

UNITED STATES OF AMERICA{PRIVATE }
NATIONAL INSTITUTES OF HEALTH

+ + + + +

SCIENTIFIC MANAGEMENT REVIEW BOARD
(SMRB)

+ + + + +

WEDNESDAY
SEPTEMBER 15, 2010

+ + + + +

The Scientific Management Review Board convened in Conference Room 6 of Building 31 at the NIH Campus, Bethesda, Maryland, Norman Augustine, Chair, presiding.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

BOARD MEMBERS PRESENT:

NORMAN R. AUGUSTINE, Chair
JEREMY BERG, Ph.D.
WILLIAM R. BRODY, M.D., Ph.D.
GAIL H. CASSELL, Ph.D.
ANTHONY S. FAUCI, M.D.
HON DANIEL S. GOLDIN
RICHARD J. HODES, M.D.
STEPHEN I. KATZ, M.D., Ph.D.
THOMAS J. KELLY, M.D., Ph.D.
DEBORAH E. POWELL, M.D.
GRIFFIN P. RODGERS, M.D., M.A.C.P.
WILLIAM L. ROPER, M.D., M.P.H.
SUSAN B. SHURIN, M.D.*
LAWRENCE A. TABAK, D.D.S., Ph.D.
HAROLD E. VARMUS, M.D.
A. EUGENE WASHINGTON, M.D.
HUDA Y. ZOGHBI, M.D.

EX-OFFICIO MEMBERS PRESENT:

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

DESIGNATED FEDERAL OFFICIAL:

AMY PATTERSON, M.D., Executive Secretary

*Present via telephone

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

ALSO PRESENT:

STEPHEN L. ECK, M.D., Ph.D.; Eli Lilly
CHARLES BAUM, M.D., Ph.D.; Pfizer, Inc.
KEN DUNCAN, Ph.D.; The Bill and Melinda
Gates Foundation
BRIAN HALAK, Ph.D.; Domain Associates
THOMAS R. INSEL, M.D.,
National Institute of Mental Health
JEAN-PIERRE PACCAUD, Ph.D.;
Drugs for Neglected Diseases
Initiative
ERIC D. PERAKSLIS, Ph.D., Johnson &
Johnson
ROBERT CALIFF, Duke University Medical
Center
JEFF ALLEN, M.D.; Friends of Cancer
Research
STEVEN M. ROWE, M.D., M.S.P.H.;
Cystic Fibrosis Foundation
GREGORY C. SIMON, J.D.; Pfizer, Inc.
AMY COMSTOCK RICK, J.D.; Parkinson's
Action Network
MARGARET A. ANDERSON, FasterCures
BARBARA MCGAREY, J.D.; NIH
BENJAMIN BUTLER, J.D.; NIH

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

C-O-N-T-E-N-T-S

Opening Remarks and Agenda Overview..... 7

Translational Medicine and Therapeutics

Session III: Cultivating Partnerships:
Setting Goals and Defining Success

Partnerships in Drug Discovery and Development

 Stephen Eck, M.D., Ph.D. 9
 President, Transitional Medicine
 and Pharmacogenomics
 Eli Lilly and Co.

 Panel Discussion 46

Moderators:

 Richard J. Hodes, M.D.
 SMRB Member

 A. Eugene Washington, M.D., M.Sc.
 SMRB Member

Panelists:

 Charles M. Baum, M.D, Ph.D. 59
 Pfizer, Inc.

 Ken Duncan, Ph.D. 60
 Bill and Melinda Gates Foundation

 Brian K. Halak, Ph.D. 64
 Domain Associates

 Thomas R. Insel, M.D. 65
 National Institute of Mental Health

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

C-O-N-T-E-N-T-S (CONTINUED)

Jean-Pierre Paccaud, Ph.D. 67
Drugs for Neglected Diseases
Initiative

Eric D. Perakslis, Ph.D. 70
Johnson & Johnson

Discussion. 72

Session IV:

Engaging in a Dialogue with the Public

Jeff Allen, M.D. 113
Executive Director,
Friends of Cancer Research

Panel Discussion 133

Moderators:

Norman Augustine
Chair, SMRB

Anthony S. Fauci, M.D.
SMRB Member

Panelists

Jean-Pierre Paccaud, Ph.D. 139
Drugs for Neglected Diseases
Initiative

Steven M. Rowe, M.D., M.S.P.H 141
Cystic Fibrosis Foundation

Gregory C. Simon, J.D. 144
Pfizer, Inc.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

C-O-N-T-E-N-T-S (CONTINUED)

Amy Comstock Rick, J.D. 149
Parkinson's Action Network

Margaret A. Anderson 157
FasterCures

Ken Duncan, Ph.D. 164
Bill and Melinda Gates Foundation

Discussion. 167

Session V:

Substance Use, Abuse and Addiction

Presentation of SUAA Working Group's
Recommendations on Optimal Organization of
SUAA Research at NIH

William L. Roper, MD, M.P.H 208
Chair, Substance Use, Abuse
And Addiction Working Group

Discussion 225

Public Comments 263

SMRB Vote on SUAA Working Group 284
Recommendations and Report

Closing Remarks and Adjournment 301

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

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

8:08 a.m.

CHAIR AUGUSTINE: (presiding) Good morning everyone. If you would take your seats, we will begin.

All right. Welcome to the second day of the sixth meeting of the full SMRB. I hope everyone had a good evening. We have got a busy day today.

Two major topics. The first is to complete the discussion and data-gathering aspect of the TMAT topic and then we will turn to the report this afternoon of Bill's group and I want to be sure that we have a quorum this afternoon and get as many inputs as we can.

So, we will try to stick pretty close to the schedule, because I know people have airplane commitments, including myself.

Let's see, I notice in terms of the attendance, the attendance award goes to this side of the table this time. You will all

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 need to work on your colleagues a little bit
2 here.

3 Two announcements, just quickly.
4 One is that for the members there is a sign-up
5 sheet that will come around that if you need
6 taxis to the airports and the likes this
7 afternoon, if you will note it on there, that
8 will be arranged.

9 And secondly, for the members of
10 the public who are here, first of all, welcome
11 and secondly, if you have comments that you
12 would like to make, and we certainly welcome
13 that, there is time allotted this afternoon,
14 albeit rather brief, but there is time, and
15 there is a sign-up sheet out in the hall.

16 We kind of do it in first-come,
17 first-served, five minutes max, and again, as
18 we said yesterday, we welcome longer inputs by
19 mail or other form.

20 With that said, let's -- Arthur
21 unfortunately is letting his regular job
22 interfere with this. He had to go back to his

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 institution today, so I will kind of try to
2 pinch hit for him in this wrap-up of the TMAT
3 data collecting, if you will, information
4 collecting.

5 And our first speaker this
6 morning, who will kind of lay the groundwork
7 for the next panel discussion, is Dr. Stephen
8 Eck, who is with Eli Lilly, and I am not going
9 to go into biographies, because you have
10 everybody's resume in your book. So let me
11 turn to Dr. Eck.

12 DR. ECK: Well, it is a pleasure to
13 be here this morning. My apologies for missing
14 yesterday's proceedings. I will try to start
15 by giving you a brief overview of the history
16 of industry-academic collaborations in drug
17 development, provide a little bit of
18 perspective -- I think most of this history is
19 known to you -- and then I will move to where
20 I think there are some constraints and
21 opportunities, and finally five areas that are
22 my favorites for how academic and NIH research

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 can improve the efficiency, productivity and
2 innovation in drug development.

3 So, there is a long and rich
4 history of collaboration between industry and
5 academe and it has changed substantially over
6 the years and I think that is worth
7 appreciating. The pharmaceutical industry
8 really flourished with academic collaborations
9 in the middle part of the 1900s and this was
10 certainly evident at Lilly, where work, where
11 we moved from a company that largely sold
12 botanicals for medicinal purposes in the early
13 1900s, to a research-based company.

14 And that research was driven by
15 our ability to interact with academic
16 investigators. And I listed some of the major
17 ones, certainly not all of them- our
18 collaboration with the University of Toronto
19 on insulin, the Indianapolis City Hospital, to
20 open a research clinic on pellagra and other
21 related disorders, collaboration with the
22 University of Rochester on pernicious anemia

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 are some of the very early events.

2 And there was somewhat of a
3 decline in this process as industry became
4 much more independent and brought more R&D in-
5 house and became more vertically-integrated in
6 this area.

7 And arguably, I thought, I think
8 the industry thought it could sort of mimic
9 the innovation cycle that had been produced in
10 the electronics industry and in other markets.

11 Notably, the Bayh-Dole Act and
12 other changes sort of changed that tide and we
13 have now gone to a situation where
14 pharmaceutical research would be essentially
15 impossible without academic collaboration.

16 And Lilly today -- I don't have a
17 slide of all our collaborations but they are
18 extremely diverse. They vary from our
19 collaborations on discovering new tuberculosis
20 drugs, to very small-scale but detailed
21 investigations of the genetics of
22 schizophrenia drug response.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, this has not been without some
2 difficulty and I think you are certainly all
3 aware of the attention that has been brought
4 toward conflict of interest of issues.
5 Frankly, this is largely a beast of our own
6 creation. I think we did not do a good job of
7 maintaining a distinction between what was
8 legitimate, scientific research and what were
9 marketing activities.

10 And although some of these efforts
11 may be well-intentioned, I think it sort of
12 spoiled the fun for lots of people.

13 So going forward, I think we need
14 to keep this in mind, there are clearly
15 different agendas at stake here, but there
16 needs to be a clear separation between the
17 research activities that we conduct and how we
18 publicize that and our marketing activities.
19 And all of these financial arrangements need
20 to be explicitly transparent and stand up to
21 scrutiny.

22 So, there are some distinct

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 cultures and resource differences between
2 academia and industry and I don't want to go
3 through all of these, but I would like to
4 highlight two.

5 One is the diverse talent pool
6 that exists outside of industry. The industry
7 approach to drug discovery and development has
8 become increasingly narrow. Clinical
9 pharmacology, which is part of my group, is a
10 very good example. We don't embrace the entire
11 field of clinical pharmacology. We embrace
12 essentially that aspect which is needed to get
13 a drug label.

14 And there is a lot more
15 interesting pharmacology out there that we
16 don't explore. As a result, we tend to employ
17 people who work on the practical matters of
18 developing a drug and getting a label and
19 there is a lot more to drug research in the
20 science around this than we are ever going to
21 pursue.

22 There is also a lot of talented

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 people out there who have different ideas and
2 different approaches that aren't ever going to
3 work for a drug company for a variety of
4 reasons. So, I think this alone is a very good
5 basis for a collaboration.

6 The second topic I want to
7 highlight is that the project has premiered
8 outside of drug companies. We tend to focus on
9 a portfolio. We are trying to drive top-line
10 revenue growth. It is a major problem in the
11 industry right now. So we are somewhat
12 agnostic to how we succeed, how we achieve
13 that goal, and make trade-offs on projects
14 constantly, much to the annoyance of some of
15 our collaborators.

16 The academic investigator has a
17 vested interest in a particular topic and it
18 may occupy a large portion of their time
19 during their career, and this sustained focus
20 of activity, I think, is very important and
21 provides a certain amount of stick-to-
22 itiveness that we often lose sight of.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Those two elements alone, I think,
2 are plenty good reasons why we need to foster
3 collaborations between academic researchers
4 and commercial drug developers.

5 This is a graph I made which is
6 not the least bit scientific and it is flawed
7 in a quantitative sense. But, it was an
8 attempt to illustrate sort of the linear
9 thinking that goes into the process of
10 developing and marketing a new drug and who
11 contributes, where.

12 And the blue roughly illustrates
13 where the contributions come from academia and
14 green, roughly, where the contributions come
15 from the industry side. And most of the early
16 work around the biology of disease and target
17 identification in recent years has occurred on
18 the academic side and not within industry, as
19 industry has moved away from this to a large
20 extent.

21 And this is in sharp contrast, for
22 example, with our company. When we founded the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Lilly Clinic in 1926, it focused entirely on
2 understanding the disease, and had nothing to
3 do with the process of discovering a drug.

4 The Lilly Clinic today, which
5 operates in Singapore, focuses entirely on
6 developing drugs and not the least bit on
7 understanding disease, so we have come -- we
8 are 180 degrees from where we were when we
9 built our own clinic.

10 In the middle part, the lead
11 generation through sort of Phase III is
12 dominated largely by the pharmaceutical
13 industry, in part because we control the
14 assets and we are a little bit secretive and
15 we are pretty particular about what gets done
16 when.

17 I would argue that that probably
18 needs to change, in that we are -- the period
19 from target identification to a new drug
20 launch has shorted considerably, and science
21 is occurring while you are running your drug
22 development program, and that new science

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 needs to be incorporated in.

2 We have gone to disclosing what
3 clinical trials were running. I think we will
4 move even further forward to disclose publicly
5 a lot more details about what those clinical
6 trials are. I think, and I would hope, that
7 more openness in this area would foster
8 collaboration and that we could bring in
9 outside ideas and use outside talent to
10 further this mission.

11 Finally, on the post-marketing
12 research side, pharmaceutical companies do not
13 do a lot research on the post-marketing side.
14 It is really market extension: how can we
15 maximize the value of the drug? We get a new
16 line indication. An example is fibromyalgia
17 where there are now several drugs marketed,
18 both by Lilly, Pfizer and others.

19 So, we have done a lot to bring
20 new drugs forward but have not contributed
21 proportionately to understanding the biology
22 of fibromyalgia, just to pick one example.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 And of course, the ability of the
2 academic community to contribute here is not
3 largely going to be impossible due to the fact
4 that now everything is public, and they have
5 free access to do the work with or without us.

6 There are several concerns and
7 benefits to the collaborations that I have not
8 touched upon, and I am going to point to a
9 couple of my favorites. First of all, we need
10 to have a greater willingness to disseminate
11 new discoveries and ideas more quickly.

12 We tend to be rather conservative
13 in this area. When I was with Pfizer before
14 joining Lilly, we had the distinction of
15 having the least number of publications per
16 R&D dollars spent. We actually looked at our
17 \$8 billion budget at the time and the total
18 number of publications produced and we were
19 last among the big pharma, and certainly well
20 behind academics in terms of the number of
21 publications per research dollar, if you look
22 at an investigator with R01 for example.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, we need to bring the
2 information forward a little more quickly, so
3 that this can be incorporated into practice
4 and I will get to that in a minute.

5 The other area I would like to
6 highlight is the exchange of scientific
7 reagents, tools, and technologies. We produce
8 a lot of tools that, I think, could be more
9 routinely made available. They are not the
10 subject of value for the company. They are not
11 the basis for revenue generation. We have
12 moved away from patenting everything we think
13 about, to patenting a much more narrow
14 spectrum of what we invent and, largely, it is
15 around the composition-of-matter patents that
16 are valuable.

17 The tools, reagents, are much less
18 valuable in terms of generating revenue, but
19 are extremely valuable if we could disseminate
20 them and see more broad use.

21 For example, our group is
22 responsible for developing PET ligands. They

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 do not have any proprietary interest to us. We
2 use them to study receptor occupancy, so we
3 can, for instance, select a dose of a new CNS
4 drug, but that tool might, if made more
5 broadly available, contribute to understanding
6 of receptor biology or some other area of
7 neuroscience.

8 So these are the fives areas that
9 I have picked where, I think, industry needs
10 help in advancing innovative medicines, and I
11 will focus on innovative medicines because we
12 have largely made money in the past by
13 incremental improvements that were valued by
14 society.

15 I think we are running out of room
16 there, in terms of the incremental approach. I
17 think we need some radically new approaches,
18 particularly in diseases such as Alzheimer's
19 and cancer, where there are still large unmet
20 medical needs.

21 So, I picked these. There are a
22 lot of others that other individuals might

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 have chosen, but these are the ones that show
2 up on my desk on a routine basis.

3 Target identification,
4 understanding patient heterogeneity, biomarker
5 development, identifying unique subsets of
6 patients that are responsive to a new drug,
7 so-called personalized medicine or, at Lilly,
8 we call it tailored therapeutics, and
9 providing tools to help physicians manage
10 complex information, and I will give examples
11 of each of these.

12 So, in target identification and
13 validation, this has been really the strength
14 of the academic community. The industry
15 previously relied on a pharmacology that was
16 known to exist in nature, aspirin was known to
17 the pharaohs, the alkyl agents were discovered
18 as a result of toxic agents used in World War
19 I and so forth and so on.

20 We have moved away from that to
21 using target-based drug discovery, which is
22 the mainstay of most pharmaceutical company

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 pipelines. And I listed here a handful of what
2 I would call popular targets, in that two or
3 three or four major pharma companies are
4 chasing these targets as a basis for new
5 therapeutics.

6 And with the exception of two of
7 them, all of them really came from academic
8 discoveries. And you can make this list much,
9 much longer. These are just some of the
10 popular ones.

11 The ones which had significant
12 discovery contributions from the
13 pharmaceutical industry, were certainly CTLA4,
14 which Peter Lindsley discovered when he was
15 with BMS up in Seattle, and that contributed
16 to the development of Orencia, the CTLA4-ig
17 fusion protein, and later to MetRx, Pfizer and
18 BMS's separate contributions to developing
19 antibodies against that receptor for cancer.

20 And then the NAV1.7 for pain,
21 which was largely an academic discovery but
22 was funded substantially, in part, by Pfizer

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and Duncan McHale, who used to be in my group
2 when I was at Pfizer and was a major
3 participant in it.

4 So, there is some work on the
5 industry side, but clearly the bulk of this
6 comes from academia, and that is not likely to
7 change in the near future and that is
8 something that should be certainly encouraged.

9 The numbers on this slide are less
10 important than the concept, but it illustrates
11 that many of the drugs we use today do not
12 have the intended effect in a lot of the
13 people that take them. That is just the simple
14 fact. There is a huge amount of empiricism in
15 the use of medicines. It is try it and see if
16 you like it.

17 As my internist says when he has a
18 new patient with hypertension, it is like
19 trying on shoes. Try some on until you find
20 ones that fit.

21 That type of empiricism is not a
22 very efficient use of resources; it is not

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 particularly scientific or rewarding for the
2 patients either.

3 So, we could improve on this and I
4 think this is the second big area where I
5 think academic-NIH collaboration with industry
6 could reap huge benefits.

7 We need to understand patient
8 heterogeneity at the molecular level with much
9 greater detail than we do now. A broad-based
10 approach to large patient populations such as
11 type 2 diabetes, schizophrenia, depression,
12 are not going to make major advances until we
13 understand that these are really much more
14 complex disorders and that new drugs need to
15 target very specific segments of this market,
16 and I will say more about that in a minute.

17 This is a slide that I borrowed
18 from our CEO. Again, I think the numbers on
19 the slide are less important than the concept
20 and the numbers will change depending on what
21 particular drug you are talking about or what
22 particular market.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 The point is that we do not need
2 to market drugs to the entire therapeutic area
3 or the entire indication to have a good return
4 on investment. Increasingly, segmenting the
5 market is the hallmark of mature industries,
6 whether you are making automobiles or selling
7 soda pop or in the drug development business.

8 You can do a better job of meeting
9 your customer needs if you segment the market.
10 And that is why markets segment. And, I think,
11 that is true in the pharmaceutical industry.

12 The current choice of statins, for
13 example, is largely arbitrary. My mother, my
14 brother, and I all have the same inherited
15 form of hyperlipidemia. I take Lipitor because
16 I like Lipitor and actually it has got the
17 best label -- I don't take Lilly's statin but
18 don't tell anybody that.

19 My brother takes Crestor. Not sure
20 why. He doesn't have hypertriglyceridemia and
21 his HDL is just fine and my mother takes
22 synthostatin because she is basically cheap.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, the market segments but that
2 is not rational. We need to provide a rational
3 basis for this and, I think, when we bring new
4 medicines forward, we identify the right
5 segment for each patient. This can be very
6 acceptable in terms of revenue for drug
7 developers.

8 The third area is biomarkers and I
9 will go through this fairly quickly in the
10 interests of time and I think this is an area
11 you all know very well. They have very little
12 proprietary value, as I mentioned, with the
13 PET scanning example.

14 They become more value when we
15 disseminate them widely, we allow a lot of
16 people to use them, the people using well
17 validated assays and share their information,
18 then the utility of that assay climbs much
19 more quickly than if it is held in a
20 proprietary way.

21 This is just one example. This is
22 Lilly's support for the biomarker consortium.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I sit on the executive committee of the
2 biomarker consortium. It is a bargain for us.
3 For every dollar we put in, it generates five
4 dollars' worth of investment because four
5 other companies will also put in money on
6 average and so we only have to pay for a
7 fraction of the work, and this is all done and
8 made available to the public.

9 This is a larger list of
10 collaborations that Lilly has had through the
11 FNIH. I think the FNIH is a great vehicle for
12 doing this. It provides openness,
13 transparency, and also can keep the research
14 at arm's length, which helps with managing
15 conflicts of interest.

16 One very good example of this was
17 the GAIN Initiative, which Patrice Milos at
18 Pfizer started with Francis Collins's folks.
19 This was -- the cost of that was roughly \$55
20 million to Pfizer. That was not in the round-
21 off area of my budget at the time. In fact, it
22 was less than what was left over in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 external collaboration budget at the end of
2 the year that went unspent. These are very
3 manageable sums of money and can produce a
4 huge amount of public good.

5 Identifying unique subsets of
6 patients I have already alluded to. This is
7 another example where, what I would describe
8 as a relatively poor CNET inhibitor, PF-
9 02341066 as it is affectionately known -- it
10 probably has a new name now -- was rescued by
11 the background work on the EML4-ALK fusion
12 gene and its relationship to lung cancer
13 progression in a subset of individuals.

14 Now that academic work, if not for
15 that backdrop, there would not be a path
16 forward for this drug, and I think there are
17 going to be many, many more examples of this
18 where the academic community can help identify
19 better subsets of patients and so use drugs
20 appropriately.

21 The last topic I will address is
22 information overload. This is a slide from

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Steve Friend. The amount of information that
2 clinicians have at their disposal is virtually
3 unmanageable today. It is not reading the
4 literature. It is understanding the literature
5 and it is being able to incorporate that into
6 your clinical practice.

7 There are lots of -- I think we
8 can address this by developing better tools
9 that are well validated, that help clinicians
10 in everyday practice manage the information
11 and use it effectively.

12 I will point to just the last
13 bullet-point, because I think this is very
14 important to us as drug developers. We are
15 going to launch medicines that are going to
16 have a very narrow use. And that narrow use is
17 going to have to incorporate lots of specific
18 information, and it is well beyond age plus
19 BUN equals Lasix dose. It is way more complex
20 than that and it is not going to be a little
21 mnemonic that you can keep in your head.

22 There is going to need to be a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 tool, and a validated tool, and frankly, if it
2 is our drug, I would like to have that tool on
3 our label, and I would like to have it FDA-
4 reviewed and approved and have it squeaky
5 clean, not some back-of-the-envelope
6 calculation.

7 If that is going to happen, that
8 is going to require a lot of input from people
9 outside the pharmaceutical industry to guide
10 how those tools are built and how they are
11 used so they are truly useful.

12 So, I will give you an example.
13 Well, this is just some areas where you might
14 think about how this could be used. You are
15 all familiar with the genetics of warfarin
16 dosing and I will say a little bit more about
17 that, HLA B5701 genotype, the risk of
18 hypersensitivity for abacavir and
19 fluvoxacillin and many other types of
20 information to become available that affect
21 drug use. But, this is going to be way more
22 complex than just this test for this drug.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, this is from the Coumadin
2 label. I actually had my check-up on Monday
3 and I shared this with my internist. It was
4 kind of interesting. First of all, he could
5 not interpret the chart. So it is not likely
6 that he is going to read the drug label and
7 know what *1/*2 CYP2C9 mean, let alone what
8 Coumadin dose I should get, based on this
9 table, okay?

10 Secondly, I didn't even know that
11 VCORC or CYP2C19 had anything to do with
12 Coumadin and that the genetics might be
13 interesting, the background for the table.
14 This is an academic internist at a major,
15 academic medical center who has got 30-some
16 years of practice under his belt, okay?

17 So, you know, we have to reduce
18 this to something that is intelligible and
19 immediately useful.

20 So, I picked this not because I
21 have studied this and know this to be a good
22 tool. It is just illustrative of the idea, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 you can go to the website and play with the
2 tool. It is kind of fun.

3 But, it is sort of idiot-proof,
4 quite frankly, not that physicians are idiots,
5 but it is simple. So, you know, it just asks
6 you for information and you put the
7 information in and there is a lot of -- you
8 put the indication in and whether they smoke
9 and have liver disease and their genotype and
10 all this stuff -- and it estimates the dose
11 for you. And in fact, with electronic medical
12 records, this could run in the background. It
13 does not necessarily have to be manually
14 inputted by the physician before he picks up
15 the prescription pad. By the way, he is not
16 going to have a prescription pad. He is going
17 to write electronic prescription and he is
18 probably going to go to Medco or some other
19 provider who can look over this and actually
20 do the genotyping for you.

21 So, I think partnerships between
22 academia and industry, between academia and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 NIH and companies like Medco, who are very
2 interested in applying these tools, is a very
3 important area for us.

4 It gets even more complex than
5 this. This is a model for -- a mechanistic
6 model for clopidogrel dosing, which is quite
7 complex. It is a very interesting drug and it
8 certainly has a lot to offer the public, but
9 it does not offer the same thing to everyone
10 equally.

11 There are lots of things that
12 influence your ability to get mileage from
13 this, including your CYP2C19 status, your
14 ABCB1 genetics, whether you can metabolize the
15 drug, whether you can absorb the drug, whether
16 you are taking a proton pump inhibitor,
17 whether you have had a prior stroke or MI,
18 whether you are old and decrepit, whether you
19 are of low body mass -- all these things we
20 have data around that influence the use of
21 this class of drugs in general.

22 And so, these can be modeled

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 effectively and we can build good decision-
2 making tools that can people can reduce
3 clinical information to dosing strategies.

4 I have a couple of more slides
5 then I will conclude. So, I think the areas of
6 collaboration on the preclinical side are
7 clearly target identification and validation.
8 If we are going to drive innovation, this has
9 to be at the forefront, and we need to
10 understand patient subgroups that are going to
11 benefit from a particular target.
12 Unquestioningly, these are areas of tremendous
13 interest.

14 On the clinical research side,
15 there is the biomarker research, comparative
16 effectiveness research, which I really did not
17 talk about in any detail, pharmacoeconomic
18 research, particularly what is value? What
19 constitutes value? And what are we going to be
20 compensated for as drug developers? We don't
21 want to work on something that nobody is
22 actually that interested in.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 We need to advance regulatory
2 science, how we review drugs, how we get drugs
3 approved and how we manage this data. It is
4 relatively unchanged in the last 20 years. I
5 think this is the time for reform of drug
6 regulation.

7 And finally, we need to be able to
8 implement personalized medicine in a regulated
9 environment by having robust decision-making
10 tools.

11 There are several key aspects to
12 the collaboration, which I think deserve
13 attention. I have mentioned most of these.
14 But, I think the bottom one is the most
15 important. We need to be absolutely
16 transparent in all aspects of the
17 collaboration. Everyone needs to play with
18 their cards on the table face up.

19 I think we have some very good
20 examples in the past. I think the GAIN
21 Initiative, which I have already alluded to,
22 is a great example where public good can be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 generated from close collaborations.

2 Nobody had any leg-up on anybody
3 else in the process. There was no proprietary
4 interest in this. So let me stop there and I
5 will be happy to answer questions. Thank you
6 very much.

7 CHAIR AUGUSTINE: Dr. Eck, thank
8 you very much. The floor is open to questions
9 from the panel. Please.

10 MEMBER KELLY: Thank you very much.
11 That was a very useful, interesting
12 presentation. So, you sort of focused on the
13 role of academia and probably by extension in
14 NIH really in the early stages of the process,
15 mostly, I would say -- discovery phase, tool
16 development, patient stratification.

17 But, we heard yesterday that NIH
18 is actually fairly heavily involved in later
19 stages of the process, high-throughput
20 screening, optimization, that sort of thing,
21 and some academic institutions are as well.

22 And I would be curious as to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 whether you think NIH and academic
2 institutions have a use for there. Are there
3 particular niches, like rare disease for
4 example, that industry will not cover, and
5 academe and NIH might have a role to play?

6 DR. ECK: I think it is hard to be
7 overly prescriptive on what that is. I think
8 everything is going to become a rare disease
9 as we segments markets more and more. So rare
10 diseases in and of themselves could be -- fall
11 into that category.

12 But, the rareness of the disorder
13 is not really a good determinant of whether
14 the pharmaceutical industry is going to be
15 interested. It is really the product of
16 probability of technical success and the
17 prevalence of the disorder.

18 I would argue that if there was a
19 path to approval of a drug, that had no
20 reimbursement, that would never be paid, it
21 was a small indication, but we had absolute
22 certainty that every dollar invested would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 lead to that product being launched, there
2 probably isn't a drug company around that
3 wouldn't do it, because it can be done.

4 The problem is the probability of
5 technical success, when put against rareness,
6 makes for a very risky business. We are more
7 likely to take risks on something that is more
8 prevalent just for financial reasons, so --

9 MEMBER KELLY: I was just sort of
10 using that as an example. I was more
11 interested in the kind of the general idea of
12 what is the most efficient and best role for
13 academe and NIH in drug development?

14 DR. ECK: It depends where your
15 expertise is. I don't think there is any one
16 formula or recipe. For example, some very
17 useful and profitable new medicines have come
18 from academic research.

19 Alimta, which had 48 percent
20 growth in the first half of this year, one of
21 our products for lung cancer, was discovered
22 by researchers at Princeton, who basically

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 developed the platform, and it was refined
2 somewhat by Lilly before being taken into
3 clinical testing.

4 Similarly, Lyrica at Pfizer came
5 out of Northwestern, so there are many
6 examples where that initial process can
7 flourish well in either -- whether it's an NIH
8 lab or an academic lab and I think that, you
9 know, if there is interest, if there is a
10 sustained focus, that certainly could be quite
11 rewarding.

12 CHAIR AUGUSTINE: Gail.

13 MEMBER CASSELL: Tom, what I would
14 say is, based on my observations with the
15 Lilly TB drug discovery effort, which I lead,
16 and as I mentioned yesterday, we are partnered
17 with NIAID and infectious drug -- or the
18 infectious disease research institute in
19 Seattle.

20 I would agree totally with what
21 Steve has said, and that is there is no --
22 should be no compartmentalization. I think it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 depends on the individuals and the
2 individuals' skills in terms of the role
3 academia can play.

4 And I have seen them be very
5 efficient and helpful in almost every phase.
6 For example, we have a compound that we are --
7 that is pre-clinical and living very well
8 along, but it is IV-only, right?

9 So, we want to explore all
10 possibilities, and one of the best aerosol
11 biologists in this country that works with
12 drug discovery/drug delivery, one is at
13 Harvard, David Edwards, the other is Tony
14 Hickey at the University of North Carolina.

15 So, working together with them,
16 writing an NIH grant, being successful in
17 getting the grant. Now, we are poised to
18 explore this. So, I am really optimistic,
19 looking forward, that the more you have this
20 iterative process, free process of going back
21 and forth between the academic investigators,
22 NIH, that you are going to get much better at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 this.

2 It's the freedom of having those
3 kinds of interactions that make it work. And I
4 was thinking about why this is working so
5 well, and I think it is because everybody is
6 committed to the same goal -- it is TB drug
7 discovery. Everybody realizes the urgency as
8 they do for rare disease and any disease,
9 really.

10 And it is the glue money to pay
11 for the project managers, the unattractive
12 daily operations, that bring all this
13 together, and I don't know if Ken Duncan, I
14 can put him on the spot, we were chatting
15 about this on the way over this morning. So,
16 it really is the glue money that, I think,
17 helps make all this happen, and that is where
18 perhaps NIH and their foundations and industry
19 can help. But, I think that you have got to
20 use all the talent, that is the bottom line.

21 MEMBER ZOGHBI: So, repurposing
22 drugs is really a very efficient way to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 advance translational research, and there are
2 many new discoveries in academia that could
3 benefit from using some of the existing drugs
4 in pharma.

5 I always find this very difficult
6 to actually accomplish. I am actually, in this
7 situation, when I am ready for very many pre-
8 clinical trials, but the pharma is very
9 hesitant to share the compounds I need from
10 them, and this is a major roadblock.

11 How can we get over this? Their
12 fear apparently is that something happens in
13 this other disease we are testing drugs in,
14 that now might prompt the FDA to put a warning
15 or something on a drug, and we can't live like
16 this, I mean, there are so many opportunities
17 so how do you propose --

18 DR. ECK: Yes. This is not a rare
19 occurrence, where a company is developing a
20 drug for an indication and someone in
21 academia, could be the NIH, or any place,
22 looks at this and says, you know, this drug

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 should be applied here and then we get antsy,
2 saying well, you know, but if we give it to
3 them and they have an adverse event, then we
4 have to report it, and then that might slow
5 our progress.

6 There have been some examples
7 where this has been done well, you know, where
8 pharma has actually allowed the academic
9 investigators to file their own IND, to cross-
10 reference the master IND that the drug company
11 owns, and do this collaboratively.

12 But, it requires a lot of
13 intestinal fortitude, and frankly we often
14 don't have that. There is no pat answer as to
15 how to make people do it, because we don't
16 have a way to make people do these things.
17 But, I think, increasingly this will become
18 more approachable, because we need a greater
19 diversity of approaches to some of these
20 ideas.

21 Many of the mechanisms we have, we
22 don't actually know the indication. I mean,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 neuroscience is a great example where we have
2 drugs that are exquisitely focused on some
3 process in the brain and we think, well, is it
4 good for depression, is it good for
5 schizophrenia?

6 We are not very clear because the
7 animal models are not very forthcoming. A very
8 good example is our mGlu2/3 agonist, which we
9 are developing for schizophrenia. The biology
10 of that pathway was largely unexplored in man
11 prior to us bringing the drug forward for
12 schizophrenia.

13 And I would argue that we are
14 still a little bit handicapped by the fact
15 that it is very novel treatment --
16 experimental treatment right now -- for
17 schizophrenia. Hopefully, it will get
18 approved.

19 But, we don't really understand
20 those pathways very well and to use anyplace
21 else, is speculative on our part because we
22 have not pursued that and it is not part of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 our current game plan. So, there are many
2 opportunities like this and there are probably
3 many more than are apparent because we don't
4 actively seek this out.

5 I think, similarly, we have well-
6 behaved pharmacologic tools that we have
7 abandoned in developing as drugs. They have
8 good oral bioavailability, they have good time
9 on target, they have reproducible biology, but
10 they fail in early development because they
11 don't -- in the study we ran, and then we lose
12 interest, and so they get put aside and they
13 are not explored elsewhere.

14 Many of these drugs, or putative
15 drugs, could be made available, I think, for
16 exploratory drug to understand biology, if not
17 to find a different indication. There is not
18 an efficient mechanism for doing it. It is
19 largely personal advocacy.

20 I think as the companies become
21 more transparent, in terms of what we do and
22 why we do it and how we do it, that will

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 create a little more pressure to seek these
2 opportunities, but I don't have a pat answer.

3 But, we are aware of this issue.

4 CHAIR AUGUSTINE: Dr. Eck, thank
5 you very much. I think the pressures of time
6 require we proceed but your comments have been
7 most helpful. We now want to turn to the panel
8 discussion. You have the biographies of the
9 panelists. Once again, as yesterday, these
10 folks have gone to a huge amount of trouble
11 changing their personal schedules to be here,
12 and we thank you for doing that.

13 Our two moderators for this
14 session are right here at the head of the
15 table, Richard and Eugene, and I turn the
16 agenda to you.

17 MEMBER WASHINGTON: We decided to
18 launch this session by having Richard provide
19 an overview or a few examples of public-
20 private partnerships that involve NIH.

21 MEMBER HODES: Thank you. As Gene
22 noted, Amy and I thought it might be useful to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 provide a little background about the
2 framework in which NIH in its current
3 activities sees public-private partnerships
4 and provide a couple of examples just to then
5 trigger discussion by the panel.

6 The aims will be -- for this whole
7 session will be to explore some of the
8 features which define successful partnerships.
9 You have heard a good bit about metrics and
10 defining goals -- they will be important --
11 focusing on what we have learned from past
12 experience.

13 So we will look at a range of
14 differing scales or scopes of public-private
15 partnerships in which NIH has been involved,
16 provide you briefly with three examples of
17 them and then we will talk about the
18 challenges, considerations, outcomes,
19 deliverables of the studies.

20 This slide is just meant to
21 indicate that there is quite a scope of
22 public-private partnerships, which can be very

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 useful, valuable from small ones on a scale
2 that may involve dollars, times, number of
3 collaborating entities, data, et cetera.

4 Could be a single institute or a
5 center, single investigator with a single
6 partner and one project, or it can scale up to
7 some very complex interactions, and we have
8 seen some examples of those, which involve
9 multiple institutes, foundations and
10 companies.

11 The first example that I will
12 touch upon briefly here, is the Osteoarthritis
13 Initiative. It began a number of years ago in
14 conversations with Steve Katz, director of
15 NIAMS, with myself, recognizing this among the
16 many areas in which there is a large need for
17 interventions, for therapies, very little
18 known about pathophysiology, therefore very
19 little in the way of targets.

20 And so, we determined to set out
21 and look for the interest in pursuing a search
22 for biomarkers, in this case largely imaging.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 A couple of points I would
2 mention. Number 1, first, relates to the
3 comments from Francis and Harold yesterday
4 about the fact that we can indeed engage with
5 the private sector, so there was no problem
6 with Steve Katz and I having conversations
7 about the scientific interest and strategies
8 with leaders in industry.

9 When it got to a point where those
10 conversations had to do with actual potential
11 financial support, we turned to the Foundation
12 of NIH and backed away and that formula, that
13 distinction, has worked very well.

14 I will just point out one other
15 anecdote that is very much in mind here and I
16 think is illustrative of what we have learned
17 in past years. As Steve and I and some of our
18 staff entertained what the scope and plans and
19 ground rules would be for this collaboration,
20 I remember being uncomfortable with the notion
21 that collaboration would involve undue,
22 inappropriate, or apparently even unseemly

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 preference given to a given entity, private
2 sector, in exchange for financial
3 contribution, and so suggested that the basis
4 for the starting point in these conversations
5 ought to be one in which there was no special
6 advantage given to the partners, that the
7 advantage would be one which was global and
8 involved common interests.

9 And admittedly, in the examples we
10 are looking at, in a pre-clinical or pre-
11 competitive scope, this was easy to do. So we
12 set out, with some trepidation I must say, but
13 the results were enormously gratifying and
14 resulted in participation in this study with a
15 budget of \$50 million, nearly \$20 million of
16 which came from private sector and is ongoing
17 now, looking at imaging techniques to try to
18 develop ways in which the biomarkers might be
19 used to better support ultimate tests of
20 intervention.

21 Now, a second study which had a
22 similar background followed thereafter. This

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 is the Alzheimer's Disease Neuroimaging
2 Initiative. And based on some of the lessons
3 learned in planning the Osteoarthritis
4 Initiative, we set out in a similar
5 partnership here.

6 It involved contacting now a much
7 broader scope of private sector, and I will
8 illustrate how broad that was. It also
9 importantly involved -- including the FDA at a
10 very early stage -- and again, just as a
11 paradigm for a meeting I remember I think in
12 this very room, we brought together
13 representatives, the senior research side of
14 many of the private sector entities that were
15 interested, as well as NIH folk, and we had at
16 that time Mark McClellan here, along with
17 staff, indicating how receptive the FDA would
18 be, should there be successful determination
19 of potential biomarkers for considering those,
20 at least, and authenticating them for use in
21 clinical trials and studies.

22 And so, we went forward in this

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 study, which in its first five years, was a
2 \$40 million contribution from NIH and I think
3 in the end nearly \$27 million from private
4 sector.

5 And the complexity is illustrated
6 here. There were some 19 companies and two
7 non-profits. This was biotech, major pharma,
8 imaging companies, all of whom worked
9 extraordinarily well together.

10 A number of products came from
11 this immediately that were hard to envision
12 beforehand. Rather than having a small number
13 of dedicated centers, realizing we needed to
14 be prepared for large-scale application, ended
15 up with some 60-plus centers in Canada and in
16 the U.S., all different hardware and software
17 platforms.

18 It led to the development of
19 technologies which allowed these all to be
20 harmonized and deposited in a single database.
21 The data were made available in essentially
22 real time to the research community,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 nationally and internationally, and has
2 already produced, I think, in terms of
3 validating the ability of imaging techniques
4 as well as recently some CSF protein markers,
5 a phospho-tau and an amyloid peptide, to show
6 very strong predictive value in tracking the
7 course of apparently early-stage Alzheimer's
8 disease in this case.

9 Global was mentioned. This has
10 been successful enough to spawn these, now
11 nascent, in some cases already existent,
12 parallel enterprises in Europe, in Japan, in
13 Australia, and others being developed, which
14 will harmonize again these techniques, allow
15 great power for quickly identifying the
16 relative usefulness of various biomarkers.

17 And I show you just one outcome to
18 illustrate how quickly this can in fact
19 translate further downstream, the real aim of
20 this study, providing potential markers for
21 use in testing drugs, some of these
22 methodologies are already being embraced in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 ongoing studies by Pharma.

2 But, this illustrates imaging
3 technique that you can see here in estimating
4 the number of patients who would be needed to
5 achieve in a 12-month, multi-center,
6 randomized clinical trial, detecting a 25
7 percent effect with 80 percent power.

8 By standard use of changes in
9 cognitive function, the numbers are in the
10 hundreds for even smaller effect size in the
11 thousands, where the ability of imaging -- and
12 this will be even more true with some of the
13 biomarkers developed -- cuts down by an order
14 of magnitude potentially the number of
15 individuals needed in these studies, already
16 potentially very valuable as we, the FDA and
17 private sector work together to try to apply
18 some of these techniques.

19 The third example I don't need to
20 go into, it was mentioned in the talk you just
21 heard. In contrast to the first two, which
22 arose from a commitment from NIH in a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 particular area, then looking for partnership
2 -- broad, but in that defined area -- another
3 style of public-private partnership is
4 illustrated by GAIN here, Biomarkers
5 Consortium another, which have set aside to
6 provide a broad context or matrix in which
7 private sector and NIH might come together to
8 explore any of a variety of issues.

9 Here some of the studies initially
10 have focused on ADHD, bipolar disease,
11 diabetes, nephropathy, major depressive
12 disorders, psoriasis, schizophrenia. So, it is
13 a somewhat different style, not targeted to a
14 particular area, but providing a framework
15 that will serve many.

16 So, there are a number of public-
17 private partnership outcomes and deliverables
18 that are illustrated here. Again, I stress the
19 examples I mentioned so far, in a sense are
20 some of the easier, because they are pre-
21 competitive.

22 But, these, broadly, can be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 identified as purposed to foster basic
2 research, which can be pre-competitive, but
3 certainly have intellectual property attached
4 to it, to enhance clinical trials themselves,
5 to expand the pre-competitive space or develop
6 products and technologies. And these are
7 clearly non-exclusive and much-overlapping
8 categories, but this is the frame that NIH's
9 office of public-private partnerships has in
10 mind for categories of such enterprise.

11 The challenges -- development of
12 appreciating of the similarities and
13 differences among partners, different aims,
14 sometimes they converge, sometimes they
15 complement, developing common goals -- we
16 certainly heard a good bit about transparency
17 -- long-term commitments are important just as
18 NIH leadership changed, and we found the
19 leadership at pharma, and many of you will be
20 well-aware of changes as well.

21 When the goals appear to be of
22 broad appeal, the support by both NIH and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 private sector, happy to say, have persisted
2 now over multiple years.

3 So, shortages of funding,
4 identifying the expenses needed, what exchange
5 there will be of non-monetary resources, the
6 desired products of partnership, importantly,
7 intellectual property rights, how NIH review
8 and management function.

9 In all of these examples that I
10 have cited and in many of the others, NIH has
11 generally carried out peer review in an
12 attempt to ensure its objectivity and making
13 sure that this is compatible with the needs of
14 our partners, is important to these
15 partnerships.

16 And then privacy and integrity of
17 data as it affects human subjects, greatly
18 important as well.

19 So this last slide, which I will
20 leave up, describes the questions which you
21 have for discussion for the panel and I will
22 now turn to the panel with these topics and,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Gene, would you like to take it away?

2 MEMBER WASHINGTON: Okay. Just to
3 further frame this session, I would remind us
4 that the overall emphasis on how we in fact
5 cultivate partnerships with an eye toward
6 developing successful projects that can be
7 measured in terms of whether or not they
8 deliver on the goals being outlined originally
9 by the partners.

10 And those of us who are involved
11 in development, in particular, know that when
12 you hear about a big gift, as in the case of
13 the development of a big hit with a drug,
14 there have been years of cultivation that has
15 taken place.

16 So, I would like to start by
17 asking the panelists, from your perspective,
18 just in terms of cultivating the relationship,
19 before you even get to the specific project,
20 what would you see as most important
21 attributes of that cultivation process? And
22 why don't we start with Dr. Baum?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 DR. BAUM: Sure. I think if -- on
2 the big picture?

3 MEMBER WASHINGTON: Yes.

4 DR. BAUM: Probably the first point
5 would be sort of an overall view that that is
6 welcomed or desired on both parties, certainly
7 from our part, we can tell you that there is a
8 number of areas where we think that this sort
9 of external innovation work, where we need
10 help, we are seeking help, we can make that
11 pretty obvious, what those areas are.

12 And then, if there is some
13 response on your side of general interest or
14 specific interest in some of those areas, then
15 that is a good place to start, those places
16 where we have shared goals and mutual
17 interests, I think you have to have that or it
18 doesn't go anywhere.

19 And then making the connection
20 between the scientists at both institutions is
21 really critical to making this work, and that
22 they have a mutual interest in working

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 together and goals that are compatible.

2 I think that really is the basis
3 for a good collaboration, for any good
4 collaboration, and particularly here. Since
5 there are challenges, I think you need that
6 strong shared goal to start with.

7 DR. DUNCAN: So, the Gates
8 Foundation doesn't really have that many
9 partnerships directly with industry, but we do
10 work through our grantees. So, I will talk
11 from some experience that we have had through
12 a number of our grantees who have gotten
13 together and who have worked together quite a
14 lot to try and look at best practices.

15 And one thing I would say is from
16 the very beginning, it's establishing mutual
17 trust and confidence at a pretty senior level.
18 That has been really, really critical,
19 establishing credibility and the commitment
20 from both sides, both from the public side and
21 from our pharma partner, then establishing
22 contacts at all levels.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 And so, starting off at a certain
2 level, but then making sure that the right
3 scientists are talking to one another, again
4 becomes really critical, so that when the
5 details start to emerge, that the right person
6 with their hands on the detail is able to have
7 the discussion and the negotiation.

8 Understanding mutual objectives
9 and constraints is just as important. Getting
10 to a situation where everybody is in a win-win
11 situation is really critical. Another point
12 that we have found quite helpful is a sort of
13 staged relationship, where we start off with a
14 project with a very specific endpoint and then
15 people can then decide whether to build on
16 that relationship or whether we have done what
17 we actually wanted to do together.

18 That has been really important, so
19 that from the beginning, you are not saying to
20 a potential partner, you know, we have got
21 this early discovery program but we actually
22 want you to supply 10 million tablets to x

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 number of patients in 10 years' time.

2 That just puts everybody off,
3 because nobody knows how things are going to
4 move. Lines of communication become really
5 critical, making sure that we have the
6 appropriate points of contact and at the right
7 times.

8 And then the final point I would
9 make, really, is oversight, establishing
10 whatever oversight is actually going to be in
11 place. Do you have the right groups of people
12 who can make decisions? Can a group from each
13 side of a partnership actually get together
14 and decide whether to start a project or to
15 end a project, or does everybody have to go
16 back to some other committee and always have
17 to be referring back and forth? And I think
18 establishing that up front is actually very
19 important for moving forward.

20 One thing that our product
21 development partnerships, like the Medicines
22 for Malaria Venture or the Global Alliance for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 TB Drug Development have done very
2 successfully with pharma is establish what
3 they call mini portfolio agreements where they
4 take a number of different targets and then
5 can move them forward through the pipeline.

6 And they have groups which work
7 jointly and can take decisions on whether
8 something has been declared a lead, whether it
9 is declared a candidate, and that has been a
10 very successful way of moving resources
11 between different projects at different stages
12 in a pipeline.

13 And those sorts of agreements are
14 things which really could be modeled anywhere,
15 and I would say that bringing together some of
16 the public efforts with pharma companies, with
17 others, is a question of trying to structure
18 the right sorts of agreements.

19 And to come back to something that
20 Gail mentioned earlier, we have found that
21 sometimes it is not about where the money is
22 coming from: it is about just getting the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 right people with the right skills together,
2 and some money, to make it happen, whether
3 that is just people in lab coats who can
4 actually get the work done, or the money that
5 allows people to meet and takes people away
6 from their day jobs to actually focus on what
7 they need to do. I'll stop there.

8 MEMBER WASHINGTON: Dr. Halak.

9 DR. HALAK: Well, the further down
10 the row you go, I guess it's harder to come up
11 with something original. I think they captured
12 most of it. I would emphasize the aspect of
13 shared -- of determining what the goals are up
14 front and making sure, before anything gets
15 started, that people are aligned.

16 And, I think, that is easier
17 probably when you are talking about some of
18 these pre-competitive, more discovery-based
19 projects, because it seems to me that that is
20 more congruent with how an academic researcher
21 usually thinks. It is more open-ended.

22 As you get to driving a specific

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 scientific discovery or project forward into
2 something that is a product, I think it gets a
3 little more challenging because then the -- as
4 someone stated -- I think it was Steve in the
5 beginning, the academic researcher is often
6 focused on very open-ended questions where any
7 answer is positive, whereas the private
8 enterprise is looking for a specific answer.

9 I think that is where the NIH
10 needs to begin to foster and sort of encourage
11 the academic side that it is okay to drive for
12 those specific goals, because that is, I
13 think, where there is often a conflict between
14 private and public.

15 DR. INSEL: Well, from the NIH
16 side, you have already heard from Richard, who
17 gave, I think, a really good summary of the
18 kinds of things we think of.

19 I think it is important for the
20 committee to realize, we do a lot of this and
21 I think we do it pretty well. We have also had
22 a number of failures and so it might be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 helpful to actually talk a little bit about
2 what has not worked at times in the past.

3 In terms of your question, Gene,
4 about making it happen, the key things right
5 now are having the fora where people get
6 together to begin to do this. FNIH, through
7 the Biomarkers Consortium, which Steve is part
8 of down here, and Larry Tabak has been on the
9 executive committee, has been one place to do
10 that. The Institute of Medicine has fora for
11 drug discovery and for neuroscience and other
12 areas where there are opportunities for
13 different partners to come together and talk
14 about possibilities.

15 So, there are a number of those. I
16 suppose the lesson we have learned best
17 perhaps from the Biomarkers Consortium, if you
18 think about what worked and what didn't work,
19 was, as Dr. Duncan mentioned, having the right
20 people at the table, and the right people
21 means, for us, having the FDA involved was
22 really important, maybe more important for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 pharma partners than for us, but important for
2 the whole group.

3 The second was having people at a
4 particular level who could speak on behalf of
5 whoever they represented. One of the problems
6 we had in the early days was having people who
7 would come to the meeting and really could not
8 represent who it was that we thought they were
9 representing.

10 And the third, for us at least
11 within the neuroscience sector, is having
12 multiple pharmas involved. The optics are
13 problematic, still for us, I think, when we
14 work with a single company on a particular
15 project and it becomes easier if there are
16 many different companies, as in the Biomarkers
17 Consortium; it becomes really a safe haven for
18 us, too, both to explore ideas and then to
19 implement them as well.

20 MEMBER WASHINGTON: Thank you.

21 DR. PACCAUD: Well, definitely
22 there is not much left on the list of answers

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that I tried to provide on that question.

2 One aspect for a PDP-like Drugs
3 for Neglected Diseases Initiative is that we
4 realize now, after seven years of existence,
5 that we have been working much more with the
6 private sector and are leveraging much more
7 good partnerships with the private sector than
8 with academia.

9 And this is probably bound to the
10 remarks that have been done before. Academics
11 have a very clear and understandable goal when
12 they are starting a project. They look at us
13 as a financing body, which we are not, or we
14 don't consider ourselves as a financing body.
15 We are an R&D organization that puts assets
16 into where we think we can provide -- we can
17 have the most successful results out of that.

18 So, one of the difficulties is to
19 really align the objectives of the few
20 academic groups we still have, we still are
21 working with, with ours, which are delivering
22 as soon as possible an answer or treatment or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 drug.

2 Whereas with the private sector,
3 we are definitely trying to leverage their
4 assets and we try to understand -- and it is
5 easier to understand why they want to work
6 with the NDI or MMV or TB alliance and we will
7 not elaborate on that.

8 But, we have found by experience
9 that, besides all the good things that have
10 been said about the commitments of everyone,
11 we need to really get the top people in the
12 private sector to be behind us, and then we
13 have found that if that is happening,
14 everything else is quite simple.

15 And the last point, maybe, that
16 has not been mentioned, within the way that we
17 have found partnerships, the most efficient is
18 that even if we are dealing with colleagues,
19 Pfizer, or GSK or Sanofi-Aventis, we try to
20 build a relationship of equals.

21 We are small organizations. They
22 are huge. It works well when we are each other

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 respecting the way we are working and trying
2 to communicate on that.

3 MEMBER WASHINGTON: Thank you.
4 Okay, just -- go ahead, thank you.

5 DR. PERAKSLIS: So, just a couple
6 of things to add to that. First, yesterday
7 something came up that I think is important in
8 this kind of pre-negotiation space, and that
9 is this really optimizing the basic biology.
10 This is the thing that pharma -- we are least
11 good at doing and, more and more, we are
12 looking to access it, so you have got a
13 product or an area of opportunity that is
14 going to lead -- so that is really, really
15 important.

16 I fully agree with having the best
17 people and the best science ready for this. It
18 is like anything else. It is somewhat of a
19 courting or a dating process, so it should be
20 low energy, it should be easy, it should go
21 well, it should build momentum, when you are
22 talking about these things.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I think the team size and
2 structure should really be optimal when you
3 are looking at this and quite frankly, though,
4 I think what I have not heard here is it
5 should be done against a framework of
6 governance.

7 An example I will give is, at J&J,
8 I know for a fact, I can confirm twice and I
9 think I have a third case where separate CTAs
10 have brought me the same proposal, that you
11 are trying to do something that is very, very,
12 very similar, and I know it has happened twice
13 because I have done enough meetings where I
14 know they are talking about the same proposal,
15 and the third time I am not sure yet.

16 But, what it has led me to think
17 of is it is kind of -- when I ask them well,
18 you know, so and so is doing this too, have
19 you considered -- what I got was criticisms of
20 the other party. So, just being honest, as a
21 partner here of what we see sometimes, not day
22 in and day out but the reality of it, that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 doing these partnerships against a framework,
2 a strategy in governance, I think, is real
3 important.

4 MEMBER HODES: I would just like to
5 -- it has been touched upon some, but Tom in
6 particular mentioned the usefulness of looking
7 at examples of failure. Taking advantage of
8 having the group of you here, can you comment
9 on -- not necessarily failure -- but areas in
10 which perhaps there has been a particular
11 difficulty in interactions with NIH.
12 Obviously, the reason for the question is to
13 look for those areas where we can modify or
14 improve the ways in which we try to deal with
15 our partners.

16 DR. ECK: Let me try to address
17 that. I think the rules of operation with the
18 federal government are substantially different
19 than operating with other parts of the private
20 sector and we don't have a harmonized set of
21 rules for clinical practice around use of
22 patient samples, around privacy issues, around

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 informed consent.

2 And this is, in some ways,
3 problematic. I was at the clinic for Special
4 Children, meeting with Dr. Morton, their
5 director, and there is work that we can do
6 with him that we couldn't do with the NIH,
7 just because of the requirements for reporting
8 and -- that are non-standard.

9 And so, there are currently types
10 of research that we wouldn't bring to the NIH,
11 because they are frankly too difficult to
12 negotiate and the disclosure requirements are
13 too complex, and it is much easier to go to an
14 academic investigator or a private research
15 institution to do that work. And that is, I
16 think, sometimes unfortunate.

17 MEMBER WASHINGTON: Others?

18 DR. BAUM: I am not sure I can
19 think of a particular instance with the NIH,
20 but I think the most common problem is that
21 the goals need to be shared and need to be
22 mutually beneficial. I think that is when you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 have a real collaboration that is good for
2 both sides so you both have skin in the game,
3 basically.

4 So, if you share funding for a
5 project, or the outcome of the project is good
6 for both parties, that really drives it
7 forward. If that is not the case, then
8 generally they run out. Things don't happen.
9 That has been the majority of cases where it
10 has not worked out.

11 The other is, where in the past we
12 have made just uncommitted grants of funds to
13 groups without clear goals or expectations and
14 that often just has not worked out at all for
15 either side really, because there were
16 expectations. It just wasn't made clear up
17 front and that has often not gone well. So we
18 have really gotten away from that sort of
19 funding.

20 DR. INSEL: Richard, you said it,
21 but we probably should emphasize that to some
22 extent this is an asymmetric partnership. So

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 we go into these things interested in making
2 sure that an NIH project that has been peer-
3 reviewed and will be in some ways NIH-managed
4 could get joint funding or support for some
5 part of it, like an ADNI or for many other
6 projects that you talked about.

7 GAIN maybe is an exception,
8 because there, what we were bringing was
9 something in kind. We were putting samples in,
10 whereas Pfizer was supporting the genotyping.

11 But, in general, we don't -- if
12 someone else comes with an idea, we cannot
13 just throw money on the table the way we are
14 asking other partners to do, and that is a
15 somewhat different relationship than others
16 may be used to. And I just think we need to be
17 clear about that, that we don't have a simple
18 way of funding something that hasn't gone
19 through the peer review system, and I am not
20 saying we should, but I think it needs to be
21 understood up front, that that is one of the
22 things that has often been a problem, at least

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 in the Biomarkers Consortium.

2 I would say the other where we
3 have failed the most in the beginning, and
4 Larry may want to chime in on this, is we did
5 this as a kind of broad solicitation. We asked
6 the community, you know, send us your best
7 ideas, and most of what we got, I think Larry
8 would agree, were the projects that could not
9 get funded through peer review.

10 And so, all of a sudden we had the
11 B- and C+ efforts instead of what we were
12 looking for, which were the A+ efforts. This
13 got fixed when NIH said we will bring you our
14 best efforts and ask for our partners here to
15 support pieces of them and grow them out in a
16 way that made them even better projects, ADNI
17 being a superb example of that, or ISPI-2,
18 which is another one that you mentioned in
19 your slideshow.

20 So, I think that is probably a
21 lesson learned that took us about, what,
22 Larry, 18 months to figure out, before we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 began to realize that we could do this but not
2 in the way that we thought going in.

3 DR. ECK: If I could just add to
4 that, I think the expectations around funding
5 need to be reexamined. I will give you a
6 specific example. We are currently involved in
7 a negotiation where another large pharma,
8 right here, has samples, well-genotyped, well-
9 curated, that they are going to contribute and
10 that Lilly has samples that are well-genotyped
11 and curated and we are going to offer these to
12 an academic investigator to study the basic
13 biology of a disease.

14 And what we ran up against is
15 while Lilly and Pfizer had no trouble getting
16 their attorneys to agree that we are going to
17 submit these samples and the data, and the
18 academic person can do the research and
19 publish this, we ran into trouble with the
20 academic institution who wanted us to pay them
21 to do the research and that is just not
22 realistic.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I mean, it is a very large
2 donation on our part, to make -- not only make
3 the resources available, but we invested to
4 get the data to where it was and we cannot
5 always be the funder of that work. It's a very
6 interesting area of biology but it is not
7 mainstream to what we need done so we cannot
8 always be expected to fund that.

9 And, I think, there is often the
10 expectation that we have very deep pockets and
11 money for everything that could be done. If
12 that persists, many good ideas will not
13 survive. I think in-kind donations from
14 industry, in terms of data sets, are valuable
15 but they cannot always be accompanied by the
16 cash needed to prosecute the work. All parties
17 need to contribute something.

18 And I don't think we have a really
19 good way of doing that with our academic
20 partners. In some cases, we have done it well
21 with NIH.

22 MEMBER WASHINGTON: Dr. Duncan and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 then Gail.

2 DR. DUNCAN: So, thinking about the
3 pre-clinical space, we have had fairly mixed
4 interactions. I would say we had very, very
5 good interactions with the intramural program,
6 with several projects through our grantees. We
7 have had a little bit less success on some of
8 the contract work that really helps to support
9 a lot of the extramural researchers.

10 I can think of things, but they
11 are pretty anecdotal, of researchers who have
12 said, you know, I have said to them you can go
13 to an NIH contract and get a particular piece
14 of work done, sometimes they have said well,
15 you know, it just takes forever, or the
16 processes are so difficult that to try and get
17 it prioritized and get the data back is going
18 to be six months or a year.

19 And for us, it is then often, we
20 are just left saying well, we just have to pay
21 to get the work done, because it is just not
22 realistic for us in any sort of turn-around

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 time to actually get things moving, or to get
2 the right sorts of studies, and it is
3 something that I mentioned yesterday.

4 Sometimes, giving people a bit
5 more flexibility to actually be part of the
6 team, to help to determine what is the right
7 study to do, and then just get on and take a
8 decision and do that study as opposed to
9 saying, well, it is on my list that you have
10 to do these ones or else you have to go back
11 for another iteration and you have to wait for
12 another prioritization of a certain set of
13 experiments.

14 And yet, these contracts are
15 really perfectly suited for getting just the
16 really critical little pieces of information
17 that can often mean the difference between a
18 project sitting on the shelf until somebody
19 writes another full grant proposal, or it just
20 moving on with another partner.

21 And so, a little bit more
22 flexibility is certainly one thing I would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 like to see, and somebody to take a hard look
2 at some of the metrics around how that is
3 certainly helping to support our projects.

4 MEMBER WASHINGTON: Gail?

5 MEMBER CASSELL: Thank you, Gene. I
6 would like to just second what Dr. Duncan has
7 mentioned as being something that someone
8 needs to pay close attention to, but also this
9 concept of flexibility to add to what Steven
10 Eck has said. It seems to me if there were
11 even a smaller pot of money available through
12 NIH, that that investigator or Pfizer, Lilly
13 and the investigator could approach and get
14 the short turn-around in terms of peer review
15 or review, it could facilitate the beginnings
16 of the work that in the meantime that
17 investigator could go through the normal
18 channels in terms of applying for a
19 substantial R01 or whatever.

20 And getting back to the question
21 that you asked, Steve, about access to
22 compounds and everything, what I find is that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 one of the biggest challenges for the academic
2 scientist is finding the right person. It all
3 goes back to the right person within the
4 company that would be sympathetic, interested
5 if you will, in working with you.

6 So Steven, one thought that I had,
7 and I realize it would be a committed
8 resource, but if in fact each of the companies
9 had a single point of contact, and Ken and I
10 have been talking about this too, Duncan, so
11 that you knew, if you went to that person,
12 then it would be up to that person to track
13 down who, within the company, and then to get
14 back to you.

15 As it is now, I must admit it, I
16 know within Lilly, it is a rather hit or miss
17 process, so a lot of time can be wasted and
18 also you don't always get to the right person.

19 And so, maybe this is something
20 that the companies can think about in terms of
21 how we could do it better, or you may have
22 some suggestions.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 But, I think this is an area that
2 one might -- well, it could be very profitable
3 and before I lose my opportunity, I just would
4 say that one of the initiatives that Lilly has
5 that is somewhat the reverse, I think, of what
6 are you saying, Huda, we launched an
7 initiative last year called PD-squared, where
8 from throughout the world, we were encouraging
9 investigators to submit compounds, no
10 structures of those compounds, just the
11 compounds, that would be screened in highly
12 validated assays in different therapeutic
13 areas.

14 And, if in fact, there are valid
15 hits, then the investigator can take the data,
16 because all the data will be turned back to
17 the investigator, go work with another company
18 and/or work themselves, just in their own
19 laboratory using that data, and/or choose to
20 work with Lilly to further develop those
21 compounds, if in fact the investigator so
22 chooses.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, what is -- I think that whole
2 process now is very automatic, mostly
3 electronic and seamless in terms of the
4 confidentiality agreement, the tech transfer
5 agreement, and we are learning a lot from that
6 process and will soon apply it to the TB drug
7 discovery effort as well.

8 So, that might be taking some
9 learnings from that, but trying to reverse
10 that might also help address the concern that
11 you have raised.

12 MEMBER ZOGHBI: Maybe I can just
13 make one brief comment. I think the problem is
14 not finding -- I found the right person at a
15 very big pharma, a fantastic person who really
16 was enthusiastic. It ended up the lawyers and
17 the marketing people who are dealing with
18 drugs in already clinical work. Therefore,
19 their sisters and brothers of these drugs,
20 they are very --

21 And I think this is really a
22 problem. This requires a cultural change at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the FDA, at the companies, to begin to -- it
2 is much cheaper to repurpose drugs than to
3 really start *de novo* every time we have a new
4 medical problem. So, it is a serious problem.

5 DR. HALAK: So, just to comment on
6 that, because, I think, one of the biggest
7 things that I know is not directly the topic
8 here, because we are talking about what can
9 NIH do, but I think perhaps NIH can force this
10 issue.

11 I think the most important
12 partnership is the one between the NIH and the
13 FDA and then I think I would also loop in CMS
14 and the PTO, because if the goal is to get a
15 product out to patients, you can't really look
16 at just the scientific process of getting
17 something proven.

18 You have to look at the whole
19 process. I mean, never -- I invest in early
20 stage companies -- never once do we just look
21 at the science. We look at what is the
22 regulatory path and one of the biggest

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 problems, for instance, is -- take an area
2 like diabetes. We were a founding investor of
3 Amylin, which had two products approved, first
4 in class, for diabetes, that are helping a lot
5 of patients right now.

6 We would never invest in that
7 company again, because getting a diabetes drug
8 approved is so difficult now. It is difficult
9 for good reason. There has been some worry
10 about cardiovascular side effects. However,
11 the answer may not be if the FDA would talk to
12 constituents like basic researchers, the
13 industry, et cetera, maybe they would realize
14 the hurdles that that imposes, and maybe the
15 answer would be something like a conditional
16 approval, where -- now I am getting into
17 specifics -- but just by way of an example,
18 where something could be approved only to be
19 used with patient registries and then only
20 after a certain number of patients have been
21 analyzed for long-term outcomes, then you
22 could get full approval.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 But, my point is, is not to delve
2 into a specific idea, but to say that really,
3 I think the FDA, NIH, CMS, PTO and industry,
4 if the goal is to push products forward, need
5 to be talking together about what an action at
6 one organization is doing to another
7 organization in terms of achieving that
8 hopefully common goal of getting products to
9 the market.

10 I think too often, from the
11 outside looking in, it feels like they are
12 operating in silos. The best example of that
13 was even within the FDA, when there was a
14 proposal by -- I guess it was mainly driven by
15 Congress -- but there was a proposal to
16 separate evaluation of safety and efficacy. I
17 don't know how you do that.

18 So, I think they need to come
19 together and all start working together.

20 MEMBER WASHINGTON: Okay, Richard?
21 He passed. Any other comments? On the original
22 question from Richard regarding what NIH could

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 do to improve access, development of
2 partnerships and if not, we are going to turn
3 to the question of metrics. And Dr. Duncan
4 mentioned metrics. We have a specific
5 question. In the context of -- yes, Larry.

6 MEMBER TABAK: Amy reminds me that
7 NIH is going to be having a meeting or perhaps
8 a series of meetings, specifically on the
9 issue of drug rescue or drug repurposing. I
10 think it was mentioned yesterday as well.

11 So, this opens up a new dimension
12 of NIH-industry partnership, so --

13 MEMBER WASHINGTON: Okay. Great.
14 Thank you. Turning to metrics, specifically in
15 reference to NIH, but even more generally, as
16 you have developed public-private partnerships
17 either with NIH or with academia, or if you
18 are in government, with private partners, what
19 have been the metrics for success and what
20 should they be? And why don't we start on this
21 end with Dr. Perakslis?

22 DR. PERAKSLIS: Thanks. So for me,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 we have got a lot of them, and I think the
2 ones that are most meaningful, tend to come
3 down to time, where there are frequent
4 milestones that showed incremental value, that
5 built momentum, built success, built
6 confidence, and built good relationships in
7 the team, or not.

8 How quick was it to sign the deal?
9 Did you end up in a protracted legal process,
10 which then, again, you are dating, it starts
11 to cause other problems. So, I think time is
12 very, very important.

13 And the fact that patients are
14 waiting in some of these cases, it is not just
15 early stage, sometimes it is late stage. And
16 some of the most interesting things I see done
17 are on the Phase IV side, or on the late-stage
18 acquisition side, and usually there is a lot
19 of money put into these, but success can come
20 very rapidly when they are done as well.

21 But, we are not at that point
22 doing the type of science that I think we need

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 NIH to be involved in, and what I will give is
2 the great news we had with abiraterone in the
3 last couple of weeks for prostate cancer.
4 There is still a lot of science to be done
5 around that. We have got a great drug, it
6 looks like, but you know, a lot of questions
7 that will come up now.

8 MEMBER WASHINGTON: Please.

9 DR. PACCAUD: On our side, I think
10 it is similar, I mean, we do have patients on
11 the one side that are expecting drugs that are
12 not existing so far. We are not going into
13 projects at a very early stage, again because
14 of this urgency, so we try to be quite
15 pragmatic.

16 And that means that we are
17 measuring our success by also the time it
18 takes to kill a project on various series we
19 have been looking at. And we can't do that
20 probably in an easier way because the ultimate
21 goal is to identify a couple of molecules that
22 will proceed successfully into the next steps

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of the clinical development without having to
2 hold on a pet molecule which you could
3 certainly have seen many times in academia.
4 So, that's a big measurement of success.

5 We have very clear milestones to
6 all our development processes and we have
7 checkpoints at committees that are joint
8 committees between our partners and that
9 ensures at least that we are hopefully trying
10 to use the money as efficiently as possible.

11 So, it's time -- time to kill
12 would actually be the summary of how DNDi is
13 trying to operate.

14 DR. INSEL: The only thing I would
15 add is that whatever this is going to be needs
16 to be shared and you can imagine the problem
17 of having two different sets of how you
18 measure success. So, that is something that
19 needs to be up front.

20 DR. HALAK: Yes. I would agree. I
21 think the key -- the metrics are going to be
22 different for every project, but I would pick

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 up on two points that have already been made.
2 Number 1, they need to be shared, number 2, I
3 think they should be frequent. I think people
4 respond to goals that are relatively near-term
5 and importantly, as they are hit, the
6 partnership can really gain some momentum
7 because people get excited about that.

8 So, I would take the project and
9 chop it up into a lot of goals and hopefully
10 in hitting the first few, you actually build
11 momentum and people realize that and get
12 excited about the partnership.

13 DR. DUNCAN: It's difficult to add
14 very much beyond that, beyond all the comments
15 that have been made and one thing I would
16 maybe say is that if things are not going
17 well, and it is really critical that teams
18 recognize that and deal with issues and don't
19 let them fester.

20 Because the worst thing that can
21 happen is for a milestone to be missed and
22 then somebody to say well we will revise this

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 at the next six-monthly meeting, nothing much
2 has happened. It just goes on for a long time
3 and then the relationship breaks down. I think
4 that's where the honesty between and the trust
5 between partners becomes really critical, that
6 people can be really open and honest about
7 what is working and what is not working and
8 address the things that are not working,
9 because if you don't, you won't be successful.

10 DR. BAUM: So a lot -- I agree with
11 the comments made previously. I think, one
12 from the very beginning that has come up
13 before is contract turn-around. So, I think,
14 on both sides that's an issue that we have to
15 be cognizant of and work together so both of
16 us can push it: we can push it on our side but
17 also we need advocates on the NIH or in
18 academia to help when things get stuck,
19 finding out why and helping push it along and
20 an internal advocate always helps with that.

21 And then, I think, what others
22 have said, that you have to have measurable

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 goals with a common understanding so it is on
2 the table, everybody knows what they are, and
3 if you have the budget for it, a project
4 manager to be in place for the project, so
5 that somebody is there to keep an eye on it so
6 that you don't get completely out of whack.

7 Once that happens it is very
8 difficult to come back so, I think, it is
9 really critical to keep that up and then to
10 come to -- if it's a revised plan, that's fine
11 -- but to do that rather than let things go so
12 far off that it's difficult to recover. I
13 think that's when the relationships usually go
14 bad.

15 MEMBER WASHINGTON: Okay. Dr. Eck?

16 DR. ECK: I think really all the
17 important ones have been mentioned. I don't
18 have much to add to any of that. But, I agree,
19 I think the conflict resolution is key. If we
20 do 50 percent of our work on the outside, we
21 could manage a lot of partnerships in conflict
22 resolution, whether it is with a corporate

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 partner or whether it is a CRO or an academic
2 investigator, it's key to the success of the
3 project and timeliness.

4 If the project cannot be done,
5 maybe it shouldn't be done.

6 MEMBER WASHINGTON: Yes, I am going
7 to open it up for questions from others, but I
8 would like for the panelists to be thinking
9 about the question of, in departing this broad
10 topic, what would be the one message that you
11 would want to convey to us, SMRB, but also to
12 our colleagues at NIH, regarding what you
13 would like to see done to ensure that we
14 accelerate the development of drugs, whether
15 it is through the partnership or whether it is
16 through some policy. But, I would like to have
17 you thinking about that while we open this up
18 to others.

19 DR. CALIFF: I just want to make
20 one comment relevant, I think, to yesterday
21 and to today, and it was really taking off on
22 Brian's comment. I take it a little

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 personally, since we are doing the outcome
2 trial with the Amylin drug, which is a 14,000-
3 patient trial in 40 countries. It's going to
4 cost about \$300 million to do it. I guess
5 that's a significant investment to --

6 DR. HALAK: Yes, that's a little
7 more than we have to spend.

8 DR. CALIFF: -- private
9 partnership, but I think an issue that really
10 struck me yesterday and today is the role of
11 the NIH as a communicator, where I think in
12 the old days that did not need to be a focus
13 of the NIH. That is because science happened
14 in the little areas where people worked in
15 their laboratories and then eventually things
16 boiled up to the top.

17 Now, there is a need for such
18 coordination, you often have one side of the
19 equation battling the other side of the
20 equation. So I mean, in the course of the day
21 yesterday and today I heard this, we have got
22 to get more drugs on the market. I was

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 involved in discussions with the FDA about we
2 have got to shut these people down because all
3 this stuff is dangerous and there's
4 significant things may happen in the next
5 month that are going to retard people who
6 think we need to get drugs on the market more
7 quickly because of concerns about safety.

8 So, the NIH is actually attached
9 to all the elements here in one way or another
10 and somehow I really agree with Brian, that if
11 these things are left sort of competing, you
12 end up with a stalemate in a lot of ways, a
13 sort of Brownian motion, and somehow the NIH,
14 I think, needs to play a more effective role
15 in coordinating communications to bring the
16 sides into a common forum where things can
17 move forward.

18 I don't know how that is going to
19 happen. Yesterday, it was striking how many
20 things within the NIH other people in the NIH
21 didn't know about, much less those of us who
22 are on the outside. Not an easy task, but it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 seemed to me a striking feature of the
2 discussion.

3 MEMBER WASHINGTON: Thank you. A
4 very important point.

5 MEMBER HODES: Just to follow Rob's
6 comments, you have heard mention of some
7 initiatives such as biomarkers and the forum
8 through IOM. Have any of these begun to serve
9 the kind of purpose that Rob is talking about?

10 Certainly, we found that a number
11 of these initiatives that having the FDA
12 specifically there has been important, but I
13 don't know that we have addressed all the
14 issues, surely not those that Rob has
15 mentioned, the competing issues of
16 effectiveness and risk.

17 Gail.

18 MEMBER CASSELL: Well, I am pleased
19 that the Forum has been mentioned. I actually
20 co-chair the IOM Drug Forum and started the
21 drug forum in 2005. But, we don't serve this
22 purpose. We haven't even thought about it.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 But, I have been sitting here
2 thinking -- Amy came and presented a lot of
3 the initiatives that have been discussed, the
4 CAN and so forth, to the Forum, and I have
5 been thinking all this time that we should be
6 doing more and could be doing more to try to
7 bring about some of the things that people are
8 suggesting and recommending and maybe even
9 setting up some interactive tools, which
10 actually probably could be done and that's
11 something that we should explore.

12 But, it is obviously, I think, a
13 void that needs to be filled, maybe by all of
14 us, but in particular I think the Forum could
15 do a much better job of it than we have in the
16 past.

17 MEMBER HODES: I suspect, if
18 Francis were here, he would comment again on
19 the new partnership, the strengthening
20 partnership between FDA and NIH. Last night at
21 a dinner, Peggy and Francis jointly received
22 the essential partnership award for what they

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 are doing, and I think that is a forum too --
2 not mutually exclusive -- where this kind of
3 conversation, I am sure, will take high focus.

4 MEMBER CASSELL: Well, you know,
5 the Forum has I think also helped to play a
6 role to bring about the recommendation for
7 this kind of joint effort between NIH and FDA,
8 and we will continue to try to push that. Our
9 report that dealt somewhat with that earlier
10 this spring will be released in the next few
11 weeks.

12 So again, I think we can do a
13 better job of that. We have great
14 representation actually both from FDA, with
15 Janet Woodcock, and Mark McClellan, Peggy
16 certainly comes and speaks fairly often and
17 Amy and others.

18 So, we can work on this as well I
19 think, Richard, that is a great suggestion,
20 yes.

21 MEMBER WASHINGTON: Okay, we are
22 going to wrap up, starting on the end with Dr.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Perakslis.

2 DR. PERAKSLIS: The one thing that
3 we didn't touch on, that I would like to, is
4 yesterday we talked about training, and you
5 know we have talked about the need for good
6 project managers. We should really consider a
7 phenotype of a good scientist, high energy,
8 highly emotionally intelligent, highly
9 extroverted, the type of folks you may want to
10 incent to run some of these translational
11 projects, both across your institutes and with
12 the private sector.

13 MEMBER WASHINGTON: Thank you. Yes,
14 please.

15 DR. PACCAUD: Okay, well just
16 jumping on the question you ask, what could
17 the NIH do for an organization like DNDi.
18 Clearly, we are seeking to better understand
19 the assets that were particularly presented
20 yesterday between the different institutes
21 having different projects on translational
22 medicine for example, and the way to access

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 those resources, not only in the terms of
2 being able to access to part of the financing,
3 but probably even more, in terms of competence
4 and networking and bringing the people that
5 have the knowledge and that can provide this
6 knowledge and the infrastructure to actually -
7 - for us to be using this infrastructure.

8 And I guess, us, from the other
9 side of the Atlantic, we don't have a clear
10 picture of all these different assets within
11 NIH. So maybe working a little bit on the
12 clarity, on the visibility of everything that
13 you have there.

14 And the second point, back to pre-
15 competitive intelligence somehow, I am just
16 wondering what else could NIH try to do in
17 terms of -- we talk about information a lot,
18 and the overwhelming amount of information we
19 have to deal with with these small
20 organizations like us.

21 We talked about these repurposing
22 drugs -- drugs that could be repurposed, where

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 this is located. Probably the NIH can play a
2 role there to try to extract this information
3 from where it is, and to some extent put it in
4 the public domain in a pre-competitive mode.

5 MEMBER WASHINGTON: Tom, you could
6 have passed.

7 DR. INSEL: I am going to.

8 DR. HALAK: Well, If I had to --
9 you had asked to sort of -- a closing comment,
10 if I had to express one message, I will make
11 two points. The first is the one that I spoke
12 about and then Dr. Califf spoke about. And
13 that is the NIH doing its part to increase
14 collaboration, and not just the FDA.

15 I talked to the -- particularly on
16 drug repurposing, I would get the PTO
17 involved, because one of the big challenges
18 with repurposing, if you want to depend on
19 industry to take those products over the
20 finish line, is what is the market protection
21 for some of those products that have dated
22 composition-of-matter IP.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CMS is very important, because
2 again, if you want to have companies take
3 things forward, you need to figure out how
4 reimbursement decisions impact decisions by
5 industry.

6 So that is Point 1, is to have a
7 collaboration between NIH, PTO, CMS, industry
8 etcetera. I guess Point 2 is something we
9 talked more about yesterday, which is changing
10 the culture amongst many academic researchers
11 such that it is celebrated, it is exciting,
12 there is an enthusiasm around, not just basic
13 science, but taking that science into
14 projects.

15 And then once you have done that,
16 you have to offer the tools and the resources
17 for those people to get that done. It sounds
18 to me like most of those resources already
19 exist. I mean, there's a ton of resources, it
20 sounds like, here.

21 I think the program managers is
22 probably what is lacking and that is what I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 would work on, is training people like that to
2 -- that can really drive a project forward in
3 the most efficient way. So, those are the two
4 things I would leave with.

5 DR. DUNCAN: So, I think from the
6 Foundation's perspective, the thing that would
7 really help us is if NIH were to support the
8 grantees that we have, especially for
9 development partnerships and one of them is
10 represented here, DNDi, and the others as
11 well, in drug development, to try and move
12 projects forward.

13 And I think that is a question of
14 bringing the right resources, which we heard
15 about yesterday, these resources really do
16 exist. And how can we try and focus that in a
17 way that maybe tries to help move some
18 projects further along, with a lot of
19 ownership of the project from whoever at the
20 NIH side is actually running these things.

21 What the PDPs actually bring is a
22 lot of the disease expertise, and a lot of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 drug discovery expertise. And one final thing
2 I would add into that is that we have been
3 having a lot of discussions with a group of
4 representatives of the pharma companies,
5 particularly in this area, and there is a lot
6 of expertise in pharma that can be accessed if
7 we can do it the right way.

8 So, advocacy with the pharma
9 companies to talk at the highest level, to say
10 how important it is to actually work in these
11 diseases would also help to free up some
12 resources internally that would really help to
13 manage projects and move them forward and
14 bring the right expertise to bear with the
15 right project management to ensure that things
16 are done in both a professional way and at the
17 standard that is absolutely required, that
18 things will not fail when they move further
19 forward.

20 MEMBER WASHINGTON: Thank you. Dr.
21 Baum.

22 DR. BAUM: So, one of the obvious

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 ones, I think, overall is in this pre-
2 competitive area, to get pharma companies
3 together with academics, with the NIH and with
4 the FDA, to advance some of these initiatives
5 and around biomarkers, if we are really going
6 to get to a place where we can use more of
7 them as surrogate endpoints to get drug
8 development going more quickly on some kind of
9 conditional approval basis, something like
10 that would certainly be of value in moving
11 drug development faster.

12 An area of specific interest is
13 also immunogenicity. We have a lot of
14 biologics going into the clinic. There are a
15 number of issues with immunogenicity which we
16 don't understand well at all. Nobody does.

17 But, I think that is a combined
18 effort with the NIH, with FDA and the pharma
19 companies bringing in a lot of biologics now,
20 could be an interesting research question,
21 actually, of predictive immunogenicity and
22 questions like that. So, I think that is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 another area that would be of great interest,
2 and the information exchange that was
3 mentioned before of common areas where you
4 could get information about some of these pre-
5 competitive areas would be very useful, I
6 think, to everyone.

7 And then, in terms of specific
8 areas, I think for us specifically, efforts in
9 regenerative medicine around stem cells would
10 be of great interest, of specific projects.
11 Rare diseases we mentioned before. RNAI and
12 antisense kinds of approaches and in
13 particular delivery, which is a big problem
14 for everyone in this area, I think would also
15 be of interest.

16 And we are developing, as I
17 mentioned before, the external innovation
18 network, and that could be an area where drug
19 repurposing could be -- we could definitely
20 make a contribution as being one of many who
21 could probably help you with that and that's a
22 specific effort which we have set up now, so I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 think that would be something we could do in
2 the near term.

3 MEMBER WASHINGTON: Thank you. Dr.
4 Eck, you have the last word.

5 DR. ECK: I would mention just two
6 topics. One is I think that the NIH has a
7 great opportunity to be the neutral convener
8 in many of these and that there are very few
9 other bodies that can do that.

10 To address some of these issues
11 like access to experimental drugs for other
12 purposes or repurposing of drugs that are not
13 going to be taken forward, I think if the NIH
14 has a relationship with the leadership of
15 these companies, it goes a long ways to
16 greasing the skids for individual
17 collaborations.

18 Companies work from the top down
19 for the most part, but the senior executives
20 of the companies are not always aligned with
21 NIH interests, and I think that gap needs to
22 be closed if we are going to make this work a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 lot more smoothly.

2 I think the other areas are areas
3 that cut across the interests of many
4 pharmaceutical companies, and across a big
5 chunk of drug use. Rheumatoid arthritis is a
6 great example. We don't really know how best
7 to use anti-TNFs. We can't even define what an
8 anti-TNF non-responder is.

9 These are -- we spend a lot of
10 money in this area in prescription drugs, yet
11 we don't get full value as a society. This is
12 not a problem that one drug company is going
13 to solve, but just to take that one disease,
14 that is a great opportunity to bring together
15 a diverse group of scientists to solve that.

16 Because I don't think that will be
17 tackled within a pharmaceutical company. As
18 much as we might want to, we won't figure it
19 out on our own.

20 MEMBER WASHINGTON: Thanks. Thank
21 you for all your comments and for your
22 participation.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIR AUGUSTINE: Okay. Again I
2 would add our thanks, and our thanks, Gene, to
3 you and Richard for your serving as the
4 moderators for this session. I think we are
5 right on time. We will pick up at exactly 10
6 o'clock. We will take a little break here.

7 (Whereupon the above-entitled
8 matter went off the record at 9:39 a.m. and
9 back on the record at 10:04 a.m.)

10 CHAIR AUGUSTINE: Okay, we will
11 turn to our next panel and we will begin by
12 thanking each of you, and some of the members,
13 I notice, are doing double duty today. We
14 particularly appreciate that.

15 The plan for the panel, in terms
16 of moderators, is that Tony and I are to be
17 the moderators, and that is a little
18 distressing because I don't see him right now,
19 but we had this great plan. I will stall.

20 In any event, you have got the
21 biographies of the panel, so we will dispense
22 with formal introductions of the various

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 members. As I said, a couple of them we have
2 met from prior sessions -- and does anybody
3 know a joke or something?

4 The man of the hour. Tony, I have
5 just said that you and I are going to do this
6 together and you are going to kind of start
7 out and then I will try to follow and back up.

8 MEMBER FAUCI: Norm, are we going
9 to have the first presentation, Jeff Allen?

10 CHAIR AUGUSTINE: Yes, do you want
11 him to --?

12 MEMBER FAUCI: Yes, why don't we do
13 that. So just as a very brief introduction --
14 as you see from the title of the session --
15 that this is engaging in a dialogue with the
16 public, and that may seem sort of like the
17 curving off of all the important things that
18 we are talking about but, as far as I am
19 concerned, this may be the most important
20 thing, because if we are going to engage in a
21 dialogue with the public, we have to
22 understand what it is that we want to dialogue

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 with them with, and as you know from the
2 discussions over the last day and a half, it
3 has not exactly been crispy clear about what
4 it is that we really need.

5 So, I think that this could be a
6 session where we might accomplish two things,
7 maybe crystallize a little bit more our
8 thoughts and what we have been discussing, and
9 then figure out what the best way to dialogue
10 with the public.

11 So, in this regard we have asked
12 Jeff Allen, who is the executive director of
13 Friends of Cancer Research, to start us off
14 with a presentation on engaging in a dialogue,
15 and then we will move to the panel, ask them
16 to give very brief statements concerning some
17 of the questions that we have posed and then
18 hopefully have a good discussion thereafter.
19 So it's yours.

20 DR. ALLEN: Thank you. I am
21 actually glad to hear you say that there has
22 been a little bit of vagueness over the last

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 couple of days because -- I guess when I got
2 the call about my assignment from Amy, I was
3 left thinking: a dialogue about what? And this
4 wasn't due by any means to her explanation of
5 what the questions were, but I think it was
6 noted yesterday by Dr. Rubinstein early on, as
7 we heard about all of these exciting projects,
8 why are we not seeing more things come to
9 fruition?

10 So I thought this was difficult --
11 to really put a thumb down on what clear
12 communications strategies look like. So I
13 thought we would step back very quickly and
14 just say, how are we doing at addressing the
15 problem as a whole? And are people really
16 understanding why things aren't coming to
17 fruition?

18 So, a number of general studies
19 have cited things like -- that have been
20 talked about already yesterday and today --
21 about what goes into the length of time, the
22 people, the money that it requires to bring a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 single drug to market, and are we summarizing
2 this too much as far as details versus
3 simplification, and what are the tradeoffs?

4 We have heard a number of kind of
5 catch phrases to engage the public and
6 describe the concept of translational
7 research, like bench-to-bedside, microscope-
8 to-marketplace. Is that really getting caught
9 up a little bit too much into what actually
10 that "to" is and how big the "to" is, as
11 compared to the challenges?

12 Have other terms like "Valley of
13 Death" helped describe, really, what the
14 challenges are, and the pitfalls to the topics
15 that we are trying to address today?

16 So, certainly the challenges have
17 been acknowledged -- and I don't know if this
18 is true for the public's standpoint -- but
19 roughly 20 percent of new drugs that enter
20 clinical testing ever actually make it to
21 market.

22 In oncology, drugs that are even

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 just starting being looked at, only eight
2 percent of those make it. So, we have our
3 challenges ahead of us, with a 92 percent
4 failure rate. I don't know how to positively
5 communicate that. But, it is certainly one
6 that I don't think is widely understood and is
7 one that is going to have to be dealt with
8 head-on as we embark into new models of
9 translational research and trying to engage
10 the public around the importance of this type
11 of research.

12 So, where is the current
13 understanding from the public? And I know
14 there was a lot of kind of excitement when
15 this article came out, and I thought it was
16 very interesting because people focused on the
17 promises that were made very early on,
18 particularly by President Clinton in
19 introducing Dr. Collins's efforts around the
20 Human Genome Project that -- I think it was
21 something to the effect of -- this may allow
22 us to prevent all diseases.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 And so an article like this comes
2 out and basically the headline is the
3 headline. Now if you actually do read the
4 article, it continues on to conclude with the
5 inherent uncertainty in science, but the
6 headline is the headline, and the public
7 oftentimes doesn't make it to the end of the
8 article.

9 But, at the same time it is not
10 wrong to wonder why it has taken so long, and
11 that is why we are here. It is really time to
12 revise the models that are focused on directed
13 translation of the biological findings to new
14 medicine.

15 But, it is equally as important to
16 make sure that we bring the public along on
17 this journey, to make sure that it is like the
18 snowball rolling down the mountain and
19 gathering steam, as hopefully we start seeing
20 early signs of success.

21 But, this is far more than a
22 communication issue. There needs to be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 fundamental changes. I think the public is
2 looking for fundamental changes, wants to
3 understand what goes on at research
4 institutions, and I think that defining the
5 problems and the road forward for progress is
6 one that is incredibly important to lay out at
7 the outset, and then that can be communicated.

8 The challenge of course is how to
9 do this for the many different audiences that
10 need to hear about complex topics like
11 translational research and drug development,
12 and it of course needs to be tailored to
13 specific outreach.

14 So, I would say it is even worth
15 taking a look in some of these. You might
16 note, even, that we separated here general
17 public, patients, advocacy. Many times those
18 get clumped together, but the messaging to
19 those individuals that represent those groups
20 are of course always very different.

21 I was struck that several -- now
22 maybe more than several -- years ago, when I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 first moved to Washington D.C. to work at
2 Georgetown University -- I am from Ohio -- and
3 telling people I am going to work at
4 Georgetown University didn't really require
5 much of an explanation.

6 And, I just Googled this, when I
7 was thinking about this, the operating budget
8 for Georgetown is a little bit less than a
9 billion dollars. When I went from Georgetown
10 to come work at the NIH, I don't think anyone
11 knew what that was, and it is not to say that
12 the 30 plus billion dollars at the National
13 Institutes of Health is responsible for a
14 communication plan.

15 But, people certainly didn't know
16 where I was going or even what I was doing
17 there. Even in Washington, D.C., I think
18 people knew where I was going and what I was
19 doing, but they didn't even know what was here
20 as far as the operations that go on and the
21 really expert science that is housed right
22 here.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, there has to be a strategy
2 with the goal of communication as far as
3 mobilizing the support from all of these
4 different components in order for it to be
5 successful. No one is fundamentally against
6 the concepts of translational research, but I
7 suspect most don't know what role they can
8 actually play.

9 So, as far as the advocacy
10 community, I think it is very important to
11 equip the advocates with information. Now, it
12 is hard for federal agencies at times to kind
13 of make the case. There is a delicate balance
14 of providing information without lobbying per
15 se.

16 And, oftentimes, government
17 officials can't give information directly to
18 Congress without first being asked.

19 But, I think this is a pretty good
20 example of why a mobilized and educated
21 advocacy community is needed. Engaged
22 advocates are seen now by the emergence of new

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 philanthropic efforts that we have heard a lot
2 about yesterday afternoon and this morning,
3 where impatience for progress is evident for
4 these changing paradigms in translational
5 research.

6 One example, I think where the
7 advocacy community is frequently fractured on
8 these issues is just the idea around research
9 in general. You know, every year -- I don't
10 know if this is readily known -- but every
11 year the advocacy community spends about three
12 months waffling back and forth about what the
13 "ask" for the NIH budget should be.

14 You know, should it be the rate of
15 inflation, should it be BIRDPI, should it be
16 BIRDPI plus three percent, should it be how to
17 maintain the ARRA funding base?

18 So, after about three months -- I
19 don't know how the decisions are actually made
20 -- but you either decide to all go along or
21 you decide to split into your different camps
22 and carry different messages on the Hill and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 really confuse everybody. And what is the
2 result?

3 Well, I would say, that at least
4 since the age of the doubling, it is always
5 less than whatever the end "ask" is, so maybe
6 this is evident of ineffective communication
7 amongst the community as a whole.

8 But, it is an important one, I
9 think, to take a look at how historically
10 research communication has happened, because
11 certainly the question, when trying to
12 mobilize elected officials, is always what is
13 the return of investment?

14 Now, this is not without its
15 challenges as well. You certainly want to
16 create excitement around research. There's
17 been plenty of studies that go around this,
18 but it is not always known, things like the
19 return on investment for research. Over two
20 dollars per dollar invested in research comes
21 back to the economy. Does that help build a
22 case?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Well, discussing what that money
2 is going to is often difficult, and now we are
3 left with one of those kind of footballs to
4 pass around of how we are going to describe it
5 with the Cures Acceleration Network.

6 And, I mentioned earlier, it takes
7 a billion dollars approximately to bring a new
8 drug to market. So we have 50 million now and
9 what are going to do with that to create a so-
10 called cure, let alone the Acceleration
11 Network to then compound that into additional
12 cures?

13 And is this an example of another
14 underestimation of the challenge in order to
15 create an important talking point to kind of
16 galvanize and mobilize the forces necessary to
17 result in progress.

18 So how are we doing? Well, at
19 three percent and slow growth rates since the
20 doubling as far as the research budget as a
21 whole is concerned, it is a little
22 disheartening to hear some of these comments

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that were made when Dr. Collins was testifying
2 with regard to the House Appropriations, where
3 the Chairman of the Committee responsible for
4 funding said, "I am disappointed by the lack
5 of aggressive activism on the part of the
6 professionals in the biomedical research
7 field."

8 So, I guess, we are not doing very
9 well. I think it is really important, you
10 know, I mentioned there is a fine line here,
11 but it is critical for all the components that
12 have been discussed, whether they be as part
13 of public-private partnerships that were
14 described earlier today, specific roles that
15 different government agencies can play to
16 really find ways to creatively talk about what
17 it is that you are doing. Whether it is the
18 successes or the failures, there needs to be a
19 better communications strategy.

20 I can tell you personally there
21 have been times when I have been on the Hill
22 talking about the activities or the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 initiatives that leadership of different
2 agencies have had, where I have been greeted
3 with things like say, "I have heard more about
4 this topic from you than I have heard from
5 agency x."

6 And that is a challenge, because
7 that is directly followed with, "That makes it
8 very hard for me to sell to my boss when I
9 don't have any information about the program
10 that you are telling me from the people who
11 are supposed to be conducting it."

12 And now, of course, this is all
13 more than money. This slide is a little bit
14 outdated, but some kind of recent figures
15 estimate that the total investment in
16 biomedical research is upwards of \$90 billion,
17 and this line is still kind of remaining the
18 same as far as if the metric is indeed new
19 drugs and devices.

20 So, throwing money at the problem
21 isn't exactly just the -- isn't the solution
22 here, so maybe we shouldn't underestimate what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 \$50 million can do if we are talking about CAN
2 or as far as if we were to parse out the total
3 amount of money that is going towards a
4 translational research effort.

5 So, the question here is what can
6 the NIH do to help? The current environment is
7 eager for medical advancement, but not exactly
8 supportive of the key players, which makes it
9 very hard. There is an increasing skepticism
10 of government. Certainly, there is zero
11 sympathy towards the industry.

12 An academic enterprise with reward
13 systems that are not always geared towards
14 start-to-finish drug development and an
15 extremely challenged economic outlook make all
16 of this exceedingly difficult to build
17 momentum behind.

18 So, I think it is really important
19 to look at the successes and the failures, and
20 why did drug x succeed and why did drug y
21 fail? I think the public is interested in
22 understanding the process, and that will be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 important to kind of gain steam as we move
2 ahead.

3 So, publicize a directed work
4 plan. I think this was talked a bit about in a
5 -- the earlier panel. If you have very
6 incremental goals that can be communicated
7 along the way, it helps to keep people
8 involved, to drive support, get people excited
9 and then of course to also hold people
10 accountable.

11 In general, there needs to be a
12 new approach to all of this. The current
13 infrastructure for clinical research has been
14 referred to as out-of-date, and, if a new
15 approach is desired, then we need to change
16 some of the old parameters.

17 I mentioned a couple of things
18 here specifically. The IOM report recently, on
19 cooperative groups in cancer, really
20 highlights the need for fundamental change to
21 clinical research as a whole.

22 My last bullet point here is not

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 to insinuate by any means that the peer review
2 process is broken or not efficient. But if we
3 are talking about a new approach to conducting
4 translational research, certainly having the
5 right expertise around drug development -- as
6 a part of the peer review process from the
7 beginning -- is critical to even make sure
8 that we are starting off with the right
9 projects in order to set them up for success.

10 With regards to the federal
11 government, I think this is a really important
12 point here. I don't want to duplicate anything
13 that was said on public-private partnerships
14 before, but certainly I think we are starting
15 to see some fruition come from that.

16 But, in order for successful
17 engagement about translational research, the
18 vital role for the other components of the
19 translational research enterprise need to be
20 described. The NIH just simply can't do it
21 alone and we shouldn't expect them to. I think
22 Dr. Fauci made the point yesterday that there

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 is often a public misnomer of questions, like
2 why aren't more drugs coming out of the NIH?

3 Well, that is not what they are
4 fundamentally set up to do alone, but they
5 certainly can be a key driver -- if not the
6 major convener -- of many of the other
7 entities that are required for success.

8 But, I can tell you that the role
9 of other agencies is even less understood. If
10 people in Ohio didn't know that the NIH was in
11 Bethesda or what they were doing, I can
12 promise you that they don't know what role
13 agencies like the FDA can play in the
14 advancement of biomedical research, and that
15 is an increasing challenge.

16 I understand that the NIH itself
17 is at times a regulated entity, but
18 coordination around activities, with directly
19 the FDA or with other federal agencies, can
20 certainly be improved. I think we saw some
21 mishaps in communications by the activities of
22 some of these agencies, most recently as last

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 fall with proposed revisions to mammogram
2 guidelines.

3 I don't think it was necessarily
4 well coordinated by the various different
5 entities that could have worked together to
6 improve that process as a whole. That's a
7 specific example.

8 But, the need for collaboration
9 goes beyond just explaining how it can work.
10 It actually really needs to happen. Last year,
11 probably really about a year ago, over last
12 summer I had the opportunity to talk to many
13 of you who have been around the table and
14 others about what your understandings or what
15 your direct contact was in working with the
16 FDA.

17 And I will say it was a very
18 interesting series of conversations that were
19 highly variable as far as how these two
20 agencies should and do work together. I think
21 we have seen some very positive steps in the
22 right direction that have been mentioned

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 already today through the leadership council,
2 that I know is planning on meeting relatively
3 soon, between the leaders of those two
4 important agencies, to try and increase the
5 open channels of communications and activities
6 that can be coordinated between the two, so as
7 to support both of those agencies' really
8 vital missions for the advancement of public
9 health.

10 And, in looking at that
11 announcement, it really struck me how
12 important the concept of regulatory science
13 is, and how this actually has begun to create
14 a bit of a public groundswell, without ever
15 once really defining the concept of regulatory
16 science.

17 Over in Building 10, when the
18 announcement was made, a roomful of advocates
19 came out to pledge their support for this
20 effort. You know people acknowledge that six,
21 seven million dollars isn't exactly going to
22 perhaps change the world here, but there was

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 such support among the external community that
2 we need to figure out how to keep that going.

3 Still now, we see the members of
4 the community out there pushing for the
5 importance of this vital collaboration, but
6 not really able to even define what it is
7 going to look like.

8 And that goes back to arming the
9 advocates. I think having a work plan for the
10 public to rally around, gain support for on
11 the Hill, on the ground, is critically
12 important for these efforts to succeed.

13 I put one example down here at the
14 bottom. Obviously, by the name on the slide, I
15 am a bit more steeped in the cancer research
16 enterprise, but as a member of the public
17 watching how over the years the debate around
18 the flu vaccines and the challenges haven't
19 necessarily all been communicated.

20 Essentially, last year we had a
21 challenge with getting the vaccine in time.
22 That was always communicated. Why? It never

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 quite got out there. The incredible
2 partnership that went into successfully
3 getting it out there? I don't think that was
4 well communicated either.

5 To try and educate the public
6 around this process of things that are
7 relevant to really all Americans, could be a
8 really great way to explain the challenges
9 associated with translational medicine, and to
10 engage the public.

11 So let me just conclude by saying
12 that doing this type of work behind closed
13 doors, without public engagement, would really
14 challenge the sustainability for the future of
15 translational medicine. So, I will stop there
16 and we can open for discussion.

17 MEMBER FAUCI: Thank you very much,
18 Jeff. So, getting back to my opening comments,
19 before I ask the panel to make some brief
20 statements so that we can get into the
21 questions, I think your presentation
22 exemplified somewhat the concern that I have,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and that is that you started off -- and I was
2 -- I don't usually take a lot of notes but I
3 was taking notes on what you were saying --
4 that you gave a good argument for the public,
5 the need for public understanding in order to
6 garner support for the NIH in general.

7 What we are talking about in this
8 session is not just the NIH in general, but a
9 very specific initiative that we are trying to
10 launch and we want the people to understand.

11 And that is why I think this
12 session is so important, because there is
13 absolute, major possibility for
14 misunderstanding what we are talking about.
15 So, you gave an example of something that I
16 have experienced many times, not just me
17 uniquely, but my institute director
18 colleagues, of sitting in front of a
19 committee, a congressional committee, and
20 somebody saying, "What have you done for us
21 lately, where are the cures?"

22 That was before we had a Cures

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Acceleration Network. Can you imagine what the
2 questions are going to be when we have a Cures
3 Acceleration Network, because we are
4 essentially putting ourselves out there?

5 So I think my own personal -- and
6 also discussing with some of my colleagues --
7 one of the major issues is to get people to
8 understand something that you said and Tom
9 Insel said and I have said, is that: we are
10 not the ones that are supposed to bring the
11 prize over the goalpost. We are supposed to be
12 participating in a much more effective way in
13 getting concepts that we fund, that we develop
14 with our grantees, into a pipeline that is
15 going to the goal line.

16 So, we don't do that except with
17 repurposing. I mean, for example, if I could
18 name -- and I don't want to take the time to
19 do it, but some that I have had personal
20 experience with in the last year -- of
21 vaccines that we funded the fundamental
22 concept. We worked with the investigators to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 link them up with a biotech company. The
2 biotech company was bought up by a major
3 pharmaceutical. The major pharmaceutical made
4 the vaccine, and when the announcement of the
5 vaccine was made, somehow or other, the NIH
6 got lost in the shuffle.

7 So, if it wasn't for the -- and
8 that was done -- what we want to do, that was
9 really taking the concept. So that is why I
10 feel really strongly about the need for real,
11 accurate communication about what is the goal
12 of what we are trying to do?

13 So, with that as the background,
14 we have a bunch of questions that have been
15 put up. How is the public going to interpret
16 and respond to this effort? I think I just
17 explained that very well. How are we going to
18 enhance communication to our stockholders
19 regarding the risk and the benefit of this?

20 One of our major stockholders are,
21 what I call affectionately the R01 crew, so
22 whenever there is -- and there is an R01 crew

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 guy right down at the end of the table, Tom --
2 when they hear of any initiative that the NIH
3 is going to do, any initiative that is driven
4 by the NIH, there is a considerable anxiety
5 reaction about resources that are going to be
6 taken away from fundamental, basic,
7 undifferentiated research. So, I would like to
8 hear what your thoughts are on that level of
9 communication.

10 The other is public input -- and
11 these questions are all delineated -- to
12 establish tangible goals and to set
13 priorities. Now to get public input is very
14 important, and we need it because we are a
15 public organization. We are funded by
16 taxpayers' money.

17 But, that also falls under one of
18 my categories of be-careful-what-you-wish-for,
19 because it may be that the public doesn't
20 really understand well, and that gets to the
21 communication, of what we are supposed to be
22 doing.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, they are going to wish -- if
2 you give them a wish list, they are ask you
3 for a cure for all of their favorite diseases,
4 and the cure has to come directly from the
5 NIH, which I can tell you today, we can settle
6 that, that is not going to happen. It is going
7 to come from the NIH playing a role in what
8 the pharmaceutical companies do.

9 And then there are other issues
10 regarding expectations. You know, as I
11 mentioned, after a few years we are going to
12 be asking you to list the several cures that
13 you have. It's like my turning to Gail or to -
14 - who was -- right, right and say can you tell
15 me the list of cures that you have done this
16 past year?

17 In any event, how are we going to
18 convey the importance of this? So, I will stop
19 with that, unless Norm has any other comments,
20 and could we -- actually why don't we just go
21 from that end first, because this end always
22 gets the short -- if you just make a statement

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 about some of the things that I mentioned and
2 then we will open for discussion.

3 DR. PACCAUD: Thank you. Quite an
4 interesting and complex topic. Again, from the
5 perspective of a private partnership
6 organization, the main thing that came to my
7 mind as a danger when you are trying to get
8 into this area, which belongs to some extent
9 largely, we have seen, to the pharma industry,
10 is that you may start blurring the message.

11 My conception as a European of the
12 NIH is of a basic research funding agency that
13 really actually is the driver of the next
14 development from ideas to product, but that
15 development part has always been taken up by
16 the industry.

17 Now, you are stepping closer to
18 what the industry knows normally how to do, it
19 is probably essential that the researcher
20 understands the process -- we have heard that
21 yesterday -- so that they know if their
22 research could one day be translated, which

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 probably to our experience, most of them don't
2 understand at least for our diseases.

3 So, my first thing would say, be
4 aware of the fact that you will have to be
5 crystal clear about why NIH would start de-
6 risking a part of the job that normally is
7 going to -- should be done by industry,
8 because if they develop a drug, they then,
9 after that, start making some profit. That
10 will be one of the aspects that I think is
11 critical there.

12 You said it very nicely as well.
13 If you ask the public about what are the
14 diseases that are important, you will get a
15 long list of very interesting diseases and
16 probably most of them rare diseases which are
17 underserved by the industry.

18 So positioning -- and again, this
19 is probably a statement from DNDi's
20 perspective, well, maybe NIH should position
21 in the diseases where the pharma industry is
22 not going and explain that if you develop

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 these translational capabilities, this is
2 because you really need to de-risk that for a
3 subset of disease. I wouldn't say that
4 diabetes is a small disease on which there is
5 no profit to be made by the industry. That is
6 their job to do that.

7 So, to some extent, from our
8 experience, we would warn that the confusion
9 between private and public sector roles there,
10 and I will stop there.

11 DR. ROWE: Well, thank you for
12 inviting me. I am representing the Cystic
13 Fibrosis Foundation and I think there is a
14 number of parallels to what you are thinking
15 about now to what the CF Foundation went
16 though 10 years ago when they transitioned
17 from primarily funding academic institutions
18 and care centers to doing active venture
19 philanthropy and funding biotech companies and
20 really pushing their therapeutics development
21 pipeline.

22 So, one point that I would like to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 make, which reiterates a point that you have
2 made, which is I think as you are setting up a
3 program that is going to be an active
4 facilitator and partner to pharmaceutical
5 development, I think communication is likely
6 going to be an expectation of your
7 constituents.

8 And so you might as well consider
9 embracing it now and developing your processes
10 to handle it. It could be a purview, for
11 instance, of your program management group.
12 Certainly, the CF Foundation had that. Once
13 they started funding these biotech companies,
14 it became an expectation of the patients and
15 the families and its stakeholders to report on
16 that progress on how well it is doing.

17 I think the other point I would
18 like to make in these opening statements is
19 that you are going to need metrics for -- that
20 are easily understandable by a wide variety of
21 people for your progress.

22 The thing that the CF Foundation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 did was develop a therapeutics development
2 pipeline, so on the x-axis is all the various
3 biologics and therapeutics that are in
4 development, on the y-axis is where each one
5 stands in its development path from pre-
6 clinical all the way to available to patients,
7 and that is shown on a regular basis, updated
8 on the website regularly, used by our
9 fundraisers as well as communication with the
10 industry.

11 And, I think, you are going to
12 want to have that, and it harkens back to a
13 concept that we talked about yesterday, which
14 is that NIH is very complex and has multiple
15 different organizations. Perhaps there is a
16 way to harmonize that in a simple diagram and
17 show that, use it as a communication tool.

18 When we look back after a decade
19 of working on our therapeutics development
20 pipeline, we developed a program that showed
21 how that therapeutics development pipeline
22 changes over time, and it was very informative

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 in that while some agents and therapies were
2 moving up the chain and eventually available
3 to patients, there was a lot of activity at
4 the low end of the scale.

5 They were coming on and coming off
6 the pipeline, and you could show that to
7 patients and constituents, and it was an
8 effective tool to help set the expectations,
9 and you might want to do that now as you start
10 that program to help combat that. So, I will
11 stop there, and I have a few other points on
12 other questions.

13 MR. SIMON: What does the NIH have
14 in common with the White House, with Pfizer,
15 and Carnegie Hall? They are all defined by how
16 hard it is to get in. And, for instance, I was
17 talking with an executive at Carnegie Hall
18 just the other day, and he said: our walls are
19 what define -- the best acoustics in the world
20 -- but they are also what keep people out.

21 And, if you have ever seen
22 Carnegie Hall from the outside, it is an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 imposing brick edifice. Most people wouldn't
2 think that they have anything to do there. So,
3 when they started a program for Chinese
4 culture, they had -- 40 percent who showed up
5 had never been inside Carnegie Hall before.

6 When they did a special program on
7 African American music, 30 percent of the
8 people who came had never been in Carnegie
9 Hall before. So their question isn't: how do
10 you get to Carnegie Hall? Their question is:
11 how does Carnegie Hall get to you? And that is
12 the question NIH is asking.

13 The fence that is now around NIH
14 has actually made explicit what has been
15 implicit for a long time, which is -- it is
16 hard to get here, it takes a lifetime of
17 devotion to science to get here, and the
18 question is: how do you get people in here,
19 out?

20 In the brief conversation with Dr.
21 Zoghbi, she made it clear to me that Pfizer is
22 a hard place to get into. I have only been at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Pfizer a year and I can tell you that after
2 just a few months, I knew it would be totally
3 possible to spend every waking moment in the
4 building and totally forget the outside world.

5 In fact, a lot of people who have
6 been there 10 years wonder and ask me why I
7 spend so much time out of the building.

8 So how does the translational
9 research in particular get out of the
10 building? Well, for one thing -- as you just
11 said, Dr. Fauci -- we need to have the same
12 sort of blue ribbon commissions that look at
13 conflicts of interest, look at congruence of
14 interests.

15 We are the only country that
16 divides our industry from our government and
17 our academia in the way that we do. We have to
18 have one large brain to get where we want to
19 go, and right now we have divided our
20 hemispheres, and we cannot get there from
21 here.

22 Other countries will get there a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 lot faster than we will, because they are
2 uniting their industry and the academics and
3 the government.

4 So, we have to start addressing,
5 head-on, that individuals have conflicts of
6 interest, and they should be dealt with
7 firmly. But, as institutions, we cannot
8 continue to demonize different parts of
9 society.

10 Marcia Angell started with a few
11 criticisms and now, every time she is
12 scratched by a reporter, out comes, "It just
13 shows the corrupting influence of industry in
14 America."

15 Well, there has been a lot of
16 corruption in academia, there has been a lot
17 of corruption in government. But, we don't
18 need to demonize those institutions because of
19 science misconduct, or political misconduct.

20 I can tell you that most of the
21 people in the industry -- if not the
22 overwhelming majority of people in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 industry -- are passionate about helping
2 people. But, they have to do it in a way that
3 funds their work, just the way you have to
4 communicate to the public your work to fund
5 your work.

6 So, my table of contents for today
7 is, what do we do about the R01 gang and the
8 mission? It was the demise of the large-frame
9 computer companies that the large-frame
10 scientists and engineers never wanted any
11 money to go to small computers.

12 So, what happened wasn't the
13 demise of small computers. It was the demise
14 of large-frame computer companies.

15 We have to talk about the value of
16 innovation to society from economic terms. We
17 have to define diseases. I mentioned this
18 yesterday. But if the NIH translational
19 program starts dividing diseases into what
20 they really are, based on what we can analyze
21 and attack, and the FDA keeps regulating drugs
22 based on antiquated disease categories, that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 won't help. We need the NIH to educate the FDA
2 about the future of medicine.

3 And finally, one thing I think we
4 need to do with the public is, we need to
5 start thinking of our young people as talent
6 to be drafted out of high school, given
7 scholarships, given the option of employment,
8 the way we do athletes.

9 It is amazing to me that we can
10 have a draft that stops everybody to watch
11 television for high school football players,
12 and yet when Intel names the top 100 high
13 school scientists, they get a page in the
14 paper, one day.

15 Those young people should have
16 their careers laid out for them in terms of
17 options, funding, opportunities, and instead
18 we offer them eight years of servitude, debt
19 and ingratitude until they are 40 and can get
20 an NIH grant. So, we have a lot of things we
21 can change. Pick one.

22 MS. COMSTOCK RICK: Thank you. How

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 do I follow that?

2 In terms of communication, I
3 think, the first question you always have to
4 ask is: who is your audience? And quite
5 frankly, patients and public for this purpose
6 I will lump together. Researchers and Congress
7 are all very different audiences with very
8 different needs.

9 So, I want to talk about each of
10 them very briefly. For the patients and the
11 public, I echo what everyone else has said. I
12 was as dismayed and concerned as everyone in
13 the room yesterday when I heard about the
14 science teacher quotes, that they had never
15 understood before the connection between
16 research and medicine, until they had gone to
17 this conference. Terrifying, to me.

18 Also, I am very active right now
19 on the hot issue of human embryonic stem cell
20 research with the case going on. I am
21 interviewed a fair amount about that. I can't
22 tell you how many science reporters ask me,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 "Well, stem cell lines were first derived a
2 little over 10 years ago, and we don't have
3 any cures yet. Doesn't that mean they don't
4 work?" These are science reporters.

5 There's a huge education
6 opportunity that NIH, I think, would really
7 benefit from taking on in terms of educating
8 the public, not just about translational
9 research, but about research, basic research,
10 the role it plays. Yes, you don't get the ball
11 over the goal line. Explain that to people.
12 Explain the pipeline to people, and I think
13 there will be a lot of benefits, not just from
14 the CAN effort, but for NIH funding as well as
15 recruiting young people. So, I think there
16 would be multiple benefits.

17 In terms of researchers, they are
18 definitely one of your stakeholders, I don't
19 want to repeat some of what was said
20 yesterday, but just reinforce it. I think
21 there is a huge opportunity with CAN to work
22 on the culture of translational research being

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 second class research, to work on the culture,
2 to support the outcome, that scientific
3 beneficial outcomes that could lead towards a
4 therapy is just as much to be celebrated,
5 maybe more, as publications.

6 How NIH does that? There is a lot
7 of opportunity. Do you take some of the CAN
8 money and start a journal for translational
9 research that is willing to publish negative
10 results? NIH is the gold standard for
11 researchers. The R01 crew is envied. Use that
12 cachet and that power and some of that money
13 to promote the culture of translational
14 research.

15 But, the last audience I want to
16 mention is the one I deal with a great deal,
17 which is Congress. I have had many
18 conversations in Congress about CAN, over many
19 years, actually. We have been talking about
20 this issue long before Senator Specter named
21 it CAN.

22 And one of the issues that, I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 think, hasn't come out in the last day-and-a-
2 half, if you will allow me that, is that
3 Congress didn't expect that NIH had all the
4 answers and knew exactly what to do with \$50
5 million, which if we are on the right track,
6 will far exceed \$50 million in a few years.

7 Congress felt -- in my opinion,
8 based on my conversations -- Congress felt
9 that NIH was the right convener to have this
10 really difficult conversation, and NIH was the
11 right place to house this. But, NIH didn't
12 have a plan in its back pocket for immediate
13 implementation.

14 And, quite frankly, what hasn't
15 been talked about in the last day and a half
16 is a piece of the statute that creates a board
17 to oversee CAN that has membership from DARPA,
18 membership from industry, membership from VC,
19 membership from patient advocacy
20 organizations.

21 That was considered a key part of
22 implementing CAN. I work for PAN, a Plan for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CAN. And part -- one of the things that is in
2 the statute that the board is supposed to
3 oversee and work with the director of NIH and
4 the Secretary of HHS on, is identifying
5 hurdles to translational research, and part of
6 NIH's role was to convene that conversation
7 with all the stakeholders and say, this is
8 what some of our problems are. We need to
9 focus on them. Could be conflict of interest.
10 We have talked some about contract issues,
11 could be a lot of things.

12 And that board is supposed to be
13 powerful, but it is also a huge opportunity
14 for public input and education about the role.

15 So, I would suggest to you that
16 when you are thinking about how to get started
17 with CAN, it is okay to step back and
18 understand that NIH was slated as the right
19 place to have this tough conversation with
20 significant input.

21 I have to say it is not lost on me
22 that I am speaking to a board about the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 creation of a board, which has the authority
2 to issue a report. That's very, very
3 government. I realize that. But the CAN board,
4 again, was slated in part to identify the
5 hurdles, and in fact if you look at the
6 statute, there is a process created for what
7 they are supposed to do when the hurdles are
8 identified.

9 MEMBER FAUCI: I just couldn't help
10 but just make one brief comment, because I
11 might forget it as we get into the others. I
12 am, as an institute director, totally, not
13 only in favor of it, but I walk the walk
14 regarding translational research. We do over
15 \$1 billion in translational research.

16 But, you said something that
17 struck me. And that has to do with
18 communication regarding what I was just saying
19 about getting the people who are fundamentally
20 in just the basic research.

21 You said the CAN number is \$50
22 million and for sure it is going to be much,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 much more than that in the next couple of
2 years. The NIH budget is scheduled to be flat
3 for the next couple of years. So if it becomes
4 more, then it is going to come out of the
5 fundamental, basic research and then we are
6 going to have a real problem in communication
7 with a very important part of our
8 constituency.

9 So, I don't want to get into a
10 discussion, but just so that people know that
11 if that happens, we have a communication
12 problem, a serious one.

13 MS. COMSTOCK RICK: Yes, I mean I
14 do think -- the focus for new money for CAN
15 has not been dropped entirely and I do think
16 that a lot of this is circular, that if you
17 are able to show that NIH is moving into a
18 truly new space, that it might require new
19 money.

20 But, education of the importance
21 of basic research is huge.

22 MEMBER FAUCI: You haven't been to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the meetings with OMB that I have been.

2 MS. COMSTOCK RICK: I understand. I
3 understand. Congress is not always easy on you
4 either.

5 MS. ANDERSON: So I want to talk a
6 little bit. I am representing FasterCures. So,
7 we have cures in our name and we deal with the
8 same sort of anxiety that you do in terms of
9 where are my cures?

10 I think the important thing to
11 talk about here in terms of this communication
12 issue is the context, and I think Jeff pointed
13 it out in his presentation: context is
14 everything.

15 So, right now we are dealing with
16 a context where the headlines are focusing on
17 where are my cures or what is working in
18 science, what isn't working in science? So I
19 think the public is getting a little bit more
20 sophisticated in terms of understanding, oh, I
21 just read that this big Alzheimer's trial
22 didn't work and it stopped.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I think all of that benefits the
2 greater good in terms of understanding where
3 we are and where we need to go.

4 I think another piece of context
5 that is important is the aging Baby Boomers. I
6 think everyone is looking around and saying
7 what am I getting, what are my peers getting,
8 the sandwich generation, I mean I am here
9 representing all of these different places,
10 the sandwich generation is looking at their
11 elderly parents who are living much, much
12 longer but with many more chronic diseases and
13 things that have to be managed.

14 I think all of this is also in the
15 context of safety and risk, so we hear a lot
16 of discussion about patients are willing to
17 accept more risk but then you are talking
18 about a regulatory framework that must ensure
19 safety.

20 And so, I think, as we speak about
21 what is needed in communications, we have to
22 recognize all of this, and to your point, Dr.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Fauci, about what the NIH does and doesn't do,
2 I think the burden comes back to NIH to be
3 part of that communication process.

4 I think Rob Califf pointed it out
5 as well. Right now, there is a little bit of a
6 vacuum for how does medical research happen,
7 how do the sectors actually collaborate, how
8 do we pass the baton from one place to the
9 next?

10 So, I think the basic research
11 community, the R01 crew, needs to get in
12 there. They need to talk about it. It goes
13 back to Greg's point about the next generation
14 of scientists. How are we going to have a next
15 generation of scientists if there is no
16 discussion about it?

17 I mean, there is a lot more
18 discussion about football than there is about
19 science. So, I think all of these things go
20 together. I think you can't have haves and
21 have-nots in terms of this communication.

22 Last night, I was flipping on the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 internet, saying if I am just Joe Q. Public,
2 Joan Q. Public, how do I get information about
3 the NIH? Well, go to the nih.gov website and
4 play around a little bit. It's not always
5 intuitive.

6 And, this isn't a bashing session,
7 but it is to say that there are a lot of
8 people out there fishing for information, and
9 they need to have it spoon-fed to them.

10 Now, can you do it all through
11 websites? Of course not. There are a lot of
12 excellent patient groups, there's coalitions,
13 there are stakeholder bodies that need to be
14 cultivated.

15 You know, you need to look at it
16 as they are part of your clientele, they are
17 part of your client base. You all need to be a
18 bit of a sales force.

19 And, I think, part of the
20 challenge is that what would we prefer to have
21 you all doing? We would prefer to have you all
22 searching for cures and doing science. I would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 rather have Dr. Fauci out and about within NIH
2 and outside talking about science and
3 translation and how do we get there.

4 But, I will also say, Dr. Fauci,
5 that I would love to hear you on Diane Rehm
6 every single day of the week, talking about
7 the challenges in infectious disease research,
8 because I think you are an eloquent
9 spokesperson. So is Dr. Collins. He whips his
10 guitar out and suddenly he is a YouTube
11 sensation and the Twitter world is all
12 aflutter.

13 But, you all need to recognize
14 that there is only 24 hours in the day and
15 there is only so many of you all. So, you have
16 to deploy this communications mission
17 throughout all of the institutes and across
18 the NIH.

19 And then, I think, you need to
20 start to collectivize the message a little
21 bit, back to Rob Califf's point, we need to
22 bring in academic medicine. We need to bring

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 in the pharmaceutical companies. We need to
2 bring in the patients.

3 And I will point out that you
4 can't just say here's our information, come
5 out to this meeting at NIH, go through
6 security, we will give you the information and
7 then go off and do it; you need to meet
8 everyone half way.

9 And, I think, part of that goes
10 back to the message of leaving the confines of
11 the campus, going to all of these various
12 constituent groups, including Congress.

13 You know, as Amy pointed out, as
14 Jeff pointed out, when we are on Capitol Hill
15 talking about these programs, we get all of
16 the anxiety, you all get it when you are in
17 front of the witness stand. There just needs
18 to be a constant dialogue about it.

19 I could give you a list this
20 afternoon of a ton of different vehicles to
21 get those messages out. What is the message?
22 Obviously, that needs to be worked on in terms

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of this translational research portfolio.

2 But, I will say that it needs to
3 go from being one-dimensional to three-
4 dimensional. So, I have witnessed Dr. Collins
5 and his Power Point presentation that he gives
6 out in all of his speeches, evolve over time,
7 as he has started to thread the needle about
8 the translational research package.

9 But, we need to expand that and it
10 needs to make more sense back to the context
11 of how does basic research fuel all of these
12 engines of discovery, what's the role of NIH,
13 what is the role of TRND?

14 I mean Chris Austin, who I
15 expected to see here, but he is everywhere.
16 There's -- we need to replicate and duplicate
17 some of this intellectual firepower because I
18 do think that the American public is starting
19 to say what am I getting for my investment?

20 It's the same thing if they are
21 saying what did I get for my TARP dollar, what
22 did I get for my Gulf Oil spill dollar, what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 did get for my auto bailout dollar, what did I
2 get for my medical research investment dollar?

3 And is it pleasant? No. But, to
4 me, it is the reality that we are in and that
5 I think collectively we need to figure out how
6 do we move forward.

7 MEMBER FAUCI: Thank you. Ken?

8 DR. DUNCAN: So, I don't have a
9 huge amount to add to the great discussion
10 that there has been. I represent the Gates
11 Foundation obviously, and working in global
12 health, we are in an interesting paradox here
13 that there is no patient population here in
14 the U.S. that can really voice the need for
15 new drugs for neglected diseases.

16 And so, we are relying a lot on
17 sort of advocacy and whatnot, and we have put
18 a lot of effort into that area, but trying to
19 get the message across as to why it is
20 important to invest in that area is clearly
21 challenging.

22 And the Foundation has tried to do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 a number of things. One very interesting
2 little side issue here is there is a grant
3 jointly made between the global health program
4 and the U.S. programs which is working in high
5 schools in Washington state to talk about
6 global health issues and to really get
7 schoolchildren engaged in understanding them.

8 And as they start to understand
9 that, it starts to raise a lot of questions
10 which then makes them very receptive to what
11 the value of science and technology really is
12 and helps them to understand why we need to
13 invest in these sorts of areas.

14 And I think getting that message
15 across, though, is very difficult. It's
16 challenging. And so one way to approach that
17 is to think about what are you trying to
18 communicate here, and to come back to some of
19 the points that were made earlier, it's not
20 necessarily about a final product, but it's
21 about what steps have come along the way? Have
22 we been successful in moving a project from

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the bench into some clinical development
2 pathway?

3 And tell some of the positive
4 stories, get that message out. And the R01
5 community is an interesting one for me. We
6 often think about the universities and how
7 people actually communicate their science.

8 Is it necessary for all R01
9 recipients to talk about their science and to
10 go out and to show that they have done public
11 engagement? So one thing -- I come from the UK
12 -- one thing that happens there is that
13 basically all scientists who are in academia
14 have to show for their metrics each year that
15 they have had some sort of engagement with the
16 public.

17 And so, there is a lot of examples
18 of where that might just involve going out to
19 a high school, talking to a group of kids. It
20 might involve bringing people in, teaching
21 them what they do. But actually making sure
22 that it is actually in their -- it is one of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 their responsibilities to go beyond just
2 teaching the students that are in their own
3 environment.

4 And they also, as I understand it,
5 I may not be absolutely correct on this, I
6 think in a lot of the grants that are given in
7 the UK, they actually have to report back on
8 what was the public engagement, how did you
9 communicate this science that goes beyond just
10 the publication in a learned journal, but also
11 some open publication.

12 It may only just be something on
13 their website, but ensuring that, at each
14 step, there is some engagement, that people
15 see what the value of that research is and
16 they can actually access it.

17 MEMBER FAUCI: Thank you. Okay so
18 let's open it up for questions, comments or
19 whatever from the board. Gail?

20 MEMBER CASSELL: So, this is a
21 problem that I have struggled with for a long
22 time. In 2007, I chaired a review of science

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and technology at FDA and realized that for 15
2 years this agency had been woefully
3 underfunded.

4 And you begin to try to figure out
5 why is that, why is it they have no advocates?
6 Industry can't be their advocates because it
7 would be too self-serving, conflict of
8 interest.

9 But really, nobody, if we think
10 that people have a poor understanding of the
11 role of NIH, I think the public has a very
12 poor understanding of the magnitude of the
13 responsibilities of FDA.

14 So, since 2007, we have been, a number
15 of us, Margaret and others of us, have been
16 trying to figure out how can we improve this
17 understanding? We have come to the conclusion
18 in the IOM drug report that was mentioned
19 earlier, we need a massive communication
20 effort.

21 And then, it became very apparent
22 you can't just talk about one end of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 chain, which is the regulatory authority, but
2 you have to talk about the role of NIH. You
3 have to talk about the role of academia and by
4 the way you have to talk about industry.

5 The poll that Mary Woolley spoke
6 about yesterday we helped to initiate and the
7 results have been consistent since 2007, that
8 the public expects that these sectors are
9 going to work together to develop new
10 therapies.

11 So the last time I went in for a
12 meeting we decided that perhaps the Foundation
13 for NIH -- Scott is a member of the forum --
14 might be a place one could house this
15 educational effort where you could get
16 legitimate financial contributions for this
17 effort, only because you have to have that in
18 order to have the type of massive educational
19 campaign that you need.

20 And I am only taking up our time
21 to suggest that because I think until we get
22 the message clear and out there, we are still

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 going to have a really hard time in terms of
2 getting CAN funded as well as it could be or
3 NIH funded as well as it could be or FDA, a
4 strong, scientifically-based agency as we know
5 it, all it has to be, if we are going to
6 succeed in developing new therapies and other
7 healthcare technologies.

8 MEMBER FAUCI: Dan and then Huda.

9 MEMBER GOLDIN: I think it is good
10 to have outreach and people in the
11 universities to speak, but the American public
12 wants to see their officials that are in the
13 charge of the program.

14 And, I know it is very difficult,
15 it is very time consuming, but if NIH wants to
16 undertake this translational activity, you
17 have got to go sell retail. There is no magic,
18 even in the age of the internet.

19 The leadership of NIH has got to
20 go to every Congressional district, talk to
21 the people there. The local media has to see
22 your presence. You have to meet with advocacy

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 groups. You have to meet with groups of people
2 that have problems and you have got to listen
3 to the problems, you have to take notes, you
4 have got to come back and you have got to go
5 back and answer them.

6 The leadership of NIH needs to
7 meet one on one, in the offices, with the
8 members not the staff of the Congress. It is a
9 huge task and there are action items that come
10 from that, and there are expectations that are
11 getting set that are beyond the control, due
12 to the internet, that cause a huge
13 communication failure, and the members and the
14 staff read the blogs, they read the papers,
15 and when there is no response from their
16 government officials, not from the people in
17 the universities -- that's nice -- but that is
18 my suggestion.

19 The communication problem is
20 really simple. Go to every single
21 congressional district at least every other
22 year. When there, take a day, take a leader,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 take some examples, meet with the people, go
2 to high schools, go to colleges, go to the
3 Chamber of Commerce, go to the Rotary Club.

4 The attendance will be absolutely
5 spectacular, but take a few people. Hold town
6 hall meetings. Have fairs. That is what you
7 are going to have to do, because modern
8 communications demands the actual officials,
9 not their surrogates, to do the job.

10 And, I hate laying this down, but
11 you could think of seven other approaches.
12 That is the only other answer. Thank you.

13 MEMBER FAUCI: Thank you Dan. Huda?

14 MEMBER ZOGHBI: So, I just had a
15 few comments, one to start with the
16 presentation. I was quite upset about the New
17 York Times article and I think it is in part,
18 perhaps, it's our fault.

19 The genome did accomplish a lot
20 and we just did not know how to sell retail,
21 using Dan's words. We forgot that now we don't
22 expose children to a variety of diagnostic

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 tests, biopsies, conjunctival biopsies, nerve
2 biopsies, nerve conduction studies. We do the
3 majority of our developmental disorders
4 testing by DNA testing. This is quite helpful.

5 Many families with terrible,
6 devastating, degenerative dominant diseases,
7 Huntington and many other inherited attacks --
8 this can now be diagnosed. So, prevention,
9 cancer, breast cancer screens, all of that is
10 really -- prevention is just as important to
11 eliminate a disease as is developing a
12 treatment.

13 So, I feel we should really
14 capitalize on that. The second thing we don't
15 make a point about is that really what these
16 discoveries do is they have sown the seeds for
17 us to pick up the fruits, 10, 20 years down
18 the line.

19 We all know the success stories,
20 the statin and Gleevec was mentioned. But, I
21 think it is really important to educate that
22 it was 25 to 30 years from that basic

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 discovery of a mutation or a translocation to
2 get to a treatment.

3 And, I think, this is important
4 for two reasons. One, for us to know how much
5 more work has to go in to come to a clinical
6 drug, but more importantly let's go back and
7 review why did it take 30 years? What were the
8 bottlenecks? And, maybe if we can do something
9 about them, this could be very important for
10 translational research.

11 The last point I want to make is
12 the importance of basic research and what am I
13 getting for it, to follow up on Margaret's
14 point. We can't always get something
15 immediately from basic research, and we have
16 to allow for failures, otherwise nobody will
17 chart a new path.

18 But, most importantly, sometimes
19 the successes will come 20, 30 years later.
20 Nobody would have thought that bacterial genes
21 imported in DNA repairs would be really
22 important for colon cancers. It took decades

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 for that.

2 So somehow, we have to do it and
3 we have to do it without overselling it, we
4 get in trouble, we oversell, the public has
5 high expectations, we fail. So, I just think
6 all these components, we have to figure out
7 how to do it better.

8 CHAIR AUGUSTINE: I would like to
9 make a few sort of random comments. I promise
10 I will handle the questions from the panel
11 here. But, we have all seen the articles
12 what's wrong with NIH. It didn't produce 70
13 million units of flu vaccine that we needed,
14 the suggestion as we have heard that the
15 public really doesn't have much of an
16 understanding what NIH does.

17 We saw the New York Times article
18 and what it refers to and some of you in the
19 last couple of weeks, one of the major news
20 magazines, weekly news magazines, I can't
21 remember which one, had a cover story to the
22 same effect, that what are we getting for our

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 investment in health research?

2 And I think there is a problem of
3 understanding the overall issue, but I think
4 we also have a problem way beyond my pay
5 grade, but the culture of the research
6 community itself, which is increasingly, I
7 think, going to be within academe, and that is
8 that the reward structure is set up to reward
9 publishing papers not producing end results.

10 And I think until that gets
11 addressed to some degree, it is going to be
12 very hard to deal with some of these issues,
13 the broader issues.

14 We saw the chart that was
15 presented this morning about the budget for
16 therapeutics, R&D budget, versus time. Some
17 years I wrote a little book of laws and I have
18 come up with a new law that shows that if you
19 double the budget for therapeutics you can
20 drive down FDA approvals by 20 percent.

21 And extrapolating that, if you
22 increased the budget by a factor of 10, you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 could drive it by zero, there would be no
2 approvals.

3 You know, that is a bit
4 troublesome, even though I injected may be a
5 bit of humor here. Clearly, here is a
6 challenge. As we all know, NIH can't lobby,
7 but NIH can inform. And I think there is an
8 important difference.

9 One of the difficulties I have
10 seen in watching the NIH and the healthcare
11 community as a whole in recent years is how
12 fragmented the message is, and I will give you
13 an example from another world I have been
14 spending some time in -- the broader research
15 community where I have kind been on a one-man
16 campaign for about 20 years to see if we can't
17 get more invested federal money in basic
18 research.

19 And I have my little spiel. I
20 wandered around Congress, sort of like Dan
21 said, and sometimes I think I made a few
22 points, then I would discover that the next

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 person after, that came in the door was from
2 the physics community and said boy this
3 research is great, but don't spend it on
4 chemistry, spend it on physics.

5 The next group that comes in says
6 yes, but don't spend it on solid state
7 physics, spend it on particle physics, and the
8 next group says quarks not bosons. Pretty soon
9 the Congress throws up their hands.

10 And we have a little bit of that
11 trouble here, where there are a lot of very
12 legitimate needs but somehow we have got to
13 get together and speak with a single voice on
14 behalf of research rather than research for
15 purpose x.

16 And I must say that physics and
17 chemistry and some of that community has done
18 a really good job in recent years of getting
19 that message.

20 The conflict of interest issue is
21 one that is immense. I guess I worry about
22 conflicts of ignorance as much as I worry

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 about conflicts of interest and hopefully --
2 well let me just say that's a message that I
3 think somebody has got to get the courage to
4 take on.

5 If not done properly, it sounds
6 like you are in favor of misbehavior. But, I
7 think maybe one way to do it is we live in a
8 competitive world with other countries who are
9 following a totally different rule set and
10 perhaps there is some middle ground where we
11 can behave appropriately, which I think we all
12 want, but also don't handicap ourselves so
13 badly.

14 And I guess the question I would
15 like to lead to with all of this, for the
16 panel, is that if this afternoon you were
17 appointed to run NIH, what would be the single
18 thing you would do that might have the most
19 impact in terms of dealing with this general
20 category of issues. A tough question, but you
21 are all highly paid.

22 MR. SIMON: I'll bite. The first

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 thing I would do is take all the labels off
2 all the buildings and change where everybody
3 is sitting so that every other month they had
4 a different suitemate so that NIH could know
5 that NIH is doing.

6 I think if there is one thing that
7 we have all learned just yesterday, it was
8 that NIH doesn't even know everything NIH is
9 doing. And it's the labels that keep people
10 apart.

11 Many of these labels are using
12 antiquated ways of dividing our bodies into
13 parts and then people study those parts and
14 then they discover that's not really the
15 point.

16 But, as long as people think I am
17 only at NHLBI or I am only at NIAID, and they
18 don't think that they are at NIH, then we are
19 going to have a problem having one mission.

20 When I was at FasterCures and we
21 did a study of the intramural program, which
22 Dr. Cassell was part of, I went online to look

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 at the intramural programs at the different
2 institutes.

3 No two websites were the same, had
4 the same way of describing it, had the same
5 way of navigating it. Anything you learned on
6 one site, you had to start over on the next
7 site and one of the biggest problems was there
8 was no common mission for the total program.

9 Now, out of \$3 billion you need a
10 common mission. I think that is changing, but
11 the first thing I would do is take all the
12 labels off, move everybody around and see how
13 they felt about working at NIH.

14 MS. COMSTOCK RICK: That is a tough
15 question, the one thing, but I think if you
16 will allow me, my perception of NIH is that
17 there is a little bit of an internal dilemma
18 in NIH, that it sees its role in the larger
19 pipeline in terms of what it offers from the
20 results, discoveries, that come from basic
21 research and what it can lead to, but there is
22 also, internally, a sense that if NIH could be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 left alone, and fund the R01 crew and get a
2 budget everything would run smoothly.

3 And I think if I were running NIH
4 for a day, I might try to truly launch not
5 only
6 an external communication effort to educate
7 what NIH does, but also within NIH, really
8 have a serious conversation about who are we
9 here for. And the R01 crew is part of what you
10 are here for, but you are spending taxpayer
11 dollars, and you are spending taxpayers
12 dollars for a reason, and I think the
13 stakeholders are the American public, and I am
14 not sure that that is truly internalized.

15 I think there is too much of a
16 perception that your primary stakeholders are
17 your grantees.

18 MEMBER FAUCI: Of course, Francis
19 isn't here, so let me -- no, but let me try to
20 at least speak for him. In fact, that is
21 exactly what he did in his very first days of
22 his tenure, when he said there are five areas

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that we feel that are important, that we
2 ultimately rely on basic research, which is
3 the core of what we do.

4 But, he realized and, I think,
5 virtually all of the institute directors
6 realized that there are programmatic issues
7 like what we are discussing today that is
8 critical to our mission.

9 You know, and Francis articulated
10 five of them, before him Dr. Zerhouni had
11 issues and before him even Harold Varmus did
12 the same thing. So, if there is the perception
13 that the NIH leadership is only wed to
14 undifferentiated research, I think that is a
15 misperception.

16 Because although we know it is
17 integral to everything we ultimately do, there
18 is a strong feeling that we have other
19 responsibilities.

20 MS. COMSTOCK RICK: Well, and for
21 many of us in life, our reputation may not be
22 accurate, but I am giving you what I see as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 reputation, yes.

2 MEMBER BERG: So, in addition to
3 NIH's role, I think another big piece, and I
4 would like to hear people's thoughts, and this
5 is my perspective and this comes in large part
6 from having a spouse who is a translational
7 clinical researcher, is that -- and Garret
8 FitzGerald touched on this a little bit
9 yesterday -- the business model for physician
10 scientists at many academic medical centers
11 is, from my perspective completely broken.

12 It is just impossible or
13 essentially impossible to try to develop a
14 real translational research career without
15 getting sucked back into the clinical
16 business, to the point that it really becomes
17 -- you know my wife used to come home every
18 day saying I can't imagine why anybody would
19 do what I do.

20 And then she left academia and has
21 now been doing research as a consultant where
22 she is completely outside the system and is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 very productive.

2 You know I think NIH is very --
3 the number of discussions that I have been
4 involved in about how to better support
5 physician scientists and how to try to
6 facilitate that across NIH is huge. NIH is
7 very interested in trying to support it.

8 But, it is really hard to do it
9 without getting the academic medical centers
10 to really think about a different model, to
11 really protect people to do research and not
12 have them get drawn back into what is
13 fundamentally just making money for the health
14 system, or keeping the health system above
15 water.

16 DR. ALLEN: So, in response to the
17 hypothetical about what could be done as a --
18 again this is hypothetical -- but I think it
19 encompasses some of the thoughts that you just
20 had.

21 You know, it's very easy for an
22 external panel to come in and point out things

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 or give a wish list of how they might want to
2 see the NIH work or where public perception
3 has gone awry or what priorities should be.

4 But, I would ask for a tradeoff
5 and say you know, you want us to knock down
6 the silos and you want us to present a new
7 model of thinking, then I would ask the
8 external community to take steps to do the
9 same.

10 Those of you who have had the
11 pleasure of working with even the cancer
12 community would know that it can at times be
13 both highly collaborative and highly
14 fragmented and I think that a lot of the
15 problems that haven't been identified are not
16 necessarily inherent to just the NIH. They are
17 often a ramification of the external parties
18 that are involved or deal with the results of
19 NIH research.

20 And so, how do we address some of
21 those external factors which are an equal
22 impediment to many of the barriers, and I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 think that can be an opportunity with the
2 efforts that are under way here, where NIH can
3 act as a bit as a puppet-master to identify
4 those challenges and then call on the external
5 community as well as what the internal forces
6 are to try and address some of those burdens.

7 So, I know that doesn't answer
8 your question specifically but there may be a
9 role here, rather than just looking at this as
10 an NIH program and I think even with
11 perspective to the CAN initiative, that was
12 the goal.

13 There were other models that were
14 being looked at that were seen as success and
15 the thought was how can we get government to
16 spur these efforts and coordinate them in an
17 effort to accelerate them?

18 It's a tall order, but a needed
19 one.

20 MS. ANDERSON: I think it goes back
21 to the issue of sausage-making that we are
22 talking about here. I mean, the comment that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 was made previously about some of the recent
2 press coverage and what it takes to get a drug
3 to market -- it is part of the communications
4 challenge here. We need to talk about all of
5 the effort and all of the discreet pieces and
6 the people who are really toiling and at
7 personal sacrifice in terms of their
8 professional careers, to explain why it is
9 challenging to get from A to Z.

10 And, I think, that is the piece
11 that is missing. I certainly think in terms of
12 the public awareness, as I have mentioned, as
13 people are hitting the stage where they are
14 starting to get their own diagnosis of who
15 knows what, it starts to beg the question,
16 well, what is going on, why can't we fix this?

17 I think we need to do a better job
18 explaining we are not making widgets here. It
19 is not a factory. This is not necessarily
20 something that has an easy fix. However, I
21 think in terms of some of the process
22 engineering aspects, and the systems fixes,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that is something at FasterCures that we have
2 heard about since our inception, that whether
3 you are talking about autism or Alzheimer's,
4 or cancer, or diabetes, there are systems
5 problems in terms of how the money is doled
6 out, what are some of the data challenges?

7 So I think CAN, I think some of
8 the translational research programs at NIH,
9 can address those and I think, it may not be
10 particularly sexy, but you can talk about why
11 fixing that will benefit such a greater good
12 and how that plays a role in the broader, sort
13 of ecosystem.

14 I use that word ecosystem, because
15 I do think people will welcome NIH having more
16 of a voice in terms of talking about all of
17 the sectors in medical research and I think it
18 will start to chip away at the 50 percent of
19 the American public who have no idea what the
20 NIH is or what this agency is that receives
21 all this money.

22 I brought with me a report that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 FasterCures did a number of years ago. It's
2 called Entrepreneurs for Cures. This focuses
3 on the venture philanthropy sector, which gets
4 a lot of media attention because these are
5 organizations that through patient power and
6 passion have said we are going to collect
7 money, we are going to dole out research
8 dollars, we are going to do it our way, we are
9 going to take what works and leave behind what
10 doesn't.

11 You know, some of you would say
12 some of that is successful and some isn't. But
13 we did that report because so many of those
14 groups would go out to meet with the
15 scientific community, the funding community,
16 and everybody would say, "Well why would you
17 give you a dollar? NIH is taking care of that
18 problem."

19 And so, many of these groups were
20 born because they realized, well, NIH can't
21 deal with the entire problem. And so, I think
22 it's part of talking about successes and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 failures and how you have to have some
2 failures to get to the successes.

3 And I go to the point of some of
4 the cancer therapies that we have now, well,
5 the people that are benefitting from those
6 today are benefitting because people
7 participated in clinical trials. So, it goes
8 back to everybody could potentially be in a
9 clinical trial at some point in our life, but
10 we have to have some basis of understanding of
11 why clinical trials matter and why you need
12 that data to get to the end point, for us to
13 consider it on that awful day when the
14 physician says you have this and would you
15 like to join us in this experiment and be part
16 of the greater good?

17 I think that there is an altruism
18 in terms of the American public and the
19 patient population, but they need to
20 understand what they are hitching their wagon
21 to.

22 MS. COMSTOCK RICK: There is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 another piece, if I can, because it is of
2 personal interest to me. The conflict of
3 interests issues have come up a lot in the
4 last couple of days, and in my prior life, I
5 actually was the director of the U.S. Office
6 of Government Ethics which oversees the
7 conflict rules for the whole Executive Branch,
8 and I ran the ethics program -- the conflicts
9 program -- at the White House before that.

10 And I have to say that I think
11 these are very connected issues in terms of
12 communication and solving some of the
13 conflicts problems. It is not a good talking
14 point, and you all know that conflicts rules
15 are keeping us from cures; that is not a good
16 talking point.

17 But I wouldn't -- I am worried
18 sometimes that the conflict rules are used as
19 an explanation for why we can't go forward
20 with certain partnerships, and I have to tell
21 you, I worked in that field for 15 years.
22 Occasionally, I saw something that was

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 impossible to do, but the vast, vast majority
2 of the time, if you had a specific goal, an
3 outcome you needed, a partnership you needed,
4 it was important and you could communicate --
5 that is what we are talking about here -- why
6 it was important -- you do have to deal with
7 the lawyers -- you will get the support on the
8 Hill or you will get the support from the
9 lawyers. It can be done.

10 And I worry -- I think there are
11 opportunities with the communication to even
12 solve some of the problems we are talking
13 about. Make your plan, seek your outcomes,
14 find the partners you need to work with and
15 then if there are hurdles, we will focus on
16 those specific hurdles and you will probably
17 make point son the Hill, because you are
18 coming with a positive plan.

19 MEMBER GOLDIN: I have a --
20 someone else wanted to make a comment.

21 DR. ROWE: I was just going to
22 return to a comment that you made regarding

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 what the reaction of the R01 crew is going to
2 be as you progress with this.

3 The Foundation went through this
4 when they started doing the venture
5 philanthropy, where a significant portion of
6 the medical budget went to a, in this case, a
7 single entity, single biopharma entity,
8 instead of what normally would have been going
9 to their R01 crew.

10 And there was a significant
11 negative backlash and a lot of skepticism
12 about whether this would work at all.

13 Now, in reflecting about where we
14 are now 10 years from that, a lot of good and
15 basic science has come out of that original
16 collaboration and I think you are going to
17 experience the same thing.

18 And I don't think it has to be an
19 either/or situation and a way to communicate
20 that would be an important message -- in fact
21 if you look at what is being published by the
22 basic scientists in CF research, many are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 using the tool compounds that came out of both
2 successful and failed discovery efforts that
3 were originally funded by the foundation.

4 And the thing that the foundation
5 did to help facilitate that is to generate
6 tool compounds the have been publicly
7 available to their scientists and clearly
8 communicate which ones were going on, which
9 ones were looking promising, so that the
10 science could follow that in part.

11 MEMBER FAUCI: That is a good
12 point. Just to make a very brief comment, what
13 we have been trying to do for some time now is
14 to not, as you say, make it an us or them in
15 the sense of the developers and the
16 translators and the basic researchers, but to
17 embrace the basic research community as an
18 important part of the process, which they are,
19 an important part of the process.

20 And I think the communication, to
21 get them to understand that is something that
22 we really need to do better at. From a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 practical standpoint, it is difficult to do
2 that when you have a completely flat budget,
3 which is really functionally a cut.

4 Because if you even have a modicum
5 of an increase, you can say, we are going to
6 have an initiative in translational research
7 and we need the fundamental, basic researchers
8 to be the source of that ideas and that
9 concept.

10 But, when it looks like you are
11 taking money away from them, that is where the
12 problem is. So, we are in a particularly
13 different time now, because this is very
14 unusual. Seven years in a row of flat budgets
15 is unprecedented for the NIH. Yes.

16 DR. PACCAUD: Just -- I was
17 thinking, because of the flat budget, the
18 fixed envelope you are working with, I
19 consider and I assume that NIH has done
20 everything to be sure that it is concentrating
21 on its major mission, for which there must be
22 a clear statement about what it is supposed to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 do, and again, my ignorance is there, it's
2 clear there. I haven't read the by-laws or the
3 statement and mission and vision of the NIH.

4 Can you cut somewhere and what is
5 your capacity of actually killing part of it,
6 because maybe you are moving to some aspects
7 outside of your primary mission,
8 communications aspect as well.

9 MEMBER FAUCI: That is a very good
10 point, Jean-Pierre. We examine that
11 frequently. We have budget retreats and
12 leadership retreats and we -- this is
13 something that is right up there.

14 And we have been cutting and
15 cutting and cutting. Remember, seven years of
16 flat is three percent lost per year, when you
17 talk about fat, muscle, flesh, we are down to
18 the synovium. Yes. Okay.

19 DR. PACCAUD: But, has this been
20 really communicated in a positive way, you
21 know what I mean, in the public? Because you
22 need the support and that is probably -- I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 mean, it seems that it is only damaging the
2 collectivity, the scientists are really hurt
3 by that. The general public, do they
4 understand that, and how this is conveyed as a
5 message?

6 MEMBER FAUCI: you know, again, I
7 don't want to take much time on this, but a
8 lot of activity is put into doing that. It is
9 not easy to get the general public to
10 understand things. I mean, you know, in
11 surveys, would you be interested in this? Of
12 course. Would you be interested in this if you
13 took money away from that? No.

14 So, the general public is a big,
15 heterogenous group. Fundamentally, with all
16 due respect to them, I don't think they fully
17 understand a lot of what we are talking about.

18 MS. ANDERSON: I was just going to
19 comment though, I do think the American public
20 understands cost-cutting right now. I think
21 every one of us has probably been impacted by
22 our economic situation in this country.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, I guess as I listen to this
2 conversation, I think it -- yes this is really
3 challenging and difficult, but it is the
4 reality and I think we are going to have to
5 figure out how do you marry this basic
6 research engine that has to be sort of held
7 sacred whilst looking at NIH's other role.

8 And I think, you know, I spoke
9 yesterday to a group of university
10 representatives about CAN and the conversation
11 was really about their anxiety and we talked
12 about how we all have to hold hands together
13 on this and be anxious together, but it's not
14 going to go away. We are going to have to
15 figure out what the metrics for CAN are, what
16 the messages are.

17 As I spoke earlier, we are going
18 to have to talk constantly about it and I
19 think that is the only thing I feel like we
20 can offer, is the ability to communicate and
21 keep the lines of communication open.

22 I think we have all the faith in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the world that NIH is going to be able to
2 construct this in an effective way, but as I
3 mentioned, meeting all of these groups half
4 way will be part of the challenge and part of
5 the solution.

6 MEMBER FAUCI: Dan, do you have
7 something to say?

8 MEMBER GOLDIN: Well, I have a
9 question that I will probably ask you each to
10 email an answer in, because we are running out
11 of time and our chairman is very tough on
12 time. But, I would like to at least frame it
13 and, perhaps if the chairman was generous and
14 gave more time, we can get some responses,
15 otherwise I would like to ask you to send in a
16 response and it goes like this.

17 We have been talking for a good
18 day on this subject, maybe more, to a very
19 sophisticated audience and presenters, on a
20 very complex issue and my observation is, the
21 NIH has conundrum. On the one hand, its core
22 mission is basic research, there's passion, of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 all the people working on basic research, and
2 they have a set of expectations.

3 And, on the other hand, there is
4 the American public, 50 percent of whom don't
5 even know what the NIH is, and now what we are
6 saying we want to explain to them how you go
7 from basic research to translation research oh
8 and by the way, this is only at the beginning
9 of the pipeline. Don't have high expectations,
10 because then you have got to depend on the
11 pharmaceutical industry.

12 I believe we are giving an almost
13 mission impossible to the NIH in this
14 communication conundrum and within the
15 American public there is a segmentation that
16 goes from the highly passionate, of people who
17 have mothers, fathers, children, sisters and
18 brothers with terrible diseases, to the young
19 population that doesn't even think they are
20 ever going to get sick and die.

21 It is easy to sell Pepsi-Cola. You
22 just buy three commercials in the Super Bowl

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and then three more for Doritos so you eat
2 Doritos, you get the salt, you drink the Pepsi
3 and the thirst goes away.

4 But, I think, as we talk about
5 this communication problem, it isn't simple to
6 beat up Tony about, you know, you have got to
7 cut budgets and explain to the public. And
8 then, who do you explain it to? The members of
9 Congress? There's passion across the boards.

10 So ,what I would -- my question
11 is, and you probably can't answer at the
12 minute, is it possible for people to have
13 incredible experience in the field of
14 communication to think through this conundrum
15 and make some recommendations on how you
16 approach this incredibly difficult
17 communication problem that relates to the
18 future of how the NIH could help the American
19 public and people around the world deal with
20 problems that just give you headaches? So,
21 that is my question. Thank you.

22 CHAIR AUGUSTINE: Tony, well, a lot

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of -- let's take three minutes and somebody
2 can answer that question.

3 MS. COMSTOCK RICK: I can't answer
4 the question, but I do want to say that in my
5 work with the Parkinson's community, I am
6 often in a position to -- for NIH funding,
7 explaining CAN, funding in general and it's
8 obviously one of the things we advocate for.

9 And it is not at all uncommon for
10 someone who is new to the world of federal
11 funding for research of any kind to say to me,
12 what do I care about federal funding for NIH?
13 I have -- fill in the name of the blank,
14 whatever university -- in my community and
15 they are doing plenty. There is no
16 understanding out there that that is even
17 federal funding.

18 And that is a key position point.
19 I am not sure that we should require that your
20 R01 crew spend x number of hours a year out in
21 the community, but it is not a crazy idea. It
22 is not a crazy idea to force them to tell you,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 not in just their papers, but in their public
2 communications, where they got their money
3 from.

4 I mean there are -- it's a
5 daunting task but you always have to start
6 somewhere.

7 MEMBER FAUCI: It is true and we
8 have actually -- again, I am not trying to
9 counter anything you are saying, I am agreeing
10 with you, is that we went through something
11 and continue it up until today of making it
12 very clear to the investigators that in their
13 releases they should be very explicit.

14 It more often than not gets
15 blunted down to the footnote by the office of
16 communication of the university. That's -- it
17 is what it is. That's what happens.

18 CHAIR AUGUSTINE: Jeremy, we will
19 give you the last word. Greg.

20 MR. SIMON: So there are three guys
21 in a truck and the high pressure hose breaks
22 and they can't get where they are going unless

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 they fix it. Okay, not very interesting. But,
2 if I told you they had to fix it with just
3 what is on the truck, now it gets a little
4 more interesting. Maybe you make on to Top
5 Gear on television.

6 But, if I told you that they had
7 to fix it with what is on the truck, and by
8 the way, the truck is the Apollo 13 and they
9 are in space on the way to the moon, all of a
10 sudden, a simple plumbing problem becomes a
11 dramatic story.

12 One option that Mary Woolley
13 pointed out yesterday is to have more
14 scientists die because she said 63 percent of
15 the people can't name a living scientist. So,
16 that is a bad option. I am not for that
17 option.

18 But, the fact of the matter is the
19 reason this country is so obsessed with movies
20 is because stories are reality to people. Dr.
21 Fauci, your story, you have saved lives of
22 individuals, some of whom are in this room.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 The people who developed the drug
2 Selzentry gave a talk at the pharma meeting
3 last year. It was unbelievable. There are
4 stories all over NIH of individual dramas that
5 start with something as simple as I wonder
6 this doesn't work in children with this gene.

7 We have got to get this out as a
8 story, not as a journal article, not as a New
9 York Times article. The New York Times is in
10 the snapshot business and anybody on any given
11 day can look bad if all you took is a
12 snapshot.

13 You are in the movie business. You
14 are talking about movies that take 20 years to
15 run, and we have got to approach it that way
16 and we have got to talk about it that way.

17 When I tell people specific
18 stories of how things got done in medicine,
19 they love it. But, that is not how we talk
20 about it, and that is what we have got to do.

21 CHAIR AUGUSTINE: That is a
22 terrific point to wrap up on. And, on behalf

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of the whole SMRB, let me thank each of our
2 panelists, Tony thank you for taking the lead
3 on this. We are now at the point we can break
4 for lunch. There is food in the adjacent room
5 for the panel members and for the SMRB
6 members. Our guests, there is a cafeteria
7 down, I think, on the first floor. We will
8 meet back here at 12:15 promptly. We have got
9 a big afternoon, so please, everybody,
10 particularly the members, be sure to get back.

11 (Whereupon the above-entitled
12 matter went off the record at 11:34 a.m. and
13 went back on the record at 12:16 p.m.)

14
15
16
17
18
19
20
21
22

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 12:16 p.m.

3 CHAIR AUGUSTINE: We can begin the
4 final session. This is an extremely important
5 topic obviously. We have set aside about two
6 hours for the discussion, including public
7 comments, and Bill, as chair of the SUAA
8 Working Group, is going to make a presentation
9 on behalf of that group. Then we will have, I
10 hope, ample opportunity to discuss it.

11 At the end of the day, we are, I
12 think, obliged to make a formal recommendation
13 to Francis and as you all have heard
14 yesterday, when we do make such a
15 recommendation, it triggers a whole bunch of
16 actions on his part and that of the institute
17 and so this is important. Bill, it's yours.

18 MEMBER ROPER: Thank you. Thank
19 you, Norm. Before I begin, I want to thank the
20 members of our working group and especially
21 the staff, Amy and Lyric and others who have
22 worked tirelessly on our collective behalf. I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 think we have had a thoughtful discussion and
2 respectful dialogue over the year and a half
3 that we have been working on this project and
4 I am pleased to report to you.

5 Our charge as a working group made
6 a year and a half ago was to recommend whether
7 organizational change here at the NIH could
8 further research into substance use, abuse and
9 addiction and to improve the public's health.

10 These are the members of the
11 working group. I thank each of you for your
12 hard work and dedication and here is what we
13 have done. Some of this -- in fact much of
14 this -- you have already heard so I am going
15 to be relatively brief, though if you would
16 wish, I can elaborate or others can as well.

17 Over the last 15 months, 17
18 months, the working group has held 12
19 teleconferences and three in-person meetings
20 and they have heard from a wide array of
21 people, some here at the NIH, NIAAA, and NIDA,
22 but also people from across the addiction and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 alcohol communities and lots of people who
2 have given us lots to think about and discuss
3 in our report.

4 First, I would like to summarize
5 our major findings. Emerging scientific
6 research indicates that there are similar
7 reward pathways that underlie compulsive
8 behavior, many substances that pose the
9 potential for abuse may have similar effects
10 on the brain.

11 There are common genetic sites
12 associated with risks of disorders related to
13 abuse, and addiction is a developmental
14 disease, particularly beginning within
15 adolescence and that causes some special
16 issues.

17 Many substance abusers suffer from
18 multiple drug dependencies or comorbidities
19 and, in addition to these general perspectives
20 that I share, we asked both the NIAAA and NIDA
21 to identify some high priority areas where the
22 current scientific work is not addressing the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 things appropriately.

2 And this is the perspective that
3 we got from colleagues at NIAAA. That is, that
4 there is a need for greater understanding of
5 the pharmacokinetic and pharmacodynamic
6 interactions between alcohol and commonly-used
7 therapeutics for other conditions, that there
8 is research needed on the novel metabolites
9 generated as a result of interactions between
10 alcohol and illicit drugs, that we need more
11 information on the mechanisms by which alcohol
12 increases the risks for certain cancers, and
13 regarding the public's health, more is needed
14 to know how to encourage patients to seek
15 treatment.

16 From NIDA, we heard that there is
17 a lack of pharmaceutical industry interest in
18 developing therapies to treat addiction, that
19 there is insufficient involvement of the
20 medical community in preventing and treating
21 addiction and alcoholism, that there are
22 treatments that are available that are not

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 being widely used and that there is, like we
2 have demonstrated the last day and a half,
3 challenges in translation of these research
4 results.

5 The text on this slide is brief,
6 but make no mistake, we heard from a broad
7 range of stakeholders on the question of the
8 optimal organizational structure for NIDA and
9 NIAAA.

10 People have made compelling
11 arguments and provided a wealth of information
12 and evidence on these issues. We have heard
13 from people on both sides, if I can put it
14 that way, or maybe more properly, we have
15 heard from people all across the spectrum.

16 Briefly, we have heard primarily
17 from representatives from the drug abuse
18 research and treatment communities' arguments
19 in favor of a structural reorganization over
20 there on the left of the slide.

21 They say that there is compelling
22 evidence regarding synergies in the science,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that certain patient populations are under-
2 served, particularly patients with multiple
3 substance dependencies, and we have heard
4 perspectives on impediments to collaboration
5 and integration between the two largely
6 separate and siloed scientific communities.

7 On the other side, we have heard
8 primarily from representatives at the alcohol
9 abuse research and treatment communities.
10 These individuals have expressed a preference
11 for a non-structural approach to
12 reorganization here, which would maintain the
13 current separate institutes.

14 This approach would involve what
15 we have been referring to in our discussions
16 as a functional approach to reorganization,
17 which would involve the establishment of a
18 blueprint of sorts across the NIH for research
19 in this area.

20 Proponents of this approach have
21 cited the potential for loss of certain
22 research foci as a serious risk of structural

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 reorganization, thinking that some things
2 would not be paid attention to and might get
3 lost in a new institute.

4 They also have said there are
5 benefits to having multiple perspectives
6 brought to bear on common scientific questions
7 and having this addiction work done across a
8 number of institutes is a good thing, not a
9 bad thing.

10 We also heard examples of
11 successful collaboration and other trans-NIH
12 initiatives and we also heard about the
13 relevance of the distinction between licit and
14 illicit substances in terms of public health
15 messages and the stigma attached to drugs
16 versus alcohol.

17 In our deliberations, we were
18 guided by the earlier work of Bill Brody and
19 his working group, which looked at how the NIH
20 should go about considering change, the notion
21 of assessing the need for change, evaluating
22 the options for change, and implementing and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 managing the change.

2 We have been looking at this
3 three-step process and I would like to talk
4 about these in turn. For our purposes, at step
5 one, assessing the need for change, we
6 identified five criteria: is there an
7 immediate crisis; are there unaddressed
8 scientific opportunities; have there been
9 changes in the scientific landscape that merit
10 doing something different; are there evolving
11 or emerging public health needs; is there a
12 need to improve the quality or efficiency of
13 research.

14 So, we have looked at each of
15 those and then, in step two of the process,
16 options for change, we have looked at a range
17 of possibilities.

18 Many of you have seen this slide
19 before, but it seeks to highlight looking at
20 things from as they are now, the status quo at
21 the far left, to the establishment of a
22 blueprint across institutes, somewhere in the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 middle there, beyond just NIDA and NIAAA, and
2 then closer to the right, the merger of two
3 institutes, or then finally at the far right,
4 the establishment of an entirely new institute
5 with new areas added in from the entire NIH
6 portfolio beyond just alcohol and drugs.

7 So, this is how we have gone about
8 our work, examining each of these in turn and
9 so now I want to turn first to our conclusions
10 and then to our recommendations.

11 Our first and primary conclusion,
12 which we are unanimously of the view, is that
13 the status quo is not ideal for fulfilling
14 NIH's mission and optimizing research in this
15 area. And therefore, we agree that
16 reorganization is needed in order to optimize
17 the science and the public's health.

18 Based on the criteria that I
19 mentioned a couple of slides ago, we found
20 evidence of a need for change in the status
21 quo, not an immediate crisis, but there are
22 unaddressed scientific opportunities, there

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 have been changes in the scientific landscape,
2 there are emerging public health needs and
3 there are opportunities to improve the quality
4 and efficiency of the research that is done.

5 Based on this initial conclusion
6 that the status quo is not ideal, we have
7 identified some key features which need to
8 define and characterize any reorganization.

9 First and foremost, any
10 reorganization needs to integrate addiction
11 research portfolios across all of NIH and I
12 urge you to hear that point, not just NIDA and
13 NIAAA, but addiction research across the NIH.

14 And this is broader than just drug
15 and alcohol research. It includes such other
16 substances as tobacco, but also other
17 behaviors such as gambling addiction.

18 To draw a picture of what we are
19 envisioning, we would make the point a mission
20 statement, if you will, for a new
21 organizational entity should include the
22 promotion of a unified vision for addiction

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 research, an interdisciplinary approach to
2 advancing that work, flexibility so that the
3 agency could do new areas of study, and a
4 multidisciplinary approach to the training of
5 new investigators.

6 For this to be successful, we
7 need, or the nation needs, commitment by
8 participants at all levels, include the strong
9 leadership of the NIH director and directors
10 of the NIH institutes and centers, would
11 require participation and contributions from
12 all stakeholders including internal staff and
13 extramural investigators, and the
14 reorganization must be underpinned by
15 functional integration. It can't be just a
16 change in name only, with the identification
17 and embracing of shared goals, enhanced
18 communication and collaboration, engagement on
19 the part of all the relevant parties to
20 identify, create and sustain synergies and
21 make the cultural shift that this is all calls
22 for.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, that is our conclusions, and
2 now our recommendations.

3 Many of our presentations to date
4 have included a discussion of two primary
5 options for reorganization and, in our report,
6 we characterize in some detail these two
7 options.

8 First, a new institute focusing on
9 addiction, or secondly, a trans-NIH initiative
10 on addiction. We recommend again unanimously
11 that one of these options be adopted and
12 implemented and I want to discuss in a few
13 minutes some of the strengths and weaknesses
14 of each.

15 But, I would add that we are not
16 recommending which of these two to do, but we
17 will have a conversation and I think you will
18 hear individual perspectives on one and
19 another.

20 In terms of the first option, a
21 new addiction institute. It would include
22 addiction portfolios from across the NIH, drug

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 addiction research from NIDA, alcohol from
2 NIAAA, tobacco from NCI, gambling addiction
3 from NIDA and NIMH. This is something that we
4 discussed at substantial length.

5 NIH will need to conduct an
6 agency-wide portfolio analysis to determine
7 which addiction-related programs should be
8 included in the new institute, to identify
9 then what things currently done in these two
10 institutes would have to go somewhere else,
11 because the non-addiction research activities
12 would need to go somewhere else, perhaps
13 alcohol liver disease reassigned to NIDDK, and
14 perhaps fetal alcohol spectrum disorders
15 research to NICHD for example.

16 Funding for each of these
17 portfolios should not be diminished, but
18 merely transferred to the new institute for
19 addiction research or to another institute for
20 non-addiction research.

21 Establishing this new institute
22 would require the recruitment of a new

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 director and will need people, personnel of
2 course, and we assume and recommend that staff
3 would be transferred from the existing two
4 institutes. There may be a need to hire new
5 staff to achieve the new mission. There will
6 need to be a new strategic plan of course.

7 And, given the long process for
8 identifying and appointing a new director,
9 there ought to be a transition committee to
10 oversee the process, to do the NIH-wide
11 portfolio analysis, to develop the
12 organizational structure, to establish a time-
13 line and so on.

14 The reason for laying out these
15 points is to give readers of the report and
16 listeners today a sense of what this would
17 really be like, or might well be like.

18 So, let me turn to the second
19 option, a new trans-NIH initiative on
20 addiction. Our idea is to have this modeled
21 after the two very successful NIH Blueprint
22 for Neuroscience Research of the new OppNet

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 for Behavioral and Social Science Research.

2 This initiative, we believe, would
3 need to be larger in scale and investment than
4 either of those two examples. And you see what
5 additional things would be brought into this
6 trans-NIH initiative on addiction.

7 To be successful, it would have to
8 have stable and dedicated funding. Several
9 members of the working group put forward the
10 notion of a majority of each institute's
11 addiction funds would need to be devoted to
12 this project. The Office of the Director would
13 need to contribute as well. A larger
14 investment than the blueprint means would be a
15 big deal, with staff support from the two
16 existing institutes and an evaluation plan et
17 cetera.

18 The basic organization of this
19 initiative would include a steering committee
20 with IC directors from the relative institutes
21 and perhaps some others, working groups tasked
22 with carrying out the various important

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 activities to bring this off and then manage
2 it over time.

3 Let me summarize, if I might, the
4 arguments in favor of first one and then the
5 other option. In regards to a new institute,
6 proponents of this approach find the
7 scientific evidence and the public health
8 needs compelling, so compelling as to
9 undertake this structural reorganization.

10 In their view, the scientific and
11 public health goals can't be met by the trans-
12 NIH initiative that I explained a moment ago.

13 On a related note, there is a some
14 sense that the divergence of the two
15 scientific communities is so severe, so
16 siloed, that it can only be remedied by
17 forcing them together with the establishment
18 of a new institute.

19 And finally, the new institute
20 would enable effective promotion of some high
21 priority areas. Research on polysubstance
22 abuse or understanding adolescent use, or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 promoting the public health message that
2 alcohol and drugs can have similar effects on
3 the brain and body, for example.

4 On the side of favoring the new
5 trans-NIH initiative, proponents have said
6 that the evidence of the scientific
7 opportunity and public health needs is
8 compelling, but there is a major question as
9 to whether a new institute is the best way to
10 proceed.

11 But rather, would suggest that the
12 trans-NIH initiative would be just as
13 successful and, building on these two examples
14 that I have already cited, there is evidence
15 for such trans-NIH initiatives accomplishing
16 what was sought.

17 There is also some fear that
18 establishing a new institute would create
19 research gaps, in particular in the alcohol
20 portfolio. Over the course of our
21 deliberations, we have discussed and carefully
22 considered the cost-benefit of establishing a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 new institute. Implementing that option would
2 be a significant undertaking and would require
3 considerable effort.

4 It might also cause considerable
5 disruption in the research community, at least
6 in the short term, and we are concerned that
7 the benefits of a new addiction institute are
8 outweighed by the burden of establishing it,
9 especially given that the trans-NIH initiative
10 would allow the agency to address science and
11 public health needs in much the same regard.

12 The trans-NIH initiative would be
13 inherently interdisciplinary, bringing unique
14 perspectives to the table to focus in a
15 coordinated way, we would hope, on these
16 important issues.

17 So, that is what we have spent the
18 last almost year and a half talking about and
19 discussing and I would be happy to answer any
20 questions if you would, or Norm, I think it is
21 time for the full board to discuss this.

22 CHAIR AUGUSTINE: Okay. Bill, thank

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 you and thank your group. You have all had a
2 chance to read the report, which is, as you
3 saw, very extensive. I thought it was
4 extremely well written. So we do have time for
5 some questions and Steve I see your hand
6 there.

7 MEMBER KATZ: Right. Thank you. I
8 thought your report was very well written as
9 well, without really a firm recommendation one
10 way or the other. I have two questions. The
11 first is was there a recommendation if there
12 is a functional -- if that is the
13 recommendation -- was there some time-line to
14 assess what is happening or was that just left
15 open? Was that discussed?

16 MEMBER ROPER: How long to try it,
17 you mean?

18 MEMBER KATZ: How long to try it
19 and how to evaluate what --

20 MEMBER ROPER: Yes. Yes. We did
21 talk about that at some length and, I think,
22 it's our view that it would need to be given

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 at least three years, or on that order,
2 meaning it would take a while to get it geared
3 up and then to give it a chance to prove its
4 worth, and then to the question of what are
5 the criteria by which it will be judged?

6 We talked some about that but we
7 didn't array it in great detail.

8 MEMBER KATZ: And the second
9 question Bill, is how did the group --
10 obviously you all dealt with this for a very
11 long time -- how did the group come out in
12 terms of the one or the other, or was it just
13 split down the middle?

14 MEMBER ROPER: There are eight of
15 us and, I think on a good day, we split pretty
16 well down the middle. I'd be happy for people
17 to speak on each of their own perspectives,
18 but we polled the group, I polled the group
19 many times, and there were times when it was
20 six to two, or four to four, or two to six, or
21 whatever, but we were pretty split on this.

22 I think, if I can be more

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 forthcoming to you and especially to Francis,
2 the best way I can formulate the question is
3 what I touched on in one of the slides towards
4 the end, and that is, is this the issue that
5 rises to the level of the director and your
6 time and attention and involvement? Is this
7 what you want to make one of your three or
8 four things to get done in the next year or so
9 here at the NIH?

10 Some of us, and I am just going to
11 be candid and speak just for myself, believe
12 that the answer to that is no, that given the
13 projects on your desk -- let me be clear, I am
14 speaking for myself, not for the working group
15 -- the things on your desk, I would not
16 encourage you to take on a structural
17 reorganization of merging these two
18 institutes.

19 But, there is compelling
20 information that says if it could be done,
21 good would result. It is just a question of is
22 the -- to use an overly trite expression, is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the juice worth the squeeze right now?

2 CHAIR AUGUSTINE: Let's see, I saw
3 Harold and then myself.

4 MEMBER VARMUS: Well, having sat
5 where Francis is now sitting, I don't
6 understand why you think this would take so
7 much time. There's obviously some problems to
8 work out, but from everything I have heard, it
9 sounds like the new institute is the way to go
10 and I just don't -- Francis is already doing a
11 lot of things, as are we all, and most of
12 those things that we are doing clearly are
13 much more time consuming than this ought to
14 be.

15 You have outlined a pretty good
16 plan for how to do it. We know, in general,
17 what programs are being moved around. Yes, it
18 would take a few meetings and the good will of
19 people who are involved, but it doesn't seem
20 to me that Francis' attempt to do
21 translational research and build a global
22 health agenda are going to be undermined by

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 taking on what, I think, would be an
2 important, but only moderately exertional
3 task.

4 MEMBER ROPER: Well, Harold, I just
5 would ask others from the group if they want
6 to comment. I would say that you have done a
7 very good job of describing what led many of
8 our group to say let's get on with it. It's a
9 pretty close call. I wouldn't say it is
10 overwhelming. I am going to sit down if I
11 could and then I will just join in the
12 conversation from there.

13 CHAIR AUGUSTINE: Okay. Bill?

14 MEMBER BRODY: So, Harold, I
15 approach this as a slam dunk. I mean this was
16 obvious that you would merge the two
17 institutions, without any data. And then we
18 gather the -- and I was not on the
19 subcommittee -- gathered data, but as this
20 whole thing unfolded, I think yesterday
21 somebody made the comment you can -- it's hard
22 to herd cats but you can move the food.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 But, the difficulty is --

2 MEMBER KATZ: That was Francis.

3 (Laughter.)

4 MEMBER ROPER: But, in this case,
5 you know a lot of the angst and vehemence and
6 perceptions came from the external community,
7 where you really can't move the food bowl. I
8 think, within the NIH, yes I would agree there
9 would be disruptions and dislocations, but in
10 the end, everybody will follow because the
11 budgets are there.

12 But, I was struck by the deep-
13 felt, deeply-held feelings of the alcohol
14 community that this would be a horrific
15 mistake and so where I would come down on this
16 is to give this a chance to do the functional
17 integration, you know, perfect is the enemy of
18 the good, but that might be a better way to
19 approach.

20 Meanwhile, also to give the
21 external community some reassurance that life
22 will go on in this transition and then if it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 works great, if it doesn't then you can take
2 the nuclear option.

3 MEMBER ROPER: Can I make one other
4 point that I should have made earlier to
5 Harold's good point? Again, speaking just for
6 myself, if this were to be taken on, and there
7 is an argument and you have done a good job of
8 making it, I think that argument is much more
9 far-reaching than just merging these two
10 institutes. I believe you earlier made this
11 point.

12 But, I would go from 30 to 10
13 institutes and, you know, really have at it
14 and make some significant change.

15 CHAIR AUGUSTINE: Go ahead.

16 MEMBER VARMUS: Ten years ago, I
17 did make an argument for six institutes and I
18 would be happy to make that argument again,
19 but that is not on the table today. I think,
20 what was the result of the furor that I caused
21 by making this drastic, but I think actually
22 quite reasonable suggestion, was to try some

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 things that looked like low-hanging fruit,
2 things that really made sense, could be
3 rationalized scientifically, and would really
4 improve things.

5 There will be resistance to that,
6 because what is at stake in the minds of some
7 is whether I am still going to get my grants,
8 whether the money will still be there for my
9 programs and this is a place where a group
10 like this needs to exercise leadership and
11 judgment and obviously there is going to be
12 anxiety about making any change that might
13 affect whether individuals have the programs
14 and access to funds that they want to have.

15 And, I think, the group has done a
16 good job of identifying the sources of those
17 anxieties, saying these programs to have the
18 support that they need -- institutes,
19 including mine, would probably see some cost-
20 shifting if we created a new institution.
21 Frankly, we are prepared to do that. I think
22 it sounds like the right thing and I think

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 just to say, you know, I understand what Bill
2 is feeling, because when I offered my
3 proposals 10 years ago there were a lot of
4 people shooting at me, and you know, nobody
5 likes to be shot at.

6 But, I can just tell you from my
7 experience as director in trying to establish
8 collaborative inter-institute programs that
9 depended upon good will and these things have
10 a limited lifetime that there is no assurance
11 -- they may have vulnerabilities of their own.
12 I am not sure the functional test that we are
13 talking about, having a trans-NIH addiction
14 initiative, would actually tell you whether it
15 would be better to go ahead and make a new
16 institute.

17 I am not sure it's the right test
18 and that could fail for reasons that I don't
19 know what the metric is for judging whether
20 this is satisfactory. It might fail. Is that a
21 reason to have the new institute? Possibly
22 not. I don't know how you would evaluate what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 these functional Band-Aids would do. I think
2 they are very much less than half-way measures
3 to doing what ought to be done.

4 CHAIR AUGUSTINE: Tom and then me.

5 MEMBER KELLY: You know, I thought
6 the report was really extraordinarily well
7 done and made a very compelling case on the
8 basis of the science, at least that the
9 creation of a new institute would probably be
10 the best route.

11 And I guess it is not completely
12 clear to me that there is a huge delta in
13 terms of effort of going down one route versus
14 the other.

15 I mean, if we are truly going to
16 have a -- fix this, some kind of a trans-NIH
17 initiative that is going to be truly effective
18 and actually get the scientific synergies we
19 want, that is going to take an enormous effort
20 as well, especially given the resistance that
21 is apparent here.

22 I think it is probably unlikely

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that going the second route will really
2 achieve the results that the committee wants
3 to achieve, which is to really change how
4 addiction research is organized and functions
5 in NIH and so, I view it as really sort of
6 postponing the decision for a merger, which is
7 probably the best outcome, then perhaps we
8 should not do that.

9 CHAIR AUGUSTINE: Thank you Tom. I
10 had two questions Bill for you. The first one
11 is that all of the members of your group, you
12 indicated, felt the status quo was not the
13 appropriate circumstance, but there was a
14 split between option one and option two.

15 Were there those who believed that
16 the option that they didn't prefer just wasn't
17 workable, or was it strictly a matter of
18 believing that they had one option they
19 thought would be better than the other?

20 That's my first question and well
21 why don't you take that and I have got one
22 other to follow on.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER ROPER: Since most of them
2 are here, I would prefer them speak for
3 themselves and I meant and should have asked
4 them to do that in general about whether I
5 fairly summarized the group, so maybe I would
6 just invite them to answer your question.

7 CHAIR AUGUSTINE: Fine.

8 MEMBER ZOGHBI: I will be happy to
9 start. I think, I just want to reiterate that
10 the reasons to merge the two institutes are
11 scientifically driven, public health driven,
12 objectively driven. Most of the arguments we
13 felt against -- we heard against, really rest
14 on two issues: one issue that alcohol is not a
15 drug. We don't want the stigma.

16 And the truth is, in teenagers and
17 adolescents, alcohol is illegal and it is a
18 drug and this is the double message we send to
19 the youth, so at least for someone really
20 thinking about it from public health, if you
21 are really going to educate youth that alcohol
22 is bad, you have to put it in the same

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 category.

2 For its age group, it is just as
3 bad for the brain. And then, there are all the
4 scientific reasons. They are well delineated
5 in the report.

6 The second big reason was a fear
7 that alcohol has so many other effects on
8 health and other organs, that those would be
9 lost by a merged institute and the truth of
10 the matter, the science will be better on a
11 brain or fetal alcohol syndrome or a
12 developmental disorder section of child health
13 or in liver disease or whatever disease, the
14 effect of cancer, all these will be much more
15 really dealt with deeply, in a more integrated
16 way, if they belong in another institute where
17 that institute has rigorous science going on.

18 So, to me, the two major sort of
19 arguments for the non-merger, I think, the
20 reasons are not there. And last, but not
21 least, to do a real successful trans-NIH
22 initiative, that means the majority of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 addiction money in any one institute, which
2 means a large sum of the alcohol institute
3 money, over 50 percent or more of their
4 budget, if you look how much of their budget
5 is addiction, has to go to that trans-NIH
6 initiatives.

7 And that is really structurally
8 quite a challenge to now start moving them
9 from their very institute, so it is much
10 cleaner and simpler, as Harold just stated, to
11 merge the two institutes. So. this was my
12 rationale, why I preferred the merged
13 institute option.

14 CHAIR AUGUSTINE: Richard.

15 MEMBER HODES: As I recall, the
16 evolution, we went from six to two, to five to
17 three, to four to four, probably, not to give
18 the impression that we were vacillating a lot
19 --

20 MEMBER VARMUS: Six-two for the
21 merger?

22 MEMBER HODES: No. It started as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 only two for the merger and six were
2 functional, so I guess self confessional is
3 permitted. I was one of the six who thought
4 that frankly, if this was being -- that simply
5 the merger of these two institutes was in the
6 context of addiction a half measure. If it was
7 a convenient way to start down the line, but
8 look -- pardon the rephrasing here -- but the
9 low-hanging fruit, you know, I was not
10 impressed that that was high motive.

11 So actually, a couple of us raised
12 the question about taking this more broadly.
13 If this was seriously being science-based, and
14 we look at addiction across all of NIH, didn't
15 we agree that this was really the goal? Once
16 we got there, to me it was no longer a half
17 measure and I also became concerned about how
18 the functional measure would work now across
19 so many institutes.

20 So, I am a big fan and participant
21 in the neuroscience blueprint. Nonetheless,
22 there is a big difference between seeing two

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 institutes putting a substantial part of their
2 money into a functional rearrangement and now
3 seeing three, four, five.

4 So, it was a combination of seeing
5 this as a more rigorously science-based,
6 trans-NIH, rearrangement, weighed against what
7 it appeared to me would be a more challenging
8 functional solution involving components from
9 so many institutes, and that was the evolution
10 of my own thinking.

11 CHAIR AUGUSTINE: Thank you.

12 MEMBER ROPER: Can I just add a
13 point? She should be here to represent
14 herself, but Josie Briggs is a member of our
15 group and I think what Richard said was pretty
16 much Josie's views as well.

17 CHAIR AUGUSTINE: Gene?

18 MEMBER WASHINGTON: Yes. I don't
19 know where I was in the beginning, but at the
20 end I was still in the trans-NIH group and
21 principally for the reasons that Bill just
22 articulated. First Bill, you did represent, at

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 least to my view, sort of the balance in terms
2 of the discussion.

3 But, at the end for me -- and
4 Harold you are right, there is no way to do a
5 randomized clinical trial here and I felt that
6 the functional solution would work. I felt
7 like we had no evidence that the structure one
8 would work any more effectively, given what
9 was perceived as being some of the resistance
10 that it would cause, not just internally but
11 externally, and some of the disruption that it
12 might cause, and that one approach would be to
13 in fact see if this works, thinking of it in
14 an evolutionary way. And if it worked, meaning
15 that we saw that there was an improvement in
16 the science in particular, then there would be
17 no reason to take on the additional burden of
18 overcoming resistance and the disruption that
19 it might cause.

20 So, at the end I came down on the
21 side of the functional.

22 CHAIR AUGUSTINE: Steve.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER KATZ: So I am still coming
2 down, but my question to me Gene is really
3 similar to what I asked Bill and that is how
4 is that assessment going to be done? In other
5 words, if it's two years or three years, when
6 you say "improved science," how -- what is the
7 metric?

8 MEMBER TABAK: Do I have permission
9 from my boss to revert to my old role for
10 about two minutes?

11 DIRECTOR COLLINS: Permission
12 granted.

13 MEMBER TABAK: So I was --

14 MEMBER ROPER: And Larry, let me
15 just do my part to day Griff and Debbie need
16 to talk after you do. Go ahead.

17 MEMBER KATZ: Are you going to
18 address that, the metric?

19 MEMBER TABAK: Well, indeed. So
20 whilst director of NIDCR I as a member of this
21 subgroup and no longer am a member of the
22 subgroup I guess.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 The problem, Steve, is -- Huda
2 made some comments about the quality of the
3 science and I respect her as a scientist
4 enormously. But frankly, I am not prepared to
5 say that the science being conducted at AAA is
6 any better or worse than any other institute
7 at NIH.

8 And I would love to see the data
9 that proves it one way or the other. Beauty is
10 in the eye of the beholder. The angst and
11 capital that will have to be expended is not
12 really internal. You are right, Harold. You do
13 it. People squawk and whatnot, but internally
14 that is not the issue.

15 The issue is externally, and those
16 of us on the subcommittee who listened to
17 many, many, many, many, many individuals
18 describe their angst. And what was the angst
19 all about? The angst is about how many loci of
20 decision-making do you have? It is going to be
21 a person making the decision, or is it going
22 to be two people? And if it's one person

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 making the decision, the possibility exists
2 that what they hold dear and think is very,
3 very important scientifically, will go away.

4 It doesn't mean it will, but that
5 is what the angst is all about. Now, I think
6 there is a lot less angst about a functional
7 merger, because you still have the failsafe of
8 having two different people making decisions,
9 okay?

10 You may disagree with that view,
11 but that is the reality. There are still two
12 people making the decision. I think the angst
13 is less because people have observed the value
14 added by the neuroscience blueprint. No doubt
15 this would be more challenging because of the
16 magnitude, but if you are really serious about
17 merging all addictive research, then if you
18 are going to do that, then you have to put
19 NIMH on the table right now. Let's be honest.
20 Harold already indicated there's a section of
21 the NCI that would have to be put on the
22 table.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So if that is what you really want
2 to do, okay, then do that. But, let's not just
3 pick out these two things because they are
4 "low-hanging fruit."

5 Okay, last point. If we are going
6 to go back to the original three institutes, I
7 think that is a great idea.

8 MEMBER HODES: Just to clarify. The
9 two recommendations, I think, actually both
10 involved the trans-NIH all institutes
11 involved, that was not a distinction any
12 longer between the two.

13 MEMBER ROPER: Richard is right.

14 CHAIR AUGUSTINE: Let's see. I saw
15 Gene and then Griff.

16 MEMBER WASHINGTON: My thinking was
17 that whether we went with structural of
18 functional you had to come up with some metric
19 of success and my thought was that that in
20 fact would be a task, one of the first tasks
21 of whichever approach was taken. So, I don't
22 see where one is different form the other, in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the case of the structural, likewise there
2 would be some metrics and if it wasn't that,
3 there would be have to be some remedial action
4 taken.

5 And so, I don't see the
6 difference.

7 CHAIR AUGUSTINE: Griff.

8 MEMBER RODGERS: Can I just make a
9 point? The -- this has truly been sort of an
10 evolutionary effort, and certainly initially
11 with the idea of just really merging these two
12 institutes just because of its convenience and
13 the situation as existed, really -- the
14 scientific argument notwithstanding it would
15 appear more reasonable, that if you are going
16 to have a single institute for addiction
17 research, that all addiction research should
18 be on the table.

19 And I think that is how we evolved
20 and that is reflected in both of these
21 options.

22 Bill was very good -- ecumenical -

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 - during these discussions with these various
2 groups that we met with, to understand from
3 their perspective, if a merger were to occur,
4 what is your greatest angst? What would be
5 lost?

6 And correspondingly, it was to ask
7 the groups, if we don't merge, what is it you
8 feel that we would absolutely need to be done
9 in order to achieve the overall goal?

10 And I think that is the starting
11 point for what the metrics would be in terms
12 of understanding what would be needed to be
13 accomplished in two or three years, whether
14 the experiment is a success or not.

15 I think we have a lot of paper,
16 several dozen trees were killed during this
17 experiment, and I think you summarized it in
18 about 15 slides. But, we actually have a
19 number of action points that we could actually
20 start with, in terms of what are the
21 deliverables that one would likely see that
22 would be a mark of success or failure over a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 course of time, if this was done in a staged
2 fashion.

3 CHAIR AUGUSTINE: Griff, you led
4 into the second half of the question I wanted
5 to ask actually, which I was going to ask you
6 Bill, in the report you did lay out a set of
7 conditions with regard to option two, that if
8 not met would met would trigger going to the
9 director and presumably then going to option
10 one.

11 In other words, I kind of viewed
12 as option two as being a conditional move
13 where you could end up at option one. Option
14 one was just let's go with it.

15 MEMBER ROPER: Yes. I think it
16 could be undertaken in that fashion. You are
17 right. Under either of these, and I have tried
18 to say this, but I will just stress it, is
19 from Francis and the folks in OD and across
20 the institutes and centers and whatever, there
21 would really have to be a serious effort to
22 try to make this work and under either option,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 to be sure.

2 I think Dr. Powell wanted to talk,
3 Norman, if I could ask her?

4 MEMBER POWELL: Well, I think that
5 the discussion from the members of the
6 committee shows, I think the amount of work
7 and energy and really considerable thought
8 that went into this report, which I thought
9 was a wonderful report and Bill really did a
10 good job steering the committee.

11 And, I think, we all respected
12 very much each other's opinions about this. We
13 also, and I think maybe this point wasn't
14 emphasized enough, in addition to the
15 testimony that we heard over and over again,
16 we read all of the reports that have been done
17 about this question, over decades.

18 So, that this is not a new
19 question. This is a question that has been
20 before various groups and bodies for many,
21 many, many years. And, I think, we came to the
22 conclusion that the science has evolved

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 considerably over those years, so what might
2 have been a very much simpler question several
3 decades ago, was a very complex question now,
4 which really brought us to the conclusion that
5 addiction research with the real importance
6 that it has for society, is a very important
7 thing, and that the science of addiction
8 research has really progressed and that we
9 really felt something needed to be done about
10 the spectrum of addiction research, which was
11 much broader than merging two institutes, so
12 it was not a simple question anymore.

13 And we thoughtfully considered it,
14 and I think the pragmatic arguments that were
15 made were very valid and very important ones.
16 But, for myself, I think first of all, it is
17 the time to make a decision, not a staged
18 decision, but a decision, because this has
19 been going on for a long time.

20 And I don't think a functional
21 solution will work. I think small, functional
22 initiatives like the neuroscience blueprint

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 have done good things. This is a major, major
2 initiative, if it is to cross institutes
3 without a structural reorganization.

4 So, I guess, my pragmatism is that
5 it's -- for me if was time to do something
6 definitive and it was really time to do
7 something that I really thought scientifically
8 would be to the benefit of the public, rather
9 than simply tweaking around the edges.

10 CHAIR AUGUSTINE: Thank you. My
11 understanding is that Dr. Shurin is on the
12 line here. Is that correct? Not yet. She is
13 dialing. Okay.

14 All right. Let's see. Gene and
15 then Harold.

16 MEMBER WASHINGTON: No, I am done.

17 CHAIR AUGUSTINE: You are done.

18 MEMBER VARMUS: I am going to just
19 speak briefly to a really critical point that
20 Larry raised about this perception that it is
21 one person versus two people making decisions.

22 It is more than just people, it is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 also a budgetary number signed by Congress,
2 and that is reflective of there being one
3 versus two. And the argument that the decision
4 is based on this idea that more might be
5 better -- I am not saying you were making that
6 argument but that is an argument that is being
7 made -- could be applied and it has been
8 applied over the years to proliferate the
9 institutes.

10 Your institute of course is very
11 easily divided into four, maybe even more,
12 that we could have not one cancer institute.
13 We have got institutes for various types of
14 cancer. We could have an institute for mouse
15 models of cancer. That would make me very
16 happy.

17 In the appropriation process, in
18 general, despite what everybody says, things
19 more or less happen in lockstep. That means
20 you end up with institutes locked into their
21 budget priorities. I know there is occasional
22 deviations, but not too often.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 If you want to generate
2 flexibility in responding to scientific
3 opportunities and give institute directors
4 more authority to do things that Congress is
5 unlikely to do, I think there is an argument
6 to be made when the scientific basis for
7 making those decisions is appropriate, to do
8 some lumping.

9 And, I think, this is a situation
10 where there is a pretty broad agreement, even
11 by those who would like to temporize with a
12 functional solution, to the notion that this
13 is an amalgamation that would work. And my
14 view is that -- I agree entirely with what
15 Deborah said, that this is a -- we have been
16 talking about this for a dozen years and it is
17 time to do the right thing.

18 CHAIR AUGUSTINE: Dan.

19 MEMBER GOLDIN: I deeply believe
20 that it is time to do the right thing. I think
21 a creeping solution of testing and with a
22 functional and then waiting another five years

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and having another team come in and review it
2 again, would be a big mistake.

3 The science clearly is driving it
4 and in science, things change. Going back
5 always feels good. It feels comfortable. No
6 one likes change. My biggest concern about a
7 functional organization, I don't know how many
8 billion it is -- 2, 3, 4 billion dollars, that
9 is a very big organization to oversee with
10 good will.

11 We talked this morning about the
12 complexities of getting across the NIH mission
13 to the public. And, in fact, I thought I had
14 the right number. I quoted a number that 50
15 percent of the Americans don't know what the
16 NIH is or does. I was corrected at lunch and
17 told it is 85 percent.

18 Now, if we add a complexity to how
19 the NIH is going to manage itself, and it is
20 going to manage itself on good will, and it is
21 addiction that needs to be addressed, you
22 cannot address a complex issue of addiction

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 with three or four billion dollars a year
2 through good will.

3 It is a no-brainer and, from my
4 perspective, I also think of the
5 constituencies. I could be wrong but what I
6 hear is the constituency of concern are the
7 people doing the research and if that is the
8 case, I subscribe to our director's metaphor
9 about move the food. And that everyone is not
10 going to be happy, change is never
11 comfortable.

12 But, unless this organization has
13 a little backbone, and shows leadership, no
14 change is ever going to occur.

15 CHAIR AUGUSTINE: Tony.

16 MEMBER FAUCI: Norm, I just have a
17 question just to clarify the -- since I wasn't
18 involved obviously in the subgroup discussion,
19 but when we were talking about if you are
20 going to merge, that you should, apropos of
21 Larry's question, all of addiction research,
22 not just two institutes. In the institutes

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 like Mental Health I can see that they are
2 almost unable to separate addiction issues
3 from mental health issues.

4 But, in the cancer institute,
5 Harold, in the work that you are doing with
6 tobacco, is it the physiological effects of
7 tobacco and its relationship to cancer, or are
8 you actually doing addiction research?

9 MEMBER VARMUS: It is behavioral as
10 well.

11 MEMBER FAUCI: There is. Okay. So
12 there would be some impact on --

13 MEMBER VARMUS: We would look at
14 the portfolio carefully --

15 MEMBER ROPER: You would know the
16 numbers but I think the amount of addiction
17 research that you do is about the same size as
18 what the NIDA, NIAAA do.

19 MEMBER VARMUS: I should have
20 looked for numbers last night, didn't, I am
21 sorry, but it is probably a significant
22 number. Sorry.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIR AUGUSTINE: Has everyone had
2 a chance to weigh in that would like to? I
3 would like to give Francis an opportunity, or
4 Susan, are you on the line? Hello? All right.
5 Francis, would you like to make any comments?

6 DIRECTOR COLLINS: Well, I think
7 this discussion has been reflective of the
8 challenge of what initially appeared to many
9 of us as maybe one of the simplest examples of
10 the organization that you could contemplate
11 when you looked across NIH and yet, as you
12 started looking a little harder, it wasn't as
13 simple as it might have first appeared,
14 certainly reflected by the fact that the
15 advisory council of one of the institutes
16 involved, NIDA, voted unanimously in favor of
17 the structural option, whereas the advisory
18 council of the other major institute, NIAAA,
19 voted unanimously against it, which is a
20 reflection of how strong the feelings are in
21 the scientific community.

22 And again, I think there are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 certainly elements there of anxiety about what
2 happens to research funding for particular
3 grantees and that is not what we are about
4 here. We are about trying to support the best
5 science.

6 I do think in some of the other
7 meetings that were held and going along this
8 long pathway, and Bill you did a fabulous job
9 of leading this complicated story, and in a
10 very thoughtful way.

11 There certainly were consumers
12 also who had strong opinions about this and we
13 shouldn't lose sight of that, and particularly
14 groups like Mothers Against Drunk Driving who
15 --

16 They were certainly strongly in
17 the camp of wanting to have special attention
18 to alcohol. But again, I am glad to see that
19 during the course of the deliberations, the
20 structural model expanded in the way that it
21 has, because clearly if we are going to do
22 something of that sort, and claim that it is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 being driven by science, then it has to be
2 driven by science, and that means addiction,
3 which clearly touches other areas than these
4 two institutes, has to be on the table. And I
5 appreciate very much that evolutionary process
6 in your discussion, which I think makes a lot
7 more sense scientifically.

8 In terms of this sort of question
9 of cost to the Director and others around him,
10 making one choice or the other, well that
11 really shouldn't be the defining issue here. I
12 do think that a structural merger probably
13 creates more of an eruption in the shorter
14 term than what seems to be more of a
15 temporizing measure and that is a reality that
16 will need to be thought about.

17 I think this discussion around the
18 table of the broader group has been very
19 helpful, because I think to have a fresh look
20 at this from those who have not been so
21 completely embroiled in it over more than a
22 year is exactly what needed to happen.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I think the opinions put on the
2 table have been strong and well-defended. I am
3 not prepared to say what the decision from my
4 perspective ought to be, but I think you have
5 given me all that I need to reach that
6 conclusion and would intend to do so in the
7 fairly near future.

8 CHAIR AUGUSTINE: Susan, are you on
9 the line?

10 MEMBER SHURIN: Yes, I am.

11 CHAIR AUGUSTINE: Would you like to
12 make a comment? We have been going around the
13 table sort of giving everybody a chance to
14 share their views.

15 MEMBER SHURIN: Well, I think a
16 closer relationship on the science would be
17 incredibly helpful and, I think, that it is
18 really difficult to mandate any structural
19 change. It ought to be driven by the
20 scientific issues. Clearly, there is huge
21 overlap of -- so I think these are
22 institutions that have been in place for a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 significant period of time and the
2 evolutionary approach makes a lot of sense.

3 MEMBER ROPER: I was going to ask,
4 Norm, if you want to turn to -- I think
5 there's some folks in the audience who want to
6 comment.

7 CHAIR AUGUSTINE: Yes, that is what
8 I intended to do after all the members had had
9 this opportunity. Let's do that at this point
10 then.

11 MEMBER VARMUS: Could I ask a
12 procedural question. Wherever we are headed
13 with this discussion, are we going to approve
14 the report as a well-written report, or are we
15 going to take a position?

16 CHAIR AUGUSTINE: I think that is
17 up to the group. Someone needs to make a
18 motion Harold and we look forward to that.

19 MEMBER ROPER: If I may, and this
20 is going to sound like I am making light of
21 something and please don't anyone take
22 offense, but there is an old joke that says

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that somebody got up at the end of a public
2 forum and said everything that needs to be
3 said on this subject has been said, but not by
4 me. And those of you in the public who do want
5 to talk, I would just ask, if you don't think
6 I fairly reflected your point of view, please
7 tell us how we did not, but I would urge you
8 not to remake all the points that we tried to
9 make.

10 CHAIR AUGUSTINE: So we have six
11 members of the public who have signed up. I am
12 going to kind of enforce the five-minute rule
13 here, so if you will forgive me, but it is
14 appropriate the public get the last word in
15 this discussion, just as you got one of the
16 early words.

17 So, the first person is Mark
18 Goldman, the Research Society on Alcoholism.
19 There is a microphone right here.

20 DR. GOLDMAN: Okay, thank you all
21 for allowing this comment. I am President-
22 elect of the Research Society on Alcoholism.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 You should also know as well that I served for
2 three years on assignment as associate
3 director of NIAAA from 2003 to 2006. I also
4 was head before that time of the national task
5 force on college student drinking and then was
6 very involved in setting up the underage
7 drinking initiative at NIAAA.

8 All of the points that I could
9 make have been said around the table and as
10 suggested, I won't repeat them. I think it
11 should be obvious to you that RSA probably
12 still does not feel that a structural merger
13 is the right way to go.

14 But, let me address something that
15 I think maybe goes a bit beyond what you have
16 all talked about here. The report begins, very
17 early, and I actually wrote it down I think,
18 line 192, with discussion of addiction.

19 And the public health problem and
20 I can speak to this because I worked on
21 underage drinking, I worked on a lot of
22 domains in which addiction is not the issue

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 despite the huge cost to the public domain.

2 And, in fact, not only is
3 addiction not the issue, but addiction is not
4 the endpoint of the issue. There are many
5 people who will have problems in relation to
6 the kinds of substance use and other kinds of
7 things we talked about here who will never get
8 to addiction. It's just not going to happen.
9 The numbers are way higher than the number of
10 people that are ever going to be called
11 addicts.

12 So, in light of the issues that
13 have to get addressed, I think I would like to
14 broaden your scope in thinking a little bit
15 when you are talking about putting pieces
16 together for multiple institutes, that it is
17 even perhaps larger than you are talking
18 about, because it is not just addiction.

19 We are talking about developmental
20 processes that don't have anything to do with
21 addiction, but do lead to use of substances
22 and behaviors that perhaps are not because of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 substance challenges but rather because of
2 behaviors intrinsic to people, to humans.

3 They have to do with epigenetic
4 factors that are not because of the substance.
5 You touched on gambling, but there are many,
6 many others. And in fact the number seems to
7 be ever-growing.

8 What we are really talking about
9 here at the end of the day, is something that
10 falls in the domain and I realize when I use
11 this word, it is one certainly when I was in
12 NIH was a bit touchy.

13 It's behavioral dysregulation.
14 It's overdriven behavior that pops up in all
15 kinds of places. So you mentioned OppNet, one
16 player in this mix that has not been mentioned
17 is OBSSR, where we are all talking about
18 behavior, but we don't really have one of the
19 major players in the room.

20 And I think that what I would
21 encourage you to do and the reason I would
22 still support, despite everything that has

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 been said, this more temporized approach if
2 you will, is because I think the size of the
3 scientific endeavor has not yet been fully
4 handled.

5 In other words, it is a larger
6 problem than addiction and its full scope has
7 yet to be defined. All the institutes that
8 might be players in this have yet to be named
9 because of the nature of the problem that is
10 being addressed and if you want to talk about
11 science driving something, I think it is time
12 for NIH to take head-on the notion that an
13 awful lot of the cost that is still going on,
14 the burden of disease in the United States and
15 other places, has to do with behavioral
16 choices that are not yet fully understood.

17 And, I think, the science could go
18 on for some time expanding itself into what
19 that domain actually is before, perhaps, a
20 consolidation into a single entity that would
21 handle that kind of problem. Having said that,
22 thank you all.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIR AUGUSTINE: Thank you very
2 much. Tom Donaldson from the National
3 Organization on Fetal Alcohol Syndrome.

4 MR. DONALDSON: Good afternoon
5 Chairman Augustine and board members. Thank
6 you very much for the opportunity to be with
7 you. I was here in April of 2009 and expressed
8 my angst as the director of the National
9 Organization on FAS and on behalf of our
10 constituents, and concern for a potential
11 structural merger.

12 Fetal Alcohol Spectrum Disorders
13 has had sort of an intuitive home at NIAAA for
14 about 30, 35 years, and it has functioned very
15 well, at least in my field. So naturally,
16 consideration of disbanding NIAAA causes a
17 great deal of concern and worry within our
18 field.

19 It also seems to me that during
20 the deliberations, that I heard often that
21 drug and alcohol use was very common, that the
22 prevalence of individuals who used both, if

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 you use one, you use the other. The research
2 that we have looked after from NIAAA and
3 operated on, doesn't show that at all, so I am
4 concerned that that is still an open question
5 that I hope we all consider.

6 We see that most people who use
7 alcohol do not use drugs. Certainly women of
8 child-bearing age that we work most closely
9 with. I was struck in looking, in recalling
10 the last meeting, a number of people seemed to
11 say, in thinking of the process over the last
12 18 months, that they were surprised that the
13 overlap wasn't as broad in the science.

14 And I haven't heard that here
15 today, but that is something of course that we
16 have always seen and we have always believed
17 and I think sort of fits with the data from
18 NIAAA that people use alcohol, that most of
19 them don't use drugs.

20 In the report, I think that -- I
21 am pleased that Fetal Alcohol Spectrum
22 Disorders is mentioned. Right now, some of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 research is in the neuroscience and in the
2 addiction area on FASD and some of it is not.

3 So, if there is an addiction
4 entity, whether it is the structural change or
5 it is the new initiative, in my field at
6 least, there is then going to be a division.
7 So, that comfort of being able to be informed,
8 have our work informed by what NIAAA has
9 found, will certainly be affected.

10 Perhaps a small consideration, but
11 obviously in my area, of great concern. And
12 the other thing that I was struck with is from
13 the very beginning, the resistance from, yes,
14 alcohol folks in the field, the researchers,
15 patient groups, groups like mine, even
16 internally.

17 That certainly seems to still
18 exist. Hopefully, there would be good will if
19 a decision was made one way or the other, but
20 it would be a concern. So lastly, it was
21 mentioned that -- by a board member that we
22 have all have the courage to make the decision

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 today, also I hope the wisdom. Include that in
2 your deliberations. I know you will.

3 And, for what it is worth, from my
4 perspective, we are pleased and I think a
5 great credit to the board, Chairman Roper, and
6 the work group to come up with the option for
7 the trans-NIH functional change. I think that
8 could be a great credit and could be made to
9 work. Thank you very much.

10 CHAIR AUGUSTINE: Thank you very
11 much. And the next speaker is James Jorkasky
12 from the National Alliance for Eye and Vision
13 Research.

14 MR. JORKASKY: Thank you Chairman
15 Augustine. Late yesterday afternoon I was up
16 here. I guess I was the only public commenter.
17 But, I talked a little bit about the vision
18 research arena, the National Eye Institute
19 work -- by the way I am with the National
20 Alliance for Eye and Vision Research, which
21 serves as the Friends of the National Eye
22 Institute. We don't speak for the NEI. We

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 speak about its accomplishments.

2 And yesterday, I spoke about its
3 accomplishments in the translational research
4 arena, as Dr. Varmus would say, the rich
5 repertoire of patient solutions that it has
6 shown in both front of the eye or corneal
7 research, and back of the eye or retinal
8 research.

9 Well, why am I back up here again
10 talking about alcohol and drug? Simply,
11 because NAEVR maintains that the breadth of
12 what I spoke about yesterday in terms of NEI's
13 deliverables over the last 40 years, as a
14 freestanding institute, pulled out of the old
15 national institute for neurological disease
16 and blindness, would likely not have happened,
17 particularly in the non-brain arena, that is
18 related to front of the eye, eye disease and
19 vision impairment.

20 As I commented to you in May
21 earlier this year, NAEVR opposes the concept
22 of the mergers, and again, I have spoken to my

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 colleagues in the alcohol research arena, and
2 I am concerned, they are expressing similar to
3 what we have expressed in the past, that a
4 portion of the research could go away based
5 upon a merger. Thank you.

6 CHAIR AUGUSTINE: Thank you for
7 those thoughts. The next speaker is Stephanie
8 O'Malley with the Research Society on
9 Alcoholism.

10 DR. O'MALLEY: Good afternoon.
11 Thank you for this opportunity to speak with
12 you briefly today on behalf of the Research
13 Society on Alcoholism, and I think many of the
14 comments have been made already and they are
15 included in the report, which is clearly a
16 large undertaking by this committee.

17 The Research Society on Alcoholism
18 is certainly in favor of the functional
19 reorganization, and it is for scientific
20 reasons as well as reasons of meeting the
21 needs of the constituents.

22 I think that it is critical to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 know that alcohol is more than addiction. But,
2 I think the part that I would want to
3 emphasize is that there is some real value to
4 having an institute that encompasses different
5 aspects of alcohol use and addiction as well.

6 And my analogy would be, as a
7 participant in the trans-disciplinary tobacco
8 use research centers, which was a
9 collaborative venture between NCI, NIDA and
10 NIAAA, that the emphasis was on the idea that
11 you had to have depth within your own
12 discipline or your own area to be able to
13 collaborate across disciplines.

14 And if I were to think about
15 investigators at NIDDK who are working on the
16 problems of obesity or behavioral dyscontrol
17 of eating, their work would not be as good if
18 they were disconnected from the work that is
19 going on in metabolism and other areas of food
20 intake that they get through that
21 participation in that institute.

22 So with this, I really believe

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that the functional approach can address
2 research on addiction while preserving the
3 expertise and dialogue on the effects of
4 alcohol on multiple organ systems within the
5 alcohol research community and the
6 dysfunctional approach will provide greater
7 flexibility, ultimately, to approach problems
8 that come up and new opportunities.

9 So with this I would like to stop
10 and thank you very much for your attention.

11 CHAIR AUGUSTINE: And we thank you.
12 The next speaker is Lyle Dennis with the
13 AASLD.

14 MR. DENNIS: Thank you, Mr.
15 Chairman. I think I am the last speaker. Oh
16 one more, okay, so I don't get all 15 minutes.
17 It was just a thought. All right, so I will
18 take seven and a half. Mr. Chairman, my name
19 is Lyle Dennis. I am a partner at Cavarocchi
20 Ruscio and Dennis Associates and I have been
21 privileged to represent the American
22 Association for the Study of Liver Diseases

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 for the past 14 years.

2 As you know, because I have
3 testified before this group before, the AASLD
4 is the leading organization of researchers and
5 clinicians in liver disease and liver wellness
6 in the world and the members are deeply
7 involved in alcohol-related liver research.

8 The association's position
9 essentially has not changed since I first
10 spoke to you in April of 2009. We are opposed
11 to merging NIAAA and NIDA or any other action
12 that would undermine the unique portfolio of
13 life-saving liver disease research, which
14 currently is supported solely by NIAAA.

15 Members of the AASLD believe that
16 any action that is taken by the SMRB and
17 ultimately by Dr. Collins must clearly benefit
18 patients. They don't conduct research for
19 research's sake. They do it to keep healthy
20 people well and make sick people better. And
21 if merging these two institutes does not
22 specifically -- as well as the other steps

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 that may be taken -- does not specifically
2 enhance that mission, or it may even impair
3 it, then it ought not to be done.

4 There are 18 institutes, centers
5 and offices at NIH that are currently involved
6 in liver disease research. We consider that to
7 be a strength of the system, not a weakness. I
8 will make just a couple of quick points and
9 then I want to address one point that was
10 raised earlier.

11 About two million Americans suffer
12 from alcohol-related liver disease. More than
13 30,000 die from it every year. About 100
14 people a day. About the number of people in
15 this room will die today from alcohol-related
16 liver disease.

17 It is heavily -- it heavily
18 interacts with hepatitis C and hepatitis B and
19 you are going to be seeing some reports in the
20 very near future on those two subjects
21 following up on the IOM report about the
22 effects of alcohol with regard to people with

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 hepatitis B and C and in fact it is believed
2 to be a co-factor driving disease progression
3 and the risk of liver cancer even when
4 consumed in very modest amounts.

5 NIAAA is the sole source of
6 extramural NIH funding on alcohol liver
7 research, although NIDDK is -- I am going to
8 get presumptuous now and talk about NIDDK, as
9 if the director were not six feet away from me
10 -- although NIDDK's research portfolio is six
11 times larger than NIAAA's, alcohol related
12 research is only done by NIAAA. And the result
13 of that focus has led to some significant
14 scientific milestones over the years.

15 The report acknowledges these
16 points, which we have made both at the SUAA
17 and before this board, but in one section
18 suggests that the research could simply be
19 moved to NIDDK and this is where I am going to
20 get presumptuous now.

21 AASLD has some problems with that
22 notion. First, in an era in which the Office

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of Management and Budget is asking the NIH to
2 present an FY'12 budget with a five percent
3 reduction, actual dollar reduction in
4 spending, that creates a very easy place to
5 remove some money, essentially moving the
6 portfolio but not moving the money.

7 Secondly, scientists recognize
8 that a systems biology approach is essential
9 to study alcohol's interconnected effects on
10 the brain and other organs, an addiction
11 institute would certainly not be involved in
12 that type of research that involves the liver
13 but also the heart, the pancreas, the immune
14 system and others.

15 Just to summarize, AASLD would
16 urge the adoption of a functional approach to
17 addressing concerns about addiction research
18 while leaving the remaining end-organ damage
19 research in its current successful mode. If
20 you go forward with a structural merger, it
21 would be impractical then to go back to the
22 current system.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 But, if you merge certain
2 functions, you can reassess the quality of
3 that research you have discussed and for a
4 reasonable period of time, and reconsider a
5 structural merger at that time if it is
6 necessary.

7 I would just say one other very
8 quick point, because I am still under my five
9 minutes, which is on the issue of the burden
10 on the director of NIH -- I am getting
11 presumptuous again, talking about people as if
12 they are not here -- on the issue of the
13 burden, one of the differences between this
14 and some of the other burdens is that under
15 the statute, there is a 180 day congressional
16 review period, and if elements of the
17 community turn this into an issue, I am afraid
18 that we may have the director of NIH up on
19 Capitol Hill testifying before 14 additional
20 committees beyond the ones that he normally
21 has to testify before.

22 So, on that basis, I will stop and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 thank you for all the kindnesses that the
2 board and the SUAA have extended to AASLD over
3 the last six 16 months. Thank you.

4 CHAIR AUGUSTINE: Thank you for
5 sharing those views. And our last speaker is
6 Mack Mitchell form Johns Hopkins. Dr.
7 Mitchell?

8 DR. MITCHELL: Good afternoon. I
9 want to start by thanking the committee for
10 some very thoughtful deliberations that I know
11 have taken place over the last year.

12 I want to just say in introduction
13 that I have a background in alcohol research
14 having started my career in that field more
15 than 25 years ago, but my primary role today
16 is really taking care of patients.

17 I spend the vast majority of my
18 time today taking care of patients with liver
19 diseases as well as other gastrointestinal
20 diseases. And so, in that context, I do often
21 see patients who have both alcohol and
22 substance abuse issues. But, I also, as an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 internist, see a lot of patients who come to
2 me with concerns about their alcohol
3 consumption that have nothing to do with
4 concerns about addiction, or even how it might
5 have caused liver damage.

6 They really come to me seeking
7 advice about what they should do with their
8 behavior of drinking alcohol and how that
9 might really impact their risk of other
10 diseases, particularly coronary heart disease,
11 and diabetes, which are still two of the
12 primary conditions that affect the majority of
13 people here in the United States.

14 When I talk with those people and
15 I try to explain to them what the risks are of
16 their consumption or what benefits there might
17 be associated with that, I rely very heavily
18 on research that has been sponsored by the
19 NIAAA. The NIAAA over the years has taken a
20 real lead role, not only in looking at alcohol
21 and its properties of addiction, but also
22 looking at the entire spectrum of alcohol use

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and trying to assess how that impacts on
2 health and behavior.

3 And I think that is a very
4 important aspect of what the research
5 portfolio of NIAAA has offered us.

6 I also know that when I talk to
7 these people, they are really not concerned
8 entirely you know with the issue of addiction
9 although that is a very important public
10 health problem and I do think that a
11 functional reorganization that stresses
12 addiction would be a way to enhance what the
13 public knows and understands about addiction.

14 But, at the same time, I think
15 that if we were to say to the American public
16 that the NIH no longer has an institute that
17 is devoted to the study of alcohol, that would
18 be disappointing news that I would have to
19 take to my patients and also to many other
20 people in the public.

21 So, I really hope that the
22 committee will, as someone said earlier, do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the right thing and vote in favor of a
2 functional merger where we can have both our
3 cake and eat it too, in other words we can
4 have more of an emphasis on addiction, so that
5 the public really sees that as an important
6 issue.

7 But, at the same time, we do not
8 lose the benefits of what we have learned
9 about all of the other aspects of alcohol
10 consumption on health and behavior. Thank you.

11 CHAIR AUGUSTINE: Thank you very
12 much and I thank all the members of the public
13 again for sharing your views.

14 MEMBER ROPER: I just want to say
15 that on behalf of the working group, I think
16 what you have just seen the last, whatever
17 time this is, 45 minutes or an hour, is a fair
18 reflection of what our year and a half has
19 been like and I appreciate everybody's
20 respectful hearing and conversation so I turn
21 it over to you.

22 CHAIR AUGUSTINE: And I will be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 back to you, Bill, but I had a --

2 MEMBER BRODY: Just a question.
3 Procedurally, what are we going -- are we
4 going to vote on the two options to get a
5 straw poll or a real vote or --

6 CHAIR AUGUSTINE: You are about one
7 second ahead of me here. I want to ask two
8 questions of our general counsel that advises
9 us here. The first question is Dr. Shurin is
10 on the telephone and I assume that she can
11 vote. Is that correct? She left. She sent me
12 an email with her vote. Can we count that?

13 MS. MCGAREY: Oh okay, I didn't
14 realize, yes.

15 CHAIR AUGUSTINE: Can we count her
16 vote?

17 MS. MCGAREY: I believe so, yes,
18 but we have to look and see if proxies are
19 allowed. No, I agree, I think this is probably
20 advice in advance of any motion. Right.

21 CHAIR AUGUSTINE: I am just trying
22 to get the ground rules here.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. MCGAREY: Okay, I will get back
2 to you. Quickly.

3 CHAIR AUGUSTINE: Okay, we will
4 find out. The second question I had for the
5 counsel is there are two ways we can handle
6 this. One, we can get somebody to make a
7 motion and vote it up or down and then let the
8 other one go.

9 The second thing we can do is just
10 vote option 1 or option 2 without getting a
11 formal motion. The latter would be easier but
12 is that okay?

13 MS. MCGAREY: I didn't bring my
14 rules with me. In other words, you are saying
15 can you vote without a motion to consider the
16 two options?

17 CHAIR AUGUSTINE: That is what I am
18 saying.

19 MS. MCGAREY: Yes. I think you have
20 discretion to -- you are the chair.

21 MEMBER KATZ: It's voting on two
22 recommendations. Either it is going to be one

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 recommendation or the other one.

2 MS. MCGAREY: The working group --

3 MEMBER WASHINGTON: Just for the
4 record, there is a third option.

5 CHAIR AUGUSTINE: Don't vote.

6 MEMBER WASHINGTON: No. No, which
7 is where I thought, actually I thought where
8 we were, and maybe I am just -- I was not
9 clued into the discussion but I thought we
10 were saying to the board that we recommend
11 these two options for Francis to, in fact, do
12 his due diligence and further analysis and
13 make a decision.

14 CHAIR AUGUSTINE: Okay.

15 MEMBER ROPER: Gene, if I could
16 answer that, at least from my perspective, we
17 did have that conversation. You didn't dream
18 that up. But, I am inferring from body
19 language as much as anything else, that the
20 NIH leadership would like us to go ahead and
21 declare more plainly what we are in favor of.
22 So --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIR AUGUSTINE: I think we better
2 do it by the book even though it is more
3 complicated, so the Chair would welcome a
4 motion, first of all with regard to the
5 group's sentiments on whether the current
6 process needs changed. Would anyone want to
7 make that motion?

8 MEMBER ROPER: So moved.

9 CHAIR AUGUSTINE: Is there a
10 second?

11 MEMBER GOLDIN: Second.

12 CHAIR AUGUSTINE: Okay. All those
13 in favor of the motion -- is there discussion,
14 further discussion? All those in favor of the
15 motion please raise your right hand where we
16 can see it clearly.

17 (A show of hands.)

18 CHAIR AUGUSTINE: That looks like
19 it -- could you --

20 MEMBER TABAK: I can't vote because
21 I no longer have that role, so I can -- one
22 way or the other.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIR AUGUSTINE: Will you count
2 the votes? Will counsel or somebody count
3 them? It is unanimous I think. Is anybody
4 voting against? All those opposed? That is
5 unanimous. Okay, would anyone want to make
6 another motion? Harold.

7 MEMBER VARMUS: I would like to
8 move that we create a new institute of
9 addiction.

10 CHAIR AUGUSTINE: Okay. A motion
11 has been made. Is there a second?

12 MEMBER GOLDIN: Second.

13 CHAIR AUGUSTINE: All right. Is
14 there further discussion?

15 COURT REPORTER: Who seconded?

16 CHAIR AUGUSTINE: Goldin.

17 MS. MCGAREY: Can I make a
18 suggestion? Do you want to amend your motion
19 that you recommend to the director? I think
20 you said that we create --

21 CHAIR AUGUSTINE: Yes that is --

22 MS. MCGAREY: I thought I heard --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 CHAIR AUGUSTINE: Okay, it's
2 recommend is I'm sure what you --

3 MEMBER VARMUS: It's recommend.

4 CHAIR AUGUSTINE: We are not going
5 to usurp his position here today. All right.

6 MEMBER FAUCI: It was just -- it
7 has been discussed but the recommendation of
8 an institute, a merged institute, all the
9 discussion about what goes into it is a
10 different story. It is just a straightforward
11 recommendation, is that correct?

12 CHAIR AUGUSTINE: No, my assumption
13 is you are talking about option 1, basically.

14 MEMBER FAUCI: Right. Right. Create
15 a merged institute.

16 CHAIR AUGUSTINE: As described in
17 the report as option 1.

18 MEMBER KATZ: With all the
19 accoutrements. With all the accoutrements.

20 MEMBER ROPER: Which would include
21 other institutes on addiction.

22 MEMBER GOLDIN: If he words it as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 option 1, we are in business.

2 CHAIR AUGUSTINE: Right. Harold, do
3 you want to move option 1?

4 MEMBER VARMUS: Yes.

5 CHAIR AUGUSTINE: And Dan, do you
6 accept that change, or that interpretation?

7 MEMBER GOLDIN: I accept the
8 change.

9 CHAIR AUGUSTINE: Is there further
10 discussion?

11 MEMBER BERG: One thing to
12 consider, I mean, the motion that Harold made
13 on addiction I think one should leave open the
14 possibility of other descriptions such as
15 addiction -- substance use, abuse and
16 addiction.

17 MEMBER VARMUS: Yes. I didn't mean
18 to give it a title.

19 MEMBER BERG: Right. But, addiction
20 but also my suggestion that we should consider
21 also including, in light of the discussion,
22 substance use and abuse.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER VARMUS: I agree entirely
2 with that.

3 CHAIR AUGUSTINE: Is there further
4 discussion. Amy, my interpretation is that
5 Susan votes no. Am I right?

6 EXECUTIVE SECRETARY PATTERSON:
7 Yes.

8 CHAIR AUGUSTINE: Okay. Would all
9 those in favor of the motion please raise your
10 right hand so we can count it.

11 (A show of hands.)

12 Twelve. All those opposed.

13 (A show of hands.)

14 The motion carries 12-3 and let me
15 just thank everybody for your reasonableness
16 in dealing with this and the constructive
17 approach people have taken. This is obviously
18 not an easy one and it is not -- in my mind,
19 it's a close decision.

20 And Bill, I thank you again for
21 your leadership. I thank your committee for
22 its work.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 (Applause.)

2 MEMBER ROPER: I assure you, it's
3 the pay that we got that made it worthwhile.

4 (Laughter.)

5 But, on a serious note I would
6 say, again, the conversation today has fairly
7 reflected what we have heard and lived with
8 for the last year and a half and I think this
9 has been a very carefully done process. I
10 thank the whole board for that.

11 CHAIR AUGUSTINE: And I think at
12 this point, it is a question of everybody
13 getting behind and helping Francis deal with
14 this in whatever fashion you deem appropriate.

15 And I am unaware of any other
16 business to come before the group but let me
17 just go around the table quickly, if anybody
18 wants to add anything. Jeremy you want to say
19 anything? Steve?

20 MEMBER KATZ: I would just like to
21 ask, what actually happens now? Barbara said
22 something about a 180-day period, what are the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 rules for Francis here?

2 EXECUTIVE SECRETARY PATTERSON:

3 Well, actually, I will call on Ben and Barbara
4 to respond to this, but I would also just like
5 to note for the record that this is advice to
6 the NIH director. It is not a decision. So,
7 there is a whole deliberative process.

8 CHAIR AUGUSTINE: Did that answer
9 your question Steve?

10 MEMBER KATZ: No, I think --

11 MR. BUTLER: Sure. Under the
12 statute there are various reporting triggers,
13 I think it is fair to say that they are
14 somewhat convoluted in how they are drafted
15 and this will be our first time down this
16 road, so we will sit down with the report.
17 There will be a report from the board, I
18 assume, and sit down with the director in the
19 director's office and work through what steps
20 are required and what steps are permissive.

21 But, it shouldn't -- certainly
22 from our perspective, we wouldn't want the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 procedural issues to impact the board's
2 decision-making.

3 MEMBER FAUCI: Amy? Just can I ask
4 a question related to that?

5 CHAIR AUGUSTINE: Sure.

6 EXECUTIVE SECRETARY PATTERSON: I
7 just want to add that we will also prepare --
8 take the work group report, reflect the
9 meeting today and the discussion so that it
10 becomes a report of the full board so that it
11 reflects the whole process.

12 So, that is one immediate next
13 step. I'm sorry, Tony?

14 MEMBER FAUCI: I think I know the
15 answer to this, but I want to make sure it's
16 clear to me and to others. If Francis decides
17 to take the recommendation of the board, would
18 the creation of a single merged institute
19 require congressional authorization?

20 MS. MCGAREY: No, the director and
21 the Secretary of HHS have organizational
22 authorities and that includes establishing or

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 abolishing institutes, so it is at the
2 secretarial level. Congressional notification,
3 yes.

4 CHAIR AUGUSTINE: Of course it
5 might not allocate any funds, but --

6 MEMBER RODGERS: But, just to
7 follow up on that question, wouldn't it be a
8 requirement for the creation of a separate
9 board, wouldn't that require a congressional
10 action? A separate --

11 MS. MCGAREY: Advisory council?

12 MEMBER RODGERS: Advisory council.

13 MS. MCGAREY: We would have to look
14 at that.

15 EXECUTIVE SECRETARY PATTERSON: And
16 Barbara, can you just clarify, as part of the
17 Department's notification of Congress,
18 Congress has a specified time frame to come
19 back to the agency or ask questions, or when
20 is the -- when is this process stuff done?

21 MR. BUTLER: I think, Amy, that
22 what you are referring to is, if at the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 secretarial level, there is a consolidation or
2 establishment or combining of institutes,
3 there is generally a 180-day period where the
4 report would go to Congress and Congress could
5 decide to take further action or not, before
6 it becomes effective.

7 MEMBER FAUCI: Because I think it's
8 important for us to understand what might
9 happen -- so let's say Francis agrees with the
10 recommendation. The Secretary does the thing
11 the Secretary is supposed to do. Can it --
12 other than what Norman alluded to, that the
13 Congress decides not to fund it, which would
14 be unusual, does this require an official
15 congressional approval or not?

16 MEMBER ROPER: Tony, if I could
17 answer you. We explored that at some length in
18 the process and it does not. The
19 appropriations subcommittees and in the
20 appropriations committees are the two bodies
21 in Congress, who will have to take note of
22 this and alter their funding in the future.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 But it doesn't have to be approved.

2 DIRECTOR COLLINS: But nothing
3 prevents them from rejecting if they feel they
4 want to object, of course.

5 CHAIR AUGUSTINE: Steve, did that
6 take care of your question?

7 MEMBER KATZ: It did, yes.

8 CHAIR AUGUSTINE: Bill, do you want
9 to add anything at all? No comments?

10 Come back -- Gene? Harold?

11 MEMBER VARMUS: I would like to add
12 a point having to do with our discussion
13 yesterday. Glad to see the floor today take a
14 motion and make a decision. Yesterday, there
15 was, I think, unanimity of opinion about an
16 issue which we deferred to the next meeting
17 for reasons, probably reasonable reasons, that
18 Francis voiced.

19 I am concerned that the
20 translational research initiative that we are
21 discussing is a large, difficult murky one on
22 which we may not have a report for longer than

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 we would like.

2 And I am concerned about seeing
3 repeated deferral of a decision about the
4 funding of the Clinical Center and attendant
5 issues, because we don't have that other
6 report on translational science.

7 I would like to think that we have
8 some clear guidelines about -- funding the
9 clinical centers is a very important issue and
10 I would hate to see it deferred and deferred
11 while we are waiting for a translational
12 science report.

13 CHAIR AUGUSTINE: I have talked to
14 Arthur about that issue and I will do so
15 again. And if, in December, we discover it has
16 slipped, which I hope it won't, we can address
17 what we want to do.

18 MEMBER VARMUS: Okay, I just wanted
19 to make sure we had that on the record.

20 CHAIR AUGUSTINE: It's a good
21 point. Gail, do you have anything you want to
22 add?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER CASSELL: No, in fact, all
2 the impressions I have as a member of that
3 group is we have a very specific charge. We
4 have no alternative, but to be through with
5 our report by December, right, Amy? Right,
6 Francis?

7 MEMBER VARMUS: That part of it
8 seemed clear. The questions we were trying to
9 answer seemed less clear.

10 MEMBER CASSELL: Well, yes.

11 CHAIR AUGUSTINE: Griff? You have
12 anything else you want to add? Anything? Do
13 you want to add anything, Bill?

14 MEMBER ROPER: No, sir. We thank
15 you for bringing this to a conclusion.

16 CHAIR AUGUSTINE: Dan?

17 MEMBER GOLDIN: I was very
18 appreciative of what the committee did and the
19 fact that they had the courage to bring us two
20 options, I thought, was outstanding and I just
21 wanted to thank them for that.

22 CHAIR AUGUSTINE: Tony?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER FAUCI: Nothing to add.

2 CHAIR AUGUSTINE: Okay, the last
3 word Francis is all yours.

4 DIRECTOR COLLINS: Well Norm, you
5 quoted Shakespeare yesterday and I don't have
6 a quote but it does seem to me we have been
7 living through a bit of a Shakespearean play
8 here, which had a lot of early acts in terms
9 of deliberations and uncertainties about where
10 it was going to go.

11 And today, with the addiction and
12 substance use issue, I think we got to the
13 climax of this particular bit of theater. But,
14 that is Act 4 and now it seems Act 5 falls
15 back on the shoulders of the director to
16 figure out exactly how do you take that climax
17 and bring it to a conclusion that leaves
18 everybody walking out of the theater going,
19 well, that was worthwhile spending our time
20 there.

21 We shall see whether Act 5 lives
22 up to that expectation. And meanwhile, we have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 TMAT barely into Act 1 with a very short
2 rehearsal period, so it will be interesting to
3 see what happens in the next couple of months.

4 In that regard, I just want to say
5 thank you to everybody who has put their time
6 into getting us this far and whose time will
7 now be called upon in a very intense way to
8 try to get us to this decision by December, a
9 recommendation about where to go with
10 translational research.

11 Because I agree completely with
12 Harold, this can't slip and, if there is an
13 issue here about whether the charge is precise
14 enough, then we need to deal with that as well
15 and maybe try to be realistic about the level
16 of specificity that can be achieved in that
17 timetable and not get so far down into the
18 details that we drown in them.

19 And I hear the concerns about that
20 from yesterday and I know Arthur did as well.

21 And I am pretty optimistic that
22 based on the track record of this group and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 their willingness to be both wise and
2 hardworking, that we will have something
3 pretty interesting by December.

4 So and Norm, thank you again for
5 being the one who makes all of these things
6 happen by your remarkable leadership.

7 CHAIR AUGUSTINE: This is the one
8 here. Francis, thank you very much and a
9 special thanks to those who are here form the
10 public. I realize that some of these results
11 are perhaps disappointing to you. I hope you
12 realize they were reached in good faith and we
13 appreciate your interest in being here today.

14 If there is no further business to
15 come before the group, Gene.

16 MEMBER WASHINGTON: I want to
17 publicly acknowledge Amy and her colleagues.

18 (Applause.)

19 CHAIR AUGUSTINE: Everyone have a
20 safe trip. Oh, excuse me.

21 MEMBER GOLDIN: One more piece of
22 business. I would like to know what the third

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 assignment for Arthur is going to be.

2 CHAIR AUGUSTINE: Right, okay the
3 meeting is adjourned, safe trip home.

4 (Whereupon the above-entitled
5 matter adjourned for the day at 1:53 p.m.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com