that.

14 MR. FOX: Thank you.

15 CHAIR AUGUSTINE: Thank you. Is
16 there anybody else who are guests today who
17 would like -- please.

18 MS. AUSTIN: I'm Bobbie --

19 CHAIR AUGUSTINE: If you could
20 introduce yourself.

21 MS. AUSTIN: I'm Bobbie Austin from
22 the Association for Research and Vision in

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1 Ophthalmology. Today I've heard a lot of talk
2 about structure and function, but the question
3 at the end of today, that I have in my mind --
4 and I'll use an intramural example, because I
5 did my training at the National Eye Institute
6 as a fellow.

7 We have almost an N of 30 for
8 institutes and centers, and all of these
9 institutes and centers have similar functions,
10 but among those functions some institutes do
11 the functions more efficiently than others.
12 I'll use purchasing as an example.

13 When I talk to other fellows from
14 other institutes, some institutes can get
15 orders in three days. Others it was taking
16 three weeks, so if we looked at functions and
17 analyzed which institutes are carrying out
18 particular functions most efficiently and
19 apply that to the other institutes, I think
20 that could improve the efficiency a lot.

21 Taking an extramural example, our
22 members actually get funding from a variety of

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1 different institutes, but a large number of
2 them get funding from the National Eye
3 Institute. Historically, eye was combined
4 with brain, but our members have concerns in
5 how grants were reviewed at that time and that
6 when vision scientists weren't reviewing the
7 grants, they didn't have a favorable outcome
8 in the scoring of the grants. Those are just
9 two things I want you to consider.

10 CHAIR AUGUSTINE: Well, thank you
11 very much for those points. We appreciate
12 your sharing that with us, and is there anyone
13 else who would like to comment? Seeing none,
14 the -- I think we are approaching the end of
15 our meeting, if I'm not mistaken.

16 Kind of the plan from here forward
17 is to continue with out three groups, start
18 preparing written reports. We've still got a
19 lot of work to do. I'm not going to try to
20 review the action items I picked up, because
21 I'm sure, Amy, you got them, and we'll be sure
22 each of the groups get them.

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1 We will meet again in May 17
2 through 19, and depending on progress, we may
3 have a conference call before that or shortly
4 after, whatever proves to be the best. Again,
5 my appreciation to everyone. I enjoy working
6 with you. I hope we can make a contribution.

7 Francis, I want to give you the last word.

8 DR. COLLINS: Well, again, I think
9 I can't express enough my gratitude to all of
10 you, and I appreciate that these are thorny
11 issues and that you probably feel like this is
12 somewhat of an interminable task. It all
13 brings to mind a quote from my favorite source
14 of quotes, which is Winston Churchill, and
15 Winston Churchill once said, "When you're
16 going through hell, keep going."

17 So, yes, consider the alternative
18 of staying where you are, so I guess that's my
19 exhortation, and I don't doubt that you're
20 going to follow up on it. Thank you all very
21 much.

22 CHAIR AUGUSTINE: To close the

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1 meeting with another Winston Churchill quote,
2 I hope we didn't close the last meeting with
3 it. Do you recall it? He said you could
4 always count on the Americans to do the right
5 thing after they've tried everything else.
6 Let's beat that. Thank you all. Have a safe
7 trip.

8 (Whereupon, the foregoing matter
9 was adjourned at 2:33 p.m.)

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