NATIONAL BIODEFENSE SCIENCE BOARD

+ + + + +

PUBLIC MEETING

+ + + + +

FRIDAY, MARCH 26, 2010

+ + + + +

The meeting convened at 8:00 a.m. in the Plaza Ballroom of the Hilton Washington D.C./Rockville Executive Meeting Center, located at 1750 Rockville Pike, Rockville, Maryland, Stephen V. Cantrill, M.D., Acting Chair, presiding.

VOTING MEMBERS PRESENT:

STEPHEN V. CANTRILL, M.D., Acting Chair
RUTH L. BERKELMAN, M.D. (via telephone)
ROBERTA CARLIN, M.S., J.D.
ALBERT J. DI RIENZO (via telephone)
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.
THOMAS J. MacVITTIE, Ph.D.
JOHN S. PARKER, M.D., Major General (Retired)
ERIC A. ROSE, M.D.
PATRICK J. SCANNON, M.D., Ph.D.

EX OFFICIO MEMBERS PRESENT (or designee):

MICHAEL D. AMOS, Ph.D., Biosciences Advisor, Director's Office, National Institute of Standards and Technology

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

DEANNA ARCHULETA, Deputy Assistant Secretary for Water and Science, Department of the Interior

HUGH AUCHINCLOSS, M.D., Principal Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health

ROSEMARY HART, Special Counsel, Office of Legal Counsel, Department of Justice

KERRI-ANN JONES, Ph.D., Assistant Secretary of State for Bureau of Oceans and International Environmental and Scientific Affairs, Department of State

PETER JUTRO, Ph.D., Deputy Director, National Homeland Security Research Center, Environmental Protection Agency

RANDALL L. LEVINGS, D.V.M., Scientific Advisor, National Center for Animal Health, U.S. Department of Agriculture

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

VINCE MICHAUD, M.D., National Aeronautics and Space Administration (designated by Richard Williams)

NBSB STAFF PRESENT:

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

TABLE OF CONTENTS

P R O C E E D I N G S

(8:08 a.m.)

CAPT SAWYER: Good morning. I'd like to welcome everyone to the National Biodefense Science Board public meeting. We're meeting here at the Washington, D.C. Hilton in Rockville, Maryland.

I'd like to begin by welcoming the NBSB voting members, ex officios and their designees, and to the members of the NBSB's Medical Countermeasures Working Group, the members of the public in attendance here as well as those participating on the phone. We also have members that are also participating by telephone.

I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board. I also serve as the Designated Federal Official for this Federal Advisory Committee.

The purpose of this meeting is to discuss and consider recommendations from the National Biodefense Science Board's Medical Countermeasures Working Group, reviewing the

Public Health Emergency Medical Countermeasures Enterprise. Dr. Lurie will be discussing this in more detail for us.

The name of the report we'll be looking at today is Defending America Against Chemical, Biological, Radiological and Nuclear Threats: Leadership Matters.

I'd like to begin by the roll call. If you could please answer yes if you're here.

Patty Quinlisk.

(No response.)

CAPT SAWYER: Ruth Berkelman.

DR. BERKELMAN: Yes.

CAPT SAWYER: Steve Cantrill.

ACTING CHAIR CANTRILL: Yes.

CAPT SAWYER: Roberta Carlin.

MS. CARLIN: Yes.

CAPT SAWYER: Al Di Rienzo.

THE OPERATOR: He's on.

CAPT SAWYER: Al?

MR. DI RIENZO: Yes.

CAPT SAWYER: Okay. Here?

MR. DI RIENZO: Here, yes.

CAPT SAWYER: Ken Dretchen.

DR. DRETCHEN: Here.

CAPT SAWYER: John Grabenstein.

DR. GRABENSTEIN: Here.

CAPT SAWYER: Jim James.

DR. JAMES: Here.

CAPT SAWYER: Tom MacVittie.

DR. MacVITTIE: Here.

CAPT SAWYER: John Parker.

DR. PARKER: Here.

CAPT SAWYER: Andrew Pavia.

(No response.)

CAPT SAWYER: Eric Rose.

DR. ROSE: Here.

CAPT SAWYER: Pat Scannon.

DR. SCANNON: Here.

CAPT SAWYER: We'll now begin introducing the ex officios or asking if they're here.

Peter Emanuel.

(No response.)

CAPT SAWYER: Larry Kerr.

(No response.)

CAPT SAWYER: Richard Williams or his alternate.

DR. MICHAUD: Dr. Vince Michaud for Rich Williams.

CAPT SAWYER: Vince Michaud. Thank you.

Frank Scioli.

(No response.)

CAPT SAWYER: Randall Levings.

DR. LEVINGS: Here.

CAPT SAWYER: Michael Amos.

DR. AMOS: Here.

CAPT SAWYER: John Skvorak.

(No response.)

CAPT SAWYER: Patricia Worthington.

(No response.)

CAPT SAWYER: Dan Sosin.

(No response.)

CAPT SAWYER: Hugh Auchincloss.

DR. AUCHINCLOSS: Here.

CAPT SAWYER: George Korch.

(No response.)

CAPT SAWYER: Carol Linden.

(No response.)

CAPT SAWYER: Bruce Gellin.

(No response.)

CAPT SAWYER: Boris Lushniak.

CMDR MAHER: Commander Carmen Maher for Boris Lushniak.

CAPT SAWYER: Thank you, Carmen.

Diane Berry.

DR. ADIRIM: Terry Adirim.

CAPT SAWYER: Terry Adirim for Diane Berry. Okay.

Deanna Archuleta.

MS. ARCHULETA: Here.

CAPT SAWYER: Welcome.

Rosemary Hart.

MS. HART: Here.

CAPT SAWYER: Kerri-Ann Jones.

DR. JONES: Yes.

CAPT SAWYER: Victoria Davey.

(No response.)

CAPT SAWYER: Peter Jutro.

(No response.)

CAPT SAWYER: Patricia Milligan.

(No response.)

CAPT SAWYER: The NBSB is a Federal Advisory Board that is governed by the Federal Advisory Committee Act. The FACA is a statute that controls the circumstances by which the agencies or officers of the Federal Government can establish or control committees or groups to obtain advice or recommendations where one or more members of the group are not Federal employees.

The majority of the work of the NBSB, including information gathering, drafting of reports, and the development of recommendations is being performed not only by the full Board, but by working groups of the subcommittee or the subcommittee who, in turn, report to the Board, and this is the case this morning.

I will review the conflict of interest rules. The standards of ethical conduct for employees of the Executive Branch document has been received by all Board

members who, as special government employees, are subject to conflict of interest laws and regulations herein.

Board members provide information about their personal, professional, and financial interests. This information is used to assess real, potential, or apparent conflicts of interest that would compromise members' ability to be objective in giving advice during Board meetings.

Board members must be attentive during meetings to the possibility that an issue may arise that could affect or appear to affect their interest in a specific way. Should this happen, it will be asked that the affected member recuse himself or herself from the discussion by refraining from making comments and leaving the meeting.

We will have a public comment period today. It will be from 10:30 to 10:50 this morning, approximately. If you're joining us by phone, you will be given instructions by the operator as to how to

signal that you have a comment. Comments will be taken in turn, and you will be notified when the phone is open for you to speak.

If you are here in person and know that you would like to speak during the public comment period, please sign up at the registration desk so that we can better anticipate how many people we will need to accommodate during the public period.

We have not received any comments to date electronically.

So I would like to remind everyone that this meeting is being transcribed. So when you speak, please provide your name. The meeting transcript, summary, and any public comments will be made available on our Website.

And now I'd like to turn this meeting over to our Acting NBSB Chair, Dr. Stephen Cantrill.

ACTING CHAIR CANTRILL: Thank you, Captain Sawyer.

Thank you all for being here and

participating in our meeting today.

A brief review of the agenda. We are fortunate to have some remarks by Dr. Nicole Lurie, who is the Assistant Secretary for Preparedness and Response from Department of Health and Human Services.

We will then have the actual presentation of the report, the co-chairs who worked on this report, Dr. Grabenstein, Dr. Parker, and Dr. Pat Scannon. Dr. Grabenstein will do the majority of the presentation.

We will then have a period for public comment followed by a break, and then discussion and vote upon the report itself by the members of the NBSB.

Dr. Lurie will offer some discussion of some potential next steps.

During the actual presentation, we will entertain comments by Board members and ex officio members concerning the content of the report.

With that being said, I would like to ask Dr. Lurie if she has any opening

comments for us.

DR. LURIE: Sure. Good morning. Thanks so much.

First, thanks for inviting me to join you this morning, and than you, Steve, for your willingness to serve as the Acting Chair in Dr. Quinlisk's absence.

And thank you to all of the NBSB for taking this real leadership role in the review of our countermeasure enterprise.

I think as everyone knows, this work that you've done is part of and is largely in support of a review of the medical countermeasure enterprise really from end to end that Secretary Sebelius charged my office with doing, and we owe her a report in a few short weeks.

This was one major component of our review. I think all of you know and had a really marathon week there as the IOM convened a workshop to deal with a set of issues, as the NBSB met to look really specifically at issues related to strategy and leadership of

the countermeasures enterprise as the President's Council of Advisors on Science and Technology met to review flu.

We've also spent a lot of time doing a huge amount of outreach to large and small companies, to venture capital people and investment banking, to academics, to all kinds of stakeholders, and all of this information will really come together in this report that we will shortly provide to the Secretary.

I think what you've done here is really remarkable, and I think about the fact that all of us had a really compressed time frame because of the snow storm, which not only gave us this marathon week of meetings, but set us back a couple of weeks sort of in the amount of time we actually really had to put this together.

And when I think about the fact that it has been just one short month between the NBSB meeting and this report, what you've produced is even that much more impressive, and I want to let you know how much I

appreciate it and how impressed I am and how helpful I think this is going to be in completing our work.

You know, I think the goal here for all of us, in particular I know for those of you who have worked so hard on this, is not just to do a report that sits on a shelf, but to do something that really helps and is not just a report that informs those of us who are here now, but is really a report that will help promote lasting and systemic change in a system that needs to transform.

And it's really in that light that we take your report very much to heart. We appreciate it greatly, and I'm really looking forward to the discussion this morning and formally receiving it and on behalf of the Secretary as well, I want to thank all of you for your incredibly hard work.

Before I close, I just want also to thank all of you for your continued service on the Board and also just to take a minute and welcome new or returning ex officio members.

I've been asked to ask them to stand if they're here so that you know who they are.

So, Dr. Peter Emanuel, I think, is not here.

Dr. Frank Scioli from the National Science Foundation.

Dr. Randall Levings from USDA.

CAPT SAWYER: He's behind you.

DR. LURIE: Good. Dr. Michael Amos from the Department of Commerce. Great.

Captain Dan Sosin from the CDC. I know he's not here.

Dr. George Korch from my office, and I know he's not here because we are furiously working on this report that we owe the Secretary.

Dr. Diane Berry from the Department of Homeland Security.

Ms. Deanna Archuleta from the Department of Interior.

Dr. Kerri-Ann Jones from the State Department.

And Dr. Vicky Davey from the

Department of Veterans Affairs, who I haven't seen either.

So let me say thank you again. I wish all of us a really productive morning and look forward to the discussion.

ACTING CHAIR CANTRILL: Thank you very much, Dr. Lurie.

Let me just review the contents of the packets that were distributed this morning. You do have a printed version of the draft report as it was on March 24th. There have been some minor changes since that time. They will be reviewed.

You also have the roster of the NBSB as well as the Medical Countermeasures Working Group.

There's also some information on Dr. Lurie as well, as well as a copy of the agenda, and there is a copy of the letter to Dr. Quinlisk concerning our challenge in terms of what we were tasked with from Dr. Lurie.

Specifically, we were asked to convene a workshop to examine the strategic

management, leadership, and accountability structure of the PHEMCE, which is the Public Health Emergency Medical Countermeasures Enterprise. You will hear it referred to as the PHEMCE during our discussions today.

And we held that workshop and then the second component was to develop a report on the issues and challenges with possible policy options regarding the PHEMCE, and that is the report that will be presented during our meeting this morning.

With that being said, I now would like to, first of all, thank the co-chairs of the Medical Countermeasures Working Group. As I said, Drs. Grabenstein, Parker and Scannon, the amount of work that went into this was absolutely astounding. It was at times somewhat like herding cats, but I think the quality of the report really is very, very good.

And with that I'll ask Dr. Grabenstein to take the floor and present his report.

DR. GRABENSTEIN: Thank you very much, Steve.

My name is John Grabenstein. I'm the pretty face of the work group. So you can see what troubles we struggled with.

So as you might imagine, this has been a rather busy month for us all, and I would like to first acknowledge all of the contributors, which would be longer than the two minutes allotted in the Emmy recipient time before the orchestra strikes back up.

But each person on the Board has contributed their own expertise in a remarkable way and in a hurry and under duress sometimes. Ruth Berkelman and Al Di Rienzo for leading our diagnostic section and Roberta Carlin and Dan Dodgen for the section on functional limitations, and when we got into the pediatric medical countermeasure dosing issues Richard Hatchett, Tom MacVittie, Andy Pavia, Eric Rose, when we were talking about commercial products, and the list just goes on and on.

I'm very grateful to the Institute of Medicine for withstanding that snow storm and prevailing to have the workshop that kicked off our effort just about a month ago. So Gail Cassell and Bruce Altevogt, especially for that.

All of you who have criticized our document, I thank you because you made it better. I hope we got all of the criticisms. I'm sure there are more criticisms to come, but for all the ones we received, we were able to work through and make clearer, I think what we intended and/or correct errors as we found them, and if you find errors, please tell us about them.

But especially the folks at FDA and NIH and CDC and the whole alphabet soup of HHS, and the NBSB staff has been phenomenal in support, and I'd like to thank my co-chairs for sticking with us as we got it all put together. And it has been really a remarkable thing.

To get into the meat of the

presentation, I'm going to ask John Parker to kind of set the stage for us. What you see on the screen are some quotes that Secretary Sebelius gave in a presentation back in December, and this was sort of the start of this whole marathon, and I ask John to reflect on this.

DR. PARKER: Thank you very much, John.

And you know, I'll say to the audience very publicly that John is a very humble person and the amount of work that John Grabenstein has done by actually being the principal writer and version control officer, idea man, counter-conscience person as different ideas came in, and his ability to work with the entire work group and with the ex officios so that we could hear various viewpoints of what we were saying and why we were saying it actually did, as he said, make the report much better.

And so I'd like a short, small round of applause for John.

(Applause.)

DR. PARKER: And I ask that, you know, at some point in time he speak privately to the Board and tell us where he gets his energy. I'd be very interested in that as an old gray-hair.

So I don't know if people on the telephone -- this is not a Webinex. So I would just say to the folks that are on the telephone that Secretary Sebelius said four principal things, you know. We don't know what's coming. The next public health emergency could be much work. We rely on NIH and other parts of the HHS and the Department of Defense for most of our early research and advanced development and putting it in the stockpile.

Preparing for an emergency is a full-time job, and I am truncating her quotes just a little bit, but I want to give you the flavor, and the ultimate review of this goal is to do this job better and better and better in the defense of this particular nation.

As we were charged with this report, the general feeling is that the segment of the Board will volunteer to be on the work group, and in this particular thing, the Board realized and recognized the importance of this particular charge, and you can see in your paper work that every member of the Board was a member of the work group, and that's a tap of the gavel on the platform to tell everybody that this was critically important.

We saw the participation of the ex officios throughout this, high degree of participation not only on the telephone, but in person as we worked through this report, and so I say to each of those folks and people within their organizations who volunteered for special telephonic conversation, when we looked at things I also say thank you very much for that.

And I'm going to turn it back to our chair, to John, and we'll get on with the elucidation of the report so that you can have

opportunities to comment.

DR. GRABENSTEIN: Thanks very much, John.

So you saw Secretary Sebelius' comments, and then about two months ago the President as part of the State of the Union Address stated that the United States is launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease, a plan that will counter threats at home and strengthen public health abroad.

And surely, this is a piece of the energy behind the current effort to assess our national security in this light. We, the Board, certainly agree with the President that this initiative is very important, and given the immaturity of the countermeasures against chemical and radiologic or nuclear threats, we would counsel that this statement needs to be expanded beyond simply bio to include the other threats as well because while there certainly has been a great effort in terms of

control of nuclear proliferation and chemical arms, the medical countermeasures against those elements are insufficient.

So come forward a little bit further. Actually I hadn't juxtaposed this. This was the day before the State of the Union Address. Dr. Lurie charged the Board with taking a leadership role in the review of the Public Health Emergency Medical Countermeasures Enterprise, given that you are in a unique position to more fully understand the complexity of the issue as a result of your sustained involvement, and so please convene the workshop, which we held just a month ago down in D.C., and second, by today, generate a written report for the Secretary synthesizing the issues and challenges facing the PHEMCE, and at your discretion suggesting policy options to optimize it, and there was never any doubt we were going to propose policy options for you.

And so we have written -- the full report today is 103 pages long. We got to 99

pages, and we said, "Now, wait a minute. We have to get over 100. We can't just let it sit there." No, we put in what we needed to put in.

But as we looked across that pretty lengthy document, we looked for what the common themes were, and I've listed them here, and it's prioritize, synchronize, and anticipate, but to do all of that you need leadership, and so the prioritization is that a matter -- we will waste time, effort, and resources if we don't focus efforts on the most important, most fruitful work. The synchronization part is getting all of the players to be part of the team. So it's about -- well, the top part of this slide talks about leadership, but sometimes there needs to be better followership of getting all of the little -- not little -- all of the boxes on the HHS org. chart synchronized, working together, rowing in the same direction with the same rhythm, pulling on the rope in the same direction to get the greatest synergy out

of the whole enterprise.

And anticipate, there must be a greater effort at doing more in advance of an incident than is currently being done, and we'll raise some examples of that.

Now, bringing those three principles together is leadership because if there is not concerted effort, if there is not a voice reminding people to keep the emphasis on these weapon countermeasures during what I'll call peacetime, during periods of calm, we will be taken by surprise.

And so if you were to think of how much work should have been put into radar in Hawaii in early 1941, you would say maybe they should have done a little bit more a little bit sooner in retrospect, with regret. So if we don't anticipate, we'll have biological, chemical, radiologic, nuclear Pearl Harbors that we will regret and have to clean up as opposed to being able to mitigate by planning ahead of time.

So the document has this structure,

a table of contents and executive summary, overview and background, and then there are five chapters, five sections that address components of the PHEMCE review in series; a situational assessment, where we are today and what we conclude from that;

Then two, a section on strategy and leadership and priorities and accountability;

Three, the resource aspects of the issue, the need for consistent, adequate and balanced funding;

Four, function and activities. What's happening inside the boxes of this organizational chart and how can that be better?

So two is sort of like getting the boxes to work better together, but then four is a look inside many of the boxes.

Five, enhance communication.

A conclusion, and then the appendices.

So let's dive into Section 1, situational assessment. Our conclusion on the

basis of all the work we've been doing is that the workers involved in discovery and development and acquisition and fielding are doing good and important work, but they are not synchronized. Their projects are not prioritized, and the oversight of these boxes has not been consistent, and these inefficiencies are prolonging our vulnerability.

Now, Ruth Berkelman will remind me that vulnerability is not a yes/no thing. It has degrees, but permit me this rhetorical device here, but if we don't get everybody together as a team, it's going to take longer to get across the finish line, and that means more than HHS.

Realize our charge came from within HHS, but we've been asked to take the broad view and comment on the whole government effort. So with respect to the other cabinet departments, you see our first two recommendations here: that the Secretary of Health and Human Services, in coordination

with the Secretaries of Defense and Homeland Security, that she confers and coordinates with the White House on how best to protect America from chemical, biological, radiological, and nuclear threats, including the merits of establishing a position on the National Security Council to lead the relevant national strategy.

And if you read the full document, you will see -- or even the executive summary -- you'll see that what we're talking about here is the need for coordination across the departments, and we call out that these threats are literally a national security priority, and that means the highest levels of government, and it means, you know, getting all of the cabinet departments contributing appropriately.

The second recommendation here, and then I'll break and we can have discussion on these two, is that the Secretary of Health and Human Services, in coordination with the Secretaries of Defense and Homeland Security,

coordinates with the White House on a unifying end-to-end national strategy to address intentional, natural and emerging CBRN threats.

And the Secretary of HHS discusses with the White House -- I'm sorry. The italics shouldn't be there. That was an old version. Right, so we can skip the italics. Sorry. Bad slide quality control on my part.

The red text is different from what you see in your paper version. So that's the key. So if you see red, that means it's a little different. We had an editorial session yesterday to check that out, and I think the pattern, Dr. Cantrill, that I would suggest is that we talk about -- I'll show the recommendations slide by slide, and then we can have a discussion on each of the slides before moving forward if that's all right with you.

Comments, critique?

ACTING CHAIR CANTRILL: Any comments from Board members or ex officios

concerning these first two recommendations?

(No response.)

ACTING CHAIR CANTRILL: Hearing none, John.

Dr. Parker.

DR. PARKER: I made some comments earlier, but as you look at these particular recommendations, I want to increase the background of the report just a little bit. I think it's important to say for the record that this report was not requested because something was going wrong. This is not an investigative report.

This report reflects on the administration's focus on improving things and changing things in Washington to be able to produce and protect our nation, and in the course of this report, there is no one that we spoke to as an individual who was not responsible, not excited about their job, did not understand their job, and I would say completely that everyone we spoke to wanted to do a better job.

So we have wonderful people in a lot of great positions wanting to do a better job. So I just want to make it very clear that this is not an investigative report. This is a report for improvement, and I applaud the President, the Secretary, the ASPR, and all of those folks who really wanted this done.

This will have an effect, and we're asking a lot in this report. We would be very pleased if we got 99.9 percent of this.

(Laughter.)

DR. GRABENSTEIN: And, Pat, you may wish to comment on the unifying national strategy part. In the work of the Board, the National Biodefense Science Board has been around for two or three years now, and we have long known about the Homeland Security presidential directives of this, that and the other number, and as we started collecting up the documents that are supposed to be providing the strategy to the departments, we kept coming across document and document and

document and a new national strategy for biodefense.

There's a footnote of them at one point, and we were worried that actually there were so many documents, and that's the source of the word unifying here.

DR. SCANNON: I don't think I could say it any better. I think we all know and are aware that there are documents that come out of the Office of the President, that come from the Department of Defense, as well as documents that have come out of ASPR and HHS. They're all valid. They all drive important aspects toward medical countermeasure responsiveness.

I think our point was which document do you choose. Which documents do you work from? And we felt that there needed to be a concerted effort to unify these into a cohesive strategic plan with strategic priorities.

That is not to say that we don't recognize the specific requirements of both

HHS and DOD in medical countermeasure development, but nonetheless, there is a lot of overlap in terms of the actual medical countermeasures, and having a cohesive and unifying strategy we feel is ultimately in the best interest of all Americans.

DR. GRABENSTEIN: Okay. Moving on, so Section 2. This chapter or section is broken up into several subchapters, subsections, wherein we talk about setting a clear strategy, having the government, all the departments, work from a common set of priorities. We talk about enhancing what we find to be a very good HHS-DOD collaboration. We simply want more of it.

Aligning the HHS divisions, this is one of the more pivotal ones.

Adopting metrics to track accountability.

Balancing the medical countermeasure portfolio across multiple axes, and the axes are chem, bio, rad, nuke. That's one axis. Another one is short-term, is time.

Another one is prevention versus diagnosis versus treatment. Another is adult and pediatric. Another is -- I think there are six or eight of them listed in the report, and those of you with some biostatistics background know I may be calling for multiple regression to figure all of this out, but that's the challenge.

And it's not a simple balance scale, the scales of justice. This is a very complicated question, and I can't minimize how complicated that is, but it's essential because there will always be a finite amount of money, and we can chase easily accomplished but low consequence event or countermeasures and declare victory, but that's not what we really want to declare victory on. We want to solve the most consequential problems.

We recommend increased attention paid to clinical diagnostics. So clinical is actually important there.

We talk about developing a brand for the PHEMCE, and then enhancing the

acquisition strategy.

So the comment pulled out here is common priorities must be adopted, uniformly accepted and adopted across agencies so that national vulnerabilities are resolved as quickly as possible. So this means the good and smart and talented people in HHS and DOD and DHS need to get together and say, okay, the thing we are most worried about is A. The next thing we're most worried about is B. The next thing we're worried about is C. Oh, wait a minute. It was a two-day discussion to figure out whether it was C and then B or B and then C.

And then that may be the easy part. So there's a list, and then NIH needs to agree to prioritize according to that list, and CDC does, and BARDA does, and FDA does, and the rest.

And so what we are calling for is every agreeing to the same play book in terms of priorities.

So the recommendations are the

Secretary of HHS promptly identifies at least three high priority medical countermeasures not in the Strategic National Stockpile that the department will develop to counter CBRN threats with target time lines. At least one of the MCMs should address radiation exposure.

I'm going to read the whole list, and then I'll come back and make some comments on these.

Four, the Secretary of HHS promptly coordinates with the Secretaries of Defense and Homeland Security to develop prioritized lists of CBRN threats, both natural and intentional origin to guide further prioritization of MCM efforts.

And then five, the Secretary of HHS empowers the Assistant Secretary for Preparedness and Response is the operational MCM leader with authority to synchronize the efforts of HHS agencies and with end-to-end oversight.

So comments.

So three, number three, we

recommend that -- and there's a paragraph in the full report that talks about with everything that's going on, creating this prioritized list is going to take some time. I described all the axes and that sort of thing.

But meanwhile with all of the review that's been conducted and all of the efforts largely since 2001. Surely the top three or the top few should rise, should be apparent. So get started on those. Number three is saying get started on those top ones while you do number four to create that big, full list.

And, oh, by the way, we heard in the workshop and elsewhere about how inadequate the medical countermeasures are for radiation syndrome or radiation exposure, and so you might want to make one of those top three something related to radiation.

Now, we are not telling you what the three should be. You might pick up short, a medium and a long. You might pick -- we've

sometimes heard the threat described as anthrax, anthrax, anthrax. Well, maybe all three should be anthrax. That's up to you all, but -- in HHS -- but we recommend you crystallize your focus and get started in terms of declaring where your top priorities are.

Then in number four, go make that full prioritized list and then have the ASPR understood to have the authority. So the Secretary we presume is a pretty busy person. In fact, we know it, and so has many balls to juggle. There's this little thing called health care reform that apparently was -- something happened with health care while I was writing this report. I'm not sure what it was, but the Secretary will always have to attend to many, many things. The ASPR is the logical focus point, but the ASPR does not have authority, direct authority over NIH that gets its funding through its own special stream, and similarly DOD or, excuse me, similarly CDC, similarly FDA. But the

Secretary needs an agent to get the various HHS agencies on the same sheet of music, that prioritized list, and working together.

So that's three, four, and five.

ACTING CHAIR CANTRILL: Any comments? Dr. Dretchen.

DR. DRETCHEN: Yes. Number five is of key importance to me, and that is that, look, we have a lot of very dynamic and capable leaders throughout the entire HHS spectrum, and in times of crisis all of those individuals will try and rise and take charge because that's obviously that's how they naturally act.

On the other hand, there has to be one responsible person in charge of this operation, and not only is she sitting to my left, but the point is this is the most responsible individual who has their fingers on all the keys that are there in the organization and is the right individual to lead this operation.

ACTING CHAIR CANTRILL: Okay, John.

Go ahead.

DR. GRABENSTEIN: Six and seven. The Secretary of HHS tasks the Assistant Secretary for Preparedness and Response to refine the HHS acquisition structure and metrics to provide accountability for the MCM program.

Seven, that the Secretary of HHS designates the Director of BARDA, the Biomedical Advanced R&D Authority, as the portfolio director to coordinate the technical aspects of balancing the portfolio.

So editorializing, so refining the acquisition structure and metrics is a matter of -- I think somebody will correct me if I make a mistake here -- but HHS at the headquarters level has not been buying many things itself in the same way that DOD has been doing for decades. I'm sorry I got that wrong, but in relative terms, the experience level, the degree of maturity of acquisition programs are not quite what they are in some of the other cabinet departments. So we have

made some recommendations along those lines.

In terms of metrics, we provide a list of monitoring systems, you know, to assess how many researchers are going to chem or bio or rad or nuke, to adult or pediatric, and a variety of metrics that would allow the Secretary if the ASPR puts those metrics together and shows the Secretary, then she can see what all of her agencies are doing and how they're allocating their resources and the degree of alignment of those resources to that prioritized list that we called for in the previous recommendation.

And then in seven we assume that the right person to be this portfolio director, which is a function that happens in all of the pharmaceutical companies that have multiple products where they have to be constantly balancing early and late stage projects in a variety of therapeutic areas is analogous to what HHS needs to have happen, and we would propose that the Director of BARDA be the person to do that balancing.

ACTING CHAIR CANTRILL: Dr. Parker.

DR. PARKER: I'd like to speak to number six. It is up there not because the department and the ASPR and BARDA haven't looked at acquisition type accountability and structure. It's up there because this is an opportunity. The Federal Acquisition Regulations and the Defense Federal Acquisition Regulations have been used for years, and there's always been a problem adapting those particular regulations to the production of medical and biologicals.

And by putting number six in this report, we hope that HHS takes the opportunity and the importance of this mission to work with the Congress, to have the flexibility with the Federal Acquisition Regulations that they actually come up with the structure and metrics to make it reasonable and productive to produce a biological.

This is a critical time, and the biologicals are not easy to produce, and the flexibility that needs to be built into this

acquisition structure must recognize that.

ACTING CHAIR CANTRILL: Thank you, John.

We also do have two Board members who have joined us remotely, and I'd just like to pause and see if either Al Di Rienzo or Ruth Berkelman have any comments to this point.

MR. DI RIENZO: Thanks, Steve. This is Al Di Rienzo. So far I really appreciate how the meeting is flowing, and again, thanks, everybody, for their hard work. In particular to me, and I've heard what Ken and John have said, I think seven is a key point because of how BARDA is not only responsible for the countermeasures, but they're also responsible for the diagnostics that will help rapidly detect a situation and then be able to get the appropriate countermeasure response for that.

So to me that one is a very key one, a very interesting one.

ACTING CHAIR CANTRILL: John, go

ahead.

DR. GRABENSTEIN: Al had a very useful sentence in an e-mail within the last couple of weeks where he reminded me of the differences between diagnosis and screening, and the differential especially in a mass casualty event or mass incidence where there's many folks who will essentially need to be triaged in one way or another, you know, even before you would get to a definitive clinical diagnosis and the importance of that aspect of this.

So the detail of what I've been talking about in this slide and the previous one are at pages 34 and 35, and I just thought I would cross-check myself to make sure that I've been describing all of the key parts.

Some of the metrics that I haven't mentioned yet today might be average times required to achieve milestones, like time till an IND filing or progress in enrolling patients or volunteers in a clinical study; program cost reports; reports of progress

between the various technology readiness levels and the like.

And I didn't yet mention in terms of balance, let's see, the axes that I was talking about: categories of threat, chem, bio, rad, nuke; modes of intervention, screening, diagnosis; pre-exposure prophylaxis, post-exposure prophylaxis; treatment; product types, whether it's drugs, vaccines, antibodies, other interventions; the screening and diagnostic devices; phases of development, early and late, early and advanced, preclinical also; adults and children and other special populations; and then single and multiple use products.

And this came up in both the IOM workshop and in our own workshop about if you can create a multiple use product, you may not always be able to, but it's certainly something to evaluate, there being advantages and disadvantages to single versus multiple use products in both directions, each having advantages and disadvantages, but something to

evaluate in the process.

And then a simplistic view of our assessment of the current state of balance would be advanced development projects are underfunded relative to basic research and very specifically there we said don't cut basic research. Increase the money for advanced development.

And as anybody who understands drug discovery and drug development knows, the cheap part, the inexpensive part of the endeavor is early, and the expensive part is late when you're into clinical trials and product development, formulation development.

We concluded that radiologic, nuclear, and chemical countermeasures are underfunded relative to biological MCMs; that children have not been adequately addressed on multiple levels. You'll see that in several recommendations coming; and that some threats, including some seemingly high priority ones, have no corresponding license countermeasure, whereas some third generation countermeasures

are being developed for some threats.

So you can see the complexity of finding the one right answer. Of course, there's no one right answer, but finding the way to balance this very complicated equation.

So we proposed some ways to approach weighting in that prioritization effort, and knowing that it's a human endeavor so it will have flaws in it. It will be limited, but at least decide and get a list and get everybody pulling together.

Okay. Eight and nine, the Secretary of HHS promptly tasks senior HHS leaders, meaning the agency leaders primarily, to develop a common set of prioritized research goals, prioritized product requirements, prioritized dispensing goals for civilian populations and coordinates these priorities with Department of Defense.

Now, remember a previous recommendation called for a prioritized threat list. We understand that's underway. So once you have prioritized threats then you can

prioritize your research goals, and you can prioritize your product requirements, and you can prioritize your dispensing goals to get the product that last mile into the hands of the person who needs it.

We realize the complexity of that because the Federal Government shares the responsibility with the state and local governments and tribal governments to get that last mile accomplished.

Then number nine, the Secretary of HHS in consultation with the Secretary of Homeland Security develops a plan to overcome existing obstacles that preclude timely distribution and administration of medical countermeasures to people in need, including children and those with limited functional ability.

And I will confess, and it's in a paragraph in the paper, we have spent most of our time talking about invention, you know, discovery of new countermeasures, their product development and their procurement, and

we fully acknowledge the essential nature of getting the product to the person. Our analytic time on that part, that last right side of the spectrum, has been a little bit less than it has been for the other portions, and so we acknowledge that, and this is an all encompassing, go figure out what your vulnerabilities are and solve them kind of a recommendation.

ACTING CHAIR CANTRILL: Any comments?

I also would encourage comments by any of our ex officio members, and, Dr. Lurie, if you have any comments or questions, please feel free to jump in as well.

I personally am very concerned about the last mile or, as we say, the last 20 miles, the last 20 hours in terms of getting the medical countermeasures to where they need to be, be that in somebody's arm or in their stomach or in their nose. That sometimes is a little messy because it involves so many steps and so many different jurisdictions, but it's

the area in which I am very concerned that we can have a perfect system, all the different links working very, very well, and if we misstep in that last step, we have essentially failed. So for me personally, that's a very important area.

DR. LURIE: Thank you.

I wonder if you might just go back a minute, thinking about your comments, Steve, in a prior recommendation in which in red you talked about three products not already in the SNS.

I very much take the point that we need new products. I guess a question I have for you in terms of the intent of this was is it the intent that product should always end up in the SNS or that products ought to quickly be able to go from, if needed, you know, manufacturer to that last mile.

So I wonder if you might just comment on your intent for a moment.

DR. PARKER: Dr. Lurie, you make a great point, and the idea of our statement

about the national stockpile in your works should be broadened just a little bit because I think there are opportunities where manufacturers may be able to manufacture something, store it in bulk, and on an emergency situation distribute it from the actual manufacturer.

So I think that the variations here are, if there are medical countermeasures that aren't currently in the stockpile, that's what we mean here; your three can't be one of something in the stockpile already. I don't think it's the intent of the paper to say that the only distribution system is the national stockpile.

DR. GRABENSTEIN: It's in red because yesterday it said new at that point. So it was at least three new, at least three high priority new NCMs. In other words, don't take credit for something that's almost finished and say, "Oop, got one." We want you to find ones that have been languishing or lingering or stuck or it could be something

that you haven't started yet, but you just say we want to land somebody on Jupiter and, you know, start something afresh.

So the intent there was to say not something that's already in your back pocket.

The other piece to your question was is the SNS the only answer, and there's a section in the paper where we say we, the country, we, the Board, haven't yet -- let me back up.

Back -- is it a year and a half ago or so -- the Board was asked questions about home stockpiling of antibiotics, and that came and went as an issue and has kind of fallen. The executive branch took no action and nothing came back to the Board, but it's still an unanswered question that we acknowledge in the report of, well, can the feds and the states and the cities get the products out in time.

And there's the Postal Service dispensing or distribution of products as an option. Does that solve the problem for rural

areas?

We've talked about med kits and home med, you know, professionally packaged med kits and the regulatory implications of such things and home stockpiling of antibiotics, and it is an unanswered question. I mean, it's a big piece that needs to get resolved, and I would say that's part of nine, which is timely. There probably isn't one wait for the big 747 to come with the boxes from the SNS solution to everything.

ACTING CHAIR CANTRILL: Dr. Rose.

DR. ROSE: I think the thing that we learned in our inquiry is that there is at least a profusion of process with regard to distribution. We heard a lot yesterday with regard to the SNS about an elaborate number of plans, particularly at the state level that are coordinated and graded even by the SNS, but I think most of us were surprised to hear that at least in some fronts vaccines are not part of the SNS.

DR. GRABENSTEIN: That was

influenza vaccine, wasn't it?

DR. ROSE: Influenza, but in terms of the arcana of what gets distributed by the SNS and what doesn't get distributed, the ultimate outcome of this has got to be the time that it takes to get a needed countermeasure to the individual that ought to get it, and right now I think there's an overarching sense that there are a profusion of processes that are being managed, but the outcome itself is really not well within sight, and all of these processes need to be managed for that outcome.

ACTING CHAIR CANTRILL: Dr. Levings.

DR. LEVINGS: Yes, just to go to number nine and some of the comments that have already been made, I guess the discussion yesterday, just to clarify, this is not about Federal control of all distribution channels. It's about coordination of those and predictability of those.

So we heard yesterday from the SNS

about the state plans and about scoring the state plans and about remediating states whose plans are not maybe up to snuff. At USDA our approach to that is to train the states in how to receive stockpile materials and then distribute them.

But I guess the comment I'm leveraging off of is the multi-jurisdictional nature of our distribution and even our response plans.

ACTING CHAIR CANTRILL: Thank you.

John, I wonder if to address that whether we should in one of the previous recommendations not necessarily call out the SNS but just say "not rapidly available." That would be one thing that we could consider just so it doesn't get misinterpreted that we're really just addressing the SNS as the only way to distribute these items.

DR. GRABENSTEIN: Right. So we would be looking for words that would have to do with early in development or, you know, maybe we could pick out a technology readiness

level and say, you know -- I don't have those numbers memorized. I'm not even sure I have them with me.

Is that your intent?

ACTING CHAIR CANTRILL: Just to not lead to the misinterpretation that we're talking only about the SNS.

DR. LURIE: Maybe just to clarify a little bit, some of my question was we've been having, you know, a lot of discussion and I think there was discussion at both the IOM and the NBSB about, you know, sort of balancing and being sure we are developing countermeasures for stuff we know we need now, but a long-term goal of having the capability as a nation to be able to make something really quickly in the face of a new emerging threat.

I was just curious about your thinking and whether your recommendation number three was an implicit statement about the goal for that capability or not because that would be something that wouldn't go

through something you stockpile.

DR. GRABENSTEIN: Yes. Well, so the report acknowledges this platform approach or multi-use approach and acknowledges how hard it will be to do it, but number three is not intended to limit you. That's your choice as to whether to pick three really hard goals or, you know, how you wish to do it.

ACTING CHAIR CANTRILL: Jim.

DR. JAMES: Just looking at the stockpile, I think one thing we haven't done is look at the things in the stockpile which are not readily available in the civilian marketplace, and for those we obviously need a distribution system that depends on the stockpile, but for some relatively simple items like N-95s, which are carried in the stockpile, but the greater percentage are available locally and from manufacturing, then we certainly can't just limit our focus on how we get those to the end user through the stockpile.

ACTING CHAIR CANTRILL: Thank you.

Roberta.

MS. CARLIN: Yes, hi. I just want to reiterate the importance of number nine and the importance of getting countermeasures to targeted populations and keeping in mind those in the non-traditional setting, such as those in institutions and aggregate living situations. So number nine is of particular importance in terms of getting to that last mile, as Steve mentioned.

ACTING CHAIR CANTRILL: Thank you. John Parker.

DR. PARKER: I want to make a comment about distribution to the point of use, in other words, to the individual that needs it, and I think our representative, Randall Levings from the Department of Agriculture really helped us in yesterday's session in overcoming the idea of the Federal Government telling a state government what to do, but we can facilitate the states in developing finite distribution systems, perhaps HHS through the CDC funding the states

so that they can increase their training and exercises, develop more points of distribution or points of receiving drugs from the Federal Government, drugs and other countermeasures from the Federal Government so that the Secretary of HHS and the ASPR not only in her job of preparedness, but in the response aspect has a warm, fuzzy feeling that when the bell rings, things are actually going to move right now to people.

The Federal Government in our federated republic doesn't mandate and try to override state sovereignty, but we can sure help them do their job.

ACTING CHAIR CANTRILL: Thank you, John.

Just to clarify, the references to the meeting yesterday, that was a work group meeting where we were putting the final touches on this report.

Pat.

DR. SCANNON: I certainly share the need for that last mile or 20 miles. I would

also like to reemphasize a point made earlier, that I think the Board and certainly the working group recognize that the middle 2,000 miles are also critical to keep in mind, and that is advanced development is, in fact, the most complex and most expensive part in any drug development, whether it be for traditional pharmaceutical purposes or for medical countermeasure purposes.

You know, Congress in a bipartisan effort recognized this through the PAHPA legislation that created BARDA and ASPR, what we have found is that while in principle these have been recognized, providing the adequate resources to actually fund advanced development is actually a critical step, and so it actually addresses two recommendations, both in synchronizing medical countermeasure development, but also in providing balance to medical countermeasure development. I just feel that's a point of emphasis.

DR. GRABENSTEIN: So I want to come back to number three.

DR. BERKELMAN: This is Ruth Berkelman.

ACTING CHAIR CANTRILL: Ruth, go ahead.

DR. BERKELMAN: Are you responding to the previous point?

DR. GRABENSTEIN: Go ahead, Ruth.

DR. BERKELMAN: Oh, I was going to just go back and re-emphasize something that Dr. Lurie said, and that's that it really is important that we improve the infrastructure and the capability to manufacture quickly when we need new things in an emergency. I just thought that was a very important point, that we as a Board, I think, also agree with.

ACTING CHAIR CANTRILL: Okay.

DR. GRABENSTEIN: So back to number three, I think there's an unsettled issue on the table, which is how best to phrase which MCMs we're talking about, and what you have in your paper copies is three high priority new MCMs as opposed to what it says on the screen, which is high priority MCMs not in the SNS.

Is our intent clear? Do we want to -- what would be the best way to convey this to the Secretary?

RADM LUSHNIAK: I'm just wondering upon sort of reflection and being part of the discussion yesterday as we were doing the editing on this as to whether anything needs to be specified regarding these three high priority MCMs other than the terms. I mean, look at the statement again. Drop the term "not in the Strategic National Stockpile." Therefore, it does not bind us to that, but the key term here is that the department will develop, which means, in essence, that these are not developed products, and so without binding us, right, to saying are they in stockpile or not in stockpile, are they new or not new, I mean, de facto if they will develop, this allows us to look at new approaches to things, a la even the concept of a med kit can be put in here, which is something that doesn't currently exist, even though they may be approved products for other

uses and yet allows us to bring to the forefront new concepts, new ideas under the rubric of we will develop those.

DR. GRABENSTEIN: How does the Board feel about that?

ACTING CHAIR CANTRILL: Just for the record, that was Boris Lushniak from the FDA who has joined us.

Thank you, Boris, very much.

I would say there may be a sense that we can just drop that phrase, and I think it would add to the clarity.

Any other comments by Board members of ex officios?

DR. DRETCHEN: Ken Dretchen.

I agree with that concept.

DR. JAMES: Concur.

DR. ROSE: I think the word "new" could go back in there.

(Laughter.)

ACTING CHAIR CANTRILL: John, I think there's a consensus that we essentially just go back to the previous statement the way

it was before we messed with it yesterday.

(Laughter.)

RADM LUSHNIAK: For the record, Boris Lushniak.

I'm the one who messed with it yesterday.

DR. GRABENSTEIN: That was at a different point. Do you want "new" back in?

ACTING CHAIR CANTRILL: Dr. Berkelman, do you have any other comments about that?

DR. BERKELMAN: No, I'm fine with that.

ACTING CHAIR CANTRILL: Okay. Now, why don't you go ahead and move on.

DR. GRABENSTEIN: So all right. Chapter 3, Section 3. Consistent, adequate and balanced funding. I would contend at the moment none of those three applies. That would be the Board's contention. It's neither consistent, adequate, nor balanced.

So to resolve that, we recommend -- well, the subheadings in the report call on

HHS to coordinate its budget request. We went into an exercise where we were trying to figure out how many different ways Congress earmarks or specifies how money shall be spent, and when we asked does anybody ever put them altogether and think about them in context we had resounding silence.

Provide adequate and sustained funding. Give special attention to FDA resources. I'll explain that in a minute. And provide multi-year funding authority to HHS.

So what we have said was a sustained and adequately resourced national effort must address a broad spectrum of threats. To the extent the government is commissioning pharmaceutical research, it has got a huge portfolio to cover. Additional Federal funds will be needed to provide for the required scope of discovery, development, acquisition, sustainment and fielding beyond levels historically provided. So our recommendations are as follows.

The Secretary of Health and Human Services promptly determines the -- well, okay. So contact.

Recommendation 10 is about the present fiscal year, recognizing the realities of Federal budget making. So Recommendation 10 is about the fiscal year 2011.

And then Recommendation 11 is about fiscal year 2012 and beyond.

So the Secretary of HHS promptly determines the coordinated budget requirements for FY 2011 relevant to CBRN medical countermeasure budget lines with the relevant players, NIH, NIAID, BARDA, CDC, FDA, and ASPR at least. If we forgot anybody, go ahead and include them, and in conjunction with DOD.

And communicates requests for revision of the President's budget to OMB. The Secretary gives special attention to FDA resource needs.

So where we are in the current budget cycle is the President and the administration has made a budget proposal and

sent it up to Capitol Hill for funding, and so it is already up on the Hill but hasn't been voted on. So get the heads together in HHS, figure out if any changes need to be made or recommended, requested of Congress before Congress votes on the 2011 budget.

Then, for subsequent years where the proposal, the budget has not yet gone up to the Hill, for 2012 and beyond, the Secretary of HHS develops a coordinated budget request relevant to CBRN MCM budget lines within NIH, NIAID, BARDA, CDC, FDA and ASPR, and in conjunction with DOD.

In other words, don't just have each of those fine agencies develop their own budget and send it forward. Think about it. You know, put them all together on the same sheet of paper, realizing they're parts of different requests and they're parts of different agencies. So the CDC has many, many budget lines any small number of which are CBRN related. Pull them out and look at them all at the same time and see if you're

balanced and see if they're aligned with those prioritized lists and see if it makes sense as a rational process that you're moving forward instead of a bunch of individual cars on the freeway, I guess, or something like that. My analogy machine is breaking down.

So those two recommendations on fundings.

Okay. Twelve and 13, that the Secretary of HHS develops a legislative plan to seek multi-year funding authority for CBRN MCM efforts and unspoken is analogous to prerogatives that the Department of Defense has now. That's in the text.

Thirteen, the Secretary of HHS develops a legislative plan to seek appropriate modification and re-authorization of the Project BioShield Special Reserve Fund before its expiration in 2013.

And I think I would ask John or somebody with DOD experience to describe what DOD's current system is with you'll hear people talk about the POM, the Program

Objective Memorandum, which is a multi-year sort of rolling advanced plan, but John might be able to describe it better than I can.

DR. PARKER: The Department of Defense has used, they call it the POM. It stands for Program Objective Memorandum, and it looks out five to seven -- it looks out at seven years, but actually five years beyond the initial two-years of what I would call the active budget so that the congressional leaders can get an idea of -- through this plan, congressional leaders and the administration can get a good look at what the Department of Defense is thinking and doing strategically over a long period of time that will need consistent funding.

And at any one time the only real dollars of this Program Objective Memorandum are in the first two years of that Program Objective Memorandum. But it's a technique where the Secretary of HHS can signal her priorities well out into the future so that those at OMB and on the Hill who are preparing

to support that are thinking about that for a long time, and they have opportunities to talk to individuals about their long-term plans.

The individual departments can determine how much of their Program Objective Memorandum is public or observable to OMB or to the Congress at any one time, but the idea of doing that represents a fiduciary way of putting a stamp on your future plans and in particular cases it can actually prepare folks to reserve funds on the year-to-year basis for the completion of a program that they recognize is important and has to have continuity.

DR. GRABENSTEIN: So I'm a retired soldier. So you'll know I'm in trouble if I'm going to use Navy analogies, but I think the way I understand aircraft carriers to be funded is that there sort of is an aircraft carrier commissioned each year, knowing that it's going to take a whole lot of years for that aircraft carrier to go from design phase to actually shakedown crews, and so there is a

knowledge that there will be a new one each year sort of, kind of, and knowing that each one is following along that pathway.

I'll take that out to -- and maybe it's never more than one at each of those years, but submarines or destroyers may be we decide that in three years we need more submarines or destroyers and so we're going to increase the number from X to Y and that's planned out and the Hill can see it coming and the like.

Is that a fair -- you're a soldier, too. So you're free to describe the Navy any way you want to.

DR. PARKER: Well, those are good examples, but I do want to just accentuate one comment that I made, is that as any agency makes their long-term plan, there's a certain piece of that that is very internal to the agency, and at precise intervals there is internal debate about how they're going to go to OMB to support their budget from one year to another, and even if the POM is shown to

somebody else, it's recognized as a plan. It's not cut in stone, and at periodic intervals the agency must work with OMB and the Congress to insure the next two years of monies against their Program Objective Memorandum.

So it does not guarantee that those monies are there, but on an internal basis, it means that there's consensus within the agency, that they do want continuity of those programs.

ACTING CHAIR CANTRILL: Pat Scannon.

DR. SCANNON: Just as an extension, the pharmaceutical industry does very similar things. So this is not new in drug development as a concept either.

DR. GRABENSTEIN: One of the comments called out in the report probably in bolded text, I think, if I remember right, is the comment that up until now the PHEMCE players, the BARDA and NIH and CDC and FDA and the like, have been doing the best they can

with the resources they have, and what we are calling for is a more rational process of figuring out what is needed and then going to the Hill and making a business case for why America needs increased resources to protect America and getting the budget process into a more rational, coordinated, needs driven approach.

Okay. You can see that Section 4 is rather large. These are the subheadings. Actually, I think we might have missed a couple of the subheadings, but anyway, the subheadings are to align the efforts to the national priorities. The previous section said have a strategy, make prioritized lists, and now we're saying put your work aligned to the prioritized list, not what you want to do; what needs to be done.

Foster and accelerate the research pipeline. We talk about decentralized discovery of new MCMs and then for some products centralized development and manufacture for efficiency reasons. Provide

the appropriate incentives to industry. Evaluate multiple use approaches. Maximize markets. Focus the basic science agenda. Address regulatory issues. Pay attention to clinical diagnostics. Harmonize the select agent regulations. Address product liability and injury compensation. Improve acquisition practices. Enhance EUA preparation. Enhance distribution and dispensing. Take care of the children. Addressing functional needs of at risk individuals, and then other.

So some general observations. The Federal MCM program to date can be characterized as a good effort conducted by talented people, but one that is poorly synchronized. With adequate resources and effective leadership, however, the various entities of the government can work together and harness the expertise of the private sector in ways similar to those used to produce aircraft carriers, land humans on the moon, and accomplish other "Manhattan projects."

So this is a long list of recommendations. So we'll just tell stories as we go.

Recommendation 14, that the ASPR promptly provide a plan to the Secretary to provide for centralized advanced development and manufacturing of selected biological MCMs based on one or more public-private partnerships or Federaly funded research and development centers.

We think that the current approach to discovery, which we use the term, "a decentralized approach to discovery," is the right one. The amount of creativity and talent and cleverness in America is enormous, some in academia, some in small companies, some in big companies, and so discovery should stay decentralized.

However, in some cases we are persuaded by a DARPA report that called for or described the advantages of centralizing for some products, advanced development in manufacturing, and we think where it makes the

most sense for that centralization to occur is not probably for tablets and capsules or even antibodies maybe, but a little more likely for other kinds of biologicals, vaccines maybe especially, where the art and the science of formulation and product development are so intricate, and we actually note that it is apprentice based in terms of the training of the workers. There's not a lot of empiric scholastic training along these lines; that you don't want to reinvent that wheel and invest in that training time after time after time, but rather do it once, retain that talent, and have that central place to go to for this. So that's what 14 is all about.

And from the regulatory section here, that the FDA Commissioner promptly provide a plan to the Secretary for designating appropriate candidate medical countermeasures for high priority review and the appropriate criteria of evidence for safety and efficacy.

Now, what you'll find in the report

is in relation to Number 15, is that what we're calling for is that the Commissioner recommend a system, a criteria, a means of designating candidates worthy of high priority review. And so, you know, find some level playing field way of which ones to devote extra resources to and keep moving along.

And then the appropriate criteria for evidence is a call-out to the discussion we have in the text about understanding how to define risk-benefit balance for products that are -- excuse me -- for situations that are low probability but extremely high consequence, and one of our observations is a concern about the pursuit of perfection of information, of knowledge before a product can be licensed, and we think that we don't want to delay licensing or approval of products while seeking a perfect collection of information, but rather get products licensed on the basis of reasonable expectations of safety and efficacy.

ACTING CHAIR CANTRILL: Why don't

you continue?

DR. GRABENSTEIN: Okay. Sixteen, that the FDA Commissioner promptly advise the Secretary on a plan to revise the draft guidance on the animal rule. This derives in part from discussion at the Institute of Medicine Workshop and at our own workshop wherein we heard frustrations from many developers that they were being held to a higher standard in the implementation of draft guidance than is actually in the original animal rule.

And so what we call for is an input gathering phase of a scientific workshop for the FDA to hold to hear those things out and then revise that draft guidance, get it in our opinion more in line with the original rule and avoid setting the bar for evidence so high that effectively it can't be reached.

Seventeen, that CDC, BARDA and NIAID Directors develop a plan for the ASPR for identifying and addressing the need for screening and diagnostic tests for CBRN agents

that can be performed in clinical settings prioritized among all those other MCM needs.

The clinical setting part of 17 is the pivotal part because we are concerned that an undue reliance on the good folks in Atlanta and the good folks at the Laboratory Response Network, the few sites that there are, is not sufficient for the country, and that we need to pay more attention to diagnostics and clinical settings, in other words, more decentralized approach that would be a good thing for the country, and we hedge a little bit by saying that here's yet another thing to put into that multivariate equation about the prioritization and balance.

One of the concerns that we had was in the -- so there were many good things that happened in the H1N1 pandemic that we called out about diagnostics, but one of the problems was state reference labs and others turning away samples because they were overwhelmed, and so we think that this is an issue that needs to be addressed.

ACTING CHAIR CANTRILL: Dr. Dretchen.

DR. DRETCHEN: Yes. So many issues on these two. I mean, clearly, the issue with the animal rule is paramount. I mean, I'm in a situation where I'm doing a lot of work dealing with antidotes to chemical warfare agents where, in a sense, the animal rule is a little bit more straightforward in terms of what you're ultimately going to see as an outcome as compared to the nuances associated with things as subtle as radiation sickness.

In terms of the 17, the clinical setting for diagnosis, I mean, the Gates Foundation has just put out a proposal or an RFP about a month ago looking for clinical diagnostics in Third World countries where, in fact, you don't have the sophistication of having a PCR machine, you know, next to you and the climate conditions, you know, will change on a daily basis.

And so this is so critically important that we have simple, rapid,

effective diagnostics that are available readily throughout the country with no false positives and no false negatives.

(Laughter.)

ACTING CHAIR CANTRILL: And hurry.

All right. Yes.

DR. ROSE: We added a section regarding aligning development pathways with the overarching strategy that I think needs to make it to the table of contents, but I'm wondering also if we should add for the title of that section with regard to align development pathways that we should align development and regulatory pathways with the overarching strategy so that the two --

DR. GRABENSTEIN: Well, I certainly agree with your intent. I think regulatory is part and parcel of the development pathway. You can't develop without having a regulatory process.

DR. ROSE: Yes.

DR. GRABENSTEIN: Sure.

DR. ROSE: But that just needs to

make it up into the --

DR. GRABENSTEIN: Yes, that's the one that I forgot because we added it late and didn't get to the slide.

ACTING CHAIR CANTRILL: John. Oh.

RADM LUSHNIAK: Boris Lushniak on behalf of FDA.

Regarding 17, we talked about this a little bit yesterday. I just want to speak for the record, is that the importance also as to whether any diagnostic paths are developed, clinical settings or for laboratory use, the importance of, again, the regulatory pathway in those diagnostic tests; that there is a clearance process, and we would recommend that although CDC, BARDA and NIAID Directors are set as the leads on this, that there needs to be an interplay obviously in terms of making sure that those tasks go through appropriate regulatory channels, that we have confidence in them, confidence in their sensitivity and their specificity and that they do their job right.

DR. GRABENSTEIN: Yes, so two comments in response. One is we could add FDA to essentially every bullet on here, I think because --

RADM LUSHNIAK: Right. I would prefer that not take place.

DR. GRABENSTEIN: Yes.

(Laughter.)

DR. GRABENSTEIN: Well, we could put your name personally on it. That might be the other alternative.

But Ken made the joke about, you know, no false positives and no false negatives. I assume it was a joke.

(Laughter.)

DR. GRABENSTEIN: Because anybody who has spent any time with diagnostics knows the dilemma of the tradeoffs between sensitivity and specificity, and you know, one of the things we call out in the report is the value of FDA in the H1N1 pandemic of the utility of the diagnostics, and we all know from pop-up ads on the Internet that people

will be happy to sell you things that would purport to diagnose, but having the FDA imprimatur of safety, efficacy and quality is pivotal.

RADM LUSHNIAK: Great, and then my next comment is if you can back up one slide to number 15, and again, this is a repeat of some comment I made yesterday, and again, this is mostly for the record here in this public forum, is that I see no issue in terms of the FDA Commissioner providing a plan to the Secretary regarding the designation of appropriate candidate for this, quote, high priority review. The difficulty the FDA will have is in terms of actually choosing those countermeasures, and I think innate within this is going to be the specific countermeasures. It is going to be working with the Secretary, with the ASPR, with other entities so that we aren't perceived of actually giving a fast lane approach to specific countermeasures, i.e., then disturbing market forces or the sense of

fairness of review when the market and sponsors are out there trying to get their products to the end, finish line.

DR. GRABENSTEIN: All right. I think I said out loud the words, "a level playing field." There needs to be an objective process fulfilling whatever those criteria are. Then you qualify and it should be qualify and appropriately so because it has met whatever the scientific objectives are or the levels of maturity or the importance of the threat. The value of the potential countermeasure should it succeed might trigger that.

The other piece is remember that clause I may not have spent enough time on previously about "and gives special attention to the FDA resources," because the place is inadequately staffed. It has excellent people, but not enough of them, and we call out in a footnote a major report from the FDA Science Board of a couple of years ago in that light.

ACTING CHAIR CANTRILL: Dr. Amos.

DR. AMOS: Yes, I just wanted to get back to Ken's comment on false positives and false negatives. So just to point out that the need for reference methods and materials and data for supporting the accuracy of these diagnostic tests. I'm not sure how many people realize, but you know, I guess the Mayo Clinic offers over 4,000 different tests, and there are internationally agreed upon reference materials for only about 70. So there is some catching up to do, and I know we talked about this. John and I had several e-mail exchanges.

But I think it is something that tends to slip the mind of people, the importance of including the measurement science and the measurement scientists in the discussion and in the planning for these things.

DR. GRABENSTEIN: good. Thank you.

ACTING CHAIR CANTRILL: Dr. Scannon.

DR. SCANNON: Just briefly, the Board or the Working Group wants to confirm Dr. Lushniak's remarks in Recommendation 15 that the spirit of 15 is to provide a plan for designation, not to designate specific things. We absolutely concur with that as a point of emphasis.

ACTING CHAIR CANTRILL: Dr. Jutro.

DR. JUTRO: I'd like to ask the Chair. I have an overarching question that has to do with the title of the report, and I don't understand the flow of the meeting well enough to know whether now is an appropriate time to make it.

ACTING CHAIR CANTRILL: Why don't you go ahead?

DR. JUTRO: Okay. The title is delightful, especially the third line in its constructive ambiguity, but I'm afraid the title will lead the reader to believe that it is a more ambitious report than it actually is. It somehow should stress that it is not evaluating the entire range of America's

defense against these threats. Rather, it's confined to a specific subset, whether it's medical defense or medical countermeasures or whatever. This would lead one to believe that the entire range of activities by the intelligence community, but the Defense Department and other agencies as well are incorporated in it, and I know that was not the intent.

ACTING CHAIR CANTRILL: Would you make a suggestion in terms of potential changes?

DR. JUTRO: I would think that it could be American medical defense or it could be medical countermeasure leadership matters. I just want to make sure that by using the word, "medical," I'm not giving short shrift to a broader range of public health issues that it addresses. However, I do think you want to narrow it down to public health and medical issues, and I'd be happy to, at the break, write four or five suggested ones and share them with you and let you do with them

as you wish. I'm sure other people will as well.

DR. GRABENSTEIN: The thought that's coming to me on the fly, I think that's a good point. The possibility coming to me on the fly is defending America's health from the threats, and we can maybe just ponder that for a little while.

ACTING CHAIR CANTRILL: Yes, sure, and we can discuss that during the break.

DR. JUTRO: Thank you.

ACTING CHAIR CANTRILL: Thank you.

DR. GRABENSTEIN: When is the break? I'm just going to keep going till you stop me.

MR. DI RIENZO: Hey, Pat. This is Al Di Rienzo. Can I make a comment, please?

ACTING CHAIR CANTRILL: Yes, go ahead, Al, please.

MR. DI RIENZO: Okay. So just back to 17 again for a moment. So while I certainly agree with the comments on sensitivity and specificity, maybe not

perfection, and of course, being under design controls and so forth, the one thing that I've noticed is that a lot of times when people talk about this area, you know, even in our industry we talk always about sort of the lab, the central lab or we talk about sort of a clear waved type of test, but this also just as a point of reference encompasses things that are occurring in molecular level imaging where you can get some of the same information that you get from, you know, a blood sample or saliva sample or whatever the case may be.

In a traditional sort of lab setting there's things that can happen in the imaging domain that sort blend molecular genetic medicine and traditional imaging.

So just a point of reference so we don't always just gravitate to think that everything has to sort of be within that lab setting.

Thank you.

ACTING CHAIR CANTRILL: Thanks.

DR. GRABENSTEIN: All right.

Eighteen we split into five parts. The Assistant Secretary for Preparedness and Response in coordination with leaders of other relevant agencies -- that's shorthand for us not having to spell them all out each time -- (a) identifies to the Secretary of HHS needs for additional pediatric products for the SNS;

(b) Provides to the Secretary a plan to determine pediatric dosages for at least three MCMs.

So the first two are about pediatrics, and we point out in the table the immaturity of the actual products themselves or the information about them to take care of, oh, ten, 15, 20 percent, depending on which age break you pick, of the American people.

So children cannot be an afterthought. Children have to be an integral part of the response, America's response plans, and we think that starts with more purchases and clinical studies actually to determine pediatric dosages.

(c) is a little bit different

tangent. Identifies to the Secretary a plan to create and maintain pre-emergency use authorization dossiers for the top 20 MCMs in coordination with DOD, and this results from our recognition in our call for greater preparedness for assembling the data packages that would be considered by the Commissioner of FDA and others in the course of deciding whether or not to grant an emergency use authorization status to a particular MCM. And better to have brought all of those materials together ahead of time than to do it late on a Friday night in the midst of a crisis.

Okay. (d) and (e). (d) Provides to the Secretary a plan to write integrated response plans for three high priority threat scenarios to describe response from alert to MCM dispensing. You see a bunch of red here that we revised these yesterday in our prep session.

And then (e), provides to the Secretary an evaluation of state level medical countermeasure distribution plans to assess

adequacy in caring for children and adults with functional limitations and a plan to resolve common problems identified.

So back to (d). Write integrated response plans for three scenarios. So that part, originally the text you see in the paper says "concepts of operations." We thought that that had multiple meanings to different people. So we tried to be more specific in terms of what we were talking about, and so we chose the phrase "integrated response plans" to mean the collection of -- we used the analogy of the stacking dolls, Russian dolls. You know, the city is going to have a plan and the state is going to have a plan and the SNS has a plan, and the ASPR and the Office of Preparedness and Emergency Operations have plans, and do they have gaps between them? Do they take advantage of each other fully or have things been missed? Are they fully digitally connected?

And so we call out in the report an appreciation of the smallpox response plan,

maybe more specifically the pandemic influenza plan as a great example and call for more detailed planning of that type where it's across the spectrum in multi-party plans.

We call out in the report that the use of the three is a number that is just get started and make it better and get yourself going. Pick three scenarios and get going. We call out in the report that you may not want to have a tularemia plan and a plague plan and a typhus plan and a glanders plan and a whatever plan. You might want to have a contagious infectious disease plan and a noncontagious infectious disease plan and a chem plan and a rad plan or something like that. You may want to bundle scenarios together to avoid or to minimize or reduce your work burden and have fewer three-ring binders on the shelf.

Then on (e) we talked about yesterday the fact that the states all had plans and I may not use the right words here, but the Federal Government has scored, I think

was the verb used, the state plans, and all of them get a passing grade. I'll opine on that.

But those plans should be read and evaluated in terms of how well they focus on children and on adults with functional limitations, and if there are patterns found in looking at I think there were 64 of these reports or something like that, state and territorial and city, big city reports. There are plans, and look to see if there are common problems across the 64 and then work a plan to resolve those common inadequacies.

ACTING CHAIR CANTRILL: John Parker.

DR. PARKER: In reference to Recommendation (d), the purpose of writing a plan is not that that particular plan is going to be executed, but in the writing of three kind of broad types of plans, it really emphasizes that the ASPR not only has a charge for preparedness, but the ASPR is also the responsible individual for the medical response, and so by doing this planning drill,

so to speak, it does uncover gaps in the response. It produces areas of the response that must be discussed not only within HHS, but other agencies, the DHS and the DOD, and at the state level to get a feeling that the response to a particular event will have a flow and a continuity, and each person that's involved in that response or agency -- I don't want to say person -- or agency knows exactly how they're going to play in a medical response.

Now, it's also important to do these integrated response plans because we tend to believe that medical is a separate silo and that we can drive a medical response down to the ground because of its inherent importance, and we don't understand that if a disaster is big enough, it is just one piece of a response, but it has to be well worked out, and by doing plans, we find out that we can actually work it out and these three integrated plans then become huge templates to go back to because when the exigency occurs,

it will never match the plan. I will tell you it will be different.

But the major paragraphs in that planning exercise will tell you what paragraphs to address in the exigency, and it will be much smoother.

I've said too much, but planning, exercise, and then eventual execution are very important parts of being an assistant secretary that's responsible for not only preparedness, but the response, and we just want to be able to brand that really strongly that the ASPR does have quite a responsibility if there's a medical emergency in this country.

DR. GRABENSTEIN: So I'm a risk taker. I'm going to suggest we have a single three-letter word to clarify a grammatical issue here, and we'll see if I'm -- how big a risk I'm taking. I think we really want to say in (e) in caring for children and for adults with functional limitations because we mean all children, and then the adults are the

ones with functional limitations.

ACTING CHAIR CANTRILL: That's a point of clarification, and I think that's appropriate.

DR. GRABENSTEIN: Anybody object to that?

CAPT SAWYER: Terry, your microphone.

DR. ADIRIM: I'm sorry. In FEMA they're using the term "individuals with functional limitations." I don't know if you want to --

DR. GRABENSTEIN: Roberta, do you have a preference?

MS. CARLIN: I was out during probably a very lively discussion.

DR. GRABENSTEIN: I'm sorry. I'm taking great hazard in opening up the document. We're talking about all children and the people with functional limitations. Do you want us to say for adults or for people or for individuals or for --

MS. CARLIN: Okay. I see. I would

say individuals. Dan, do you have any comments?

PARTICIPANT (Dan Dodgen): I agree, Roberta.

MS. CARLIN: Yes, okay. I'm sorry. I was having a very lively conversation out in the hall. So I apologize.

ACTING CHAIR CANTRILL: Okay. Everybody okay with that?

DR. GRABENSTEIN: All right. Then the other thing I want to call out is a table on page 73 because this took a lot of work, and I owe a debt to many people here in the room and who are not in the room to try to figure out where we stand with the regulatory status and the information status of the various countermeasures with respect to children.

And what you'll notice is categories of product and then categories of threat agent, and then an assessment of whether those medical countermeasures are currently licensed or approved for use in

children for that purpose, and that would be A -- and there are very few A's on that chart -- or they are approved for other uses or they're approved for use in adults but not in children, but some pediatric information is available, and there's a fair number of B's. C is licensed or approved for adults, but no real understanding of what the pediatric dose is. D and E are just increasing levels of uncertainty.

So this has been compiled and it's pretty, and I've got all of the -- it's spelled correctly, but it has not necessarily been subjected to peer review, and so if anybody spots any flaws in this, I will happily fix them, but I think it begins to give you an assessment of where we stand and where the inadequacies are, and I will readily acknowledge fudging on the antibiotics a little bit by just saying selected antibiotics because we haven't -- I mean, I haven't done an exhaustive package insert level review of which ones for which indications and even some

of the DTPA products. It depends on whether you're talking about injection or nebulization, and so there's complexities that are not reflected in the table, but we're hoping to give you a starting point to begin to assess how readily we can take care of the kids.

ACTING CHAIR CANTRILL: Dr. MacVittie.

DR. MacVITTIE: Just a quick response. Richard and I were involved in filling it in for the acute radiation syndrome and you can see there's only one letter there, but I think we were remiss actually in adding a term called medical management. So certainly we would apply antibiotics, fluids, things like that to the pediatric population, and they are very effective. So we were remiss in adding that.

DR. GRABENSTEIN: That's reflected in the text. I think I would like to keep the text focused on the specialty -- the definitive products as opposed to the

supportive care products.

Eric.

DR. ROSE: I think it's a very important table. I think it belongs in the document, and it could inform a good deal of regulatory science research, for example that hopefully will propel a good deal of this forward.

So I'd leave it.

DR. GRABENSTEIN: One of the comments we heard was, yes, but it would be unethical to do research in children, and I recognize the conundrum and the steep or the intricate, deep ethical requirements before one does research in children, but I would suggest to you that in the 2001 anthrax attacks there were child cases, pediatric cases, and so this is not an abstract issue. We have had pediatric casualties, with anthrax, and it's something that needs to be taken into account.

Okay.

ACTING CHAIR CANTRILL: Dr. Parker.

DR. PARKER: As we discuss the report, I think we have said it in the report, but probably not putting it in a recommendation, and I would want to think about a recommendation in this area if it's amenable to the Board.

But during the course of putting this report together, it was abundantly clear to the Board and to the work groups that the ASPR has a huge amount of responsibility and minimal manpower within the office of the ASPR to execute that.

So you know, on an overall basis if the Board believes that we should say that, I would recommend an additional recommendation in the report that particular focus be addressed to the manpower within the ASPR so that the ASPR can execute the responsibilities afforded her by the legislation under PAHPA, SF-8, and other documents.

DR. GRABENSTEIN: Do you want to change a recommendation or do you want to go back in the document and make sure we have a

sentence that makes that clear or --

DR. PARKER: My first approach would be to go back in the document and just see if we've addressed that and not bring it to a vote for a new recommendation, but I wanted to publicly state the fact that we recognize that the current situation against the responsibilities the office is not properly manned.

DR. GRABENSTEIN: So, Roberta, I actually should have asked you in the interest of people who are color blind what color I should have chosen for the slides perhaps because I think green is a problem, isn't it?

No, no, no, no.

(Laughter.)

DR. GRABENSTEIN: Red and green. All right. Obviously I don't have the problem. That's why I don't know.

ACTING CHAIR CANTRILL: Dr. Scannon.

DR. SCANNON: In reference to John Parker's remarks about making sure that ASPR

has adequate resources, I absolutely agree. However, I don't think we need another recommendation because I think within earlier recommendations, such as 11 where we're looking at and 12 where we're looking at legislative plan to seek multi-year funding, implicit in that is to have the capability of managing that funding, and I think adding it to the text would be the appropriate place.

ACTING CHAIR CANTRILL: Thank you.

DR. GRABENSTEIN: Good. Okay. Moving on, 19, the NIH Director and the NIAID Director provide the Secretary a plan on how to align basic science resources for MCMs to the national prioritized list of research goals and product requirements.

Twenty, that the Secretary working with NIH and NIAID, BARDA and DOD develops a plan to rationally allocate limited animal resources and facilities to CBRN animal model development and testing in alignment with the national prioritized list of research goals.

The Secretary develops a plan to

fund the countermeasures injury compensation program (CICP) for all covered countermeasures and to extend the filing deadline to a consistent three-year interval.

So one at a time, 19 relates to having an explicit plan for making sure that the monies that go to NIH whether for chem, bio, rad or nuke are matched to the prioritized list of research goals and the products that are needed to meet the threats based on the threat priorities and the product priorities and the research goal priorities that were in one of the earlier recommendations.

Twenty relates to the fact that non-human primates especially are finite resources, and we only have certain kinds of facilities, certain numbers and certain limitations to optimize the use of the limited animals and buildings to get the animal models developed and conduct the animal testing that will be needed to stay aligned with that prioritized list of research goals.

And then the countermeasures program, the text talks about the PREP Act and which calls for immunity from tort liability and a compensation program of recipients of covered countermeasures and notes that the CICP has been allocated enough money for the H1N1 influenza vaccine, but not for other countermeasures for which EUAs have been granted, and that seems inappropriate. People may be offered the opportunity to take those products, and the bureaucracy hasn't gotten around to putting the money in the pot that is designed to take care of them.

And the filing deadline deals with the fact that the PREP Act calls for that one must file within one year after receipt of the product. People have already received the H1N1 vaccine, but the regulations have not yet been promulgated to administratively process those claims, and so HRSA, Health Resources and Services Administration is accepting letters of intent in lieu of because they have no mechanism to process the claims. The

claims can't officially be received because there's no process to handle them.

So extend the umbrella to all of the products under EUA and rather than have a one-year interval for some intervention, some medical products, and a three-year interval as the standard well known now for the National Vaccine Injury Compensation Program that HRSA runs, let's have a uniform standard across the government of a three-year interval.

ACTING CHAIR CANTRILL: Comment over here. Hugh Auchincloss, NIH.

DR. GRABENSTEIN: Oh, sorry.

DR. AUCHINCLOSS: In the text under Line 19, you make the suggestion that NIH should do something to its study sections to be better organized to deal with biodefense, and CSR should deal with this problem. I hope that the Board recognizes that in general in developing science for these measures we issue RFAs and RFPs that have special study sections that are specially convened precisely for this purpose, and that actually has nothing to do

with CSR.

So I just hope that the Board recognizes that we do, in fact.

DR. GRABENSTEIN: So have we stated something incorrectly that needs to be fixed? Can you scratch up what you've got and help us get it right?

ACTING CHAIR CANTRILL: Mike Kurilla will help.

DR. GRABENSTEIN: Okay.

DR. AUCHINCLOSS: Later you talk about the emblematic friction between BARDA and NIH which frankly was news to me. In the issue of the transition from NIH to BARDA, which is an important issue, the central issue is the total inadequacy of BARDA funding in order to pick up the ball and do the job that they're trying to do, and I think that should be the part that's emphasized rather than some, frankly, I don't believe friction between BARDA and NIH.

DR. GRABENSTEIN: Okay. So the funding I think we've called out rather

clearly. What we have not been able to reach a clear resolution on is an understanding of products that are, quote, unquote, at BARDA that are at seemingly technology readiness levels that are ready for consideration, but because of delays in the review cycle time have, in my words, are languishing.

I'll acknowledge that we ran out of time and didn't get a chance to take a look at the list of what those products are and figure out the right way to describe them, but our prime driver is to get the work of each of the agencies aligned to a common set of prioritization goals. That's really the overarching thing.

ACTING CHAIR CANTRILL: Mike Kurilla.

DR. KURILLA (NIH/NIAID): John, I think there has to be a recognition that simply because someone applies to the BARDA BAA for advanced development does not by definition mean that they are, in fact, ready for advanced development, and many of those

projects, in fact, that come in are more appropriately placed at NIH, and we have ongoing discussions in terms of being able to interact with those entities.

Now, there may be a disagreement in terms of the assessment of where they feel they should be in terms of advanced development and where they actually are, but in point of fact, when we have reviewed many of those programs, those proposals that have come into BARDA, the ones that BARDA itself has identified, self-identified as high priority within their programmatic emphasis, we are already supporting at least half of them so that they feel they're ready to advance. Whether or not they are, that still remains to be scientifically and technically assessed.

So I don't really understand where the term "friction" came from between NIH and BARDA. In fact, I have a meeting this afternoon, my monthly meeting with the BARDA Director. So that is an ongoing, regularly

scheduled meeting to discuss transition issues.

ACTING CHAIR CANTRILL: Okay. John.

DR. PARKER: I'd kind of like to suppress the idea of friction. I don't know where that came from.

I think one of the reasons for this recommendation, Hugh and Mike, are based on -- we fully understand that there's good conversation and everything, but the visibility, it's not a plan. We'd like to be able to have a visualization of, you know, the dollars that are given to NIH for biodefense. We'd like to have a better visualization of how those dollars are aligned and basic science resources that are actually supporting, you know, the threat list that HHS is working against.

I'd like to speak for myself. I believe that the work between NIAID, NIH and BARDA is probably pretty good, but we have no visibility on how you do that and what

documents you use at that time.

DR. AUCHINCLOSS: I think that's a fair point, and we understand where you're trying to fundamentally go with this recommendation and have no problem with it at all, nor the underlying test.

I would say, however, that the term "basic science" up here, I think makes the recommendation verging on sort of nonsensical. To align a basic science portfolio with a product outcome is really probably not what you want, if I understand "basic" correctly.

I think your use of the word "basic" is probably designed to separate it from BARDA's product development pipeline, but I think of it as sort of really early on. I would just drop the word "basic" and leave it to science.

DR. PARKER: The point, you make a good point, and that's probably a good idea if we're going to do anything with that particular recommendation. But I have limited experience with drug development, just enough

to be dangerous, but I do know that in this particular area of medical countermeasures against these very difficult agents and diseases, that the perceived slowness of the development is not because people don't want to develop it. There's a science gap that needs to be solved, and whether we call it a basic science or whatever, but this is to get at those science gaps.

DR. GRABENSTEIN: This is John again.

Are we okay with striking the word "basic"?

DR. SCANNON: I have a comment. I think at least in my experience in addressing medical countermeasures, the term "basic science" is used to delineate the difference between the steps before advanced development and the steps from advanced development forward. It is not anything more than that.

However, it is a term of communication that is commonly used, and I would be careful about eliminating it for that

reason.

DR. GRABENSTEIN: Right. So Mike and I went back and forth on within his own group he's got basic, advanced, and some applied, and they don't match. They are technical categories in his realm that I don't think would be -- well, I'm confident are not the same usage as most people would be familiar with. So this is basic in our sense, not basic in your sense.

So do you want to keep it or do you want to drop it?

DR. SCANNON: My personal recommendation is to keep it because the spirit of what we're talking about is not the spirit in which we were discussing it with regard to the way NIH uses and NIAID uses the term. It is really to distinguish the difference in separation between what NIAID does and BARDA's advanced development program.

So my recommendation would be to keep it.

ACTING CHAIR CANTRILL: Dr. James.

DR. JAMES: And I would strongly support what Pat said because we have to look at who's using this document, and it's not a bunch of basic scientists. They are people we want to get a message across to, and that connotation does it.

ACTING CHAIR CANTRILL: Dr. MacVittie.

DR. MacVITTIE: I agree as well, and I think within the rad-nuke community, I don't know whether Mike or Hugh mentioned it. There is an effort putting out RFAs and RFPs that pulls together that middle piece where it asks those groups that are doing the basic science or the more R01 level type basic science to take the step up if they have the potential there to develop a medical countermeasure.

Earlier this week we had an example of that in, I believe, one of the NIAID RFA's on thrombocytopenic drugs. I sat in on that meeting and a number of those presentations, and I felt, boy, this is all pretty basic.

Have they moved to the translational piece yet?

But at least the carrot was there and was bringing people from the basic community into the more translational community, and I think that is of significant value, just speaking from the rad-nuke community. So I would keep alignment.

ACTING CHAIR CANTRILL: Dr. Dretchen.

DR. DRETCHEN: Yes, Tom said exactly what I wanted to say, but in my community, if you will, the term basic science is a very specific, you know, group, and I would want to keep that in there.

ACTING CHAIR CANTRILL: John, I think it's essential to the Board that we keep that in, and then I would suggest if there are no other comments, we move on.

DR. GRABENSTEIN: All right. Are there comments about any of the recommendations? Mike.

ACTING CHAIR CANTRILL: Dr. Amos.

DR. AMOS: I mean, I think the simplest approach is just to define what you mean in the recommendation. I mean just spell it out so people -- it's very clear. Nobody has to guess.

DR. GRABENSTEIN: So, Mike, if you can stay after we adjourn, I'd like to settle the text language stuff today so that we can finish the report.

Are there other issues about the recommendations? Anything on the screen?

(No response.)

DR. GRABENSTEIN: Okay.

ACTING CHAIR CANTRILL: Point of comment. The Chair's prerogative is to move the break to as soon as we finish these last two recommendations before the public comment section.

DR. GRABENSTEIN: Okay, all right. So Section 5 is about enhanced communications. The government needs to prepare a threat and risk assessment suitable for public communication to provide a basis

for public engagement on the consequences of CBRN threats.

We've tried to do our part by inserting some boxes throughout the text that pull from the published literature various peer reviewed articles about what the consequences of CBRN threats might be. We are not asserting that we agree with these documents, but as any good scientist knows, these kinds of models are very heavily dependent on the assumptions that you put into them, but we think it's important to get the conversation started.

Why should the American taxpayers invest whatever the amount of money ultimately selected is to counter these efforts? And the considered opinion of the Board is that we should -- America should, indeed, invest a substantial amount because, well, because it's a matter of national security and analogously to the way we have invested in many other aspects of defense over the last 50 years.

So the recommendations are that the

ASPR provides to the Secretary of HHS a plan to release more information on CBRN consequences to the public as part of a sustained, multi-faceted education and communication plan. Education was added yesterday.

And 23, that the ASPR provide to the Secretary a plan to make information about MCMs available to the public before and after emergencies in appropriate, accessible and alternative formats, accessible and alternative being terms of art for Braille and the methods of delivery on the Web that are appropriate for people with limited vision.

"Accessible" has another definition that I'm forgetting, and "appropriate" we mean culturally appropriate and linguistically appropriate and the like.

ACTING CHAIR CANTRILL: Comments on these recommendations?

(No response.)

ACTING CHAIR CANTRILL: Okay.

DR. GRABENSTEIN: There's one

other. I'm going to pop out an idea now before the break in case people want to talk about it. Now that we've -- I was going to use the word "solved," but I know that's not the right word -- now that we've addressed human health, what we have not talked about is our issues of animals and plants and agriculture, and it's not really the scope of this report, but with the Board's okay, I would like to insert a paragraph reminding the U.S. Government that they need to take stock of where the country stands in terms of preparedness on the agriculture tangent.

ACTING CHAIR CANTRILL: I think the sense of the Board is we would certainly agree with that.

Any other comments?

If not, I have 10:23 currently. We will stand in recess for 20 minutes. We will reconvene at 10:43.

(Whereupon, the above-entitled matter went off the record at 10:23 a.m. and resumed at 10:46 a.m.)

ACTING CHAIR CANTRILL: This will be the public comment period. There will be two components to it. We will be taking public comments from our call-in participants as well as in the room. I would ask that if anyone in the room has a public comment they will need to stand at the microphone.

For anyone making a public comment, I would remind them to please preface their remarks with their name and organization if they represent one.

Operator, do we have any public comments from our telephonic partners?

THE OPERATOR: You have a question from Susan Chu from ReadyMoms.

ACTING CHAIR CANTRILL: Please put her on.

DR. CHU: Hi. I'm on?

ACTING CHAIR CANTRILL: You're on.

DR. CHU: I am Susan Chu from ReadyMom Alliances.

I want to thank the NBSB for this wonderful work, particularly for addressing

specifically the countermeasures.

I'd like to make two points. One is that I think 2009 H1N1 response shows very clearly that children are the first to be assessed. We see all over the world it's very obvious. The other obvious thing about it is that the most likely children countermeasure was the vaccine in the pandemic was not available to the bulk of the emergent infections that occurred. Again, that's not new to the U.S. We see that around the world.

So clearly the status quo is not acceptable in a severe pandemic. Children will not be protected. So I think this may be one example where the issue of centralized expertise that was raised earlier that may be justified, but this is one situation where it should be considered.

There was another question or comment about a EUA idea where I think that it is a good idea that you need to collect data ahead of time. You don't want to be running crazy, you know, when time is short, and so

on.

However, I live in Europe and I want to share the experience in Europe where the pandemic vaccine was approved using the same system with a mockup, and the approval since it was based on the scenario from 2001 where it obviously was for a severe pandemic and immunize the public one hundred percent. But in the 2009 pandemic what happened was that countries kind of got, for want of a better phrase, got on autopilot where they just went for the track that was available without additional risk-benefits, and so the majority, the bulk of the best cases were evidences and the time scenarios were 400 percent population uptake, which in the event there was a large assistance, and like in England where I live absent among children and also among pregnant women became very low, and I think that's very unfortunate and it's not necessary.

In any case, the preauthorization wasn't used correctly. So I think that while

the EUA is a good idea, I'd like to make a couple suggestions for the vote to consider. One is that whatever ways to put down robust safeguards and metrics in the qualifying process to make sure that the products don't get on that autopilot.

A second that is sort of related is to make sure that any EUA would stop short of being an actual authorized agent. That needs to be made very clear I think.

Thank you.

ACTING CHAIR CANTRILL: Thank you.

We did have some problems technically understanding all of your questions. Does anyone hear it well enough to be able to paraphrase it?

I know one of the concerns, and correct me if I'm wrong; I think your last question dealt with that you would want the EUAs to stop short of actual approval, and I think that is the intent of what we've written. It's just so we have the necessary pieces together to make it expeditious if we

choose to go forward.

DR. CHU: Yes, absolutely I agree. I think you're right.

ACTING CHAIR CANTRILL: Thank you very much for your comment.

DR. CHU: You're welcome.

ACTING CHAIR CANTRILL: Operator, do we have any other remote comments?

THE OPERATOR: At this time I'm showing no further questions from the phone lines, but if anyone would like to ask a question, please press star one.

ACTING CHAIR CANTRILL: Thank you, Operator.

Do we have any comments amongst those present at this room? Yes.

MS. CASSELL: I'm Gail Cassell, Vice President for Scientific Affairs for Eli Lilly, and I was the Chair of the IOM meeting that you have taken under consideration with respect to your recommendations, and I would, first of all, like to thank you for having taken that workshop and the output into

consideration in the report, and I felt very good reading the report because I think you've made a lot of progress in solidifying a lot of the issues and making some very valuable recommendations.

I guess one concern that I had, however, was the idea that while I agree very much that the preclinical research should be decentralized and a value of that especially as it relates to the very early phases of discovery, but I think you should not underestimate the requirement for larger companies in the biopharmaceutical companies, not just the smaller biotech companies to be involved in that phase, and the reason being is I think there's a lot of lessons to be learned from the Malaria Venture for Medicine and the TB Global Alliance and other PPPDs that have been established in that they need great access to very well characterize large chemical libraries. I think you really need this in developing new antibiotics in particular, as well as new antivirals.

And in addition, you need experienced medicinal and organic and synthetic chemists, and you don't often find that in the smaller companies. So I think that you may want to take into consideration that grants may not be sufficient to engage that effort, and that perhaps public-private partnerships might also be a mechanism that could be attractive for the larger companies.

So that would be one thing that I would ask you to take into consideration.

The other thing that I wanted to just mention, I certainly endorse the concept and the emphasis on the need for diagnostics. It has been said earlier today, but I think that we don't need to only focus on those to be used in a clinical or hospital setting or even the physician's offices, but the point of care diagnostics is a huge, I think, need and one that there needs to be a lot of attention paid to and will not be as easy, I think, developed as some of the more sophisticated tests.

Thank you.

ACTING CHAIR CANTRILL: Thank you very much for your comments, and, Gail, thank you for all your efforts in helping to make that IOM session a success.

MS. CASSELL: Thank you.

There were many people behind that as you well know, and I also forgot to thank you for taking into consideration the FDA Science Board report and the request that I made when I came before you to talk about the IOM report and the attention that I think FDA needs in terms of the resource issues to make everything happen that we know needs to happen.

And after reading your report, I couldn't feel more strongly about that, realizing all of the responsibilities.

Thank you.

ACTING CHAIR CANTRILL: Thank you.

Yes, sir.

DR. ROMANOSKY: Good morning. I'm Al Romanosky. I'm the Medical Director, State

Emergency Preparedness Coordinator for the State of Maryland, Office of Preparedness and Response in the Maryland Department of Health and Mental Hygiene.

One area that I think needs to be addressed within the document under Section 4, Function and Activity, Regulatory Issues, is I believe that it would be beneficial to have a relationship with the Department of Justice and the DEA, especially the drug diversion control because currently we're addressing an issue related to CHEMPACK and controlled substances and the proper type of DEA registration that's required in terms of particular modeling of how the distribution of CHEMPACK materials would be sent out.

So there is the practitioner DEA, that is, registration that's used to prescribe and dispense narcotics to your patients, but on the other hand, there is the wholesaler, warehouser, manufacturer DEA registration, and for most, I'm willing to bet, for most CHEMPACK programs, that is the DEA

registration that's required in terms of warehousing controlled substances and then distributing them out to the health care entities that will subsequently dispense those controlled substances.

And within the State of Maryland we have 21 CHEMPACK sites, and under current regulations it will require 21 individual DEA wholesaler, warehousing registrations, and then the question becomes is the DEA registration the duty of the warehousing site or the health care entity or does it belong to the state.

So as the state medical director, am I going to be filling out on an annual basis 21 DEA wholesaler warehousing registration certificates to meet the issues related to the CHEMPACK program?

So in terms of regulatory issues, I think that there needs to be that working relationship. It has been my experience that working with the Baltimore field office and DEA investigators, I had to educate them about

SNS vendor managed inventory and the CHEMPACK program, and I'm not quite sure they truly understand completely until I actually take them out to our CHEMPACK sites or our RSS sites.

In addition, I've been getting nice cooperation from the CDC at the SNS, but I don't think they understand the difference between the DEA registration required of practitioners and the DEA registration required of wholesalers and manufacturers.

Complicating this within the State of Maryland is that the Maryland Board of Pharmacy now requires any wholesaler to go through their certification process. So technically the State Department of Health has been in a little bit of violation with its own regulations, but we're working to address that internally at the moment.

So I think that that's another government agency that you need to build this working relationship with.

DR. GRABENSTEIN: Could I ask you

some questions?

DR. ROMANOSKY: Yes, sir.

DR. GRABENSTEIN: What does RSS stand for?

DR. ROMANOSKY: Receipt storage and shipping site, part of the SNS program. Sorry.

DR. GRABENSTEIN: And the sites holding those CHEMPACKS, are they state or governmental sites or are they private sector sites?

DR. ROMANOSKY: A combination of all three.

ACTING CHAIR CANTRILL: They are monitored by the Federal Marshals.

DR. GRABENSTEIN: So it's not just a -- the problem isn't that there's 21 sets of paperwork to fill out. That's a clerical burden, but it's -- what would you call the problem? Is it response -- if you centralize it, you can't really be responsible for the security aspects there or how would you characterize the problem?

DR. ROMANOSKY: Well, under the CHEMPACK program, there's a rather strict guidelines through the DS&S as it relates to the CHEMPACK program. So all of the CHEMPACK programs have to be secured, alarmed, monitored. They are subject to unannounced inspection through our office.

In addition, the containers containing the materials are sealed. They're also alarmed with a direct CSP line to CDC, as well as to the, within Maryland, to our central communications so that if that seal on that container is broken, if somebody gets through the locked door and the alarm, it will automatically notify via the telephone line to CDC as well as to the central monitoring station in Maryland.

So in addition, the rooms are temperature and humidity controlled for the SLEP program and activities related to it. So there's rather strict security guidelines related to these.

Now, although the CHEMPACK supplies

and materials are housed or warehoused within the either governmental for profit, not for profit institutions, they remain under control of our office, administrative control. So technically, those materials through CHEMPACK cannot be accessed without first notifying, making a request of our office, and then we grant permission to go ahead and utilize those materials for countermeasure administration.

DR. GRABENSTEIN: So are you advising us that the world is complex or are you asking for something to change?

DR. ROMANOSKY: Well, I think it is complex. At least I'm spending a lot of time going back and forth between CDC and the DEA field investigators, but I think that in recognition of countermeasure administration, I see no mention of bringing in the Department of Justice and the DEA.

This issue did not really come to the forefront until about five years ago when through some other activities that I'm involved with and I investigate the DEA

registrations I came to our SNS coordinator. I said, "Don't we need a DEA certificate for this?" And then we started working with the DEA.

And they said, "Ah-ha, yes." And so they started talking with the CDC. This is now a subsequent issue that has come up.

ACTING CHAIR CANTRILL: Thank you, Dr. Romanosky.

Dr. Dretchen.

DR. DRETCHEN: Yes, just to expand on that a little bit because I think you raise a very, very valid point, I mean, with the CHEMPACK if you're dealing with a Schedule IV drug like midazolam or valium, I mean, the fact is you're right. You have a control issue. What happens if any one of our hypothetical MCMs that we come up with has got a Schedule II drug like a narcotic involved in it?

I don't know that we can solve the issue today, but I do think that sensitizing through the document that, in fact, if this

problem exists, I think it is logical.

DR. ROMANOSKY: Well, one other issue related to this is ARCOS reporting. So they require warehousers, manufacturers to report on a quarterly basis their inventory of controlled substances, again, to identify massive drug diversion outside the normal chain.

And I can't really relate my shock when I got a letter from the DOJ saying that we're in noncompliance and that I may go to jail because I haven't been reporting for the past four years into the ARCOS system.

So I subsequently learned that through the SNS program, that if a state monitored or state sponsored program that I could request an exemption from reporting quarterly, but if the inventory or the drugs shipped to the state changed, I'm going to have to start reporting into the system if I meet the requirements for the controlled substances that will subsequently come into the State of Maryland.

ACTING CHAIR CANTRILL: Thank you.

Greg Burel.

DR. BUREL (CDC/SNS): Greg Burel. I'm the Director of the Division of Strategic National Stockpile at CDC. I apologize that you're having difficulties in this area. If you'll make sure that I have your card before I leave, I'll ensure that the right people at SNS contact you and we make sure that this is taken care of. We have dealt with this in a couple of other areas, and I think we can provide you a little assistance to help with this specific issue for you.

DR. ROMANOSKY: Well, I want to make clear. Your staff has been fantastic.

DR. BUREL: Thank you, sir.

DR. ROMANOSKY: And more than responsive in terms of addressing the issues.

DR. BUREL: Thank you.

DR. ROMANOSKY: So I don't want to give the impression that I'm not happy with the service provided to me as a customer to the state.

DR. BUREL: Understood completely, and we appreciate hearing that, but obviously we need to do something else for you to take care of this problem with you. So if you'll make sure I have that information we'll help with this specifically.

DR. ROMANOSKY: I see also it could be pretty big because how many CHEMPACK sites do states like California and Texas have in terms of do they have the appropriate DEA registration certificate.

DR. BUREL: Understood, sir.

DR. ROMANOSKY: So we can certainly talk.

DR. BUREL: Thank you.

ACTING CHAIR CANTRILL: Thank you.

Ms. Hart from DOJ, do you have any comments?

MS. HART: This is an enforcement issue that I wasn't aware of until hearing from the gentleman right now. So I'm going to follow up with DEA.

ACTING CHAIR CANTRILL: Good.

Thank you very much.

Operator, do we have any other remote public comment? Operator do we have any other remote public comment?

THE OPERATOR: I'm showing no questions or comments from the phone lines.

ACTING CHAIR CANTRILL: Thank you.

Any other public comment from the room?

(No response.)

ACTING CHAIR CANTRILL: If not, thank you very much for your comments, and I think that at this time the Chair would entertain a motion to accept the report.

DR. GRABENSTEIN: Not quite yet.

ACTING CHAIR CANTRILL: Okay.

(Laughter.)

DR. GRABENSTEIN: Well, Mr. Chair, I request permission to continue. I guess I should say it that way. We're almost done, but not quite.

First of all, I want to acknowledge as John did the ex officio partners. We

haven't figured out how to get somebody from the Internal Revenue Service here. That would be the next one we need, and that's where I'll be putting my attention this weekend, I can assure you, because I've not done anything yet, but I've got a couple weeks to go.

I want to come back to the question of 19 and whether or not basic should be there in that sentence, and it relates to -- it comes from a comment that Tom MacVittie made and some conversations during the break, and I fear that we can -- Tom used the word "translational," and NIH has got lots of kinds of science going on there, some of which is basic in the meaning that I think most of us have been using, and I'm wondering if this is a case where having an adjective in a sentence restricts us in a way we don't really want to be restricted.

And so I think the intent here is for all of the NIH efforts to be assessed in terms of their alignment to the national prioritized lists, not just the basic science.

And so we want the translational science to be aligned with national priority goals.

So I would submit under that rationale that maybe basic ought to come out of that sentence, but I turn it over to you all.

ACTING CHAIR CANTRILL: Dr. Scannon.

DR. SCANNON: I didn't put my card up.

(Laughter.)

DR. SCANNON: You know, again, this is a term that I'm familiar with and I've seen used many times to describe something. I mean, basic science in my mind covers everything up to, you know, where BARDA takes over in terms of advanced development, and so I don't think it's restrictive. Personally I don't think it's restrictive. However, if the Board feels the term is restrictive, I will stand down from my opinion.

I do think it is a term of art that is used very commonly in delineating something

different from advanced development, and I would prefer using it.

DR. GRABENSTEIN: So the specific comment that came up at the break was a concern that on the Hill basic science might be a color of money, a pot of money, and that, you know, we might have unintended consequences by retaining that.

DR. PARKER: Is there any reason to leave -- if you just removed basic science and said align resources for MCM?

DR. JAMES: Yes, just take out basic science.

ACTING CHAIR CANTRILL: Dr. Dretchen.

DR. DRETCHEN: Yes. I would go along with that because, I mean, the term "science" by itself, I mean, doesn't do anything for me, and those of us who are basic scientists, you know, all of a sudden tomorrow I'm a scientist. You know, I'm a different person. I mean, the concept of either making it basic science and translational science

resources is fine, but I think that the easiest fix is just to say align resources. That probably is a better approach.

ACTING CHAIR CANTRILL: Richard Hatchett.

MR. HATCHETT: Maybe a slightly different take on this, and it does depend on the intent of the recommendation, but you could -- I mean what has happened over the last decade with the emphasis on translational research at NIH and the development of the NIH road map is that NIH has tried to assemble resources to support translational medicine and early product development in some cases that are actually quite a bit of it is at NIAID, but it is sprinkled across all of NIH, and you could revise this to say, you know -- to provide the Secretary of HHS a plan on how to leverage trans-NIH resources to support the translation promising medical countermeasures in alignment with the national prioritized list, yada-yada-yada.

I'm just thinking of resources like

the probe development and the National Chemical Genomic Center, all of which are outside of NIAID, all of which would be very relevant to taking the true basic science investment at NIAID in biodefense and translating that into candidate products that could then be brought forward through the preclinical services and then through the advanced development services.

DR. GRABENSTEIN: So I'm inclined to say let's take out the adjective and not try to make any more complicated sentence because, again, we would be specifying a type, and I think we intend this in the broadest meaning.

How do you all feel?

DR. JAMES: Couldn't you address Richard's concerns and some of the other concerns in the body of the text and keep the recommendation without the basic science?

CAPT SAWYER: That was Jim James.

DR. GRABENSTEIN: I think the answer is yes.

ACTING CHAIR CANTRILL: Pat.

DR. SCANNON: I agree with that.

ACTING CHAIR CANTRILL: So then the suggestion is to remove the term "basic science" and address the issue in the corpus of the report.

Dr. Lurie.

DR. LURIE: Just a quick three-letter word addition to that sentence so that the intent is clear to others that it should say "aligning its resources," as opposed to "resources throughout all of HHS."

ACTING CHAIR CANTRILL: Thank you.

DR. GRABENSTEIN: Well, we've actually called for in lots and lots of places, we're calling for everybody to align NIH resources because it's compound. Okay.

ACTING CHAIR CANTRILL: Okay.

DR. GRABENSTEIN: So are there any other comments on any of the other recommendations or any other advice or any other requests for change?

ACTING CHAIR CANTRILL: Dr. James.

DR. JAMES: This is just a comment that was going through my mind and then reaffirmed outside. Yesterday we had a lot of discussion about the linkages between national, state, and local, and the absolute need to exercise at the local level, especially in terms of distribution, and I just want to be sure that's accentuated, you know, at least within the body of the report.

ACTING CHAIR CANTRILL: Dr. Parker?

DR. PARKER: Jim, it is, and it's in a tabular form, and as we discussed it, we actually made a word change, and Randy Levings from USDA helped us with that. We talked about funding exercising and to exercise the states more.

DR. JAMES: No, no, I understand. I just wanted to be sure it was in the record.

DR. GRABENSTEIN: So the only other remaining issue, I think, is do you want to arm wrestle over the title now or do you want to empower the writing committee to take the intent and incorporate health in there

somewhere, health or medical or something and just leave it to a smaller process rather than making the sausage here in front of you.

ACTING CHAIR CANTRILL: And any concerns about not having to be part of the smaller process?

That's fine.

DR. GRABENSTEIN: Okay. Then I will ask Dr. Scannon to wrap up for us.

DR. SCANNON: Today the Medical Countermeasures Working Group has presented to the National Biodefense Science Board and to ASPR, Dr. Lurie, 23 recommendations with the corresponding text in the form of a report to consider in her response to Secretary Sebelius' challenge to Federal medical countermeasure responsiveness. I think you can tell from the discussion that this was not a trivial process, that people dedicated a great deal of time, not just the three co-chairs, but literally all of the ex officio members spent a great deal of time contributing to provide us and make sure that

our recommendations are in the context of what is in existence today.

We view these as very important recommendations to consider. I think fundamentally we view that there are three, if you will, golden threads that weave these 23 recommendations into a cohesive document. These are the unified national strategy, centralized leadership, and adequate and sustained funding. All three of these principals we feel are essential together to ensure a strong Federal response to CBRN threats of natural or intentional origin, and it is our hope that Dr. Lurie and Secretary Sebelius will find these recommendations in the text useful in their deliberations toward enhancing effective medical countermeasure responsiveness.

On behalf of all three co-chairs, you know, I certainly want to thank everybody who has been involved in this. As I mentioned, the effort has been enormous, especially when you consider that we all have

day jobs, and all I can say is that it has been, I think, a privilege for the working group, as well as for the National Biodefense Science Board, to be involved in this very important process.

Thank you.

ACTING CHAIR CANTRILL: Thank you, Dr. Scannon.

The Chair will now entertain a motion for the approval of the MCM Working Group's report on medical countermeasures.

DR. GRABENSTEIN: Mr. Chairman, I move that we adopt the report, the recommendations with the changes marked that we worked out today, marked on the slides, empowering the writing committee to insert a few edits as we go without changing the intent of the recommendations, and submit it and transmit it on to the Secretary.

ACTING CHAIR CANTRILL: Thank you.

DR. PARKER: Second.

ACTING CHAIR CANTRILL: That was Dr. Grabenstein, and Dr. Parker seconds.

Any discussion on the motion?

(No response.)

ACTING CHAIR CANTRILL: Hearing none and since we do have telephonic participation I will ask for a roll call vote of the members.

CAPT SAWYER: Okay. So I'd like to know if you are for the motion that's on the table. Ruth Berkelman, are you still on the phone?

DR. BERKELMAN: Yes, I am and I'm for it.

CAPT SAWYER: Yes. Steve Cantrill.

ACTING CHAIR CANTRILL: For.

CAPT SAWYER: Roberta Carlin.

MS. CARLIN: For.

CAPT SAWYER: Al Di Rienzo.

MR. DI RIENZO: For.

CAPT SAWYER: Ken Dretchen.

DR. DRETCHEN: For.

CAPT SAWYER: John Grabenstein.

DR. GRABENSTEIN: For.

CAPT SAWYER: Jim James.

DR. JAMES: For.

CAPT SAWYER: Tom MacVittie.

DR. MacVITTIE: For.

CAPT SAWYER: John Parker.

DR. PARKER: For.

CAPT SAWYER: Andy Pavia.

(No response.)

CAPT SAWYER: He's not joined.

Eric Rose.

DR. ROSE: For.

CAPT SAWYER: Pat Scannon.

DR. SCANNON: For.

CAPT SAWYER: It's unanimous.

ACTING CHAIR CANTRILL: Thank you very much. The motion passes unanimously, and I appreciate all of the participation.

And I would like to extend a personal thanks to Captain Sawyer and her support staff for the NBSB to make this all possible. Please join me in a round of applause.

(Applause.)

ACTING CHAIR CANTRILL: Thank you.

And now, Dr. Lurie, do you have any closing comments?

DR. LURIE: Thanks so much.

I was sitting here remembering back just shortly after I started in this position. The Board was meeting and invited me to have dinner with them, and it was a lovely dinner and a lovely evening, but they asked me some pretty pointed questions, and the first thing was do you still need us and do you still want us.

And the second was, well, if you think you do, is there anything meaningful that we can do for you.

I think you've shown yourselves that we still need you. We still want you. You've done an incredibly meaningful piece of work, and it's incredible to see what you can do and how helpful you have been both with the last document and this that really came at my request, and I want to let you know how much I appreciate it.

I do want to extend a special

thanks to John Grabenstein and John Parker and Pat Scannon, as well as to the work group and all of the ex officio members who really worked very, very hard.

I know from looking at the staff around the department that I've been interacting with, you know, everybody is looking and feeling a little ragged around the edges, and I notice that John has a little less hair and the rest of us are a little grayer as a result.

(Laughter.)

DR. LURIE: I also want to just say how much I appreciate your personal offers of help and advice going forward. That means a lot to me.

I think this has been an incredibly great discussion today, a very, very thoughtful, meaningful, sometime provocative report that is really the kind of thinking that I was hoping for when we asked you to take on this challenge.

It's a really long report. It

seems like it can be boiled down to either three themes or three or four words which I caught: prioritize, synchronize, anticipate, and probably most importantly, to lead.

I feel acutely the urgency here to get moving on this, as well as the leadership responsibility. It makes me wonder why there wasn't a recommendation about human cloning because there's an awful lot here that's on my plate, and I say that for the record tongue in cheek.

You know, I know that some of you have heard me say that in looking back on our experience with H1N1, one of the things that I've been really struck with is that if I think about the process from end to end, there was not a single person in this country, probably not a single person in the world who really understood the whole process from end to end, and we've learned an awful lot about that whole process from end to end.

I heard a great term yesterday discussing this with somebody who told me that

it was like mapping the response genome, and yes, in that vein I think I need an awful lot of scientific help, basic science, translational science, and applied science to do just that, to map that response genome and then to do something really important with that mapping.

So I really look forward to transmitting these recommendations to the Secretary as well as obviously our continued deliberations on them.

As I said at the outset, you know our goal really with this is not to do something that sits on a shelf. It's not simply to tinker around the edges. It's also not to break what's working well, and I want to really stress that because I think there's an awful lot that is working well here, some of which could work better, but some of which we have just an unbelievably important infrastructure, incredibly talented people, committed people, set of processes, et cetera, as John Parker has pointed out, and I think

that's really important.

But also while we don't break what is working, that we don't simply tinker around the edges, to really be bold and transformative as we move forward to getting us to a much better and more effective and sustainable system.

I've made a commitment at previous meetings and when we first met to come back to you as my Advisory Board with a report about what we've done with your recommendations. I know that you will see some of those and get a first peek as we, I think, give our first report to the Secretary.

But even after that there's a huge amount of strategy development decisions to be made and implementation to be done, and I know that we will continue having that dialogue.

Somebody this morning came up to me and said that they had heard you gave a talk a couple weeks ago about H1N1 or I said that I was sort of a folk music aficionado and that I sort of thought that sometimes when we did all

of this preparedness and response stuff that it all happened in this folk music tradition, you know, of a song getting handed down from generation to generation, and each time it happened the song kind of changed and sometimes the story line kind of changed and, you know, whether people loved each other or killed each other, you know, there was always some ending, but that always sort of vested the song in the individual and not necessarily with the system.

And I think our goal here, as I said and I'll stress, is really to create systems change as opposed to just change to individuals or change the boxes.

So in that spirit, I actually took last night off from work and on the review and I went and heard some folk music, and I heard a wonderful song that I think I first heard last fall, the refrain of which is if not now, tell me when.

So we have both the opportunity and, I think, the responsibility to do this.

The policy window is open right now. So I'll just conclude by asking if not now, tell me when.

And thank you all for your incredible contributions and look forward to more dialogue and really getting this right.

Thanks.

ACTING CHAIR CANTRILL: Thank you, Dr. Lurie, very much.

Captain Sawyer, do you have a comment?

CAPT SAWYER: No.

ACTING CHAIR CANTRILL: Okay. This will conclude this meeting. I want to thank everyone for their participation to make this efficient and organized and successful.

So with that we stand adjourned. Thank you.

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