

## NATIONAL BIODEFENSE SCIENCE BOARD

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## PUBLIC TELECONFERENCE

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WEDNESDAY, FEBRUARY 10, 2010

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The meeting convened telephonically at 2:00 p.m., Patricia Quinlisk, Chair, presiding.

## VOTING MEMBERS PRESENT:

PATRICIA QUINLISK, M.D., M.P.H., Chair  
STEVEN V. CANTRILL, M.D.  
ROBERTA CARLIN, M.S., J.D.  
ALBERT J. DI RIENZO  
KENNETH L. DRETCHEN, Ph.D.  
JOHN D. GRABENSTEIN, R.Ph., Ph.D.  
JAMES J. JAMES, Brigadier General (Retired),  
M.D., Dr.PH., M.H.A.  
JOHN S. PARKER, Major General (Retired), M.D.  
ANDREW T. PAVIA, M.D.  
ERIC A. ROSE, M.D.  
PATRICK J. SCANNON, M.D., Ph.D.

## EX OFFICIO MEMBERS PRESENT (or designee):

PETER EMANUEL, Ph.D., Policy Analyst, Office  
of Science and Technology Policy, Executive  
Office of the President

BRUCE GELLIN, M.D., M.P.H., Director, National Vaccine  
Program Office, Office of the Secretary, Office of  
Public Health and Science, U.S. Department of Health  
and Human Services

EX OFFICIO MEMBERS PRESENT (or designee)  
(Continued):

ROSEMARY HART, Special Counsel, Office of  
Legal Counsel, U.S. Department of Justice

CAROL D. LINDEN, Ph.D., Principal Deputy  
Director, Biomedical Advanced Research and  
Development Authority, Office of the  
Assistant Secretary for Preparedness and  
Response, U.S. Department of Health and  
Human Services

BORIS D. LUSHNIAK, M.D., M.P.H., Rear  
Admiral, Assistant Surgeon General, USPHS  
Assistant Commissioner, Office of  
Counterterrorism and Emerging Threats,  
Office of the Commissioner, Food and  
Drug Administration, U.S. Department of  
Health and Human Services

VINCENT MICHAUD, M.D., M.P.H., Director,  
Medicine of Extreme Environments, Office of  
the Chief Health and Medical Officer,  
National Aeronautics and Space  
Administration (designated by Richard  
Williams, M.D.)

COL JOHN SKVORAK, D.V.M., Ph.D., Commander,  
U.S. Army Medical Research Institute for  
Infectious Diseases, U.S. Department of  
Defense

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD  
PRESENT:

LEIGH SAWYER, D.V.M., M.P.H., CAPT,  
U.S.P.H.S., Executive Director

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

2 (2:06 p.m.)

3 ADMINISTRATIVE MATTERS

4 CALL TO ORDER AND CONFLICT OF INTEREST RULES

5 EXECUTIVE DIRECTOR SAWYER: I

6 would like to welcome all of you to the  
7 National Biodefense Science Board public  
8 teleconference. It is Wednesday, February 10,  
9 2010. And it is on this day federal  
10 government offices in the D.C. area closed due  
11 to blizzard conditions. So the staff are all  
12 calling in from remote locations, and no staff  
13 are on site. So if there are disruptions, I  
14 do apologize in advance for the inconvenience.

15 Also, we are not able to monitor  
16 the NBSB mailbox, as we generally do, during  
17 the teleconference. So any of your e-mails we  
18 will be responding to following the  
19 teleconference.

20 I am Leigh Sawyer, the Executive  
21 Director of the National Biodefense Science  
22 Board. I serve as the designated federal  
23 official for this federal advisory committee.

1                   We have convened this two-hour  
2 meeting by teleconference today due to the  
3 urgency of the request from Secretary  
4 Sebelius, Secretary of Health and Human  
5 Services, for a review of the public health  
6 medical countermeasure enterprise and the  
7 charge from the Assistant Secretary for  
8 Preparedness and Response, Dr. Lurie, to the  
9 Board.

10                   I would like to begin with a roll  
11 call of the voting members. When I call your  
12 name, please respond "Here." Patty Quinlisk?

13                   CHAIRPERSON QUINLISK: Here.

14                   EXECUTIVE DIRECTOR SAWYER: Ruth  
15 Berkelman?

16                   (No response.)

17                   EXECUTIVE DIRECTOR SAWYER: Steve  
18 Cantrill?

19                   MEMBER CANTRILL: Here.

20                   CHAIRPERSON QUINLISK: Roberta  
21 Carlin?

22                   MEMBER CARLIN: Here.

23                   EXECUTIVE DIRECTOR SAWYER: Al Di

1 Rienzo?

2 MEMBER DI RIENZO: Here.

3 EXECUTIVE DIRECTOR SAWYER: Ken

4 Dretchen?

5 MEMBER DRETCHEN: Here.

6 EXECUTIVE DIRECTOR SAWYER: John

7 Grabenstein?

8 MEMBER GRABENSTEIN: Here.

9 EXECUTIVE DIRECTOR SAWYER: Jim

10 James?

11 (No response.)

12 EXECUTIVE DIRECTOR SAWYER: Tom

13 MacVittie?

14 (No response.)

15 EXECUTIVE DIRECTOR SAWYER: John

16 Parker?

17 MEMBER PARKER: Here.

18 EXECUTIVE DIRECTOR SAWYER: Andy

19 Pavia?

20 MEMBER PAVIA: Here.

21 EXECUTIVE DIRECTOR SAWYER: Eric

22 Rose?

23 MEMBER ROSE: Here.

1 EXECUTIVE DIRECTOR SAWYER: Pat  
2 Scannon?

3 (No response.)

4 EXECUTIVE DIRECTOR SAWYER: Pat, I  
5 know you were on earlier. Okay. We'll come  
6 back to Pat. Okay.

7 I will now call the names of the  
8 ex officio members. When I call your name,  
9 please respond "Here." If you are a  
10 designated alternate ex officio, please  
11 provide your name and "ex officio" as your  
12 name is called. Daniel Fletcher?

13 (No response.)

14 EXECUTIVE DIRECTOR SAWYER: Carter  
15 Mecher?

16 (No response.)

17 EXECUTIVE DIRECTOR SAWYER: Larry  
18 Kerr?

19 (No response.)

20 EXECUTIVE DIRECTOR SAWYER:  
21 Richard Williams?

22 DR. MICHAUD: Vincent Michaud for  
23 Richard Williams.



1 EXECUTIVE DIRECTOR SAWYER: I'm  
2 sorry? Who was that?

3 DR. MICHAUD: Dr. Vince Michaud.

4 EXECUTIVE DIRECTOR SAWYER: Oh,  
5 Vince. Thank you.

6 Frank Scioli?

7 (No response.)

8 EXECUTIVE DIRECTOR SAWYER: Joe  
9 Anelli?

10 (No response.)

11 EXECUTIVE DIRECTOR SAWYER: Willie  
12 May?

13 (No response.)

14 EXECUTIVE DIRECTOR SAWYER:  
15 Colonel Skvorak?

16 (No response.)

17 EXECUTIVE DIRECTOR SAWYER:  
18 Patricia Worthington?

19 (No response.)

20 EXECUTIVE DIRECTOR SAWYER: Dan  
21 Sosin?

22 (No response.)

23 EXECUTIVE DIRECTOR SAWYER: Hugh

1 Auchincloss?

2 (No response.)

3 EXECUTIVE DIRECTOR SAWYER: Carol

4 Linden?

5 DR. LINDEN: Here.

6 EXECUTIVE DIRECTOR SAWYER: Bruce

7 Gellin?

8 (No response.)

9 EXECUTIVE DIRECTOR SAWYER: Boris

10 Lushniak?

11 DR. LUSHNIAK: Yes. I'm here.

12 EXECUTIVE DIRECTOR SAWYER: Anne

13 Berry?

14 (No response.)

15 EXECUTIVE DIRECTOR SAWYER: Susan

16 Haseltine?

17 (No response.)

18 EXECUTIVE DIRECTOR SAWYER:

19 Rosemary Hart?

20 MS. HART: Here.

21 EXECUTIVE DIRECTOR SAWYER:

22 Victoria Davey?

23 (No response.)

1 EXECUTIVE DIRECTOR SAWYER: Peter

2 Jutro?

3 (No response.)

4 EXECUTIVE DIRECTOR SAWYER:

5 Patricia Milligan?

6 (No response.)

7 EXECUTIVE DIRECTOR SAWYER: Okay.

8 Has Pat Scannon joined?

9 (No response.)

10 DR. ADIRIM: Leigh, this is Terry

11 Adirim for Diane Berry.

12 EXECUTIVE DIRECTOR SAWYER: I'm

13 sorry? What is your name?

14 DR. ADIRIM: Terry Adirim for

15 Diane Berry.

16 EXECUTIVE DIRECTOR SAWYER: Terry.

17 Oh, Terry, thank you. Sorry. I'm having a

18 hard time hearing. Thanks.

19 DR. EMANUEL: Leigh, can you show

20 that Peter Emanuel is sitting in for Dan

21 Fletcher?

22 EXECUTIVE DIRECTOR SAWYER: Yes, I

23 will. Thank you so much, Peter.

1 DR. EMANUEL: And, Leigh, Jim  
2 James is being moved to a speaker line now.  
3 He is on.

4 EXECUTIVE DIRECTOR SAWYER: Okay.  
5 Thank you.

6 Has Pat Scannon been able to be  
7 switched over? Maybe he dropped off and will  
8 be rejoining. Okay. Please let me know when  
9 Pat joins, if you would.

10 Okay. I would like to also  
11 introduce the rapporteur for the meeting is  
12 Dana Trevas. She is on the line.

13 And we also are having this  
14 meeting transcribed. So when you speak,  
15 please state your name.

16 Now, members of the public have  
17 been invited to join the call today. And we  
18 will have an opportunity to invite them to  
19 speak during the public comment period, which  
20 will be roughly 2:45 to 3:00 o'clock today.  
21 You will be given instructions by the operator  
22 as to how to indicate that you would like to  
23 speak. And a phone line will be open for you

1 in turn.

2 Of course, the voting members and  
3 the ex officio members are invited and  
4 encouraged to join in the discussions today.  
5 The NBSB is an advisory board that is governed  
6 by the Federal Advisory Committee Act.

7 The FACA is to govern the  
8 circumstances by which agencies or officers of  
9 the federal government can establish or  
10 control committees or groups to obtain advice  
11 or recommendations where one or more members  
12 of the group are not federal employees. The  
13 FACA employs several procedural requirements  
14 of federal agencies that convene advisory  
15 committees.

16 The majority of the work of the  
17 NBSB, including information gathering,  
18 drafting of reports, and the development of  
19 recommendations is being performed not by the  
20 full Board but by the working term report  
21 directly to the Board.

22 There is ethical conduct for  
23 employees of the Executive Branch. Documents

1 have been received by all Board members who as  
2 special government employees are subject to  
3 confidential laws and regulations therein.

4 Board members provide information  
5 about their personal, professional, and  
6 financial -- whoever is at the airport, please  
7 mute the phone.

8 Information will be used to assess  
9 real, potential, or apparent conflicts of  
10 interest that would compromise members'  
11 ability to be objective, giving advice during  
12 Board meetings.

13 Board members must be attentive  
14 during meetings for the possibility that an  
15 issue may arise that could appear or affect  
16 the interest in a specific way. If it  
17 happened, it would be up to the affected  
18 member to recuse himself or herself from  
19 discussion by refraining from making comments  
20 relating to the discussion.

21 So what I would like to do now is  
22 to make sure that for all of you on the phone  
23 that you have the documents that we will be

1 discussing today. We will not be able to send  
2 them out again at this time, but they are on  
3 our website.

4           You should have an agenda for the  
5 meeting today; a draft executive summary for  
6 the report that will be discussed during the  
7 first hour; the draft report from the Medical  
8 Countermeasures Markets and Sustainability  
9 Working Group of the NBSB; a speech delivered  
10 by Secretary Sebelius on December 1st at the  
11 American Medical Association Third National  
12 Congress on Health Systems Readiness; a letter  
13 from the Assistant Secretary for Preparedness  
14 Response to the Chair, NBSB requesting that  
15 the Board form a working group to explore NBSB  
16 priorities and future activities; and,  
17 finally, a letter from the Assistant Secretary  
18 to the Chair, NBSB requesting NBSB take a  
19 literature poll in the review of the public  
20 health emergency medical countermeasure  
21 enterprise.

22           Has everyone been able to hear  
23 what I have been saying?

1                   (Whereupon, there was a chorus of  
2                   yeeses.)

3                   EXECUTIVE DIRECTOR SAWYER: Okay.  
4                   Good. Okay. Good. So let's proceed on now  
5                   to the next portion of our meeting, which is  
6                   the agenda overview and goals. Patty  
7                   Quinlisk?

8                   CHAIRPERSON QUINLISK: Thank you  
9                   very much, Leigh.

10                  AGENDA OVERVIEW AND GOALS

11                  CHAIRPERSON QUINLISK: I would  
12                  first like to just start out with commending  
13                  Leigh and her staff for continuing and getting  
14                  this conference call organized, even though  
15                  they have been challenged by the weather for  
16                  the last several days. So thank you very much  
17                  for all your work trying to make sure that  
18                  this went on schedule and without any hitches.

19                  I would like to now just go  
20                  through a little bit of what is on our agenda  
21                  for today. We are going to look at the  
22                  Medical Countermeasures Markets and  
23                  Sustainability Working Group report.



1                   And at that time I will ask the  
2 two co-chairs to lead the discussion. After  
3 that, we will have public comments starting  
4 sometime around 2:45, at which time the public  
5 will be encouraged to comment.

6                   Then I anticipate that we may have  
7 a vote after the comment period on this  
8 report. Then we will be joined by Nicki  
9 Lurie, the Assistant Secretary of Preparedness  
10 and Response at HHS, to talk to us about  
11 Secretary Sebelius' call for the review of the  
12 Public Health Emergency and Medical  
13 Countermeasures Enterprise, or PHEMCE.

14                   We are going to then discuss that  
15 request, et cetera. And then that will  
16 probably take us to the wrap-up and  
17 adjournment sometime around 4:00 o'clock.

18                   I think what I would like to do  
19 now, then, is to go ahead and turn the next  
20 part of this discussion over to John  
21 Grabenstein and John Parker for discussions of  
22 the report of the Medical Countermeasures  
23 Market and Sustainability Working Group.

1 MEMBER JAMES: Patty?

2 CHAIRPERSON QUINLISK: Yes?

3 MEMBER JAMES: Yes. Dr. James  
4 here. I am sitting on an airplane and have to  
5 leave in about five or ten minutes. My  
6 question is, is there a proxy kind of setup  
7 where if a vote is needed, you can give a  
8 proxy to somebody?

9 CHAIRPERSON QUINLISK: Let me ask  
10 Leigh if she could address that for us.

11 EXECUTIVE DIRECTOR SAWYER: Jim,  
12 thank you for joining. We actually have a  
13 quorum.

14 MEMBER JAMES: Okay.

15 EXECUTIVE DIRECTOR SAWYER: So  
16 that is not necessary.

17 MEMBER JAMES: No problem.

18 EXECUTIVE DIRECTOR SAWYER: We do  
19 appreciate your vote if you can stay on the  
20 line.

21 MEMBER JAMES: So thank you.  
22 You've got a quorum. That's great. And I  
23 will catch up with you later.

1                   CHAIRPERSON QUINLISK: Okay. Jim,  
2 thank you very much for offering. And we are  
3 glad you came in, even for a few minutes.

4                   MEMBER JAMES: Okay.

5                   CHAIRPERSON QUINLISK: Thank you.

6                   I think, then again, John and --  
7 John, if I could turn it over to you?

8                   MEMBER GRABENSTEIN: Patty, thank  
9 you.

10 MEDICAL COUNTERMEASURES MARKETS &  
11 SUSTAINABILITY WORKING GROUP REPORT WITH  
12 RECOMMENDATIONS FOR INVENTORY ISSUES  
13 CONSTRAINING OR ENABLING  
14 INDUSTRIAL INVOLVEMENT WITH  
15 MEDICAL COUNTERMEASURE DEVELOPMENT

16                   MEMBER GRABENSTEIN: This is John  
17 Grabenstein. And on behalf of John Parker and  
18 myself, we would like to start by  
19 acknowledging Leigh's staff in helping us get  
20 through the last two years worth of work, two  
21 and a quarter years.

22                   David Noll at the beginning and  
23 Don Malinowski most recently have just

1 provided extraordinary service to help us to  
2 do the review and accomplish the assessment  
3 that we have.

4           What we have assembled is the  
5 longest report from the NBSB yet perhaps if  
6 you adopt it later. So it's got a good number  
7 of pages and a lot of detail and charts and  
8 graphs and writing.

9           I would like to give a broad  
10 overview of what is contained in the report  
11 and then go into the discussion with the full  
12 Board.

13           The title is a little different  
14 from the way it appears on the agenda. The  
15 title of the report is as it appears on the  
16 PDF file that posted at the website and has  
17 been distributed, "Optimizing Industrial  
18 Involvement With Medical Countermeasure  
19 Development." And the report begins with  
20 describing the need for medical  
21 countermeasures.

22           There is a table that shows in  
23 broad terms the various countermeasures being

1 developed noted by their status with regards  
2 to licensure by the FDA and by whether or not  
3 they are current stockpiled in the strategic  
4 national stockpile by the CDC.

5           We described the methods we used  
6 to develop an inventory and incentives and  
7 barriers to industrial involvement. And I  
8 should note that we have in this report also  
9 incorporated findings and analysis conducted  
10 by another workgroup, chaired by Pat Scannon  
11 and others, which was the MCM, Market and  
12 Medical Countermeasure, Research and  
13 Development Workgroup that we last heard from  
14 about a year ago at a Board meeting. So their  
15 comments and views are reflected in this  
16 report as well.

17           Then we go into eight findings of  
18 this process or -- go into the findings of the  
19 process with regard to the enterprise  
20 historical comparison to other national  
21 industrial efforts, talk about some of what  
22 has been accomplished in terms of  
23 countermeasures against radiologic and nuclear

1 threats, and then come into eight  
2 recommendations to the U.S. government.

3 There is a large appendix 1, which  
4 is inventory of issues that we have identified  
5 across several themes, regulatory,  
6 legislative, legal and others, that take up a  
7 good bit of the end of the report.

8 I think what I would like to do is  
9 stop at this point and see if there are any  
10 points of question or comments from any of the  
11 Board members or any of the folks on the  
12 speaker line and address those now.

13 MEMBER SCANNON: While we're  
14 waiting, this is Pat Scannon. I was  
15 disconnected, and I am back online.

16 EXECUTIVE DIRECTOR SAWYER: Thank  
17 you, Pat.

18 MEMBER GRABENSTEIN: Discussion or  
19 comment?

20 DISCUSSION

21 MEMBER PAVIA: John, this is Andy  
22 Pavia. I want to commend you and the working  
23 group for writing a detailed, thoughtful, and

1       extraordinarily helpful report.

2                       I just have a process question.

3       Are we ready to proceed to a vote on the  
4       report and its Executive Summary today or is  
5       the Executive Summary still a draft that might  
6       get some fine-tuning?

7                       MEMBER GRABENSTEIN:   The Executive  
8       Summary that was attached is essentially  
9       sentences or sentence fragments pretty well  
10      verbatim from the body of the text.   So it is  
11      attached, and we would be proposing to adopt  
12      it and just ask for a little bit of editorial  
13      discretion to fix some acronyms and formatting  
14      issues and the tables that we would propose to  
15      adopt this morning.

16                      MEMBER PAVIA:   The reason I ask is  
17      because the report is long and rich.   And  
18      given the audience of senior policy-makers,  
19      the Executive Summary may be much more widely  
20      read than the report itself, and it probably  
21      deserves to be really perfected because it,  
22      unfortunately, is really the base of the  
23      report.





1 editorials and it's essentially elaborating,  
2 using the content of the report to better  
3 enhance the Executive Summary, I think that  
4 should be appropriate.

5 CHAIRPERSON QUINLISK: Maybe what  
6 I can propose, John, if it is all right with  
7 you, is we will go ahead and assume that that  
8 is fine. But certainly any members of the  
9 Board who wish to preview the summary or, sort  
10 of, making some editorial comments, we will  
11 certainly allow that to happen.

12 MEMBER GRABENSTEIN: Sure. That's  
13 consistent with my understanding of other FACA  
14 committees, specifically the advisory practice  
15 of -- we certainly would not -- you know, that  
16 would be considered editorial, not changing  
17 opinions or changing recommendations.

18 CHAIRPERSON QUINLISK: Exactly.

19 MEMBER GRABENSTEIN: Good. So,  
20 Andy, if you could mention any of them, Andy,  
21 or if you wanted to send them to me, that  
22 would be great.

23 MEMBER PAVIA: Yes. I mean, the

1 primary one I think is that on bullet 1 of the  
2 findings, Federal Funding for MCM Development  
3 -- if you go on in the report to really sort  
4 of document the uncertainty of funding and the  
5 absence of consistent funding year to year  
6 hampers long-term investment.

7           And I think you just need a  
8 sentence bringing that in place because it is  
9 asking for more money as promised, but what  
10 you are really asking for is for consistent  
11 money to be guaranteed year to year, not just  
12 more. And that I think belongs in the  
13 Executive Summary.

14           MEMBER GRABENSTEIN: Perhaps I  
15 should read aloud the eight recommendations  
16 just to make sure that we have got them on the  
17 record, national industrial base, the U.S.  
18 Congress and the Executive Branch, must  
19 provide adequate assistive funding. That's a  
20 point that Andy just mentioned.

21           The U.S. government must  
22 accelerate the pace of MCM countermeasure  
23 development. The U.S. government must

1 centralize its leadership of MCM development  
2 in acquisition and optimize the distribution  
3 methods.

4 The U.S. government must  
5 demonstrate long-term commitment to industry  
6 collaborators. That passage gets into a  
7 multi-year contract. The U.S. government must  
8 create, sustain, and enhance innovative  
9 partnerships with private industry.

10 The U.S. government must expand  
11 countermeasure markets to state and local  
12 first responders and allied governments. The  
13 U.S. government must do a better job of  
14 preparing for anticipatable emergencies.

15 That's a bit of a jargony term we  
16 use to refer to some things related to  
17 pediatrics and free and emergency use  
18 authorization documents. Various departments  
19 and agencies of the U.S. government must act  
20 in concert to ensure success.

21 CHAIRPERSON QUINLISK: John, this  
22 is Patty. I have a question. In number 6,  
23 you have the term "allied governments". Maybe

1 it is just me not being in the Washington  
2 area, but I must admit I don't quite know what  
3 that means.

4 MEMBER GRABENSTEIN: I think it is  
5 -- if there's a government benefit, it -- we  
6 could adopt that, but essentially NATO and the  
7 like.

8 CHAIRPERSON QUINLISK: Ahh. To  
9 best honest, when I first read it, when you  
10 talk about state and local responders, most  
11 people when they think of first responders  
12 think of police, fire, that kind of thing.

13 And then allied governments I must  
14 admit is me sitting in state government. I  
15 was thinking state governments because first  
16 responders are usually local.

17 MEMBER GRABENSTEIN: Yes.

18 CHAIRPERSON QUINLISK: So I am  
19 wondering if we need to keep the intent of  
20 that statement but to ensure that we are  
21 trying to be all-encompassing, understanding  
22 that these countermeasures are going to be  
23 things that people are going to be dealing

1 with both at the local, county, state, and  
2 federal and international levels?

3 MEMBER GRABENSTEIN: Yes. The  
4 treaty allies comes out. If you get all the  
5 way to page 21 without falling asleep, you  
6 would know that I was talking about treaty  
7 allies, but we can bring that up in the  
8 portions that we have been talking about.

9 CHAIRPERSON QUINLISK: Well, and I  
10 think Andy's comment is very appropriate in  
11 that people are probably just going to be  
12 reading the Executive Summary. And, again, I  
13 think we just need to be as clear and succinct  
14 as possible there because people may not get  
15 to page 21.

16 MEMBER GRABENSTEIN: Thank you.

17 MEMBER PAVIA: Patty, are you  
18 suggesting an editorial change in that  
19 recommendation so that it might read something  
20 like "to include state and local governments  
21 and first responders"?

22 CHAIRPERSON QUINLISK: Something  
23 like that. I just would like the intent to be

1 clarified to truly mean what I think the  
2 intent was. We are talking about state and  
3 local first responders but then also talking  
4 about allied state government agencies as well  
5 as probably federal government agencies and,  
6 of course, you are talking about the  
7 government but then on to our international  
8 partners.

9 I just think that we don't want to  
10 make it sound like that we're being exclusive.  
11 In fact, we are trying to be inclusive to  
12 every partner that we might have to work with  
13 when dealing with these countermeasures.

14 MEMBER GRABENSTEIN: So is that  
15 sentiment all right with everyone? We'll work  
16 out the final wording, just the editorial  
17 process?

18 All right. Then other topics that  
19 anyone wants to raise?

20 MEMBER PAVIA: John, when we  
21 received a couple of public comments on the  
22 need to make more clear the need to develop  
23 pediatric countermeasures and obviously that

1 strikes, you know, close to my heart -- have  
2 you given any thought to the way to work that  
3 in or what are your thoughts?

4 MEMBER GRABENSTEIN: Yes. So  
5 distributed with the e-mail and I think also  
6 available at the website are three e-mailed  
7 comments, an e-mail string that we had  
8 received from members of the National  
9 Commission on Children and the American  
10 Academy of Pediatrics.

11 The three comments -- I will read  
12 them, actually -- point out the need, the  
13 national need, for countermeasures that have  
14 pediatric dosing and perhaps specific  
15 pediatric products.

16 At first I thought, well, we have  
17 already taken that into account in our report  
18 because it is reflected in one of the findings  
19 of recommendation number 7.

20 And I was a bit chagrined to  
21 realize that it was more a matter of it being  
22 in the document, in our edit -- I think I  
23 speak for John Parker and others as well.

1                   And so, as I was looking through  
2 this this morning, it occurred to me we could  
3 insert a sentence at each of three places that  
4 I think would make it more clear how important  
5 this is for the children of America.

6                   And also we have been planning in  
7 anticipation of the topic for the second half  
8 of today's call about the future efforts of  
9 the Board ways to address the pediatric issue  
10 more directly, such as revising table 1 just  
11 to show which of the products have a pediatric  
12 known use or a pediatric product specifically  
13 corresponding to it.

14                   If others on the Board felt well  
15 about it, I would propose that we adjust three  
16 sentences to make our pediatric thoughts a  
17 little more explicit.

18                   CHAIRPERSON QUINLISK: John, this  
19 is Patty. Do you want to go ahead and state  
20 where you had proposed to put those three  
21 sentences in and what the sentences are?

22                   MEMBER GRABENSTEIN: Sure. So in  
23 the big 33-page PDF file on what would be PDF



1 page 5, in the paragraph that begins last, I  
2 would propose that we add a new sentence after  
3 the current first sentence that reads, "The  
4 scarcity of MCMs for pediatric use is  
5 especially troubling."

6 That fits in where we are talking  
7 about the shortcoming in what the country has  
8 available to it today.

9 Then on page 7 at the top, there  
10 is a sentence that ends with "unacceptably  
11 slow." This is right at "The development is."  
12 I would propose that we add "Further, the  
13 unique needs of children for MCMs have not  
14 been worth adequate attention or effort."

15 Then you get to page 19. At the  
16 very end, -- what is it? -- the last  
17 paragraph, the first sentence, "Adding  
18 licensed CBRN medical countermeasures for both  
19 adults and children," that would be the new  
20 clause.

21 How does that strike you all?

22 CHAIRPERSON QUINLISK: This is  
23 Patty. Are there any comments on those

1 additions to the report? I guess any other  
2 comments on the report?

3 MEMBER DRETCHEN: This is Ken  
4 Dretchen. I think they're fine.

5 MEMBER CANTRILL: This is Steve  
6 Cantrill. I am fine with the report.

7 MEMBER PAVIA: It's well-done,  
8 John. Andy.

9 MEMBER CARLIN: Yes. This is  
10 Roberta. I would agree. I have to say that  
11 when I first read the public comments, I had  
12 not really given as much thought to the  
13 pediatric piece I thought it had been somehow  
14 incorporated into the lengthy report, but I  
15 then began thinking about just the whole  
16 special needs population.

17 I really don't understand the  
18 issues well enough to know if that is even  
19 appropriate to get that far in descriptive  
20 language, but definitely the pediatric piece  
21 I would support.

22 MEMBER GRABENSTEIN: Yes. We're  
23 trying to stay germane to the task we were

1 given in terms of markets and sustainability.

2 MEMBER CARLIN: Right.

3 MEMBER GRABENSTEIN: And, again,  
4 anticipating that we're going to get asked to  
5 do more, we will do more, you can look at the  
6 broad range of issues of disability.

7 But pediatrics is a special case I  
8 think in terms of the pharmaceutical  
9 development of what is the right dose, what is  
10 the right dosage form is a very unique and  
11 specific one, really, in germinating the  
12 market.

13 MEMBER PAVIA: It adds a specific  
14 set of needs to the development process  
15 without greatly increasing the size of the  
16 market or the amount of money for that  
17 particular problem.

18 EXECUTIVE DIRECTOR SAWYER: Please  
19 identify yourself.

20 MEMBER PAVIA: I'm sorry. That  
21 was Andy Pavia.

22 CHAIRPERSON QUINLISK: And this is  
23 Patty again. Given our previous discussion,

1 I would want to make sure that in the  
2 Executive Summary, again, we have some kind of  
3 specific statement in there talking about the  
4 need for attention to pediatrics.

5 MEMBER GRABENSTEIN: Yes. We'll  
6 go in and find the corresponding clause where  
7 this sentiment would fit.

8 CHAIRPERSON QUINLISK: Thank you.

9 Okay. Are there other comments or  
10 questions on the report?

11 (No response.)

12 CHAIRPERSON QUINLISK: Okay.

13 Well, hearing none, I think we can go on to  
14 the public comment period. Leigh, do you want  
15 to go ahead and have that set up?

16 EXECUTIVE DIRECTOR SAWYER: Patty,  
17 would you like me to read the comments that we  
18 have been referring to?

19 CHAIRPERSON QUINLISK: You know,  
20 that would probably be a good idea. Could you  
21 please do that first, Leigh?

22 EXECUTIVE DIRECTOR SAWYER: We  
23 will be posting these comments on our website.

1 And, as we have done in the past, they will be  
2 added to the summary of this meeting.

3 PUBLIC COMMENT

4 EXECUTIVE DIRECTOR SAWYER: I will  
5 begin with an e-mailed letter that was shared  
6 with me by Patty Quinlisk. It was to Patty  
7 Quinlisk from Mark Shriver dated February 7th.

8 "Dear Dr. Quinlisk:

9 "As a member of the Disaster  
10 Mental Health Subcommittee of the NBSB, I  
11 recently received a copy of the draft report  
12 from the NBSB regarding optimizing industrial  
13 involvement with medical countermeasure  
14 development and was glad to see that the NBSB  
15 included mention of the need to consider the  
16 unique needs of developing medical  
17 countermeasures for children, page 17 under  
18 the seventh recommendation.

19 "As a member of both the National  
20 Commission on Children and Disasters and the  
21 Disaster Preparedness Advisory Council of the  
22 American Academy of Pediatrics, I know that  
23 this has been one of the top concerns for both

1 groups.

2 "If it is possible, I think it  
3 would strengthen the report a good deal if  
4 further discussion of the unique needs of  
5 children as it relates to the unique barriers  
6 for pediatric countermeasure development would  
7 go above and beyond the financial,  
8 institutional, and regulatory barriers already  
9 present for adult countermeasures to either  
10 add a paragraph to the report to discuss them  
11 further and/or insert a citation to the  
12 reference in the interim report of the  
13 President and Congress related to release in  
14 October 2009 of the National Commission, which  
15 already includes some of the language on this  
16 topic.

17 "We had the opportunity to meet  
18 with Dr. Lurie several days ago in her office  
19 to discuss the unique needs of children as it  
20 relates to medical countermeasures and to urge  
21 ASPR and others in the federal government to  
22 devote the attention to this issue it most  
23 definitely deserves. Quite frankly, this has

1 not been received to date.

2 "I know from my participation  
3 within the meetings of the NBSB that the Board  
4 as a whole and you personally understand and  
5 appreciate the importance of the unique needs  
6 of children. I am not sure, though, that the  
7 rest of the federal government is on the same  
8 page.

9 "I have copied Mark Shriver and  
10 Chris Revere, Chair and Executive Director,  
11 respectively, of the National Commission on  
12 Children and Disasters; and Steve Krug, M.D.,  
13 and Laura Aird here in AAP staff,  
14 respectively, of the Disaster Preparedness  
15 Advisory Council of the AAP. We all stand  
16 ready to assist you and the NBSB with  
17 preparation of any language that may be added  
18 to this important report.

19 "Thanks in advance for your  
20 assistance. Sincerely, David." And that was  
21 David Schonfeld.

22 I'm sorry. This particular  
23 letter, I may have misstated that. It's from

1 David Schonfeld.

2                   And now I will read the second  
3 e-mail. This is a series of e-mails that were  
4 received. The second was to Dr. Quinlisk. "I  
5 would like to echo David's comments. The  
6 development and deployment of appropriate  
7 medical countermeasures for children is an  
8 area of great concern for the American Academy  
9 of Pediatrics. And we stand ready to assist  
10 you and the NBSB towards addressing this  
11 important issue in the report." That is from  
12 Steven Krug, the Chair of the Disaster  
13 Preparedness Advisory Council of the American  
14 Academy of Pediatrics.

15                   The last e-mail that we received  
16 was from Mark Shriver to Dr. Quinlisk, "I  
17 greatly appreciate David's request on the  
18 continuous report of Steve and the AAP. I  
19 also sincerely appreciate the ongoing support  
20 of the NBSB for the work of the Commission and  
21 vice versa.

22                   "The challenges surrounding  
23 medical countermeasures for children will not



1 be addressed unless they are called out  
2 specifically and confronted directly by the  
3 federal government. The report being  
4 developed by the NBSB presents a great  
5 opportunity to bring these challenges into the  
6 light. I hope the NBSB agrees and will  
7 augment the report to devote more attention to  
8 children.

9 "Warmly, Mark Shriver, Chair of  
10 the National Commission on Children and  
11 Disasters."

12 CHAIRPERSON QUINLISK: Thank you  
13 for reading that, Leigh. This is Patty. I  
14 will just say that I think that this  
15 reiterates the several discussions that the  
16 Board has had in the past about this issue.

17 And particularly, Andy Pavia, you  
18 brought this issue up multiple times. And I  
19 think that the Board is well-aware that this  
20 is an issue that needs to be addressed. And  
21 so we thank them for their comments on this  
22 specific report to bringing this to light  
23 again.

1                   I think that is all the comments  
2                   that we got via e-mail. Is that correct,  
3                   Leigh?

4                   EXECUTIVE DIRECTOR SAWYER: Yes,  
5                   that's correct.

6                   CHAIRPERSON QUINLISK: So I think,  
7                   then, we're ready to open it up for other  
8                   comments from the public.

9                   EXECUTIVE DIRECTOR SAWYER:  
10                  Operator, will you please queue up the public  
11                  who has questions?

12                  THE OPERATOR: At this time if you  
13                  want to ask a question, please press \*1 on  
14                  your keypad. Again, if you have a question,  
15                  please press \*1. We will pause for just a  
16                  moment to compile the Q&A roster.

17                  (Pause.)

18                  THE OPERATOR: Your first question  
19                  comes from the line of Steve Brozak.

20                  MR. BROZAK: Yes. Good afternoon.  
21                  I wear a couple of different hats. I run a  
22                  small company that does bioresearch,  
23                  specifically on pan flu. What we look to do

1 is to transfer for preclinical to clinical in  
2 terms of therapeutics.

3 I also run a bank that does  
4 biotech research. And one of the areas that  
5 we focus on specifically is the different  
6 commercial companies that do business with the  
7 government.

8 Frankly, there's a bit of a  
9 disconnect in terms of what the reputation is  
10 of doing business with the government. It's  
11 problematic at best.

12 And for those companies that know  
13 how to do business, they do get contracts for  
14 those companies that go out there. They get  
15 a bloody nose. And if they're publicly  
16 traded, that is the end of business with the  
17 government.

18 And it's one of these things where  
19 the transparency -- and I applaud your efforts  
20 as far as going out there and having these  
21 calls, but the idea is that there has to be a  
22 situation where industry, companies -- and  
23 there are stakeholders' meetings I understand

1 for different workshops.

2           There has to be a call from the  
3 CEOs that, even if it's done on paper, asking  
4 them a list of one to ten on several different  
5 issues. What are the problems that you  
6 encountered? And, frankly, anonymity would  
7 probably serve best here.

8           What are the problems that you  
9 encountered? And how do you think you could  
10 properly do a better job or see a better job  
11 being done in terms of working with the  
12 government and in addressing the most pressing  
13 issues that you have identified? How do you  
14 feel about something like that?

15           CHAIRPERSON QUINLISK: I think at  
16 this point we will hear other public comments  
17 also. Go ahead and see if there are other  
18 public comments.

19           THE OPERATOR: We do have a  
20 comment on the line of Tom Zink.

21           EXECUTIVE DIRECTOR SAWYER: I  
22 think at this point we will hear other public  
23 comments also.

1 MR. ZINK: Hello?

2 EXECUTIVE DIRECTOR SAWYER: Go  
3 ahead, Tom.

4 MR. ZINK: Thank you.

5 I'm with St. Louis University's  
6 School of Public Health. I'm Associate  
7 Professor with an adjunct status. We're  
8 working with the Institute for Biosecurity out  
9 of that school and working with a number of  
10 emergency responders, especially in our  
11 homeland security regional response system in  
12 Missouri.

13 I am also collaborating with a  
14 number of other homeland security regional  
15 response systems throughout the nation, who  
16 all are running into the same sort of problem  
17 in terms of the acquisition of vaccines  
18 because of the roadblock that is involved with  
19 the designation of vaccines is not an  
20 appropriate countermeasure and is listed as  
21 such on the standardized equipment list and  
22 the authorized equipment list.

23 I believe SEL, the standardized

1 list, is something that is managed by and  
2 adjusted accordingly by the interagency group;  
3 whereas, the authorized equipment list is  
4 something FEMA does.

5           And these lists are periodic.  
6 People can inquire as to whether or not their  
7 product can be placed on those. What we find  
8 is that the system is very slow. It does  
9 oftentimes not make much sense.

10           And it serves as a barrier to  
11 individuals of local emergency responders,  
12 state homeland security coordinators, urban  
13 area security initiative coordinators, and the  
14 like, to go for grants for vaccines or  
15 anything that is not on one of those lists  
16 because the answer is almost uniformly no.

17           There is an exception process that  
18 people go through, but that is also an  
19 unnecessary roadblock which yields  
20 inconsistencies is the best way to put it.

21           And so what I would like to convey  
22 is the word from the front line. If you could  
23 review this issue of the authorized equipment

1 list, standardized equipment list very  
2 thoroughly -- I see it is on your agenda --  
3 and make some common sense discussions  
4 relative to the fact that if we're really  
5 wanting to prepare our emergency responders at  
6 the front line for an attack -- and in some  
7 cases that is the best time to actually act  
8 in preparation -- this would clear the way if  
9 vaccines were allowed to be on that list.

10           And everyone that I have spoken to  
11 says that that would certainly help increase  
12 access to vaccines as those countermeasures  
13 could then be actually applied for grant  
14 monies, sustainability fund boosters. And I  
15 think that would then go a long way to improve  
16 adult immunization vaccination rates and  
17 coverage for the common things that they  
18 encounter every day, such as H1N1 now,  
19 hepatitis, and so forth, as well as the select  
20 bioterrorism agents, like anthrax.

21           Thank you for your time.

22           EXECUTIVE DIRECTOR SAWYER: Okay.

23           Thank you very much for your comment. Could

1 we go on to the next comment, please?

2 THE OPERATOR: Your next comment  
3 comes from the line of Michael Eichberg.

4 MR. EICHBERG: Hi. Yes. I work  
5 for a small drug development firm focused on  
6 antibacterials. We do have several projects  
7 with the government currently. So I read this  
8 report with great interest.

9 One of the questions I have is  
10 around the issue of market incentives. And  
11 there is a little bit of a disconnect, I would  
12 say, between some of what is referred to in  
13 the report as problems associated with market  
14 size and the need for government involvement  
15 and what are new incentives versus what our  
16 experience talking to the government directly  
17 has been.

18 If one looks at table 1, you'll  
19 see that antibiotics are a key aspect of the  
20 need to address a number of the agents and,  
21 therefore, our top priority, medical  
22 countermeasure.

23 Already numbers of agents are



1 stockpiled, as noted by this chart. And, in  
2 fact, most of those have been acquired and  
3 stockpiled without any investment on the part  
4 of the government in the development of those  
5 agents because there is already a commercial  
6 market for a lot of those agents. And that  
7 perception continues with some of these areas  
8 where new agents aren't included, such as  
9 tularemia or plague.

10 The government perceives in our  
11 discussions with them that there is a  
12 commercial market because of the fact many of  
13 these would be broad spectrum and, therefore,  
14 there is really no need to invest in the  
15 advanced development of these agents.

16 These types of things will kind of  
17 come to fruition on their own. And then the  
18 government can then take advantage of that  
19 once it is already introduced into the  
20 marketplace.

21 So I guess I would be interested  
22 in the nature of dual use agents, where there  
23 is an existing market, how the Board has or

1       how the group, the subgroup, working on this  
2       has considered that.

3                   CHAIRPERSON QUINLISK:   Okay.

4       Thank you very much for your comment.

5                   Let's go on to the next comment,  
6       please.

7                   THE OPERATOR:   Again, if you have  
8       any comments, please press \*1.

9                   CHAIRPERSON QUINLISK:   Okay.  It  
10       sounds like we don't have any other comments  
11       at this time.  I think, then, if I am not  
12       mistaken, that we are ready to go on and  
13       consider voting on this report.

14                   MEMBER GRABENSTEIN:   Patty?  John  
15       Grabenstein.

16                   CHAIRPERSON QUINLISK:   Yes?  Go  
17       ahead, John.

18                   MEMBER GRABENSTEIN:   Okay.  I  
19       thought I would respond just real briefly to  
20       the three commenters.

21                   To the first speaker, I didn't get  
22       your name.  We did not do a random survey of  
23       all biopharmaceutical CEOs, but we did collect

1 data in a variety of means that are discussed  
2 in the report. And the problems identified  
3 are in that inventory.

4 But if you think that there was  
5 anything but this, I would encourage you to  
6 make a submission to the website, to the NBSB  
7 website, and point out to us anything that you  
8 think.

9 I don't think we're done. I think  
10 we're going to be at this for a while yet in  
11 one form or another and look forward to  
12 hearing your e-mail comments.

13 With regard to the equipment  
14 lists, they are mentioned on pages 21 and 22  
15 in the report. And they are the heart of  
16 recommendation 6. And we would certainly  
17 encourage the government to make the market  
18 bigger by a lot of numbers used to be  
19 incorporated with.

20 And then with regard to dual use,  
21 I'll ask Andy Pavia if he wants to make a  
22 second comment after I'm finished. Dual use  
23 agent, where there's a commercial market and

1 a countermeasure market or need, is an easy  
2 case because there is the commercial market to  
3 help pull along the countermeasure  
4 development.

5 Andy, in your work with IESA, you  
6 may have a perspective on that as well.

7 MEMBER PAVIA: Yes. Well, not all  
8 commercial uses have been found to be terribly  
9 profitable. And the example, of course, is  
10 antibiotics for hospital-acquired infections,  
11 but we would like to encourage development of  
12 dual use technologies, the same issues of  
13 sustaining markets and driving research  
14 development in production for both uses. I  
15 think that is going to come out a lot more  
16 over the next months as the enterprise is  
17 reviewed.

18 MEMBER GRABENSTEIN: Thank you.

19 CHAIRPERSON QUINLISK: Okay.

20 Well, let me do one last call, then, for any  
21 other comments or discussion.

22 THE OPERATOR: We do have a  
23 comment on the line from David Gilbert.

1                   CHAIRPERSON QUINLISK: Okay. Go  
2 ahead.

3                   MR. GILBERT: David Gilbert. I'm  
4 with the Antimicrobial Availability Task Force  
5 of the IESA. Just to second the last two  
6 comments by Dr. Pavia and others, it seems  
7 that dual use, at least for antibacterial  
8 agents, is a must if the industry is going to  
9 have any substantive incentives to proceed.

10                   And then on top of that, we are  
11 really looking for some excitement at the  
12 basic level that would add not only financial  
13 incentives but intellectual incentives to meet  
14 unmet medical needs, new classes, new targets,  
15 and so forth.

16                   So it's not exactly clear to me  
17 that this report indicates the potential  
18 leadership by the National Institute of  
19 Allergy and Infectious Disease in pulling  
20 together all the various stakeholders looking  
21 for new targets and treatments for new  
22 targets.

23                   CHAIRPERSON QUINLISK: Okay.

1 Well, thank you for your comments. John, do  
2 you want to respond in any way?

3 MEMBER GRABENSTEIN: Not me.

4 CHAIRPERSON QUINLISK: Okay.

5 Well, we'll take that comment under  
6 advisement, then. And I appreciate you making  
7 it.

8 Are there any other comments?

9 (No response.)

10 CHAIRPERSON QUINLISK: Okay. Then  
11 unless I hear something else, I think I am  
12 ready to turn it over to you, Leigh, to go  
13 ahead and take the vote.

14 Let me just remind people we are  
15 going to be voting on the report from the  
16 Subcommittee on the Markets and  
17 Sustainability. And the report is the  
18 "Optimizing Industrial Involvement With  
19 Medical Countermeasure Development: The  
20 Report of the National Biodefense Science  
21 Board."

22 We have agreed that the Executive  
23 Summary, which is not quite completed at this

1 time, we are still going to vote on that given  
2 that it will basically take from the report  
3 itself the contents and try to just present it  
4 in a clear and concise way.

5 There are several minor changes  
6 that will be made to the document based on the  
7 discussion that we just had in the last hour.  
8 And we are voting on the entire report, the  
9 Executive Summary report, as well as the  
10 tables.

11 Let me just stop there and see if  
12 anybody has any other comments before we go to  
13 the vote.

14 MEMBER GRABENSTEIN: Patty, this  
15 is John. I would move to adopt the report  
16 with the modifications you just talked about  
17 with Pavia and the treat allies discussion,  
18 the pediatrics discussion, to adopt the  
19 report, then, and discharge the committee.

20 MEMBER PARKER: This is John --

21 CHAIRPERSON QUINLISK: Okay. I'm  
22 sorry? Did somebody second that?

23 MEMBER PARKER: Yes. John Parker.

1 I second it.

2 CHAIRPERSON QUINLISK: Okay.

3 Thank you, John. I think what I'll do, then,

4 I'll ask Leigh to go ahead and call the roll.

5 And if you are in agreement, say, "Yes"; if

6 not, "No."

7 Leigh, can you go ahead?

8 EXECUTIVE DIRECTOR SAWYER: Yes.

9 I'm here to do that. I just want to make sure

10 that it is clear that people heard the second

11 part of John Grabenstein's comment that this

12 would be a report out, then, of our Market

13 Sustainability Working Group.

14 VOTE ON RECOMMENDATIONS FOR INVENTORY ISSUES

15 CONSTRAINING OR ENABLING INDUSTRIAL

16 INVOLVEMENT WITH MEDICAL COUNTERMEASURE

17 DEVELOPMENT

18 EXECUTIVE DIRECTOR SAWYER: And so

19 I will begin now with a call of those who are

20 for the motion that has been seconded. Patty

21 Quinlisk?

22 CHAIRPERSON QUINLISK: I vote yes.

23 EXECUTIVE DIRECTOR SAWYER: Did



1 you say yes?

2 CHAIRPERSON QUINLISK: Yes, I did.

3 EXECUTIVE DIRECTOR SAWYER: Steve

4 Cantrill?

5 MEMBER CANTRILL: I vote yes

6 EXECUTIVE DIRECTOR SAWYER:

7 Roberta Carlin?

8 MEMBER CARLIN: Yes.

9 EXECUTIVE DIRECTOR SAWYER: Al Di

10 Rienzo?

11 MEMBER DI RIENZO: Yes.

12 EXECUTIVE DIRECTOR SAWYER: Ken

13 Dretchen?

14 MEMBER DRETCHEN: Yes.

15 EXECUTIVE DIRECTOR SAWYER: John

16 Grabenstein?

17 MEMBER GRABENSTEIN: Yes.

18 EXECUTIVE DIRECTOR SAWYER: Jim

19 James?

20 (No response.)

21 EXECUTIVE DIRECTOR SAWYER: John

22 Parker?

23 MEMBER PARKER: Yes.

1 EXECUTIVE DIRECTOR SAWYER: Andy

2 Pavia?

3 MEMBER PAVIA: Yes.

4 EXECUTIVE DIRECTOR SAWYER: Eric

5 Rose?

6 MEMBER ROSE: Yes.

7 EXECUTIVE DIRECTOR SAWYER: Pat

8 Scannon?

9 MEMBER SCANNON: Yes.

10 EXECUTIVE DIRECTOR SAWYER: And I

11 did not call Ruth Berkelman because I don't

12 think she joined. Is that true?

13 (No response.)

14 EXECUTIVE DIRECTOR SAWYER: Tom

15 MacVittie, did you join?

16 (No response.)

17 EXECUTIVE DIRECTOR SAWYER: Okay.

18 That is a quorum of the Board, and it's

19 unanimous for all of those members attending

20 today.

21 CHAIRPERSON QUINLISK: Okay. And

22 I appreciate that. I again just would like to

23 thank all the members of that working group

1 for all the work that went into this report.  
2 I think they've done a remarkable job, and we  
3 appreciate all the work.

4 And we just want to clarify that  
5 you will be putting the Executive Summary  
6 together. And that will be sent out to those  
7 members on the Board who are interested in  
8 seeing it before the sort of the final to give  
9 comments. Is that correct?

10 MEMBER GRABENSTEIN: Yes.

11 CHAIRPERSON QUINLISK: Okay. I  
12 think that concludes the discussion on the  
13 report. Is there anything else we need to do  
14 in that area, Leigh, before we go on?

15 EXECUTIVE DIRECTOR SAWYER: No.  
16 We're about ten minutes ahead of our schedule,  
17 but I am hoping that Dr. Lurie is on the line.  
18 I'm sorry. I can't see the attendees on the  
19 line at this moment. We might be able to  
20 proceed or we can wait.

21 CHAIRPERSON QUINLISK: Well, let's  
22 just --

23 EXECUTIVE DIRECTOR SAWYER: Dr.

1 Lurie is here.

2 CHAIRPERSON QUINLISK: Great.

3 Okay.

4 MEMBER PARKER: Leigh, this is  
5 John Parker. Do we want to make a comment  
6 about the endpoint of that work group at this  
7 point in the conference or is that going to be  
8 later?

9 EXECUTIVE DIRECTOR SAWYER: Well,  
10 actually, that is why I wanted to reiterate  
11 what John said. I wasn't sure it was clear in  
12 his last motion. So, John, maybe you want to  
13 restate that, John Grabenstein.

14 MEMBER GRABENSTEIN: Part of my  
15 motion was to discharge the committee, having  
16 fulfilled its work. And that is what you all  
17 just adopted. So I think we are now ready for  
18 future work.

19 EXECUTIVE DIRECTOR SAWYER: It's a  
20 good thing. So let me just clarify. We did  
21 just vote on both the report and the discharge  
22 of the working group or did we just vote on  
23 the report?

1                   CHAIRPERSON QUINLISK: John made  
2 the motion. He stated with the changes in the  
3 report and also to discharge the working  
4 group. So that is what was voted on, although  
5 I am not sure. John Parker apparently did  
6 hear that, but I think unless there is an  
7 objection that is a part of what the vote was  
8 that we just took.

9                   MEMBER PARKER: I heard that,  
10 Leigh, and that is what I seconded. But I  
11 just wondered if the discussion of what was  
12 going to happen to the workgroup was going to  
13 occur now, but I think it is going to occur  
14 later in the meeting.

15                   EXECUTIVE DIRECTOR SAWYER: Right.

16                   MEMBER PARKER: Okay.

17                   CHAIRPERSON QUINLISK: This is  
18 Patty. There are two pieces here. Let me,  
19 one, just see, is everybody in agreement that  
20 what we voted on was the two pieces, accepting  
21 the report and discharging the working group,  
22 the Markets and Sustainability Working Group.  
23                   Let me just stop there. Are there

1 any comments on that?

2 (No response.)

3 CHAIRPERSON QUINLISK: Okay.

4 Since there are none, I will accept that we  
5 voted on that. And this working group is now  
6 discharged.

7 Now, your second comment, John,  
8 about what we are going to do from here, I  
9 think I would prefer to have that discussion  
10 after Dr. Lurie is given a chance to discuss  
11 what she has requested from the Board. It  
12 would make more sense to me to do it after  
13 that.

14 So if I hear no objections, I  
15 think we will go ahead. And I will introduce  
16 Dr. Lurie. Are there any objections?

17 (No response.)

18 CHAIRPERSON QUINLISK: Okay. I  
19 think what I will do now is I would like to  
20 introduce Dr. Nicole Lurie, who is the  
21 Assistant Secretary for Preparedness and  
22 Response at HHS, who is going to discuss with  
23 us both Secretary Sebelius' call for the

1 review of the Public Health Emergency Medical  
2 Countermeasures Enterprise and NBSB's charge  
3 from the ASPR.

4 So, Dr. Lurie?

5 DR. LURIE: Great. Thanks so  
6 much.

7 SECRETARY SEBELIUS' CALL FOR THE  
8 REVIEW OF THE PUBLIC HEALTH EMERGENCY  
9 MEDICAL COUNTERMEASURES ENTERPRISE (PHEMCE)  
10 NBSB CHARGE FROM THE ASPR

11 DR. LURIE: And let me start by  
12 thanking all of you for your continued efforts  
13 and for the markets and sustainability report,  
14 which I have now had the opportunity to read  
15 several times. It is very much appreciated,  
16 especially in the context of this review.

17 As I know that you all know, in  
18 December, Secretary Sebelius asked me to  
19 conduct a major review of the issues and  
20 challenges facing our medical countermeasures  
21 enterprise.

22 It's fair to say the reasons for  
23 this were several-fold, you know, first, sort

1 of coming out of our experience with H1N1 and  
2 asking ourselves the question, boy, if some of  
3 the biggest and best manufacturing companies  
4 in the world are unable to produce vaccines as  
5 quickly as we need it, how are we going to  
6 depend on capacity from a number of start-up  
7 biotechs who are primarily the ones engaged in  
8 much of the biodefense industry and the  
9 countermeasures enterprise there?

10           Secondly was certainly some  
11 frustration with our being able to move  
12 forward with the next generation anthrax  
13 vaccine. And as we sort of took a look at  
14 those things, you know, one of the things that  
15 I think struck the Secretary as well as struck  
16 me is we have learned a lot over the last  
17 several years as we have tried to move this  
18 whole enterprise forward.

19           But it may be that not all the  
20 forces are aligned the way we want them to  
21 produce success. And so I think we have all  
22 been somewhat disappointed in our ability to  
23 get to countermeasures more quickly. And so



1 she really asked that I leave this with you.

2           As we structured how to do this,  
3 this review has a couple of different  
4 components. You know, one is really a  
5 synthesis of what is known in this area as I  
6 started pulling together everything I could  
7 lay my hands on to read. What was clear is  
8 there just weren't enough hours in the day to  
9 get through it all; and, secondly, that it  
10 really needs to be synthesized with an eye to  
11 the future.

12           So, to that end, we have  
13 commissioned a set of white papers to capture  
14 a couple of different areas and then have  
15 asked the Institute of Medicine to put  
16 together a workshop to discuss those white  
17 papers and the issues involved.

18           The reason that we did that, in  
19 part, was I wanted to be sure that the white  
20 papers found their way to the public domain  
21 and because of the convening ability of IOM.

22           Now, unfortunately, neither we nor  
23 IOM were able to anticipate this lovely

1 snowstorm that we're having here. And so  
2 while the meeting was to begin tonight, it has  
3 to be delayed. And it is rescheduled for the  
4 week after next.

5           Those papers really focus on a  
6 couple of different areas. The first has to  
7 do with I think the methods that are used to  
8 create a robust pipeline of candidate products  
9 for advanced development, sort of looking at  
10 it to sort of get some sense of the scientific  
11 versus the engineering approach to getting  
12 something done. What are the best ways to  
13 prepare science, et cetera?

14           Second is some of the work that  
15 you have has been focusing on here in the  
16 markets and sustainability report and probably  
17 going beyond that to look at the market forces  
18 and incentives that contribute to or detract  
19 from the government's ability to meet its  
20 preparedness goal because I think, as we all  
21 recognize, even by the name of the markets and  
22 sustainable working group, in large part,  
23 although certainly not entirely, some of the

1 challenges are challenges related to the  
2 markets and not only to the BioShield  
3 procurement piece at the back end but all  
4 kinds of other ways in which the market does  
5 or doesn't work to support us getting the  
6 kinds of products that we want to; and then,  
7 finally, an analysis of stockpiling and  
8 distribution and dispensing strategies, what  
9 people have sort of termed the right-hand  
10 side.

11           You know, to that end, I want to  
12 pick up on some of the conversation that I  
13 think you were just having because I think  
14 within there, there are two particular areas  
15 where the NBSB and others have weighed in very  
16 constructively.

17           The first is in the area of some  
18 of the behavioral issues and recognizing that  
19 the behavioral issues involved with medical  
20 countermeasures, their acceptance, et cetera,  
21 are really critically important here. And  
22 those things in the long run may drive some of  
23 the kinds of requirements and delivery

1 mechanisms we want for these countermeasures.

2 I don't think that we want to be  
3 in a situation when a much more aggressive  
4 disease than H1N1, where 50 percent of the  
5 public won't feel comfortable accepting the  
6 countermeasure.

7 The second has to do with a set of  
8 special population issues related to children,  
9 related to pregnant women and some other  
10 groups and the recognition that you need  
11 different dosing schedules. Different routes  
12 of administration, metabolism,  
13 bioavailability, all of these kinds of things  
14 are different.

15 And because there are smaller  
16 subgroups of a potentially already smallish  
17 market, they changed sort of the market  
18 equation for how some of this gets done. And  
19 so I think we need to really address all of  
20 that at the front end of the review.

21 In addition, we would really like  
22 to be able to focus on the set of issues  
23 related to leadership, accountability, an

1 overall strategy of the current countermeasure  
2 enterprise.

3           And so we have started that off by  
4 commissioning another white paper, which  
5 really looks at some case studies of our  
6 experience so far, some areas in which we have  
7 actually been quite successful in getting to  
8 the countermeasures we want and some areas in  
9 which we have fallen short to look and to  
10 learn to the extent to which the strategy, the  
11 leadership, the accountability structure, all  
12 of those things are informed by our experience  
13 to date.

14           And so we have asked the NBSB, all  
15 of you, as I think you know, to help us once  
16 again in this review by really doing two  
17 things. One is convening a workshop to look  
18 at the strategic management, leadership, and  
19 accountability issues and, by all means, use  
20 this white paper and whatever else as a  
21 springboard to doing that; and, secondly, to  
22 generate a written report for the Secretary  
23 synthesizing the issues and challenges as you

1 see it that faced the countermeasures  
2 enterprise.

3 All of this work, the work by IOM,  
4 the work that you are doing, the work that my  
5 staff and others are doing, the outreach we  
6 have been doing to the pharmaceutical  
7 industry, both large and small, et cetera,  
8 will come together in a report that I owe  
9 Secretary Sebelius by March 31st.

10 It is a very short timeline. And  
11 so what I expect is that the majority of the  
12 recommendations and the further development of  
13 the strategy will follow pretty quickly those  
14 recommendations but won't all be presented on  
15 the 31st.

16 It's fair to say that we have been  
17 learning an awful lot in our review already.  
18 And I think it has already surfaced a number  
19 of interesting and very valuable ideas for the  
20 way forward.

21 So that is really the gist of what  
22 it is that we are asking you to do. And I  
23 want to thank you again in advance for taking

1 this on. I know any one of these is a huge  
2 amount of work.

3 And having looked at the markets  
4 and sustainability report and, in particular,  
5 that very impressive appendix with all of the  
6 different kinds of incentives that are out  
7 there compiled, I know how much work it is.

8 And I know how much more work it  
9 is going to be to go through each one of those  
10 things now and for us to figure out which ones  
11 make sense and which ones are going to be  
12 harder for us to pull off. But it is a really  
13 wonderful list to be able to start from and  
14 build off. And I am very appreciative of  
15 that.

16 I know that today's discussion is  
17 really focused on the markets and  
18 sustainability review and also the  
19 countermeasure enterprise, but I did want to  
20 highlight just one other issue because I know  
21 that there are members of the Disaster Mental  
22 Health Subcommittee on the phone.

23 And I know that during H1N1, that

1 you provided a lot of information on mental  
2 health that we picked up and used pretty  
3 quickly. And I know I talked about that in a  
4 prior meeting or teleconference and again  
5 wanted to thank you for that.

6           The other thing I wanted to say is  
7 that a number of the recommendations you have  
8 made throughout your working together have  
9 also been things that we have really been able  
10 to pick up and use during our response to the  
11 ongoing situation in Haiti.

12           And so, in fact, we have greatly  
13 enhanced the mental health piece of our  
14 response, both in terms of working with people  
15 in Haiti in terms of our own workforce  
16 protection activities as our teams go to Haiti  
17 to work and, finally, in terms of working with  
18 the large Haitian community within the United  
19 States. I wanted again to just say how much  
20 we really have appreciated that work and how  
21 helpful it has been and already being put to  
22 use.

23           So why don't I stop now and see if



1 you have questions about the countermeasure  
2 review and where we are headed.

3 CHAIRPERSON QUINLISK: This is  
4 Patty. Thank you so much, Nicki. When I got  
5 the letter, I thought this was great. I think  
6 it is easier to deal with boards like this one  
7 when we have very clear goals and exactly what  
8 we can do to best assist you and the people  
9 that you respond to. So I appreciate you  
10 helping us define some of these specific areas  
11 in which we can give you the most support.

12 So I think I will just go ahead  
13 now and open it up to the members of the Board  
14 to see if they have comments or suggestions or  
15 questions for you.

16 MEMBER PAVIA: This is Andy Pavia.  
17 Dr. Lurie, you asked us to focus on management  
18 strategic planning and accountability in the  
19 enterprise, kind of looking at the way  
20 government organizes itself.

21 I think that is going to be  
22 critically important, but I also, at least  
23 personally, feel I am not well-trained for

1 that task. And in a previous life, you  
2 actually did that sort of review of the way  
3 enterprises were organized.

4 I wonder if you have thoughts or a  
5 vision about what kind of expertise to bring  
6 in to bring in a fresh and creative look  
7 quickly so that you can get at that.

8 DR. LURIE: I think that is really  
9 a great idea. And I think what I would say,  
10 you know, in previous experience doing that,  
11 you know, I think the kinds of things that we  
12 tried to do, which I found really helpful and,  
13 in fact, which our team has reached in as part  
14 of this review, at least to some extent, is to  
15 sort of map out what all of the moving parts  
16 are of this and to look at the ways in which  
17 they do and don't relate to each other and  
18 relate to the end goal.

19 That helps figure out sort of who  
20 is accountable for what, where the different  
21 moving parts are, and then allows you to sort  
22 of focus I think on allowing us to focus on  
23 sort of are the incentives for each part of

1 this system aligned the way they ought to be  
2 and those kinds of things.

3 I think you have all struggled  
4 with a lot of the issues in getting to  
5 countermeasures for a long time, in fact, a  
6 lot longer than I have. And so we sort of ask  
7 some about the overall strategy that the  
8 countermeasures enterprise has taken so far.  
9 And I think you guys are well-suited to do  
10 that.

11 Certainly there are low cost  
12 accountability systems. And I have learned a  
13 lot from my colleagues, for example, in  
14 quality improvement about how you set up  
15 metrics and measures that help you figure out  
16 whether you have reached reasonable sort of  
17 milestones and targets and then how the system  
18 if it needs to can adapt and pivot.

19 So those would be other places  
20 that I might look to potentially for some help  
21 and expertise to bring into this. Is that  
22 helpful?

23 You know, a question I guess I

1 would ask you is as we have been looking at  
2 this and reading, I think a thing that has  
3 struck me is that the issues in the biodefense  
4 industry are not at all unique to the  
5 biodefense industry.

6           They are issues that have plagued  
7 many areas where you try to do drug  
8 development for niche markets. And so I have  
9 actually spent part of today listening to an  
10 IOM workshop that is going on in  
11 pre-competitive collaboration around oncology  
12 products. They're struggling with the same  
13 kinds of issues.

14           Certainly there are a lot of other  
15 public health threats, including naturally  
16 occurring ones in emerging diseases, that we  
17 have to have a way to have a countermeasure  
18 for quickly when the next pandemic or whatever  
19 else it is arises.

20           And so I would ask you to take a  
21 look at sort of our strategy of going after a  
22 specific kind of threat versus whether there  
23 are approaches in which things that might fly

1 under a banner of dual or multi use might make  
2 more sense, whether there are kinds of  
3 approaches to developing any development of  
4 products where there might be commercial  
5 applications that might be built off some  
6 platforms but then might be good biodefense  
7 applications that are similarly built off of  
8 them, so whether there are ways to decrease  
9 the cost of development for a number of these  
10 products.

11 So do we have the right strategy  
12 overall here? And are we managing the process  
13 of development from end to end in the best way  
14 that we can?

15 I am hopeful that the case studies  
16 will help inform that.

17 CHAIRPERSON QUINLISK: Dr. Lurie,  
18 this is Patty. The case studies white paper  
19 -- I'm sorry. I may have heard, but when is  
20 it anticipated that that would be available?

21 DR. LURIE: I think soon. I think  
22 the idea had been that that would also be part  
23 of what might be presented at the IOM workshop

1 so that you would be able to often think about  
2 that in advance.

3 And so I would ask you to touch  
4 base with Leigh after this and try to get a  
5 sense of when it might be available to share.  
6 I haven't seen it yet.

7 CHAIRPERSON QUINLISK: Okay.  
8 Thank you.

9 DR. LURIE: But I guess I am  
10 always a person who to the extent I can sort  
11 of lives and dies by evidence. And so I sort  
12 of wanted to say okay. Case studies are  
13 hardly a randomized trial.

14 But, by the same token, they are  
15 the evidence we have. And we ought to be  
16 learning from the experience that we have had  
17 so far in a pretty rigorous and objective way.

18 CHAIRPERSON QUINLISK: I totally  
19 agree with you. And I do feel that these  
20 kinds of case studies can at least bring up  
21 issues that we may not have recognized or  
22 thought about very much before. So I think  
23 this can be very helpful to us as we try to

1 address some of these issues.

2 Let me see if anyone else has  
3 comments or questions.

4 MEMBER SCANNON: Yes. This is Pat  
5 Scannon. Dr. Lurie, thank you for giving your  
6 insight today. One of the things that is  
7 different about more routine drug development,  
8 medical countermeasure development is that  
9 medical countermeasures are, in fact, a  
10 response to national security matters, whether  
11 --

12 DR. LURIE: Absolutely.

13 MEMBER SCANNON: -- accidental or  
14 intentional. And I was wondering what your  
15 thoughts are on how national security affects  
16 the prioritization and leadership and the  
17 topics that we are going to be discussing and  
18 summarizing for you.

19 DR. LURIE: Well, I think we exist  
20 because we have to address a set of national  
21 security threats. I don't think that there is  
22 any question about that.

23 That said, I think that there are

1 certainly other public health threats. If we  
2 had a pandemic that was considerably worse  
3 than the one we were just getting through that  
4 can sicken or kill enough people to  
5 destabilize a government, for example, that is  
6 also a national security kind of threat.

7 MEMBER PAVIA: I totally agree.

8 DR. LURIE: What?

9 MEMBER PAVIA: I totally agree.

10 DR. LURIE: Yes. So I would ask  
11 us, really, to think about it in that context  
12 and think about -- let me just say think about  
13 it in that context.

14 MEMBER PAVIA: Okay. Thank you.

15 DR. LURIE: Yes. But I guess the  
16 question is, you know, I am struck that  
17 everybody is solving this problem in their own  
18 stovepipe. And I am hoping our lessons will  
19 be learned from all of these different  
20 stovepipes and struggles with these issues.  
21 So I would urge you to -- you have done a lot  
22 of looking in your particular area and a lot  
23 of looking within the national security



1 stovepipe. And the work has been really,  
2 really helpful.

3 I don't know if there is stuff  
4 from outside of there that is also helpful.  
5 And so I know that one of the favorites is a  
6 paper on sort of procuring science and the  
7 pipeline.

8 I am hopeful it is going to look  
9 at a lot of different models, you know,  
10 looking at models at NASA or the Department of  
11 Energy or other places where they have a  
12 scientific challenge that they have had to go  
13 after and solve and whether we can learn  
14 anything different from those kinds of  
15 approaches as we move forward.

16 MEMBER PAVIA: Thank you very  
17 much.

18 CHAIRPERSON QUINLISK: Are there  
19 any other comments or questions for Dr. Lurie?

20 MEMBER GRABENSTEIN: This is John  
21 Grabenstein. Well, a question to those  
22 listening, which is we will be entering into  
23 a new work stream, it would seem. So all of

1 those who are listening on the phone have an  
2 interest in the matter.

3 And I would just ask if any of  
4 them have any reactions to Dr. Lurie's  
5 comments or anything we have been talking  
6 about today to send their comments into the  
7 website so we can -- you know, we are trying  
8 to keep a very open mind. And we don't want  
9 to lose any bright ideas that come from  
10 outside the circle of folks that --

11 CHAIRPERSON QUINLISK: That's a  
12 good point. Thank you, John.

13 NBSB RESPONSE TO ASPR REQUEST

14 Okay. Well, I think at this point  
15 I would like to have a discussion with the  
16 Board. And, Dr. Lurie, you are certainly  
17 welcome to stay on and maybe assist a little  
18 bit with the discussion if you are able, but  
19 we do understand that your time is probably  
20 short.

21 I would like to talk a little bit  
22 about how we structure the Board and how we go  
23 forward given the two tasks that you have laid

1 before us. What is the best way for the Board  
2 to move forward to address these tasks? I  
3 know that there are a couple of members on the  
4 Board who have been thinking about this and  
5 have some suggestions.

6 So I guess at this point I would  
7 like to open up the discussion on moving  
8 forward with these two specific activities we  
9 have been asked to address.

10 DR. LURIE: I can stay for a  
11 little while longer. And when you hear a  
12 beep, I have just dropped off.

13 CHAIRPERSON QUINLISK: And, by the  
14 way, I will just say this because I do know  
15 you have to drop off. We just really do  
16 appreciate you not only being here with us  
17 today, Dr. Lurie, but, with all the work you  
18 have been doing over this past year and  
19 especially with the H1N1, we know that that  
20 was a challenge and appreciate all the work  
21 you and your staff did to deal with it. And  
22 we are certainly looking forward to working  
23 with you into the future on these and probably

1 many other issues. Thank you.

2 DR. LURIE: Well, thanks. It has  
3 been a great team effort. As you know, NBSB  
4 was really instrumental and pretty  
5 game-changing in our approach. So I will put  
6 myself on mute and listen to your  
7 deliberations.

8 CHAIRPERSON QUINLISK: Okay.  
9 Thank you.

10 Okay, Board members. We need to  
11 address both the workshop and I think there --  
12 maybe we should just do this one by one.  
13 Let's take the first one. Our first activity  
14 is to convene a workshop to examine the  
15 strategic management leadership and  
16 accountability structure of the PHEMCE.

17 I believe there has already been  
18 obviously some activity in that area. So  
19 let's go ahead. And maybe we could be brought  
20 up to date on what sort of already has  
21 progressed in that area and then where do we  
22 need to go from here.

23 DISCUSSION

1                   MEMBER GRABENSTEIN: This is John  
2 Grabenstein. When Patty received a request  
3 from Dr. Lurie, she asked John Parker, Pat  
4 Scannon, and I to begin thinking through how  
5 this might be accomplished.

6                   And so the three musketeers have  
7 begun a very preliminary drafting of what  
8 goals for that workshop might be, but  
9 structurally I think we probably will need to  
10 or I would suggest that we form a new working  
11 group to do this new task of conducting this  
12 workshop and developing the policy options  
13 that are requested in Dr. Lurie's letter.

14                   CHAIRPERSON QUINLISK: Okay.  
15 Thank you, John.

16                   So we have basically got two sort  
17 of pieces here: the markets and  
18 sustainability group, which we have already  
19 sort of voted to now that the report is out  
20 sort of stand on that. Then we also have the  
21 research and development component of that  
22 group also.

23                   So we are sort of discussing

1 taking those two pieces and bringing up a new  
2 working group to address the issues that have  
3 been presented to us by Dr. Lurie and, in the  
4 process of doing that, opening it up to any of  
5 the Board members how are interested and ex  
6 officio members and then as we progress, if  
7 that is accepted, just decide how to progress  
8 with that new group.

9           So I guess at this point I would  
10 like to see what people think about putting  
11 together a new working group to specifically  
12 address these two activities that have been  
13 presented to us.

14           MEMBER PARKER: Patty, this is  
15 John Parker. I think what you proposed is  
16 excellent. I think those two workgroups could  
17 combine very easily. And I think you have  
18 said it all because you have not only  
19 suggested that, but you have suggested that  
20 others may want to be a part of this  
21 particular workgroup.

22           The reason that I think that that  
23 last part is very, very important is that this

1 work will contribute to a probable, if not  
2 absolute, enterprise change in the business of  
3 development of medical countermeasures for  
4 these entities that are important for our  
5 national security. And, for that reason, I  
6 think that most of the members on the Board  
7 would like to at least be a part of it.

8           And then the second part of it is  
9 that I think we have to be very careful that  
10 we don't -- we learn as we live. And I think  
11 we have to make sure that we don't saddle so  
12 much responsibility on one person, as we have  
13 done with this last workgroup on John  
14 Grabenstein with not only pulling it together  
15 but being a chief writer. We have got to look  
16 at how we are going to do our work a little  
17 differently as we form this new workgroup.

18           CHAIRPERSON QUINLISK: Yes. Thank  
19 you, John, for those comments. I think they  
20 are very apropos. I know when I was thinking  
21 about perhaps putting together this new  
22 working group and thinking about what members  
23 we have, just because of the broad aspects of

1 these two activities, I don't think there is  
2 anybody on the Board whose expertise and  
3 advice couldn't be used in the new working  
4 group, just because it does seem to encompass  
5 a wide range of issues.

6 So I guess let me see if there are  
7 any other comments on putting together a new  
8 working group to address these two activities.

9 MEMBER SCANNON: This is Pat  
10 Scannon. As part of just thinking very  
11 broadly, I take to heart some of, again, Dr.  
12 Lurie's comments about how much we can achieve  
13 between now and the end of March.

14 I really think we have to focus on  
15 defining the issues and at least laying out  
16 some concept for solutions but not necessarily  
17 solving in great detail between now and March  
18 30th what the solutions in detail would be.

19 I think that that would -- I mean,  
20 the point is it would be at -- it could be a  
21 distraction to start digging too deeply on any  
22 one subject given the amount of time that we  
23 have. And we really have to think about where



1 we draw the line toward March 30th and what we  
2 plan on doing after March 30th.

3 I think that will greatly help the  
4 efficiency of the review by just saying here  
5 is where we draw the line in terms of detail  
6 now versus detail which could follow shortly  
7 after.

8 CHAIRPERSON QUINLISK: This is  
9 Patty. And I totally agree.

10 Go ahead.

11 MEMBER DRETCHEN: This is Ken, Ken  
12 Dretchen. I must say that is wise, sage  
13 advice for us because if you bite off too much  
14 and try and do it too quickly, I think we will  
15 wind up with a report that may not be our  
16 best.

17 And here we can define the problem  
18 in literally six weeks. Then of the whole  
19 group of the 13, it starts dividing into the  
20 groups that can handle each of the points that  
21 we bring up. I think we play our strengths  
22 and not to our weaknesses.

23 CHAIRPERSON QUINLISK: Yes. Thank

1 you, Ken.

2 Other comments?

3 MEMBER PAVIA: In that regard, I  
4 agree with everything that everyone has just  
5 said, that it might be helpful to make this a  
6 little bit iterative.

7 So if we sort of figure out what  
8 the major questions, the larger questions,  
9 that we want to tackle, we can tackle between  
10 now and the end of March, we might want to get  
11 some feedback from the ASPR about whether that  
12 is what they are looking for in this phase.  
13 And they can help us rephrase the question.  
14 It is always nice to answer questions that  
15 people want to have answered.

16 EXECUTIVE DIRECTOR SAWYER: Please  
17 identify yourself.

18 MEMBER PAVIA: Sorry. Andrew  
19 Pavia.

20 CHAIRPERSON QUINLISK: That makes  
21 perfect sense, Andy. I think given the very  
22 short time period -- by the way, this is Patty  
23 -- I think for us to continually ensure that

1 we are staying on target will be very  
2 important to make sure that we come out in our  
3 six-week period with something that is very  
4 useful and directs future activities.

5 DR. LURIE: So this is Nicki  
6 Lurie. A comment. You know, the reason I  
7 think that I commented that we're not going to  
8 have the entire solution set put together  
9 March 31st is because it is a very short time  
10 frame.

11 I would hope that your review and  
12 your recommendations would at least highlight  
13 the major areas where you think change is  
14 needed.

15 To the extent that the Committee  
16 has a perspective about what those changes  
17 should be, I think it would be helpful to  
18 offer those for consideration, but I think, as  
19 I think I commented at another meeting, I  
20 would like at least the major parts of the  
21 diagnosis before we attempt the treatment.

22 CHAIRPERSON QUINLISK: Thank you,  
23 Nicki. What I'm hearing from you is that --

1       sorry, this is Patty -- you would like us just  
2       to ahead, identify the issues as best we can,  
3       put in some of our insights on the subject  
4       matter and some analysis and sort of again the  
5       challenges in the future in where to go, and  
6       that you wouldn't want to be proscriptive on  
7       that, but if there are areas that you would  
8       like to see particular interests or if you  
9       feel we are not addressing and you know about  
10      it, then you will let us know.

11                   DR. LURIE: I think that sounds  
12      very reasonable. And I think the other thing  
13      I would just offer is given the amazing amount  
14      of work you have done on the broader set of  
15      issues, again, feel free to pull in your  
16      experience and your insight from the other  
17      pieces of work you have done together, such as  
18      the markets and sustainability work.

19                   CHAIRPERSON QUINLISK: Okay.

20      Thank you.

21                   Any other comments or suggestions  
22      maybe? We could go on and see if people are  
23      okay with the proposed strategy of putting

1 together a new working group perhaps, as I  
2 believe it was John Parker's suggestion,  
3 within the working group, maybe even splitting  
4 the working group to have different parts  
5 focused on the different pieces of these  
6 activities but have as many people on the  
7 Board as are interested be a part of that  
8 overall working group.

9 Let me throw that out there and  
10 ask for comments. Is that the way that you  
11 would like to progress?

12 (No response.)

13 CHAIRPERSON QUINLISK: Okay.  
14 Well, hearing no comments, I will take that  
15 sort of as a yes. Let me just maybe throw it  
16 out there and see if people would like us  
17 basically starting out this working group with  
18 full Board involvement and maybe then just  
19 people being as actively involved in the  
20 pieces as they are capable of being.

21 Go ahead.

22 EXECUTIVE DIRECTOR SAWYER: I  
23 wonder if we should use the approach that we

1 have used since our first meeting in December  
2 of 2007 to ask the members to identify, then,  
3 the activities around this new working group  
4 and then to ask those who are interested in  
5 participating to let us know.

6 And then they can begin to be a  
7 part of this working group and allow the chair  
8 or chairs, however it is decided, then, to see  
9 how best to resolve this response that has  
10 been requested by Dr. Lurie.

11 I know people have been thinking  
12 about it. It was really a matter of having to  
13 start things that I asked the -- and you also  
14 asked that I do this -- bring the market  
15 sustainability leadership together with as  
16 many people as we thought might be interested  
17 to begin thinking about how we might respond.

18 So I think if we could formally  
19 offer the formal working group and then invite  
20 those who want to participate, we could move  
21 forward with working more particularly on  
22 these issues.

23 CHAIRPERSON QUINLISK: That sounds

1 very good, Leigh. This is Patty. So we will  
2 assume at this point that everybody at least  
3 wants to receive sort of invitations to become  
4 involved in various parts of this.

5 I think the next thing that I  
6 would like to throw out -- and I know somebody  
7 has sort of already started thinking about  
8 this -- was given that we have two different  
9 activity areas and given that this is going to  
10 be quite a bit of work in a very short period  
11 of time, I do think that we would need perhaps  
12 at least two chairs to sort of take on each  
13 one of these focuses as sort of the point of  
14 contact for each one.

15 So I would like to propose that we  
16 have at least co-chairs for this new working  
17 group. Any comments on that?

18 MEMBER GRABENSTEIN: This is John  
19 Grabenstein. The Army taught me never to  
20 volunteer, but I will violate that as long as  
21 I can get a very vibrant co-chair.

22 CHAIRPERSON QUINLISK: Okay. Let  
23 me just ask this of the thing. I mean, we

1 have two pretty big things. One is to put  
2 together the workshop, and the second one is  
3 to generate a report.

4 I am wondering now that I just  
5 sort of look at this and see if we need to  
6 have maybe a primary chair for each one of  
7 those activities and then a -- I don't know  
8 what you want to call it -- an assistant chair  
9 or something to be in each one of those  
10 activities, too, just because that is an awful  
11 lot of work to do. And just, even with each  
12 one of those activity areas, that would be a  
13 lot of work for one chair.

14 MEMBER PARKER: Patty, this is  
15 John Parker. I would not like the work  
16 separated for the reasons of continuity  
17 between the workshop and the report and the  
18 work that has gone on before.

19 So, in writing this report, I know  
20 how you can see it as two entities. I see it  
21 as a continuity of two entities. And I would  
22 recommend that we have one set of co-chairs.

23 And if John accepts me as a



1 co-chair, I would like to volunteer for that  
2 also.

3 MEMBER SCANNON: This is Pat  
4 Scannon. Actually, I have worked very closely  
5 with John and John. And although I will be  
6 out of the country for part of the time, I am  
7 certainly willing to pick up whatever I can as  
8 a co-chair as well.

9 So I think the three of us, as an  
10 example, have worked very well together and  
11 support what John Parker just said.

12 MEMBER GRABENSTEIN: This is the  
13 other John. The report and the workshop are  
14 hand in glove. So I wouldn't separate them.

15 CHAIRPERSON QUINLISK: Yes. And I  
16 guess I didn't mean separating but maybe  
17 putting the onus on a particular person,  
18 rather than trying to say two people have both  
19 responsibilities.

20 That could certainly be something  
21 left up to the co-chairs to deal with and sort  
22 of work through on their own.

23 So I hear the John and John and

1 then Pat sort of offering to take on this  
2 responsibility. Let me see if anybody has  
3 anything else they would like to add or  
4 suggest.

5 Well, number one, to say no to  
6 somebody who volunteers to do a bunch of work  
7 I think we do have -- and let me just make  
8 sure I have this right. We are having John  
9 Grabenstein and John Parker agree to be  
10 co-chairs with Pat Scannon agreeing to sort of  
11 be willing to step in or support the  
12 activities of the two co-chairs. Do I have  
13 that correct?

14 MEMBER PARKER: Sounds good to me.

15 MEMBER GRABENSTEIN: Well, or you  
16 have three co-chairs. I mean, then if  
17 something goes wrong, you could spin the  
18 needle, Patty. And where it stops, you can  
19 shoot the arrow.

20 CHAIRPERSON QUINLISK: Okay. I am  
21 all for three co-chairs. That sounds fine  
22 with me, too. Is that all right with you,  
23 Pat? I know you are a little bit concerned

1 about being out of the country, but are you  
2 willing to take on sort of the formal title of  
3 co-chair?

4 MEMBER SCANNON: Sure. I will. I  
5 may have to pick up more of the work when I  
6 get back, but I am willing to do that. And I  
7 can stay in e-mail contact along the way.

8 CHAIRPERSON QUINLISK: Okay.  
9 Great. Any other members have any comments or  
10 questions or suggestions?

11 MEMBER PARKER: Well, Patty, maybe  
12 not for the Board, but let me tell you there  
13 hasn't been anything that the Board has done  
14 where we haven't been super dependent on Leigh  
15 and her staff and the people that she puts in  
16 support of us.

17 So this is a big job. And perhaps  
18 I would ask Leigh to think of maybe putting  
19 more than just one person in support, in staff  
20 support.

21 I know she is critically short,  
22 but it might be good to have -- we would love  
23 to have Don. And we would like to have a

1 couple of folks with Don if that is possible.

2 EXECUTIVE DIRECTOR SAWYER: Thank  
3 you.

4 I'm sure that I would have Dr.  
5 Lurie's support in that request. I think the  
6 formation of a working group will be very  
7 helpful so we can begin working immediately on  
8 the request of the ASPR. And I do believe we  
9 will be able to access and task I know support  
10 from staff within ASPR.

11 So thank you. I will use your  
12 comments to seek that support. And I do know  
13 that it will be available to us.

14 MEMBER PARKER: Thank you, Leigh,  
15 because you and the staff have been absolutely  
16 great. And we could not do what we do without  
17 you.

18 CHAIRPERSON QUINLISK: I think you  
19 just heard a rousing "hear hear" behind that.  
20 I think all of us understand all of the work  
21 that the staff really does and how incredibly  
22 -- I know it is important to have not only the  
23 staff members but the quality of staff members

1 you have behind all of us.

2 I think that we have reached a  
3 conclusion, if I'm not mistaken. We have  
4 three co-chairs to work on both of these  
5 issues that we are going to basically send  
6 information out to all Board members and then  
7 ask them to identify the areas in which they  
8 feel they could be most effective or have the  
9 most to contribute in trying to get these two  
10 issues done.

11 Maybe I should stop here and just  
12 see from either the three co-chairs or Leigh,  
13 are there other things that we need to discuss  
14 on that right now or do we need to take a vote  
15 or anything? I don't think we do, but let me  
16 just ask.

17 EXECUTIVE DIRECTOR SAWYER: I  
18 don't think a vote is necessary, but I would  
19 like to do two things. One is to establish  
20 the name of the working group.

21 CHAIRPERSON QUINLISK: Yes.

22 EXECUTIVE DIRECTOR SAWYER: I  
23 would like to suggest that we convene a call

1 of the working group if we can on February  
2 16th. And at that time the voting members and  
3 ex officios who would like to participate can  
4 do so and we can begin to put together our  
5 plans, then, for these two strategies.

6 CHAIRPERSON QUINLISK: Absolutely,  
7 Leigh. Thank you.

8 Let me throw it out primarily --  
9 well, to the Board but also primarily to the  
10 three co-chairs. What would you like your  
11 working group to be named?

12 MEMBER GRABENSTEIN: I'll propose  
13 it as the PHEMCE Workgroup but listen to the  
14 other comments. John Grabenstein.

15 CHAIRPERSON QUINLISK: Okay. This  
16 is Patty. Hearing no other comments or  
17 suggestions, go ahead. And we'll just name  
18 this the PHEMCE Working Group with our three  
19 co-chairs and --

20 MEMBER ROSE: I'm not sure that  
21 anybody other than us or even within our group  
22 is going to know what that means. So how  
23 about calling it the Workgroup on Optimizing

1 the Countermeasure Development Enterprise or  
2 Development and Deployment Enterprise?

3 EXECUTIVE DIRECTOR SAWYER: Please  
4 identify yourself.

5 MEMBER ROSE: Eric Rose.

6 DR. LINDEN: This is Carol Linden.  
7 I believe the review that Dr. Lurie is doing  
8 for the Secretary is kind of going by the name  
9 Medical Countermeasure Review.

10 MEMBER ROSE: Yes.

11 DR. LINDEN: And so I would  
12 suggest maybe including that in the title of  
13 the group somehow. And just to avoid  
14 confusion with the existing PHEMCE body  
15 enterprise governance board, enterprise  
16 executive committee, I would maybe suggest not  
17 calling it the PHEMCE Working Group because I  
18 think that would be very confusing.

19 MEMBER ROSE: Yes. I agree.

20 DR. LINDEN: Well, with regard to  
21 the comment about nobody knows what it is, I  
22 agree it is a little bit obscure, but I have  
23 to sort of respectfully disagree that we

1 actually got a lot of recognition of that  
2 awful acronym and what the enterprise is, at  
3 least in some sectors of our stakeholder  
4 community.

5 MEMBER ROSE: I think in the  
6 stakeholder community, it is well-understood.  
7 It's just a concern as to beyond that.

8 DR. LINDEN: Yes. No. I agree  
9 with you if we go on with that.

10 MEMBER ROSE: Yes, exactly. What  
11 do those initials stand for?

12 DR. LINDEN: Right, yes.

13 MEMBER PAVIA: Yes. I know. This  
14 is Andy Pavia. I agree with what Carol said.  
15 I think that often that PHEMCE is tied into an  
16 existing structure in the concept and, as she  
17 stated, is medical countermeasures.

18 CHAIRPERSON QUINLISK: This is  
19 Patty. Maybe I will just throw out there  
20 maybe we should just be very clear and not use  
21 acronyms and just call it the Medical  
22 Countermeasures Working Group.

23 Now, that is essentially the name



1 that we had before of the two subgroups that  
2 we sort of took down, but this is sort of  
3 replacing that. That might be the easiest and  
4 most straightforward.

5 MEMBER PARKER: Patty, John  
6 Parker. I add one word to that, Medical  
7 Countermeasures Development Group.

8 CHAIRPERSON QUINLISK: Okay. Any  
9 comments?

10 DR. LINDEN: Yes. This is Carol.  
11 I think the overall review is much broader  
12 than only development of medical  
13 countermeasures.

14 I think you sort of refer to the  
15 whole spectrum and what we refer to as the  
16 distribution and so forth of countermeasures.  
17 That certainly is part of the review.

18 So I guess my comment is that I  
19 would urge caution in narrowing the focus  
20 simply to or only to development of medical  
21 countermeasures.

22 MEMBER GRABENSTEIN: Yes. Carol,  
23 I would suggest -- this is John -- I think you

1 make a good point. And since Dr. Lurie used  
2 the words "strategic management" in her  
3 charge, perhaps someone on the phone could  
4 think of how we could work in the word  
5 "strategic" or "management" into a title.

6 EXECUTIVE DIRECTOR SAWYER: John,  
7 this is Leigh Sawyer. That particular aspect  
8 of the review is only one part. So that  
9 strategic management leadership and  
10 accountability structure is the topic for our  
11 workshop. So I wouldn't want to narrow the  
12 focus there.

13 Maybe Medical Countermeasures  
14 would be a good name just because it isn't  
15 narrowing us in any particular way.

16 MEMBER GRABENSTEIN: Okay. I  
17 think you're working with a bunch of people  
18 that can drive their head for a definition in  
19 the title.

20 I think broadness is good.  
21 Medical Countermeasures Workgroup might be the  
22 right answer.

23 MEMBER PAVIA: I would second

1 that, John. Andy Pavia.

2 CHAIRPERSON QUINLISK: This is  
3 Patty. So what I am hearing right now is we  
4 just go with the Medical Countermeasures  
5 Working Group.

6 MEMBER GRABENSTEIN: Aye aye.

7 CHAIRPERSON QUINLISK: How about  
8 we go with that for a working title? And then  
9 we can at the conference call next week on  
10 February 16th re-discuss with people  
11 overnight, have a sleepless night, and just  
12 don't think that is the right title. But  
13 we'll go with that for now.

14 Leigh, do you want to say anything  
15 more about the conference call on February  
16 16th?

17 EXECUTIVE DIRECTOR SAWYER:  
18 Actually, I would like to turn it over to John  
19 Grabenstein if he is comfortable with taking  
20 this next part.

21 CHAIRPERSON QUINLISK: John?

22 MEMBER GRABENSTEIN: All I was  
23 going to say was we were going to have it and

1 talk about the agenda.

2 EXECUTIVE DIRECTOR SAWYER: Okay.

3 So I will send out an invite to all of the  
4 voting and ex officio members. And please let  
5 us know if you are not able to attend but want  
6 to participate as a working group member, make  
7 note of that, please, and we will convene that  
8 call.

9 I believe the call -- I can't  
10 check my calendar right now, but I think it's  
11 at 2:00 o'clock. Is that right, John?

12 MEMBER GRABENSTEIN: That's right.

13 CHAIRPERSON QUINLISK: Yes. I  
14 have it on my calendar for 1:00 o'clock  
15 Central, which would be 2:00 o'clock Eastern,  
16 as a potential time that we've got.

17 MEMBER GRABENSTEIN: That's  
18 correct. That's right.

19 CHAIRPERSON QUINLISK: Okay.  
20 Leigh?

21 EXECUTIVE DIRECTOR SAWYER: I  
22 could make a point now that in the letter from  
23 Dr. Lurie, she indicated that she would like

1 our report, a final report, from the Board by  
2 March 26th.

3 So based on that particular date,  
4 we have organized to have a face-to-face  
5 meeting of the Board. We had originally  
6 planned a public meeting in April. We have  
7 canceled that meeting. And we have moved it  
8 back, then, to the March 26th date.

9 So we will be holding a public  
10 in-person meeting on March 26th. And at this  
11 time, we expect the group will be presenting  
12 the report.

13 It will be the assimilation and  
14 synthesis of all of these different pieces  
15 that we expect to come together by that time.  
16 And that will be presented.

17 MEMBER SCANNON: This is Pat.  
18 That means that we have -- would we then  
19 distribute it five days in advance of the  
20 meeting?

21 EXECUTIVE DIRECTOR SAWYER: You  
22 know, Pat, I think based on the schedule for  
23 the numbers, we always try to have it out at

1 least 24 hours beforehand. We would work to  
2 have an early draft possibly, but I am even  
3 thinking only the 25th we might be able to  
4 distribute it, just because of the short  
5 timeline.

6 MEMBER SCANNON: I am on your  
7 side. Just, you know, we have in the past  
8 done it for longer periods, which would cut  
9 down the amount of time available. So I am  
10 just trying to clarify that. Twenty-four  
11 hours is okay.

12 EXECUTIVE DIRECTOR SAWYER: We  
13 would post it on our website as soon as  
14 possible. We would expect it on the day of  
15 the 25th. And then, of course, we will be  
16 keeping people abreast of it because, as I  
17 just indicated, the ASPR will be also putting  
18 together her report. And so we will want to  
19 keep Dr. Lurie informed.

20 They will have essentially a draft  
21 before the 25th, but we will have a more  
22 formal draft by the 25th.

23 CHAIRPERSON QUINLISK: And, Leigh,

1 this is Patty. I have just a question. Dr.  
2 Lurie talked a lot about the help the Mental  
3 Health Subcommittee had on that. I guess I  
4 don't have a clear vision whether they would  
5 be involved or invited onto being part of this  
6 new working group or they would be consulted.  
7 How do you see that playing out?

8 EXECUTIVE DIRECTOR SAWYER: That's  
9 a good question, Patty. The format that we  
10 have used in the past for our working groups  
11 is that, first, we have allowed all voting  
12 members to be on a working group if they  
13 wanted to.

14 Then we have also asked all ex  
15 officios if they would like to be on the  
16 working group that they could be on the  
17 working group for their expertise or if they  
18 have some component within their department  
19 that has more relevance to the particular  
20 topic that they could designate someone to  
21 represent them at that working group.

22 In addition, discussing in this  
23 case where we have such a large scope of

1 activities and input that we want to obtain,  
2 we will be asking that if there are additional  
3 members of the federal government that we want  
4 to attend, they can also attend and be named  
5 as invited federal experts.

6 With regard to people who are not  
7 federal experts, we would like to ask them to  
8 participate in those activities where we can  
9 invite them as invited experts to participate  
10 in, for example, a workshop.

11 So that is how we plan to  
12 incorporate those members who are not federal  
13 employees or especially government employees.

14 CHAIRPERSON QUINLISK: Okay. So  
15 what I see that meaning for us is that between  
16 now and the conference call next week, we  
17 might be thinking about other areas outside of  
18 what traditionally has been working with the  
19 Board and just see if there are other areas  
20 that we feel we need to invite people in to  
21 become involved in this process.

22 EXECUTIVE DIRECTOR SAWYER: Sounds  
23 good.



1                   CHAIRPERSON QUINLISK: Okay.  
2           John, John, and Pat, any other things you want  
3           to bring up at this point? We're coming sort  
4           of to the end of our two hours but want to let  
5           you have sort of the last chance to say  
6           something.

7                   MEMBER GRABENSTEIN: We always  
8           appreciate hearing from our fellow Board  
9           members. The more ideas that come in, the  
10          better the work product is.

11                   CHAIRPERSON QUINLISK: Well, and I  
12          would like to just take one last time. I know  
13          the three of you were very involved in this  
14          report and all of the work that is being done  
15          so far and now sort of volunteering to take on  
16          even more work.

17                   And I just on behalf of the Board  
18          just really appreciate your willingness to not  
19          only work on this stuff but to take the lead.  
20          We really do appreciate that.

21                   Okay. Leigh, do we have anything  
22          else that we need to address today?

23                   EXECUTIVE DIRECTOR SAWYER: Are we

1 now at the wrap-up and adjournment, Patty?  
2 This is where you had thought about the other  
3 letter that we received from Dr. Lurie.

4 CHAIRPERSON QUINLISK: Right. I  
5 was going to mention that just as we get to  
6 the end. Is there anything more on the  
7 medical countermeasures or the new workgroup  
8 that we need to do today?

9 (No response.)

10 WRAP UP AND ADJOURN

11 CHAIRPERSON QUINLISK: I think we  
12 pretty much hit everything. I think what I  
13 will do, then, is just in this last minute, as  
14 you know, several conference calls ago, we  
15 talked about wanting to sit down and talk a  
16 little bit about just the Board, where we are  
17 going, what our priorities are for the future.

18 Obviously that is something that  
19 we don't want to lose sight of. However, with  
20 these new activities that we have been asked  
21 to address by the ASPR, I think that probably  
22 at this point needs to not be forgotten but  
23 put on the side so that we can direct our

1 energies towards addressing these new  
2 activities.

3 But on behalf of sort of the  
4 Board, I don't want to lose sight of that. So  
5 I guess what I would like to propose is we put  
6 that sort of on the back burner for right now,  
7 allow us to meet the March 26th deadline for  
8 these activities. But once we get done with  
9 that, I would like to pick this back up and  
10 discuss it.

11 So is that acceptable to the  
12 members of the Board?

13 (Chorus of yeses.)

14 CHAIRPERSON QUINLISK: Okay. And  
15 I think that is all I had that I wanted to  
16 talk about right now. Leigh, anything else  
17 from your standpoint?

18 EXECUTIVE DIRECTOR SAWYER: No,  
19 nothing new. I again wanted to thank the  
20 voting members for attending this call and the  
21 staff, everyone here in Washington, D.C. who  
22 is calling in in these blizzard conditions, to  
23 make it possible for us to hold this call

1 today. And I greatly appreciate the public  
2 audience participation in today's proceedings.

3 I want to remind people that they  
4 can check for updates on our website. And the  
5 address for that website is  
6 [www.hhs.gov/aspr/omsph/nbsb](http://www.hhs.gov/aspr/omsph/nbsb) or you can put  
7 NBSB in your search engine, and it will come  
8 up.

9 So please check our website. And  
10 thank you.

11 CHAIRPERSON QUINLISK: Okay. And  
12 I would like to thank the Board and the staff  
13 also for all your work on it, particularly in  
14 these adverse conditions. And, not to make  
15 you feel bad, but, for once, Iowa is blue  
16 skies and sunshine.

17 So thank you all. And we will  
18 look forward to talking to everyone next week  
19 on the 16th. Thank you.

20 (Whereupon, the foregoing matter  
21 was concluded at 4:01 p.m.)