

**PUBLIC MEETING TRANSCRIPT
FRIDAY, JANUARY 10, 2014
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(Charlotte Spires):

This is Captain Charlotte Spires and I would like to call this meeting to order. Welcome everyone to today's public meeting. I'd to welcome our NBSB members, ex-officios, federal officials and also members of the public.

I am the Executive Director of the National Biodefense Science Board and I also serve as the designated federal official for this Federal Advisory Committee. The purpose of this public meeting is for the board to discuss and vote on the Public Health Emergency Medical Countermeasures Enterprise Strategic Preparedness Goals, Working Group draft report.

Before we move into the introductions, I would like to read the Federal Advisory Committee Act (FACA) overview and also the conflict of interest rules. The National Biodefense Science Board is an advisory board that is governed by the Federal Advisory Committee Act.

The Federal Advisory Committee Act is a statute that controls the circumstances by which 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 National Biodefense Science Board, including information gathering, drafting of reports and the development of recommendations is being performed not only by the full board but by the working groups, who in turn report to the full board.

Regarding 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 therein.

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 a member's 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.

Please note that this meeting is conducted via teleconference and Webinar. Please visit our Web site at www.phe.gov/nbsb for instructions on how to call in and log in to access this meeting.

The public has been notified to send in any comment using the NBSB forms available on our Web site. Public comment will only be received via forms. Please refer to the agenda at NBSB Web site at www.phe.gov/nbsb the detail of today's meeting. Written comments can be sent in after the public meeting by submitting an inquiry using our NBSB form available at the aforementioned Web site.

To date, we have no public comments relevant to the topic of today's meeting. As a reminder, the meeting summary and transcript will be made available on our Web site. So before we begin today's meeting, I would like to take roll call.

First, I will call out the names of the NBSB voting members and then I will call out the names of the NBSB ex officio members. So please indicate that you're here, that you're on the call when I call your name please. John Parker.

(John Parker): Present.

(Charlotte Spires): Georges Benjamin. John Bradley.

(John Bradley): I'm here.

(Charlotte Spires): Thank you. (Nelson Chao).

(Nelson Chao): Present.

(Charlotte Spires): Jane Delgado.

(Jane Delgado): Present.

(Charlotte Spires): David Ecker.

(David Ecker): Present.

(Charlotte Spires): (Daniel Fagbuyi). (Emilio Emini). Kevin Jarrell.

(Kevin Jarrell): Here.

(Charlotte Spires): Manohar Furtado, Furtado, excuse me. Steven Krug.

(Steven Krug): I'm here.

(Charlotte Spires): Betty Pfefferbaum.

(Betty Pfefferbaum): I'm here.

(Charlotte Spires): Sarah Park.

(Sarah Park): Here.

(Charlotte Spires): Here. (Justin) do we have a quorum?

(Georges Benjamin): Yes. And this is Georges Benjamin. You couldn't hear me before.

(Charlotte Spires):

Oh excellent. Thank you Dr. Benjamin. I appreciate it. So we do have a quorum of voting members. Now I will call the names of the NBSB ex-officio members. When I call your name, please respond.

If you are a designated alternate, please provide your name. (Andrew Hebbeler). Anne Dufresne. Could the folks on the speaker line please put your line on mute, please? Thank you. Richard Williams.

(Marc Shepanek): This is Marc Shepanek for Richard Williams.

(Charlotte Spires): Thank you, Marc. Amber Story. Randall Levings.

(Randall Levings): Present.

(Charlotte Spires):

Dianne Poster. Colonel (Erin Edgar). Patricia Worthington. (Ollie Kahn). Hugh Auchincloss. George Korch. Carol Linden. Bruce Gellin. (Luciano Borio). (Kevin Wench).

(Kevin Wench): Here.

(Charlotte Spires): Lori Caramanian. Rosemary Hart. Kerri-Ann Jones.

(Robert Sorenson): Yes, Robert Sorenson for Kerri-Ann Jones.

(Charlotte Spires):

Thank you. Victoria Davey. (Peter Jutro). And Patricia Milligan. Is there anyone else whose name was not called?

(David Howell): This is David Howell from ASPR.

(Charlotte Spires):

David Howell from ASPR. Okay. Anyone else? Okay. Thank you all so much and now I would like to turn this meeting over to Dr. John Parker, our NBSB Chair. Thank you.

(John Parker):

Thank you, Captain Spires. And thank you for making sure that we have a quorum present for this particular public meeting. I want to welcome the members of the board, and ex-officios, who

are on the call. I also want to extend a very special thank you to the work group and the co-chairs of the work group that worked on this PHEMCE Strategic Preparedness Goals task.

And I also want to especially thank Captain Spires and her staff for working so closely with the work group and providing specialty editors for the report. We're not a tremendously, heavily funded organization. But our quality of our report is very high.

I wish we could publish in glossy form but we, we depend on the public being able to see our report by accessing our Web site that was carefully mentioned and pointed out by Captain Spires in the opening. I'm not going to continue my welcoming speech, I think we want and need to spend most of our time on the presentation by Dr. John Bradley and Dr. David Ecker. And with that, I'd like to welcome them to open their presentations.

Take as much time as you want so that everybody understands what the task was and how it was deliberated and what your recommendations are. Following that, we'll make one last check for public comment, for comments from the board, and then we'll vote. So, John and David, the podium's yours.

(John Bradley):

Thank you very much Dr. Parker. Dr. Ecker and I are going to split this presentation into two different parts, one about the process of how the working group was organized and how we approached the task. And Dr. Ecker will actually go over the recommendations of the working group that comprised the draft document on strategic preparedness goals that has been posted for NBSB and public comment.

Dr. Ecker and I were very pleased to have the opportunity to co-chair the working group. We both have a particular interest in bioterror strategic preparedness goals. And before I begin on how we created our report, I would like to start with the fact that the Assistant Secretary for Preparedness and Response (ASPR) wrote a letter to the NBSB, to Dr. Parker, specifically asking questions about strategic end-states which are now defined as strategic preparedness goals.

And I would like to read the four questions that ASPR asked the NBSB to address. First, what methodology or process should be used for assessing requirements for strategic preparedness goals versus real resource capacity? Second, how should we think about what levels of risk are acceptable given the tradeoffs?

Three, how do we effectively communicate the levels of preparedness versus the level of risk tolerance to the public? Four, what do we need to know in order to make decisions on future investments to achieve the next level of preparedness. Next slide please.

The members of the working group were actually comprised both of voting members of the NBSB, Drs. Emini, Jarrell, Park and Parker, who represent broad diversity backgrounds, and from industry to academics to public health to research. And we had two invited representatives as part of the working group, David Franz and Brian Richard to offer additional perspectives. Next slide please.

In the presentation, as I mentioned, I'll talk about the process and Dr. Ecker will address the response of the working group to all of the questions presented by ASPR to the board. Next slide please.

The process, of course initially was to create the working group to address all of these questions. Dr. Parker, based on interests of the group and responses to requests, created this working group that we felt had the expertise to address the questions. We originally created some draft responses to ASPR questions.

The first draft had a number of conference calls to discuss our responses. And during these conference calls we identified additional areas of expertise that we needed as a working group in order to achieve our task of answering these questions and coming up with recommendations.

The two primary areas which we felt we didn't have particular expertise, including identification of experts to inform us about threat assessment, and to provide us with some background in the ethics of deciding what an appropriate response would be to a disaster, realizing that it would be impossible to ever achieve 100% response to 100% of all potential threats.

We contacted Dr. Tim Lant of the Biomedical Advanced Research and Development Authority (BARDA) in Health and Human Services. He is the director of analytic decision support. And Dr. Ecker and I both had the opportunity to have a conference call with him personally, as well as having Dr. Lant present how BARDA assesses threats to the entire working group on a teleconference call.

We were actually quite impressed with the level of sophistication of threat assessment that currently is ongoing. And obviously there were many areas where information could not be provided to us because of national security issues. But the overall concept of how the threats were assessed I think was clearly provided to the working group.

On September 24, we had the opportunity to have a teleconference call with Dr. George Annas who is both a public health expert with an MPH as well as a legal expert, a lawyer. And he's a distinguished professor at Boston University and is a recognized national expert on bioethics and has published on the bioethics of death, disaster and public health.

This was very enlightening to all members of the working group, to get a more expert view of how people assess disaster, both personally and on a public health level in order to allow us to better how we could better understand how we could put together recommendations that could be followed.

So with these extra pieces of input, with several subsequent (iterative) rounds of the draft report, getting input from ex-officio, federal representatives for the NBSB as well as the entire NBSB, we finalized the final draft and shared it with Dr. Parker, Captain Spires and the entire NBSB. So the final draft was posted and Dr. Ecker will now go into the recommendations that our working group has come up with to present to the NBSB and the public. Dr. Ecker.

(David Ecker):

Thank you Dr. Bradley. Our recommendations are organized around the questions that we were asked. I'm not going to read all the words on the next seven slides verbatim. But rather instead

try to summarize the key messages that hopefully convey the spirit of our intentions. So I've made some notes for myself to do this and I'll just work through them.

So the first question is what methodology should be used to assess the requirements for strategic end-states versus real resource capacity? The board felt that it was important to first define the components of preparedness. Preparedness should be thought of as a whole system and it only makes sense when thought of this way.

Some of the components of the system are listed here on the slide and the rest in our report. It's important to consider not just the materials in the Strategic National Stockpile (SNS) but the entire infrastructure and human effort needed to use them effectively.

We also consider surveillance and situational awareness capability to comprehend the scope and magnitude of the event, an essential part of preparedness. In particular we emphasize the need to match up materials with the day to day capacity of the local and state resources required to deliver these materials to the people who need them.

In fact, throughout our entire report, we repeatedly encourage close coordination and the matching of the federal resources with the state, local, tribal and territorial resources with careful and deliberate coordination. This comprehensive, whole system approach is the right way to define preparedness needs.

Second, regarding methods to assess requirements, as an outside body we've had a look behind the curtain at what the government currently does to assess threats and needs. And as Dr. Bradley mentioned, we are very impressed by both the methodology and the people who are doing it.

Therefore, we express strong support for this existing process and encourage continued investment in analytical tools, but more importantly the training of the expert analysts and decision makers within the government. Ultimately, the experienced experts in the government are most important assets now and will be so in the future. Okay so the next slide please.

Next question is, how should we think about what levels of risk are acceptable given the tradeoffs? Again as Dr. Bradley mentioned, here the board emphasizes ethical considerations. These should be front and center in government decision making.

The government needs to focus on preventing lost lives and be absolutely sure to consider all vulnerable populations like children, pregnant women and the elderly, just to name a few, to equitably support the entire population.

Second, the board recommends the concept of establishing a target level of preparedness, where the target is defined as sufficient to mount an effective response to maintain the basic necessities. So, food, water, shelter, sanitation, health care, all these things and to preserve national security. So how should the target be set?

This is the heart of our recommendation. The target should be set by PHEMCE experts using analytical tools available to them. But in the end, using their experienced judgment as to what the target should be, taking into account all the tradeoffs.

It shouldn't be a number, like 80 or 90% of some ideal preparedness level. It shouldn't be managing a portfolio of threats against a fixed budget. A target should be sufficient to mount an effective response, as we have described, taking a whole system approach.

We further recommend two kinds of target levels. First, a specific target level for the most important specific threats, you know, as exemplified by say anthrax and smallpox.

Second, the target level of all hazards preparedness for a wide range of other threats, the less specific and harder to define. Once these targets are established, the NBSB recommends that achieving these target levels should be our policy goal. Nothing less should be considered acceptable. Okay next slide.

The third question is, how do we effectively communicate the levels of preparedness versus the levels of risk tolerance to the public? The NBSB members are actually quite protagonist for more rather than less communication to the public.

While our deliberations and documents are already available to the public and this is a public meeting, unless you're specifically tuned in to these kinds of topics, the good things that the government is doing to protect its people are kind of hidden.

So we advocate a more proactive approach to informing the public. We believe an informed public will be an empowered public. This can start with a more informative Web site and use of modern Web and social media. But communication should also be active. We want there to be a federal spokesperson to convey these messages actively. Frankly we're not exactly sure who this should be.

But someone like the Surgeon General might be appropriate. Some of us actually miss the communications from the Surgeon General that are highly visible to the public. We don't really seem to have that like we used to.

Basic messages of this report and other government reports like the National Health Security Strategy should be simplified for non-expert consumption and actively communicated to the public. This also gives the opportunity to communicate and re-emphasize the importance of preparedness to individuals, families and communities. And the next slide.

The fourth question was, what do we need to know in order to make decisions on future investments to achieve the next level of preparedness? Here I'll admit that we didn't so directly answer the question about what we need to know. More so, we answered the question what do we need to do.

We live in a world with an evolving landscape of threats. The government needs to continue to encourage and motivate innovation in new and better ways to protect against both intentional and natural threats. Innovation will always be important to protect against threats and continued investment will always be required.

This is my summary of the recommendations that's displayed out in detail on these slides, and then in much more depth in the report itself. With that I'll stop and open it up to board discussion.

(John Parker):

John and David, this is John Parker. That was an excellent presentation. And I'll just reiterate that we will now open it up to specific members of the board for comment and just raise your voice if you have comments.

Hearing no comments from the members of the board, ex-officios, do you have any comments? Thank you. Captain Spires and Ayah, have we heard anything via email at this point in time?

(Charlotte Spires): We have not received any public comments to this time.

(John Parker):

As a total voice to the board, ex officios, are there any questions for discussion or questions about the report?

(Steven Krug): Just a comment. John?

(John Parker): Yes.

(Steven Krug):

I was a member of this working group and congratulations to David and John for your very accurate reflection of what the group deliberated on and what the group's recommendations were.

And I would just like to point some attention to the perspective of the working group, whereas prior practice, with an understanding that there is obviously security concerns in a way, and there may be things we can't tell everybody.

Now is the time in the face of the reality of limited resources so we can't be 100% prepared for 100% of the threats, that more direct communication, a little more transparency with the public and efforts to promote personal preparedness, I think may go a long way towards helping the PHEMCE to do what otherwise appears to be an impossible task.

(John Parker):

Thank you, Steve. Has anybody else a comment? Okay. I would, before I ask for a vote, I thought I'd mention that the NBSB board and the working group as we take on tasks have been absolutely excellent in using technologies today that eliminated travel expenses, meeting expenses. And it took time and patience to be able to have a discussion over a teleconference line and be able to know how to operate in a teleconferencing environment.

I just want to say to, not only the public, but I want to say to the members of the board and the ex-officios and those experts that we've asked to work with us on work groups, thank you very, very much for understanding how to use the technology. It really showed that we can do high quality work at minimum cost for the public and for HHS.

So thank you all for being able to work within the realm, the technology of the day. I'll make one more check for email. Spires?

(Charlotte Spires): Dr. Parker, we don't have any comments from the public.

(John Parker): All right.

(John Bradley):

Dr. Parker, can I make one comment? This is John Bradley on behalf of Dr. Ecker and myself?

(John Parker): Hey go right ahead.

(John Bradley):

Thank you so much. Dr. Ecker and I wanted to get this comment on the table. And I'm not sure exactly where it fits. But in this several months' process of collecting information and getting input from all the working group members of the committee, like Dr. Krug who just commented, we were absolutely impressed by how willing everyone was to contribute.

There was never a point at which we felt we couldn't get all of the necessary information for compiling this report. We just want to thank everyone, working group members, invited representatives, federal ex-officio representatives for helping with this process. Without everyone's help, we couldn't have accomplished this.

(John Parker):

Thank you very much John and David. And you can be assured that kind of support is going to be with every member of the board who takes on tasks like this. So thank you for saying that in a public forum. Captain Spires, could I ask you to poll the board for a vote?

(Charlotte Spires):

Certainly, Dr. Parker. Okay I'm going to go through and call the names of the voting board members. If you approve the report, when I call your name please say approve. If you do not approve the report then please say not approve. John Parker.

(John Parker): Approve.

(Charlotte Spires): Georges Benjamin.

(Georges Benjamin): Approve.

(Charlotte Spires): John Bradley.

(John Bradley): Approve.

(Charlotte Spires): (Nelson Chao).

(Nelson Chao): Approve.

(Charlotte Spires): Jane Delgado.

(Jane Delgado): Approve.

(Charlotte Spires): David Ecker.

(David Ecker): Approve.

(Charlotte Spires): (Dan Fagbuyi). Kevin Jarrell.

(Kevin Jarrell): Approve.

(Charlotte Spires): Steven Krug.

(Steven Krug): Approve.

(Charlotte Spires): Betty Pfefferbaum.

(Betty Pfefferbaum): Approve.

(Charlotte Spires): Sarah Park.

(Sarah Park): Approve.

(Charlotte Spires): Okay. We have all approves and no non-approves Mr. Chairman.

(John Parker):

Thank you very much, Captain Spires. As chair of the National Biodefense Science Board I note to the public that without exception, and within a full quorum, the National Biodefense Science Board approves the PHEMCE Strategic Preparedness Goals Report. At this point, a cover letter will be drafted and attached and will be transmitted to the Secretary.

In wrap-up and conclusions on this, I'd like to say that the reason that these calls are so well organized is directly related to our support by Captain Spires and her staff. When we're in a public forum, we want to be expressive of what we're doing, how we're doing it and make every opportunity for the public to look at our report beforehand, comment on the report, and be able to comment on it in public forum.

And so in the light of the board, we are not a clandestine board, we are wide open. And what we say and what we do is freely open to the public. And we live with that every minute of our lives.

As you know, as Captain Spires opened this, we are very sensitive to any types of conflicts of interest, especially if we speak about specific things that HHS is doing or will do in the future. We are very careful, we understand the law and we're very careful about it, but we are very protective of the public in everything we do.

So please go to our Web site frequently. See what we're doing, see what we're posting. And encourage your friends to dial in to the open public meetings or come to the public meetings if we do have an in-person meeting.

I want to thank the ex-officio members of the board for their continued support in our work and especially those folks we call upon that are inside government or outside government to give us very specific advice on specific programs.

So with that I'll end with just saying, thank you John Bradley, thank you David Ecker. Kudos to you both and just imagine a huge round of applause and with that, I'm going to turn it back to Captain Spires for adjournment of the meeting.

(Charlotte Spires):

Thank you Dr. Parker. In closing, I'd also like to thank the NBSB voting and ex-officio members. And also to thank those members of the public who participated in today's proceedings. I'd also like to give a special thanks to the members of the NBSB staff here who supported the NBSB board and the production of this report.

And an extra special thanks to Dr. Maxine Kellman, you know, who worked so laboriously and so consistently and so closely with the chairs and with the board members in order to produce this excellent, excellent document. So please check NBSB Web site for additional information.

Again we're at www.phe.gov/nbsb. And thank you again and today's meeting is hereby adjourned. Have a wonderful day everyone. Bye-bye.

(John Parker): Thank you.