

**PUBLIC MEETING TRANSCRIPT  
THURSDAY, SEPTEMBER 12, 2013**

**1:00 PM - 3:15 PM ET**

**THOMAS P. O'NEILL, JR. FEDERAL BUILDING  
200 C STREET, SW, WASHINGTON DC 20024**

**LOWER LEVEL -L1J13 / S103 – WILLOW CONFERENCE ROOM**

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**(Charlotte Spires):** Greetings everyone. I would like to call this meeting to order. I am Captain (Charlotte Spires) Executive Director of the National Biodefense Science Board. I'd like to welcome our NBSB members and ex officios, federal officials and any members of the public who may also be attending this meeting.

The purpose of this public meeting is for NBSB's Situational Awareness Working Group to provide a progress report on their findings and for the ASPR to present the new task to the NBSB for deliberation and vote. Before we move into the introductions, I would like to read this Federal Advisory Committee overview and conflict of interest rule.

The National Biodefense Science Board is an advisory board that is governed by the Federal Advisory Committee Act or FACA. The FACA 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 on 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 development of recommendations is being performed not only by the full board but by the working groups or the subcommittee who in turn report directly to the board.

Regarding the conflict of interest rule, 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 rules and regulations therein. Board members provide information about their professional, personal 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 and 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 is an in-person meeting and it is also being hosted by teleconference and webinar. Please visit our website at [www.phe.gov/nbsb](http://www.phe.gov/nbsb) for instructions on how to log in to view the slides for meetings from your computers.

The public was asked to provide comments via email by September 9th 2013. As of today no public comments have been received. For those of you present in person the comment period session will be held from 2:30 to 2:40 PM and the public will have an opportunity to provide comments. Please refer to the agenda for details of today's meeting.

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 comment period. If you are joining us virtually, please send in your written public comment prior to the public comment period by emailing the NBSB mailbox. To date we have no public comments sent to us via email.

As a reminder, the meeting transcript will be made available on our website. Members, please note that today's meeting is being recorded. Before we begin today's meeting, I would like to take roll. First I will call the names of the NBSB voting members and then the NBSB ex officio members. When I call your name, please respond. If you are a designated alternate or an ex officio please provide your name.

Okay, (John Parker).

**(John Parker):** Present.

**(Charlotte Spires):** (Georges Benjamin).

**(Georges Benjamin):** Present.

**(Charlotte Spires):** (John Bradley).

**(John Bradley):** Here.

**(Charlotte Spires):** (Nelson Chao). (Jane Delgado). (David Ecker).

**(David Ecker):** Present.

**(Charlotte Spires):** (Daniel Fagbuyi).

**(Daniel Fagbuyi):** Present.

**(Charlotte Spires):** (Emilio Emini).

**(Emilio Emini):** Here.

**(Charlotte Spires):** (Kevin Jarrell).

**(Kevin Jarrell):** Here.

**(Charlotte Spires):** (Manohar Furtado). (Steven Krug).

**(Steven Krug):** I'm here.

**(Charlotte Spires):** (Betty Pfefferbaum).

**(Betty Pfefferbaum):** Present.

**(Charlotte Spires):** (Sarah Park).

**(Sarah Park):** Here.

**(Charlotte Spires):** Ex officios. (Andrew Hebbeler). (Anne DuFresni). (Richard Williams).

**(Michaud Vincent):** This is (Michaud Vincent) for (Richard Williams).

**(Charlotte Spires):** Okay, thank you. (Amber Story). (Randall Levings). (Dianne Poster). Col. (Erin Edgar). (Patricia Worthington).

**(Bonnie Richter):** (Bonnie Richterr) for (Patricia Worthington).

**(Charlotte Spires):** Okay, thank you. (Ali Khan).

**(Sam Groseclose):** (Sam Groseclose) for (Ali Khan).

**(Charlotte Spires):** (Hugh Auchincloss). (George Korch). (Carol Linden). (Bruce Gellin). (Luciano Borio).

**(Carmen Maher):** (Carmen Maher) for (Luciana Borio).

**(Charlotte Spires):** Thank you. (Sally Phillips).

**(Sally Phillips):** Present.

**(Charlotte Spires):** (Lori Caramanian). (Rosemary Hart).

**(Rosemary Hart):** Here on the phone.

**(Charlotte Spires):** Okay, thank you. (Kerri-Ann Jones).

**(Robert Sorenson):** (Robert Sorenson) for (Kerri-Ann Jones).

**(Charlotte Spires):** Thank you. (Victoria Davey).

**Richard Martinello:** (Richard Martinello) for (Victoria Davey)

**(Charlotte Spires):** (Peter Jutro).

**(Peter Jutro):** Present.

**(Charlotte Spires):** Thank you (Peter). (Patricia Milligan). Okay, thank you. Are there any other voting members - ex officio members - that I have not called? Okay, I will now turn the meeting over to (John Parker) our NBSB Chair.

**(John Parker):**

Good afternoon. It's a pleasure to convene the public meeting of the National Biodefense Science Board. I welcome all that are in the room and I welcome all of those that are on the telephone both as members of the board, ex officios or public listeners that are indeed interested in our work.

Yesterday was September 11th and the board was in session and I want everybody to know that the Assistant Secretary of Preparedness and Response reminded everyone that that day was indeed a tragedy and that we still have people in pain. And that number of people is large compared to the number of those who lost their lives that particular day.

So the work of this board and the work of the ASPR and the work of Health and Human Services have that in their mind at the highest level as we prepare to protect our people every day. With that said I want to tell you that we are meeting in a brand new building. This is the Tip O'Neil Building. It has a beautiful glass front. It's behind the Humphrey Building which is the headquarters for Health and Human Services and as you enter the building, it's slightly sterile but it has all these great features of meeting rooms.

There are walls in every room which you can write upon without having easels or hopefully you're using eraser ink but it's really meant for communication, sharing of information and getting work done for the American public. It really is a great building.

We're in a conference room that is technologically, I would say, top notch. From this room - we are in a basement with no windows but from this room we are able to reach out through video communication, telecommunication, voice, email and webinar with ease. So it really is an example of moving in the direction of huge technology advancements so that people can be involved at any time.

Before I give you an overview of the agenda, I just want to say that any board and its ex officios are only as good as the staff that support us and we are extremely lucky to have extraordinary people in the assistant secretary's office that are supporting us and over time you will know who they are. And I just want to tell you that as the board's work increases, they become more involved, and actually the quality of that support is logarithmically aligned with the amount of work that we do.

So I want to give special thanks to our support and to those who have chosen us to be members and ex officios of this board. Today we're going to hear from the assistant secretary for preparedness and response and in that she is going to present a new task to the board. There'll be time for discussion and then at the end of the discussion the board will vote on whether we accept it or not. I'll keep you in suspense on that one.

Now then as Captain (Spires) said that we will bring you up on on the situational working group and its progress and that's a very positive report. And later on in the meeting I'll kind of talk a little bit about where the board's been and where we're going, what we've done and how it fits in with the - with the things that you're interested as we move forward protecting people in this nation and taking care of them.

And with that it gives me a great deal of pleasure to introduce the Assistant Secretary for Preparedness and Response Dr. (Nicole Lurie) and with your permission I'm not going to go into a great narrative about your exploits and capabilities. You were selected by the President. That's good enough for me. **(Nicole Lurie):** Well thanks and it's terrific to be with all of you again and to see you two days in a row. I was very grateful for the discussion yesterday and your review and it sounds like it was quite productive and I anticipate that that all will continue today.

You know, your comments about our new building cause me to remark on two things before I get going. You know, the first is I was really grateful that this was named the Tip O'Neil building because all disasters are local and he was known for saying all politics are local.

The other is I know just when we opened, the Secretary and Deputy Secretary came over and, helped us open the building and, she and everybody went back and talked to us about their building envy. And just yesterday I heard that actually, she went back and asked the assistant secretary for a briefing. How on earth did ASPR afford that? And I just listened and I said well this was a pretty easy call, you know. I'm kind of a numbers and science and evidence geek. So we actually did a pretty formal assessment of how long it would take us to get a return on investment from having all of our staff together in one building, because before this we were scattered five or six ways to Sunday in different buildings throughout the southwest complex. People didn't communicate and collaborate well. They spent lots of time walking back and forth to see each other.

And if you just started calculating out the STE costs of how quickly we could get that return, the estimate was 18 months to three years. So it actually seemed like a pretty good value proposition to us and just so you know in terms of just trying to be responsible with taxpayer dollars and doing it with evidence. I think even this new building and all of the features that support collaboration are really a testament to our commitment to do that.

So with that let me sort of launch into really what I wanted to talk more with you about today. Obviously this meeting is being held sort of under our new proper reauthorization as you know and many of you helped and were involved with. The Pandemic and All Hazards Preparedness Act was reauthorized in 2013 and we have been really off to a running start in that.

PAHPRA reauthorization, built on a lot of work that HHS and ASPR undertook to advance national security in lots of different ways. And the reauthorization provided for us some new authorities and new responsibilities, many of which frankly we've already asked you to help us work with. But just to sort of review them, obviously first authorizing funding for us to continue as well as authorizing funding for the e-grant program that helps us reach the state and local communities and help us get better and those include the National Hospital Preparedness Program and the Public Health Emergency Preparedness Cooperative Agreement that's funded through CDC.

As I think you know we've spent a long time over the past year, and year and a half, aligning those programs, getting us up to a single set of capabilities, working so that the grantees in the states only have to do things once have a single look and feel. And we pushed them to work together, because although public health and medical care required different capabilities and different skill-sets, they really do need to come together and cannot be like trains on parallel tracks never to meet as Donna Schalala said.

So we have renewed authorities to do that. The Public Health Services Act was amended in some important ways. Some of them gave us flexibilities in the use of Emergency Use Authorization and you will recall - for those of you who were with us for H1N1 - we faced lots of different challenges and a lot of different decision making. And so they've given us more flexibility so that you don't have to have a public health emergency declared in order to have these flexibilities, - the Secretary can declare that the conditions for public health emergency exist or are likely to exist in the future.

And that is really sufficient to authorize some products to be used under emergencies. That's already proven to be incredibly helpful as we first saw the emergence of H7N9 and CDC developed diagnostic kits that we wanted to push out to states and the world, and we're able to do that through this flexibility and working with our FDA partners and then again with MERS - the Corona virus - a similar situation.

And now it's particularly important because we're not yet in a situation where there are serum samples available to fully validate the test. So it definitely has to be used under emergency use and people who meet our threshold of suspicion are tested under that authorization with some frequency.

Another thing I think that we saw during H1N1 - and I know that again many of you were involved in - was the fact that on the ground and in health departments all over the country, public health departments didn't have the authority to use staff funded under one program - let's say Maternal Child Health Program or something else - to help with H1N1. So technically they couldn't necessarily help vaccinators or help do other sorts of things.

And so the law gave us the flexibility to do that and it told us in a number of cases that we had a 180 day time clock to put a number of things into action and all the required documents in those things I think are in clearance to do that. It also gave us some increasing flexibility in bio shield to support advanced research and development in some other important ways. And I know you've heard a lot about BARDA and Bioshield.

As you know, and I think are acutely aware from your discussions this morning and the ongoing tasks this afternoon really directed us to develop a surveillance and situational awareness strategy and implementation plan..

Being in this area--in particular--reminded that one of the very common leadership and management challenges for me in this job, and one that I encounter frankly almost every day, is that we get into trouble when we use the same words to mean different things. And this whole area of bio-surveillance and situational awareness is just fraught with all kinds of definitional problems and challenges and it's a good reminder of why seasoned diplomats always start with the terms of reference, even if it takes a really long time. And I think we've made a lot of progress on that and I think that that's really terrific.

As I said yesterday, we've also given the NBSB some really big problems to tackle and we have come a long way in tackling a lot of those. One of the first things that I think we've been involved with since the very beginning is special populations in one way or another and pediatric populations are no exception to that.

I imagine that you heard yesterday and will hear more about the development of medical countermeasures for children. We gave you a really hard assignment - probably the hardest one we've given you - and asked you to make some recommendations about the pre-event use of anthrax vaccine and I think you made a very thoughtful set of recommendations. And you all know that since that time the President's Bioethics Commission has issued its recommendations which I think were very consistent in developing an ethical framework for a way forward.

Those, barring studies, and other points discussed in the (report have been underway and we're expecting to get some preliminary results from those shortly. They also told us things that we have to do that are maybe not as challenging as something - as anthrax vaccine - that figuring out how to put countermeasures in different substances like peanut butter and chocolate pudding so that kids don't spit them out when you put them in their mouth.

One of the things that we've been very involved in working and doing over the past couple of months is making plans to get the pediatrics back up and running and I'm pleased to be able to tell you that we anticipate that that will be up and running early 2014. I want you all to know that that work is well underway and, , we'll be looking for nominations for the pediatric federal advisory, committee and we'll be able to share more details of that with you as we move forward.

You know, some of the other big problems, and we talked about some of these yesterday, is you all helped us think through and redesign how to deal with market failure and a countermeasure enterprise. And I hope you heard yesterday a lot from my BARDA colleagues about the really robust pipeline of products that we have now, largely as a result of science, innovation - frankly doing things differently - better business practices, our own progress reviews with companies, having science available from FDA and NIH and CDC and BARDA and DOD all at the table at the same time when we work with companies.

We knew of 12 medical countermeasures in the SNS under project bio shield and we anticipate that by 2019 or 2020 we should have another 12 more. The public private partnerships that have been established I think have been really fabulous. I just came from a meeting at the White House. We were talking about how important the animal studies network is and how important being able to test countermeasures in animal models are and those things are up and running. The centers for advanced development and manufacturing are taking shape and we're looking forward to our first product getting worked on in those centers probably this year.

And again, for those of you who remember all of the challenges with H1N1 you remember that the rate limiting step for getting vaccine out the door ultimately was that we didn't have enough national fill and finish capacity. We could make lots of bulk vaccine but we couldn't get it into vials and syringes fast enough. And so as you probably heard yesterday we're standing up a warm base fill and finish network so that we are not in that problem again.

This investment also probably has added benefits in, having the potential to be responsive in drug shortage, helping certain entities upgrade their quality and doing other things. So we are excited about that.

I have said to my staff that aspirationally 80% of the funds that we spend in the medical countermeasure arena need to have a return on investment. They need to have multipurpose benefits. So to that end BARDA has prioritized our repurposing and multipurpose drugs. We are - as you know - moving away from one bug one drug to looking at things that support host mechanisms of disease. We've started to do some work to create antimicrobials for some of the known viral threats but that also address some important antimicrobial resistance challenges we have in this country and the list goes on.

And then if I just think about where we are right now with H7N9 compared to where we were when we first met during H1N1 we have - as you know - clinical loss, vaccine made, enough vaccine filled and finished now that clinical trials are now underway so that we can establish what the dose - do we need one dose or two. Do we need antigens? Those trials started the week before last or last week because of one of the companies fully enrolled. NIH will start the other set of trials I believe early next week and I think we're well on our way.

We're giving a lot of thought to once we have information from those trials, should we be developing a small stockpile of H7N9 vaccine to shorten that timeframe again between when we start to see significant person to person transmission and when we could get moving with vaccinations.

So you see that we've really incorporated a lot of the lessons learned and while I'm sure if we have another pandemic we'll be coming to you with advice. At least the questions will be different and we will have addressed and solved a number of the issues that we dealt with before and that's great.

You heard yesterday a lot about our efforts to improve our response capabilities and as you have heard, we're really trying to modernize NDMS and in fact the reason our leadership couldn't be there is because we've really revitalized NDMS training in lots of different ways and they've been out doing NDMS training.

And then part of our response also involves frankly this next generation work we're doing with IT and fusion.

We also asked you to give us some advice about where to go with being scientifically ready for different emergencies and Hurricane Sandy actually provided for us a bit of a silver lining in this regard in that for the first time in the Sandy supplemental we were able to get some funding to make grants to support research on resilience and recovery for survivors of Hurricane Sandy and their affected community.

So I believe any day now we will be announcing our first series of awards for grantees to do this work. The other thing that we're doing I think really for the first time is trying to develop a prototype research data set, collaborating with folks at CMS and FEMA and HUD and Census and others to put together a linked de-identified data set that could be available in a research enclave to the research community to ask and answer questions about disasters and response and recovery.

It seems to me that not every researcher who wants to do research should have to put together their own data set and we shouldn't do it multiple times and so we're trying to do it just once. We hope that it will serve as a foundation and template so with each future event we're able to stand up and put together quickly that same kind of a data set to stimulate the community of sciences out there and research and we're looking forward to doing that.

We've set aside a little bit of the money from the family supplemental to make additional grants for people to use that data set once it's put together and that's been a very exciting development for me. While we've been talking about science I know you all had a lot of discussion yesterday about evaluation and measurement which is really critical and scientific inquiry and discovery and evaluation and measurement feed on each other. You can't have good measures and evaluation without good science to underpin them, etc.

We are in the process of searching for somebody to lead evaluation efforts in ASPR. While that person will be focused a lot on the hospital preparedness program, we anticipate that program will serve all of ASPR. So I ask to all - as you see this position description come out in the next couple of weeks - if you know people who would be terrific measurement and evaluation leads for us to help us move forward scientifically, we'll send you the announcement. Please circulate it to them or please let us know of people who you think we should be looking at.

We talked yesterday I think about mental health and our social services CONOPS and those things are moving and underway and we talked yesterday about innovation and how we're using data in really unprecedented ways to address multiple populations. I'm not going to get into that today, instead I just want to transition really briefly to talk about your work with the bio-surveillance and situational awareness.

And I know there's been a robust discussion of that yesterday and today and I know that I gave you a bit of a reprieve from the deadline because the issue's so complicated and because I thought that there was more information that you needed. In addition, I'd like to ask you to review the do as review the various implementation models for our National Health Security Strategy. And I think ASPR's staff will provide the proposed NHSS implementation models to you as well as well as others that you might be aware of to think about implementation models that are likely to be the most successful as we move forward not only with completing the strategy with the implementation plan.

It's - as you know - an extremely complex arena. Just as soon as we think we have a way for the science then technology changes in different and exciting ways. And so we need a way to continue to be dynamic, to always be on the cutting edge of this, to not implement something that's going to be obsolete by the time it's implemented. And I believe that there are models and strategies for doing that, not implementing something that's going to be obsolete by the time it's implemented in particular that I would very much appreciate input on.

So with that I'll stop and see if people have any comments or questions or (Captain Spires) if you want to add anything else related to the statement of tasks.

**(Charlotte Spires):** No, I don't.

**(Nicole Lurie):** Okay.

**(Charlotte Spires):** I know your last few comments were in relationship to the national health security strategy and the models that have been presented in draft form to the board, correct?

**(Nicole Lurie):** Right.

**(Charlotte Spires):** Okay, thank you.

**(Nicole Lurie):** Thanks for the clarification. I've got so much of the surveillance data in my head. But the bio surveillance thing is also essential to the national security strategy.

**(Charlotte Spires):** That's right.

**(Nicole Lurie):** End of story.

**(John Parker):** Any questions from in the room? Well be thinking about it. Any questions on the telephone - the board members and ex officios on the phone. Any questions for Dr. (Lurie) or comments?

**(Georges Benjamin):** Yes (Nikki) just to congratulate you on the work that you folks have been doing. You're right. We've come a long way and I think we're all really excited about where you're going and where ASPR's really taking the nation so thank you very much.

**(Nicole Lurie):** Well thank you and, you know, I have to tell you I didn't think I would be sitting here thinking about the next generation of the national security strategy but here we are and it's exciting to be able to take the lessons we've learned from the first one, think about where we're heading in the next one and hopefully next time I talk to you I'll be able to read again. So good.



**(John Bradley):** This is (John Bradley). Excuse me. As an infectious disease pediatrician your progress on making a vaccine for H7N9 also deserves a round of applause because the surveillance, the recognition, putting together the manufacturing and the trial is being done in record time and I think most people out there don't recognize your capability and I just want to acknowledge that. I think it's spectacular.

**(Nicole Lurie):** You know, it's record time and it's still not fast enough and that's for me the thing that is the continued challenge for us. I mean we got a lucky break with H7N9 but were this to have done quickly, you know, we would have had to make some decisions without the luxury of going through all the steps that we're going through and it is a continued reminder that we need to do everything we can do to speed up the process.

And I also just want to say we've had in this incredible collaboration not only from our colleagues at CDC, NIH and BARDA but from the scientific community and industry. We're seeing for the first time really what reverse genetics can do and how it can speed up the processes and how with every new process comes a new anticipated set of challenges that need to be worked through but we're getting there.

**(John Parker):** (Steve)?

**(Steven Krug):** Yes. You know, the problem is when you do a great job, people raise the bar and expect you to do even better so that's I guess a curse of your success. I actually just wanted to comment and congratulate you and the other entities or sectors of government that are present for your excellent work in developing relationships outside of government.

So I think that's contributed tremendously towards some of the success that we've talked about and towards how we're going to try and achieve so much in relatively short periods of time with limited resources. That's being done at the CDC, the FDA, homeland security. You're leveraging available resources well.

**(Nicole Lurie):** And many of you are helping in that effort so I appreciate that as well.

**(John Parker):** Well I absolutely am thrilled first of all with your ability to tell us in a very short period of time the scope of work that's being accomplished and that leads to one further comment that a lot of people don't understand the position of the assistant secretary of preparedness and response and I will tell you that I appreciate it. I know there's others in this room appreciate that these things are only done through good leadership.

You raise the bar of the goals and missions of the ASPR and therefore all those people that contribute to all of those things that you talked about do their job well with excitement and it's extraordinary and we see ahead that it's going to be huge.

Now on the business of the National Health Security Strategy and its implementation it's an exciting project for the board and up front I'll tell you we have accepted it even with the short timeline. We've gone ahead and we've developed a small workgroup so that we can work quickly.

When we first started to discuss the National Health Security one of the first things that came to mind was have we really broadcasted this that the Federal Government and the ASPR is interested in looking at an integration - not control - but an integration of the health activities in the United States of America with the goal of sustainment, effectiveness, quality, coalitions and cooperation.

And I think that as we look at this through a non-strategy we will look at the implementation models, hopefully make a short letter report to you and part of that report we already have talked about that that the end would be that we would be very interested in taking as soon as the 2014 strategy is written that we would like to look at that and perhaps contribute to that as we move along.

**(Nicole Lurie):** Thanks and I appreciate your acceptance of the task and the fact that you've already gotten to work on it and absolutely we very much want you to be involved in the 2014 strategy and it going forward.

You know, the issues about implementation models really get also to Dr. Krug's comments about the external partnerships and all of this work is so dependent on partnerships and collaboration and people stepping up to the table voluntarily for all kinds of reasons. Thoughts about, you know, ways to continue to do that that are important. Your comment just also stimulated me to reflect on one of the comments yesterday which was about our uses of challenges and competition.

And as you think about implementation plans it may or may not be one of the things that you want to think about but I'll just sort of put it on the table as a placeholder for now but there are a lot of different ways to broadcast it and I think you're point's really well taken. It would be interesting to hear what advice you have for us in that regard.

**(John Parker):** I think you really hit it on the head. And I think, you know, as we get older we worry about the younger generation for some reason or another but the younger generation is great and they learn rapidly and they come along fast. And the idea of coalitions and cooperation will increase I believe.

The good story of all of this is the United States has been very, very good at a lot of things and when you really burrow into why - when the going gets rough there's a lot of cooperation. And the National Health Security Strategy is making sure that when that cooperation bell rings and the coalition bell rings that the people are aware. It costs time and I think it will be a very interesting project to take a look at that as we move forward.

So with that said I'll reopen for any comments from the board or last comments to Dr. (Lurie) and also on the telephone. Just chime in if you want to make a comment.

**(Nicole Lurie):** Well thanks again all of you for being here and for sticking with us and all your hard work and I look forward to our next conversation.

**(John Parker):** Thank you Dr. (Lurie).

Operator, this is (John Parker) Chair. If you could open the lines to any public participants and ask them have they registered for any comments. No one's registered. We have no emails.

**Coordinator:** Absolutely. I'll open everyone's line. All lines are open. You may speak freely.

**(John Parker):** So hearing none, operator you can close the lines to those that are not labeled as speakers. That would be great.

**Coordinator:** Okay.

**(John Parker):** Thank you very much and I'm going to continue. You know, Dr. (Lurie) did a good summary so a lot of my remarks are about the accomplishments of the board or things like that. I think she alluded or not alluded - I think she directly was very complimentary of the board and the direction that we take.

I've been very fortunate to be a member of the initial Board and then Chair and over the years since the board came into being we've had some membership change and we've had lots of things to work on. But a central theme that the board has had is protecting the nation. And because of our name - National Biodefense Science Board - the initial forces were very sharply focused at medical countermeasure development, medical countermeasure stockpiling and the research and development required for the medical countermeasures and with that the building of the FEMC Organization and the bringing together of a lot of people to do the tremendous jobs that you see being done today.

So if you go back to our early reports on medical countermeasures you will see that a lot of those recommendations have been successfully implemented or acted upon and the BARDA presentation yesterday really brought to life that maturation of the organization that's responsible for that. And with the number of licensed, you know, a very tight metric was the number of actually FDA license countermeasures which were seven if I believe the number correctly along with others that are on the shelf but able to be used under an emergency use protocol.

Just to take a look at what's on the table, you know, you're going to hear in a few minutes where we are in the situational awareness report. You're going to be very pleased with that. We have a very interesting task given to us about trying to look at the situation of what is prepared. How much is preparedness? How much of something do you need? How much is enough or when is enough, enough?

And if you put yourself on the top of a mountain and you're totally unrestrained except by the lack of air you might say that we need 100% preparedness all the time and we need to reduce risk to zero. Well although there are a lot of people in our population that might feel that, the reality of it is that resources are involved and probability's involved and we want to take a look at that so that the taxpayer's money is leveraged to its max in trying to answer the question to the PHEMCE of when is enough, enough.

I think we were given a task that's very difficult but I think the right people are on that workgroup and their energy is what I would call top notch. This new letter of tasks of the national health security strategy is interesting. We're given the short amount of time that we're given to comment on it and really we're not asked to dissect the strategy or anything like that. We're asked to comment on the strategy in conjunction with its models of implementation and I'm sure more will come on that.

And we have set up a workgroup. We have accepted the task and we expect to respond by letter so that we meet the suspense and that letter will be presented both publicly and to the board on the 31st of October.

We also reconvened or we never really close our workgroups down because they have so much overlap but we activated the anthrax vaccine working group and they are currently asked to take a look at our report in conjunction with the report from the Presidential Ethics Commission and look at the results of both of those reports and make a determination as to whether the commission's response demands a secondary response from the Board to the Secretary. They will report out to us very shortly on that. They've been working hard on that already.

We entered kind of new territory by joining two Federal Advisory Committee's together to look at a very important issue with the CDC's Board of Scientific Counselors.

**(John Parker):** Board of Scientific Counselors at the CDC and the NBSB each put forward membership to a workgroup to take a look at what the strategic national stockpile should look like in 2020. That workgroup works quite hard. A report was put together fairly promptly on that and that report was presented to each board, ratified and a cover letter was sent to the secretary with the remarks of that.

Needless to say just in not a long summary but some of the things that were nailed by that joint workgroup was that a strategic national stockpile is necessary. It is a jewel in the crown of being prepared in the United States of America and the board doesn't see that in the next five, ten years or in the future that technology or anything short of having no threats will ever reduce the workload or the task of the SNS. That's important and we were rather adamant about that and I hope that as people read the report they will understand the importance of maintaining funding for that.

We're in the process of selecting new board members. You know, there is a rotation of the board. Captain Spires and members of the ASPR are involved - first of all an announcement was made, applications have been received and the selection committee is doing their job with the expectation that we'll be able to announce to you in December the new board memberships. And hopefully we have the initiation and bringing on board in January.

And those applications were open to board members who are retiring from the present board. Retiring's not quite the word but their term is up and with great expectation that some of those will be selected.

**(Lisa Kaplowitz):** The, NIH, FDA, CDC, and ASPR are engaged. We have lots of help from our partners.

**(John Parker):** Thank you. Good.

A couple of different things. The board was asked to participate in the development of a couple of documents and that's a new operational process where the board actually worked with their federal partners in developing the PHEMCE strategy and implementation plan. And that was a very interesting opportunity to use the expertise of the board in conjunction with the huge spectrum of expertise across all the lines that Dr. Kaplowitz just mentioned - NIH, FDA, CDC and the headquarters - to develop those strategies and implementation plans.

Even with all that work on the table the board's energy is such that during the meeting this morning and yesterday in the workgroup sessions of the board, I guess the board's hungry for new work. They have some ideas about things that they would like to - not individually but as a group - put forth to contribute to the effort of our basic thrust of defense and protection of the nation.

And because the scope of the work of the board has gone well beyond the word biodefense and right away after the board was formed the second charter redefined the biodefense portion of our name by saying that it expanded to chem, bio, nuclear, radiological and explosives. And with the work that we've had as I've iterated here, some of our work has gotten into policy and implementation strategies and looking at current problems.

And so in the near future you will see that the ASPR or the Assistant Secretary of Preparedness and Response will work with the proper authorities and congress to change our name a little bit so that it reflects that we're more than just a biodefense board.

Another task that we're taking on has to do with community health resilience - I just want to tell you that the federal government is now on an accelerated slope looking at different models and programs to encourage and build community resilience across the nation and most of those efforts are in what I call the hard structure ideas - transportation, communication, signal towers, power lines, physical plants like hospital structures and things that must survive both nature and perhaps terrorist attack.

And so as the board's been given a task to look at a very special subsector of community resilience and we'll be looking at community health resilience and from a very strict perspective that really when you get down to it health and human services is about people, families, children and the at risk populations. And we're going to take a look at a definition of community health resistance and how the task here is very focused from the standpoint it says come up with a recommendation that the federal government/HHS can effect rapidly and effectively to do something about resilience.

And I think I'm going to wrap up on that- and we're fine in our schedule I think. The - oh just - we'll go for questions and comments, yes.

**(Steven Krug):** That was a great summary. You reminded me of an extraordinary experience that I was fortunate to be a part of which was the joint board of scientific counselors NBSB deliberation on the Strategic National Stockpile. Not that this isn't a fabulous group because it is but that was a really incredibly well run process. The folks I met from the BSC were amazing and it's maybe a strategy to consider going forward as we address issues that are of, you know, crossover and joint interest where both groups can bring something to the middle.

**(John Bradley):** Just a quick acknowledgement. As (David Ecker) and I work on - co-chair one of the working groups and we take our task very, very seriously as every member of the working group. We can't thank you enough for putting us in touch with experts from academics, from government, industry - everyone that we need to help us provide an informed opinion so that our working group can put together the best document but I want to acknowledge that you've provided the resources for us so that we can do our job the best way possible and I want to thank you for that support.

**(John Parker):** I want everybody to know I varied a little bit from the schedule because I really wanted to take advantage of Dr. (Lurie)'s introduction and the empowerment of the board. And if you listen carefully Dr. (Lurie) very, very specifically talked about the terms bio-surveillance, situational awareness and how important definition of terms and looking at those particular areas was. And she knows that because she sent us the task that was very clear that we were to look at situational awareness.

And you all know we found a working group and a working group was - chaired by (Sarah Park) and (Manohar Furtado) and (Manohar) is in Russia so it's hard for him to just pop in and stand next to (Sarah). So I'm going to turn the microphone over to (Sarah) and she's going to give us a great update of where they are.

**(Sarah Park):** Thank you very much. So standing in for both (Manohar) and myself I will proceed to give you a sort of a high level brief overview of the draft such as it is thus far.

We had hoped to finalize support for voting by the board during our meeting this period but had a little bit of a delay and we anticipate being able to finalize that report in about a month's time for a vote to the board for them to finally be able to send that report to the ASPR at the end of August - sorry - October. I'm going backwards instead of forward.

So just as a review - the task as we received it from the ASPR was to assess the current bio-surveillance activities, identify efficiencies and make recommendations in coordination with the applicable existing CDC advisory committee.

And then this pursuant to the 2013 or referencing the 2013 PAHPRA which basically in it said to identify the steps necessary to achieve national bio-surveillance system for human health with international connectivity, identify any duplicate surveillance programs under the HHS or changes necessary to existing programs to enhance and modernize activities, minimize duplications, strengthen and streamline activities and achieve real-time data for both human and global health activity and finally coordinate with applicable existing CDC advisory committees.

So that is the background as what the workgroup considered. And we back in April came to the group - to the board - with an initial - a preliminary recommendation that was then voted on and passed and presented to the ASPR and our central recommendation or our primary recommendation was really to help achieve a national bio-surveillance system for human health with international connectivity and insure comprehensive real-time all hazard bio-surveillance capabilities.

We - the NBSB - reemphasized the need for the HHS secretary to convene aHHS lead centralized public health and healthcare situational awareness oversight authority to act as the central focal point to assure the compatibility, consistency, continuity - I especially stress that - continuity and coordination and also definitely integration - I can't stress that one any more - of all disparate systems and information requirements hereafter referred to as a central executive strategic group or the CESG.

So the CESG task or the primary task of this CESG is to develop then a strategy to coordinate the effective integration of activities across federal agencies and partners currently engaged in public health and healthcare situational awareness including human health bio-surveillance. They're really focused on public health and healthcare situational awareness.

So again, calling back to the ASPR's reference to the fact that there are many definitions out there and wanted to make certain that everyone is on the same page that when we're talking about situational awareness in this case we are referring specifically to public health and healthcare situational awareness and that we really are stressing the need for coordination integration.

In addition to that we also recommended the establishment of a strategic integration group (SIG) composed of management representatives including lead bio-surveillance subject matter experts from the relevant US government agencies. In the task we present to the SIG is specific to insure the implementation of that strategy developed by the CESC with a goal of integrating again and coordinating bio-surveillance activities and analysis.

I think you guys are probably sensing a theme here. The initial focus won't necessarily be on the evaluation of existing bio-surveillance redundancies and gaps. I think it's very important to note that we never intended and we do not intend for the SIG or even a CESC to be yet another permanent federal agency organization. We do not want to have yet another sort of institution be developed.

Rather our recommendation is to fulfill or fill a perceived need for coordination among all existing key players who are involved in public health and healthcare situational awareness activities including bio-surveillance. And we hope that through periodic evaluation of the CESC and the SIG's progress the secretary of HHS at his or her discretion will determine whether or not that need has been fulfilled by either standing down one or both groups.

So we recommend that the CESC consider the following especially among it's - as it devices its strategy for implementation by the SIG. Integrated advice involving the national public health surveillance and bio-surveillance advisory committee which is the committee essentially that is being stood up by the CDC.

Involving them in integrating the advice with the CESC's activities and in addition adding a focus of review and defining the utility of nontraditional informational sources to traditional ones. So we all are aware of or folks can think about traditional bio-surveillance activities that do exist among public health entities currently from sort of specific - data specific - such as electronic laboratory reports and such and confirmation of actual existence of disease.

What we're referring to is then the marrying or the complimenting of those - that information with information from nontraditional sources such as from social media, from news media, from other informal reports and determining the value of such and how they may compliment the sort of more specific existing systems.

And then finally the standardization of strategies and standardizing how these data are collected, how they're recorded essentially to address the same baseline needs for consistency and continuity is especially important.

For the workgroup we considered - this is just to provide you an idea of all of the different aspects that we considered in sort of key supporting information that we considered in making our recommendations. We looked at various definitions of bio-surveillance, what could be the current definition scope of bio-surveillance and then actually attempted to then bring a number of those sources together to actually define what we were talking about when we were making our recommendations for bio-surveillance.

We looked at efforts - current efforts to leverage nontraditional bio-surveillance capabilities with traditional ones. We considered previous work and there has been previous work to develop strategies, recommendations to improve public health and healthcare situation awareness and outline ongoing nationwide bio-surveillance capability efforts.

We didn't want to basically duplicate that previous work and actually tried to make an effort to incorporate some of that and recognize some of that previous work into our recommendations. We acknowledged an existence of ongoing integration initiatives within agencies and departments involved in public health and healthcare, bio-surveillance and situational awareness and the development - as I mentioned earlier - of the CDC's new committee we anticipate to be set up some time later this fall.

This year the CDC's National Public Health surveillance - bio-surveillance advisory committee that should will probably - we anticipate will probably be very key in providing some very much needed subject matter expertise in the area of bio-surveillance.

And then finally our report will include an appendix that will have a pretty exhaustive list I would say of existing multiple coordinating bodies involved in public health and healthcare bio-surveillance activities toward national, international situational awareness. There are a number of groups and folks out there among the federal entities that are already doing very important and very good work in this area. And so I think our key recommendation really is hopefully that those groups will then be brought together in some shape or form for a unified sort of national situational awareness or contributing to the unified national situational awareness.

And that's pretty much - I think that's it.

**(John Parker):** Thank you (Sarah). Are there any comments or questions in the room? And then I see none. Are there any people on the telephone that are members of the board or ex officios that have any questions or comments for (Sarah)?

**(Georges Benjamin):** This is (George). No, (Sarah) you nailed it. That's exactly with respect to coordination and integration

**(John Parker):** Well thank you very much (Sarah). That was excellent and the - as the chair I want to thank you and (Manohar) for a huge amount of work.

**(Sarah Park):** Mind if I respond to that?

**(John Parker):** You may.

**(Sarah Park):** Again, I just would like to acknowledge the tremendous amount of effort that has basically contributed to our almost final report especially by our support staff (Jomana Musmar) without whom we could not have been able to synthesize so many ideas that were brought forth by the various working group members and I want to also thank them again for their contribution to this report which is a true collaboration among - across many, many different groups.

**(John Parker):** Thank you again. There's opportunity for public comment and Captain (Spires) actually in her opening narrative designated a time for that but I want to check with (Jomana). We've had no emails? Have we had any and no one in the room for public comment?

Operator, could I ask you to open the lines to all our listeners to see if there are any comments?

**Coordinator:** Yes. One moment please. All lines are open.

**(John Parker):** I know you've been listening to the National Biodefense Science Board session and I just want to make sure that if there are any folks that are listening that are not members or ex officios and have comment, this is an opportunity for you. The operator will tell you how to announce yourself.

**Coordinator:** Yes. All lines are open. You may announce yourself before your question.

**(John Parker):** I'm giving people time because they may be sitting across the room and had put their phone on mute and we might have caught them off guard but we'll - I think we've given everybody adequate opportunity. If we haven't you certainly know how to email us and that doesn't - and it doesn't mean that you can't make comment tonight or tomorrow morning or any time you'd like. You have the ability to do that.

So before I wrap up, are there any comments from the board or ex officios for the good of the order or to pick up certain things that we might have missed in our deliberation today? Okay, hearing none my wrap up is only 35 minutes so don't worry. My wrap up is actually rather concise and quick. It's a big, big capitalized and bold thank you for your coming here. Thank you for being on the phone. Thank you for all the work on our tasks. Thank you for accepting new tasks and continue to look forward to work together.

It's been a real thrill for me and certainly hopefully it's been a thrill for you as we meet wonderful partnerships i at the federal, state and local level to accomplish our mission. And I thank the staff, thank the board and with that back to Captain (Spires) for adjournment.

**(Charlotte Spires):** Okay. Anything - last words for the good of the order? In that case, this meeting is adjourned. Thank you.

**Coordinator:** This concludes today's conference. You may disconnect at this time. Thank you.