NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC MEETING

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THURSDAY,
APRIL 28, 2011

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The meeting convened at 10:15 a.m. in the Federal Ballroom of the Washington Plaza Hotel, 10 Thomas Circle, N.W., Washington, D.C., Patricia Quinlisk, Chair, presiding. Leigh Sawyer, D.V.M., M.P.H., CAPT, U.S. Public Health Service, Designated Federal Official.

NBSB VOTING MEMBERS PRESENT:
PATRICIA QUINLISK, NBSB Chair, M.D., MPH
GEORGES C. BENJAMIN, M.D., FACP, FACEP(E), FNAPA, Hon. FRSPH
STEPHEN V. CANTRILL, M.D.
DAVID J. ECKER, Ph.D.
DANIEL B. FAGBUYI, M.D., FAAP
JOHN D. GRABENSTEIN, R.Ph., Ph.D.
KEVIN A. JARRELL, Ph.D.
THOMAS J. MacVITTIE, Ph.D.*
JOHN S. PARKER, M.D.
BETTY J. PFEFFERBAUM, M.D., J.D.*
PATRICK J. SCANNON, M.D., Ph.D.

NBSB EX OFFICIO MEMBERS PRESENT:

HUGH AUCHINCLOSS, M.D., Principal Deputy Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, U.S. Department of Health and Human Services

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

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

GEORGE W. KORCH, JR., Ph.D., Acting Principal Deputy, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

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

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

CARMEN T. MAHER*, R.N., CDR, U.S. Public Health Service, Policy Analyst, Food and Drug Administration, U.S. Department of Health and Human Services (designated by Luciana Borio, M.D.)

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

TRACY DEWESE PARKER*, Ph.D., Office of Health Affairs, U.S. Department of Homeland Security *(designated by Sally Phillips, R.N. Ph.D.)*

BONNIE S. RICHTER*, Ph.D., M.P.H., Director, Office of Illness and Injury Prevention Programs, Office of Health, Safety, and Security, U.S. Department of Energy *(designated by Patricia R. Worthington, Ph.D.)*

FRANK SCIOLI, Ph.D., Director, Division of Social and Economic Sciences, National Science Foundation

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

DANIEL M. SOSIN, M.D., M.P.H., FACP, CAPT, U.S. Public Health Service, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services (designated by Ali S. Khan, M.D., M.P.H.)

NBSB STAFF PRESENT:
LEIGH SAWYER, D.V.M., M.P.H., CAPT, U.S.P.H.S., Executive Director
JOMANA MUSMAR, M.S., Policy Analyst, Contractor
MacKENZIE ROBERTSON, Program Analyst
BROOK STONE, M.F.S., LT, U.S.P.H.S., Program Analyst

*Present via telephone

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

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

10:20 a.m.

CAPT SAWYER: I'd like to call to order the meeting of the National Biodefense Science Board.

I'd like to welcome everyone today to the NBSB meeting. I'd like to welcome the NBSB voting members, ex officios and designees, members of the All Hazards Science Response Working Group and members of the public.

I am Leigh Sawyer. I am the Executive Director of the National Biodefense Science Board. I also serve as the Designated Federal Official for this federal advisory committee.

Today's meeting includes a discussion and consideration of recommendation from the All Hazards Science Response Working Group. And we will hear presentations from two of our colleagues in HHS. Dr. Quinlisk will be reviewing the agenda shortly.

I'd like to begin with a roll call.

As I say your name, I'll start with the voting members, please indicate if you are here.

Patty Quinlisk?

CHAIR QUINLISK: Yes.

CAPT SAWYER: Georges Benjamin?

Steve Cantrill?

DR. CANTRILL: Here.

CAPT SAWYER: Jane Delgado?

David Ecker?

DR. ECKER: Here.

CAPT SAWYER: Dan Fagbuyi?

John Grabenstein?

DR. GRABENSTEIN: Here.

CAPT SAWYER: Kevin Jarrell?

Tom MacVittie?

DR. MacVITTIE: On the line.

CAPT SAWYER: Thank you, Tom.

John Parker?

DR. PARKER: Present.

CAPT SAWYER: Betty Pfefferbaum?

DR. PFEFFERBAUM: I'm present. I won't be here the entire meeting. I'll just be here the first few hours.

CAPT SAWYER: Thank you, Betty.

Pat Scannon?

DR. SCANNON: Here.

CAPT SAWYER: Thank you.

Next, I will call out 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.

Franca Jones?

Larry Kerr?

Richard Williams?

DR. MICHAUD: Vince Michaud for Richard Williams.

CAPT SAWYER: Frank Scioli?

DR. SCIOLI: I'm here.

CAPT SAWYER: Randall Levings?

DR. LEVINGS: On the phone.

CAPT SAWYER: Michael Amos?

John Skvorak?

DR. SKVORAK: Here.

CAPT SAWYER: Patricia Worthington?

Ali Khan?

CAPT SOSIN: Dan Sosin for Ali

Khan.

CAPT SAWYER: Hugh Auchincloss?

DR. AUCHINCLOSS: Here.

CAPT SAWYER: George Korch?

Carol Linden?

DR. LINDEN: On the phone.

CAPT SAWYER: Bruce Gellin?

DR. GELLIN: Here.

CAPT SAWYER: Luciana Borio?

CDR MAHER: Carmen Maher for Luciana Borio on the phone.

CAPT SAWYER: Sally Phillips?

Deanna Archuleta?

Rosemary Hart?

Kerri-Ann Jones?

Victoria Davey?

Peter Jutro?

DR. JUTRO: Here.

CAPT SAWYER: Patricia Milligan?

Thank you.

The NBSB is an 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 advisory recommendations where one or more of the members of their group are not federal employees.

The majority of the work of the NBSB including information gathering, drafting of reports and the development of recommendations, as you will hear today, is being performed not only by the full Board but by working groups who in turn report directly to the Board.

Standards of Ethics Conduct for Employees of Executive Branch document has been received by all the 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 interests that would compromise members'

ability to be objective in giving advise during Board meetings. Board Members must be attentive during meetings to the possibility that an issue may arise that could effect or appear to effect their interests in a specific way. Should this happen, the affected Members recuse himself or herself from the discussion by refraining from making comments and leaving the meeting.

Today we will have public comments from 11:45 to 12:00. At this time the public will have an opportunity to provide comments, opinions. If you are joining us by phone, you will be given instructions by the operator as to how signal that you have a comment. The comments will be taken in turn and you will be notified when your phone line 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 need to

accommodate during the public comment period.

I would also like to remind everyone that this meeting is being transcribed. When you speak, please provide your name. The meeting transcript, summary and pertinent documents will be made available on our website. In fact, there are documents that were posted as late as yesterday, including a letter from Dr. Lurie to the Board which is available on the website and has been passed out here at the meeting. That letter will be discussed later this afternoon.

I'd like to now turn over the meeting to Dr. Patty Quinlisk, NBSB Chair.

CHAIR QUINLISK: Good morning, everyone and welcome to the NBSB.

As Leigh said, I am Patricia Quinlisk, the Chairman of the NBSB. And I'd like to very briefly go over the agenda that we have.

There is one change to the agenda that occurs this afternoon. The two speakers we have this afternoon, George Korch and

Richard Hatchett are actually changing places. So we will first hear from Richard Hatchett from the 1:15 to 1:45 and then we'll hear from George Korch after that presentation at approximately 1:45 this afternoon.

I would like to just ask everybody, since we will be going into a discussion session, that if you have comments you would like to make for the discussion, if you'd take your name tag and place it upright. And then we'll by the timing of you putting it upright so we can keep track of who wants to make comments. And again, when you start to make your comments state your name first so we can keep track of who is making what comment.

I think that's about all I have to say. I think what we'll do is go right into our first agenda item. And Dr. Steve Cantrill is going to talk about the Working Group Report on All Hazards Science Response.

Thank you.

DR. CANTRILL: Thank you, Patty, very much.

I appreciate being able to address the Board. This is a culmination of a several month process that involved most of the Board Members and many of our ex officios, and several other partners both inside and outside the Federal Government.

This is a brief review of the 37 page report that you have in your folder which deals with the issue of scientific investigations as part of a response to a disaster or other event of national significance.

We have entitled the report "Call to Action," to include scientific investigations as an integral component of disaster planning and response.

This started January 21st with a letter from Dr. Lurie who, as you all know, is the Assistant Secretary for Preparedness and Response, asking us to investigate strategies to deal with knowledge gaps and research needs for improved response to future hazards and public emergencies. And she asked us to look

at what the major components might be, what could be done in advance to better prepare ourselves for this scientific response and how to operationalize this.

Why do we even want to think about this? Well, it turns out if you look back historically, that there are always or almost always scientific investigation done after major events. Certainly true after World Trade Center. Certainly true after H1N1. And certainly true after Deepwater Horizon. The problem is often there is no advanced planning so we're playing basically a pickup game. It's a scramble to try to get the science done. Often there's limited organization and integration to do that.

But if we can get this integration done and if we're successful, then it really will benefit the victims and responders of future large scale events when we're dealing with a public health emergency. So, that's really the driving force here; is if we can do some thinking in advance, kind of tease

apart some of the different issues and know what to expect, then in fact we can get more bang for our buck.

At our last public meeting of the National Biodefense Science Board on the 25th of January we established our All Hazards Science Response Working Group and we set a date for a workshop, which would be March 1st and 2nd of 2011.

Subsequently, we developed a mission statement for the Work Group, which I will review in a moment, and then started working on an agenda and questions to deal with for our workshop. The goal was to have a final draft report ready to present to the NBSB at the public meeting on April 28th, and here we are. So we hope that it goes successfully.

Let me just read this. It's a little long, but I think it's important. It sets the tenure for what we were trying to do.

"The All Hazards Science Response Working Group will investigate strategies on

how the United States Government might better deal with knowledge gaps and research needs as part of an inclusive response to future hazards in future health emergencies.

The topics to be addressed will include, but not be limited to, what must be done in advance to enable this response, the specification of the major components of such a science response and how this response might be operationalized.

The Working Group will develop recommendations to the NBSB on a way forward to the development of an all hazards science response strategy by exploring these vital topics."

So that was a good start.

We put together the workshop, as I said for March 1st and 2nd. It was not a public workshop. It was by invitation only. And we stipulated early on that the proceedings would be confidential, not for attribution. The goal was to get honest participation by all participants, and I think

we were very successful in that. I was very impressed about how frank and honest people were about what has worked well, what hasn't worked so well in the past.

I was also very impressed that there was overall unanimity in the issue that science investigation needs to be an integral component of disaster planning and response. It really does have to be a priority. There were no dissenters. And I, as just an outside person, only an intermittent government employee, I was very impressed, as I say, with the unanimity.

Just an overview of the agenda. The agenda in its entirety is one of the appendices to the report if you would like to review that.

We looked, first, at the science of past crises, specifically we looked at Deepwater Horizon, we looked at H1N1 pandemic, also some information on Haiti as well. There were presentations from multiple groups that were involved in those different events.

We then looked at the regulatory issues which can be complicating factor. We, again, had multiple presentations there. The individual that was going to present for the OMB, in fact, had to decline at the last moment because of a summons to the White House. But we dealt with that later.

We also had presentations on HIPAA and other aspects of that as well.

The second day started looking at operations components, specifically data gathering and again multiple presentations from multiple people such as NIOSH, CDC, and other groups that were involved in gathering data for several events.

And then we looked at operations from the response point of view. And here we had presentations from, again, multiple groups including FEMA, as well as private industry.

The workshop attendees, it was quite a group of individuals. We had both voting NBSB Members, we had ex officio members. We had our NBSB staff. And we had

multiple other invited federal folks as well as the private sector subject matter experts at this as well.

We were able to convene a teleconference with Mr. Michael Fitzpatrick from the Office of Information and Regulatory Affairs, OMB to address some of the Paperwork Reduction Act (PRA) issues which are felt to be sometimes a complicating factor.

We also had a teleconference with Dr. Richard Heron who is the Vice President for Health and CMO for BP International. Obviously, a lot of firsthand experience dealing with some of the problems following Deepwater Horizon.

We also had a discussion with Rear Admiral Mark Tedesco of the Coast Guard who is the Director of Health, Safety and Work-Life, again dealing with some of the issues that presented themselves during Deepwater Horizon.

In terms of, again, the timeline. We developed background and recommendations. We had multiple drafts circulated to the

Working Group. We had several conference calls. We had a preliminary final draft report that we circulated to the full NBSB with a subsequent preparatory conference call. And then the final draft was posted on the NBSB website and its contained in your folder.

In terms of the structure of the report itself, we thought we would follow the Institute of Medicine letter report format, which we did. It starts with an executive summary with the actual ten recommendations in skeleton form listed.

We then went to the body of the report itself. It starts with the charge to the NBSB including the letter from Dr. Lurie, which you find in the first appendix.

Then we had some background looking at some of the issues of scientific investigations during disaster responses. How essential planning is in advance of these responses. And then dealing with the thorny topic of research involving human subjects.

We then listed the recommendations

with some explanatory notes on each.

And then our seven appendices.

Let me just review the recommendations with you.

Recommendation #1: Immediately convene Strategic Science Planning Panels made up of leading expert government and civilian scientists to identify research questions and knowledge gaps likely to arise during a variety of incident types, including those foreseen in the FEMA National Planning Scenarios, but not limited to that. That's important. If you look at the Deepwater Horizon, not part of the National Planning Scenarios. So we have to cast our net a bit more broadly.

So this really does deal with content experts. We felt that our job as the Working Group was to address some of the structural issues as the first step. Then would come the second step in terms of dealing with some of the content issues.

Second recommendation, and

personally I feel this is probably the most important: Add a Scientific Response Support Annex to the National Response Framework and amend the National Oil and Hazard Substances Pollution Contingency Plan, the so called NCP, to include the scientific response.

If scientific response is really going to be a cardinal piece of our overall response to disaster, it has to be part of the framework. That framework is stipulated by the NRF, the National Response Framework. There is nothing in there, to a great degree, about science. So there is no science annex as there are other annexes dealing with aspects of the National Response Framework.

So we strongly recommend that a scientific response support annex be developed. That, obviously, would require a fair amount of work with Department of Homeland Security that is the keeper of the NRF to bring this to pass.

Third recommendation: Establish with leadership and staff from the Office of

the ASPR an interdepartmental center for scientific investigations during disaster response. This is what we refer to as The Center. The Center will have a dedicated staff, and its primary mission will be to anticipate, plan for, coordinate, facilitate, and evaluate scientific investigations conducted before, during and after disasters.

There is a lot of research that goes on after an event by a lot of different groups. But one of the big issues is that there is no coordinated body. And we look at this group, this so called Center, to be that coordinating body both before, during, and after. It's quite a challenge, but we need to have such an integrated body.

The Center would have full time staff and additional liaison staff as needed. And it would have the primary responsibility for successful implementation of the following recommendations, recommendations 4 through 10. Now they are listed in no particular order of priority.

The fourth recommendation: To develop the concepts doctrine, infrastructure and personnel needed to begin scientific investigations in data collection rapidly in various types of incidents. Again, this is a kind of subcorollary to the whole concept of coordination and integration. You will have different groups involved in gathering data, but you may not have those groups specified in advance. This would be an attempt to specify those groups in advance, have them trained appropriately and, again, have coordination of what's going to be done.

The fifth recommendation: Integrate the Public Health Emergency Research Review Board, the so called PHERRB, into standard operating procedures for review of research before, during and after a disaster response. And this deals with the issue of the so called IRBs, the Institutional Review Boards. And the PHERRB would be a federal level institutional review board which may facilitate some aspects of doing science in a

timely fashion following a specific event.

The sixth recommendation: Appoint a liaison with The Center to the Office of Management and Budget's Office of Information and Regulatory Affairs to facilitate review of scientific protocols required by the Paperwork Reduction Act, or the PRA. It became pretty clear to us in discussions that there is some misunderstanding and, in some cases, lack of knowledge of the requirements of the Paperwork Reduction Act and how best to facilitate the satisfaction of those requirements. So we think by having a liaison individual that this can be addressed, again, before events and during events as well to streamline the OMB approval process.

There are good examples of how it has been streamlined in specific instances. And I think what we want to do is generalize that experience.

Seventh: Establish funding mechanisms to support a rapid, robust scientific response to disasters. In this

time of fiscal austerity, this could be seen as a giant no-no. But this may not be new money. This may be repurposing money that's already present.

One of the ideas would be to take National Centers of Excellence in specific areas; NIAID has several across the country, and address with them how they might be very quickly spun up to do specific types of research if there is a national event. So, again, not necessarily new money, but creatively using what we have available.

Another thought is following somewhat the model of the National Science Foundation where they have a rapid research review process where in a matter of days they can approve a limiting grant for beginning research on specific issues. So there are some ways that we can address some of these issues.

The eighth recommendation: Integrate individuals and communities affected by a disaster as full partners in scientific

investigations related to the disaster. So this gets to the point of community participatory research. It's very important very early on to integrate with the community to understand where the leaders are, who the leaders are and how the research can be done as a united front. This makes the research easier and, in many cases, makes it more valuable.

Nine: Standardize approaches to data collection and sharing by federal, state and local response organizations and encourage the same among private and volunteer organizations giving special attention to the collection of baseline data. As we've discussed, a lot of people gather data, very often that data is not interoperable. So, in fact, we're all working in our different silos. That should be minimized to the degree possible.

And then the whole challenge of gathering baseline data is a very important issue. There are some national databases

which are referenced in one of the appendices of the report. They have strengths and weaknesses. They can possibly be used for some baseline data, but the challenge remains how best we can get that baseline data in a timely fashion.

The tenth recommendation: Is to identify, acquire or develop, deploy and maintain new information technology for collecting data in the field. There was a fair amount learned with Deepwater Horizon about things that can be done, whether you're talking about RFID badges that know where you are at a specific time. There are even things like now using social media for data gathering that we can include as well. There's a lot that can be done here and should be done, and put in place in addition.

So, that is a brief run through of the report. I would hope that you have an opportunity to review the report in its entirety. Several other points are raised that we don't have the time to address here.

And I would like to present that report to the Board.

Before I stop, I'd like to give special thanks. One to the Workshop participants. I think that was really an exciting time. We had about 70 people there and very honest sharing of experiences and opinions.

I'd also like to thank the Working Group members for our numerous conference calls and the input that they all gave to this developing product.

And then Jomana Musmar, who is the Executive Secretariat of the Working Group, without whose ongoing efforts we wouldn't be here today discussing this report.

And then Captain Leigh Sawyer, who worked very hard on this with me and was the inspiration and a guiding light to getting this done.

With that, I'd like to, I guess, open it up for discussion.

CHAIR QUINLISK: Thank you very

much, Steve. And I just would like to second that all the people worked very hard on this report, and especially you, Steve. Because I know that that was a large effort to put together. Thank you very much for your help.

I think what I'd like to do is first to acknowledge that Dr. Nikki Lurie, the Assistant Secretary of Preparedness and Response has joined us. And maybe see if she would like to start by making a comment or two?

ASSISTANT SECRETARY LURIE: Sure. I really actually just came to listen, but do very much want to thank the NBSB and the Working Group for this report.

As I think you all know, this has become an extremely high priority for me as we move forward. I have a really hard time thinking about how we can advance the quality of our response in a number of areas without thinking about the science components up front. And in this year of system changes that I've come to believe need to happen

through the work that I've been doing, this is one of them.

So, there's been a lot of really good thinking and hard work that's gone into this. And I look forward to hearing this discussion today, seeing the final set of recommendations and moving forward. I used to say God willing. Now I can say budget willing to think about how to move forward with a number of these recommendations. And I think as we continue to talk about them over time, not just today but into the future, that we'll continue to have a number of ideas about how to do this and to really make all of this a very sound and rigorous process.

So, I just want to say how much I appreciate this. I've read this version of the report and some detail on this. As I said, I'm really excited about the conversation. And now I think that we have the flexibility for us to have some direct conversation as part of our regular Board proceedings as well. You know, I would love

to understand a little more about some of the give and take that you had about some of these recommendations so that I can be in the best position possible to think about how to move forward implementing them.

Just as I did when you finished the terrific work on medical countermeasures, I was reminded about my first meeting with many of you where this question was: Was NBSB still needed? And, boy, once again you've really shown us how important a group this is and how you've come through.

And I guess you've gathered now that I intend to keep you really busy because, you know in your folder there's another issue that I would really like some help and input on going forward. And as my staff will attest to, very much to their frustration I think, I'm never wanting for questions. So, I'm sure that there will be more after that.

But I really just want to thank you for your hard work and the thoughtfulness that's gone into this and look forward to

working on this issue as with our other issues for a long time to come.

Thank you.

CHAIR QUINLISK: Thank you, Dr. Lurie.

I'd like now to open it up for discussions of the report. Hopefully, everybody's had a chance to sit down and take a look at it. And so we'll go ahead and start, and I'll just have people begin to put their things up. So, go ahead.

DR. GELLIN: Thanks a lot, Steve, and workers on this one.

I was on many of the calls and really appreciate all the work that went into this. And I think having heard from Dr. Lurie about her desires to move this along, I really think this is the direction that we should be going.

This is really, maybe it's a semantic or a clarification, on recommendation three it seems that the headline might not fit exactly with the body. And what I'm getting

at specifically is what you intend with this coordinating, facilitating, evaluating investigations conducted before a response. I think that means planning for things rather than looking -- because it has a ring a little bit of in the pandemic world they divide time into the pandemic and then the pre-pandemic period over time. So you're always in something approaching a pandemic or you're in peacetime.

So just some clarity on what you meant for the things that were supposed to be going on before. The during and after I think is pretty clear, but the before part wasn't as clear and how that lines up with what's in the text.

DR. CANTRILL: Thanks, Bruce.

I think, and John I ask you to respond as well. I think the intent here was to in terms of the before component there's a lot that can be done trying to anticipate some of the research questions. And I think part of it is getting the different expert panels

together to deal with some of those issues and determine how do we prepare for gathering data concerning the specific questions. So I think that's really what we're really talking about in terms of the planning component.

I don't know if that clarifies it or not for you.

DR. GELLIN: It does. And I think that's the intention I get from the text. But that part, just if people only read the headlines, they may think it's you're supposed to be looking at all kinds of things going on prior to that that may not have direct relevance to some future event.

DR. CANTRILL: I would take any friendly amendments in terms of how we might rephrase that to make it clearer.

DR. PARKER: John Parker.

I think if we go back to Dr. Lurie's initial charge, you know beyond the words in her letter was that the idea was to anticipate what hazards, what conditions, what entities could cause problems for the American

people or anyplace where there's a disaster. And to look ahead and kind of develop a menu of all those things that we think about, and then kind of do a gap analysis and say before hand, you know in the biochemical -- in the petrochemical area or in the agricultural communities, or the insecticides communities we don't know much about this particular one and we need to do some preliminary research in case of a tank car accident or something like that.

Now, it was a unanimous decision among the Working Group that this report wouldn't be a menu of all those things. And we were very strongly in the mode of setting up a framework and looking at The Center to really do that work, to do that analysis and do that menu.

And one other comment I have is that, yes, we all are very sensitive to the budget these days, not only as American citizens but members of the government and now government spends their money. I just want to

put out to the group and to Dr. Lurie specifically this is such an interesting important task that I suspect if the Health and Human Services Secretary wanted to, this would be a great thing to call for volunteers and people. Whether the law would allow that or not, I'm not sure. But what a great opportunity for experts throughout the country, universities, corporations to volunteer to make this really work.

CHAIR QUINLISK: Thank you, John.

I'd like to acknowledge that Daniel Fagbuyi has joined. Hi, Dan.

And then we'll go to another Dan, Dan Sosin.

CAPT SOSIN: Thank you.

Let me also offer my congratulations to the Working Group and the Board thoughtful, very step-wise recommendations highlighting both the big issues which we're all to be aware of but that would benefit from visibility at the highest levels, which is what you do. But also

incremental steps that are in this report that aid in the implementation of the scientific activities during response.

It's with great respect for the Working Group, the Board Members and those presenters to the Working Group that I'd like to challenge you, though, to revisit one set of conclusions. And those are relating to OMB PRA.

I'm speaking really as an individual here, not representing my agency. I'm not convinced that even in the forum that you created for federal workers to be open and up front with terminology, "frank and honest" I think is what you used around PRA. And because of the critical important role that OMB plays in all the agency functions.

And the challenge I have for you is not that this is necessarily an impediment to science during a response, or that it's wrong for science during response but that we shouldn't assume that it's a significant regulatory program, which is what this is

within the U.S. Government, is valuable and worth the resources we put into it.

I particularly personally don't think that we should assume that the value of calculus would be the same in an emergency as it is during everyday government activities. Obviously time is critical during an emergency. You yourself in this report called the critical importance of specialized judgment, having predesignated expertise within and outside government that could be ready to assist this kind of work during a response. So to assume that a bureaucratic function, say it what it is, staffed with well intended people but who are not experts in the particular work at hand should have the final say on the data collections that are involved, not just research, but programmatic data collections, is I think something worth challenging at least.

So, I'm only calling for the evaluation on the veracity of the conclusions about benefits in response of the PRA

function. I think it's important to point out this isn't about IRB, this isn't about human subject's protection; this is about a bureaucratic process that we've assumed within the Federal Government that, as best to my knowledge, has never really been evaluated for its net benefit versus what has gone into managing that process.

And further, I believe if you look in the particular context of emergency response, that there are probably ways to improve or adjust the process for emergencies that would still allow for the core functions to be addressed.

So, I call it out not with any particular data, although I will say the aftermath of responses when we're faced with illegal data collections, it does cause pause as one thinks about what we do in response, and maybe that isn't in our best interest. But just to take on the premise, assumption that we take at the front end that this is a valuable necessary critical piece of

government response.

CHAIR QUINLISK: Can I ask you, Dan, if you have a suggestion on how what you said might modify what we've got down here?

CAPT SOSIN: I struggled with this a little bit on the plane coming up this morning because I knew you have a report that's really in its final stages. And I guess what I concluded was that you called for it outside of this process. Simply to acknowledge that we don't know enough about the cost benefit of this program and its role specifically in emergencies. And call that a separate look. And maybe it's not you, maybe it's some other process to do that.

But to at least give pause to the assumption that we take going in that this is a necessary, valuable activity.

CHAIR QUINLISK: I'd like to again take a second to acknowledge that Georges Benjamin has joined us this morning.

Good morning, Georges.

And, Steven, do you have a response

to Dan's comment?

DR. CANTRILL: I think we could make that kind of an appendage to recommendation six. And I think in terms of calling out for an evaluation in the emergency situation of the cost versus the benefit of the Paperwork Reduction Act and whether some exclusions should be incorporated. That is something that we struggled with. And we talked with many folks would it just be futile to even discuss a legislative fix to this issue. Because I know many of us have stumbled on this. And I think it's a bigger boogeyman in some ways than it really is, but I think that's still a very valid point.

CHAIR QUINLISK: This is Patty Quinlisk.

I'm going to ask just a quick question, Dan. Can I ask you, how does this whole issue effect if states gather the data and then a federal agency like CDC then uses that data? So if I in Iowa, for example, we had a flood and we collected baseline data but

then you all came in and the flood moved down to Missouri and we started talking about interstate stuff; how does that effect that whole issue data collected by an agency who is not under the Paperwork Reduction Act?

CAPT SOSIN: My understanding, and I acknowledge up front that I'm not an expert in the bureaucracy of PRA, is if we direct you to collect. So if it's a flood in Iowa and you've done your own collection, you willingly share that information with us, there's no grant to do that work specifically and there's no national strategy on that data collection, that that would not fall under PRA because you're not under PRA.

But should we try to have coordination upstream/downstream to have the data collection the same and direct that from a national level, that would be.

CHAIR QUINLISK: Okay. Thank you very much.

Let's go on. I believe Frank Scioli. I'm sorry, I'm saying that wrong. I

apologize. You have a comment.

DR. SCIOLI: That's quite all right, Patty. Frank Scioli. You're not the first person.

Two comments --

CHAIR QUINLISK: With a last name like Quinlisk, I understand completely.

DR. SCIOLI: Two comments, if I might, please?

First, I think we do know the net loss from not pursuing in a timely way the scientific investigations that ensue from a disaster.

What I think may be of concern in the report is that there's a comment about "the study design." What I envision, and I think we've been successful at the National Science Foundation in implementing this, are response teams that are expert around particular kinds of disaster.

For example, we have an Earthquake Hazards Mitigation Program that has an earthquake research team that responds when

these horrible tragedies occur. And that consists of social scientists, behavioral scientists, engineers, public health official, et cetera. So they're on hand.

In advance, as the number six statement articulates, is a 90 day -- I believe it's 90 day, perhaps it's 60 day submission through the responsible channels as to the kinds of data that may be collected under different kinds of hazards.

I think that an expert group, a workshop of some kind, could anticipate the kinds of data that would be lost if these teams were not present. The public health data that physicians and public health officials would anticipate, the social science data; these things become contaminated quite quickly, as you all know, if there's not a response that's ready to go.

And the only problem I have with the bureaucratic structure, having been in government since Teddy Roosevelt was President, is that often times the paperwork

impedes and in fact damages the research process. The comments "if we had only had the opportunity to gather these data before they were contaminated." And I don't mean in a voyeuristic sense or really in a catastrophe anticipatory sense, but I mean that physicians, et cetera, et cetera know the kinds of data that we need in order to make response. Submitting those requests through the Paperwork Reduction Act folks is perfectly okay, unless it happens the day of the disaster. Then I think we're really not responding to the challenge of serving the public.

CHAIR QUINLISK: Okay. The next comment I believe is Kevin Jarrell.

DR. JARRELL: So I have a couple of comments.

I would, so this is the idea of what individuals at a center or teams associated with a center might do prior to the response. And so I want to make a couple of points.

I would say, one, what impresses me about this direction is the idea that it would be an all hazards response. And so I think that some coordination ahead of time allows a preassembled group to come up with the things that are really generic to any particular response, and certainly positions people to efficiently collect data in an emergency situation when there's really only time to act, and often not so much time to think.

So, certainly that's something that I see occurring before or sort of prior to the event, is this standard or sort of generic organization in terms of data collection.

And also I would say avoiding -- you know there's some advantage to putting together ad hoc teams sort of on the spot when these things occur. But, you know it takes so much time and you're sort of trying to sell to people the idea that they should sort of come on board and help with a problem as opposed to having commit to this and talk to each other, and even work together to some extent. You

know, to know each other before the event I think is incredibly important.

So, I think we do need to work to be more specific about what might happen prior to an event, but I think that that's just a critical element in terms of being able to respond effectively.

CHAIR QUINLISK: This is Patty Quinlisk.

And I'm actually going to respond a little bit to this, too. And as Steve knows, one of the things that I struggled with in this is something that we struggle with in public health, and that is where do we have public health, emergency response, et cetera, that we can do because we're responding to emergency. And that may involve collecting data and everything, and when does it go over into a research data where you do need to start concerning yourself with IRBs, oversight and all of that?

And this was talking just about research, so there's not much in here about

that. But there is the ability of public health to do some response, to gather some data, to do some things without concerning yourself with a lot of these more bureaucratic kinds of things and IRBs and all of that. But I must admit, that the line sometimes is a little bit blurred and maybe I could ask Dan Sosin does this seem to impact what we're talking about here today or do you feel that really that's totally separate and it's not an issue here?

CAPT SOSIN: I would say that the scope of the report very broadly, intentionally so --

CHAIR QUINLISK: Right.

CAPT SOSIN: -- to include program and research. And I think it's very important throughout to be reinforcing that this is also programmatic data collection. So this is public health practice.

CHAIR QUINLISK: Yes.

CAPT SOSIN: I mean how we do this effectively and in a consistent way, in an

optimal way with the mechanisms, et cetera.

I will say that OMB PRA specifically is not a research requirement. It is a data collection requirement.

CHAIR QUINLISK: Yes.

CAPT SOSIN: So that includes all programmatic as well as research.

CHAIR QUINLISK: Right. But let me just ask you, when you're doing programmatic kinds of collection data where you're looking into the future and you're putting together grants that you're going to give the state, I can totally understand the need to have it reviewed and meet some of these requirements. But I guess in an emergency when, for example, Iowa has a flood and we're dealing with what do people need on the ground right now, we go out and ask them right now. It doesn't go through these kinds of, you know a 60 day notification that we're going to collect data and all of that. Because that's part of our job is that we need to find out that data immediately to ensure that a response to the

people is appropriate.

But again, that's at a state level. So I struggle a little bit with the difference between us, but I certainly know that CDC sends EIS officers out who start collecting data and they're not waiting 60 days for it to be --

CAPT SOSIN: There are expedited mechanisms within this process.

CHAIR QUINLISK: Okay.

CAPT SOSIN: Ultimately OMB says yes you can go, and you can go with that data collection.

CHAIR QUINLISK: Okay.

CAPT SOSIN: It doesn't require a Federal Register posting for all of these mechanisms.

CHAIR QUINLISK: Okay. So how fast, for example, if CDC were sending people out to respond to an emergency and they're getting on a plane tomorrow morning, does that happen overnight so that when they hit the ground they can start collecting data?

CAPT SOSIN: So depending on the circumstances you can get near immediate response on these.

CHAIR QUINLISK: Okay. Okay.

CAPT SOSIN: There are broader questions, I would say though, about who is it that's making that final determination and what is the context --

CHAIR QUINLISK: Right.

CAPT SOSIN: -- in which this question is substituted for that question.

CHAIR QUINLISK: Yes.

CAPT SOSIN: And in an emergency where you are adapting to the crisis at hand, it's great to do all the prework --

CHAIR QUINLISK: Right.

CAPT SOSIN: -- and to get these generic pieces set up, it's just like a response plan. It helps you think through issues, be ready. But the response plans we have we know are always wrong and the generic data collections will not be the ones we want. And if you make an adjustment and you have to

go back through OMB again, that's the challenge.

So maybe there are tweaks to the process for emergencies, and you could look into that.

CHAIR QUINLISK: Yes. Thank you.

John Grabenstein?

DR. GRABENSTEIN: Thank you.

So a couple of responses, one to Bruce and one to Dan.

So I think Bruce was concerned that recommendation 3 did not adequately address the before the disaster. But I'm seeing in that item anticipate and plan for. So I'm being a little bureaucratic here. I think we covered it, but if others didn't think we covered it there, we should amend it.

But the longer response back to Dan on the Paperwork Production Ac issue. Your comments were my premise going into this process. And in the teleconferences and the workshop I kept saying "Give me an example of a case where a good project didn't happen,

couldn't happen because it got stuck?" And I couldn't get an example back.

We heard the OMB people tell stories of walking things around to get them signed right away to get emergency authorities granted. I think some of the examples were CDC ones where it was CDC requesting the emergency pathway, and they got it quickly. But we asked multiple agencies the question.

So, we couldn't find an example where something that had to happen tomorrow was held up.

Now I also saw, you know that's a six month process and if you've got a durable emergency like Deepwater Horizon, you know in the second month you may need to plan that this thing might be going out eight months and act accordingly. So, that's a comment.

Cost benefit isn't the way to analyze this equation. I've done cost benefit analyses and we're not going to be able to measure costs adequately to do this. So I think what I heard in Dan's comments was, "Why

is the step there at all? What's the value added to this review? How are we safeguarding the public interest in some way?", which is the goal of the Act?

And I heard a little bit in the workshop or the teleconference, I guess, about some survey methods kinds of value added that you're asking, "Did you really mean to ask item six that way because it can be misconstrued." And that's probably less an issue for CDC where there's lots of survey research done and maybe apply to other agencies more.

But, you know a review of why bother at all is fine with me, but I had a hard time finding an example of the bureaucracy getting in the way of worthy research, was usually the way I put it.

CAPT SOSIN: So let me respond first to the given example.

It's hard to give you an example, in part because there are legal implications. There are instances where certain data

collections have been deemed to be illegal data collections, and therefore those who implement them are subject to legal proceedings, potentially.

So in the context of not fully understanding this law, not fully understanding the enforcement powers of it, you will be hard pressed to have people jump forward with examples of where this became a problem or not.

But I would frame it a little differently, and I would frame the question yes, we can support this process. Is it worth it? Are we getting something sufficiently to put the extra person time, the effort, distraction and the modification that may come as a result of it better sometimes? Worse sometimes? In order to achieve the PRA.

And so, again, I challenge you to think about the evaluation of what we have achieved through PRA, particularly in the context of emergencies, and whether there are adjustments to the process that could

streamline, simplify and improve the value of that value added there?

CHAIR QUINLISK: That as Dan Sosin. Steve?

DR. CANTRILL: Steve Cantrill.

Hearing the discussion, I would propose that we graph an addition onto recommendation six which might read: "There should also be an independent review of the benefit versus the net loss of the effect of the PRA on a timely emergent scientific response with consideration of possible approaches for remediation." Does that capture the essence of what you're trying to say?

CAPT SOSIN: I think that's well stated. Thank you.

"There should also be an independent review of the benefit versus the net loss of the effect of the Paperwork Reduction Act on a timely emergent scientific response with consideration of possible approaches for remediation."

CHAIR QUINLISK: I think our next comment is from Peter Jutro.

DR. JUTRO: Thank you. I think this is a superb report on an immensely difficult problem. I've lived through probably more than some people and fewer than other people, disasters where I have looked and seen the problems that arise both with after the fact recognition "Gee, I wish we'd had that data," or sort of a desire that the entire science advisory mechanism during the length of time of an incident be improved.

So, as a result, I have a couple of comments that might be able to move this forward.

One, I recognize that when Dr. Lurie commissioned this report she was exquisitely sensitive to the fact that she has some measure of control over the HHS role in a disaster, but it also reflects the fact that she and the Committee were quite aware of the fact that there are other agencies that are involved other than HHS. So, with those two

things in mind, and recognizing that the report stressed the need for advanced research, I think it is important to explicitly recognize that there is a need for a full temporal evaluation of a disaster.

Obviously, the immediate aftermath of a disaster is the point at which one most exquisitely recognizes the need for public health and for life safety measures. But in fact if you look at how the government has responded to the planning scenarios through originally TOPOFF and now through National Level Exercises, you realize that none of them go more than a few days, maybe 14 beyond an incident, and then they turn it over to CDC and to us and say "Okay, it's yours now." This doesn't require planning. That's, perhaps, a bit of an exaggeration, but that is what we are frequently seeing happening.

So, I believe that we have to make sure that this is applicable to the full range of a disaster, even if parts of those are beyond the specific needs of HHS. How do you

prepare for a disaster can minimize the effect on health and how you respond to a disaster many months or in some cases years following a disaster can have an important effect on health.

But the purpose here is to look at the research you might set up in advance. One of the issues is that the report is very clear on this, but it does speak of science in addition to research. And one of the challenges I think will be to differentiate clearly between the two and to make certain that when the recommendations on revisions, for example to the National Contingency Plan, begin to move forward there's a recognition of the extent to which the people who are responsible for ICS, for the Incident Command System, feel that they already have scientific advice well built in. And I think it's important to examine this to make certain that there's a clear understanding of where these recommendations complement that and where these recommendations make suggestions for,

perhaps, a broader notion of what constitutes science advice or what's needed in advance in order for science advice to be effective.

Two other things. I would like to ask, unfortunately Franca Jones is not here from OSTP today. I don't know if she's on the telephone or not, she wasn't at the beginning. But I do know that she has convened an OSTP Working Group to look at questions that are very similar to this. And I would like to ask her if she would be willing to invite Dr. Cantrill or someone from HHS to come to the White House and give a presentation to that Working Group on this report so it can help inform our work.

And finally, one of the things that all of us know is that any new idea needs a champion. And we clearly have that champion in Dr. Lurie. And I think her challenge will be to take this beyond the realm of HHS into the broader intergovernmental range of essentially trying to reduce the impact of disasters on the country or on the world. And

that's going to be a challenge. And I think my guess is that everyone of the ex officio members of the Committee would be happy to help her with that.

CHAIR QUINLISK: Thank you.

I'd like to take a minute and just see if anybody on the telephone has a comment.

OPERATOR: At this time if you would like to ask a question, press star and the number one.

CHAIR QUINLISK: No. This is not for the public. I want members of the Board if any of the Members of the Board who are on the call have comments.

Okay. Sorry. I wasn't explicit. Okay.

Patrick?

DR. SCANNON: This report, as various people have noted, is broad by intention and meant to provide a general framework for how to address the collection of scientific information. And my comments are not meant to cause any change in the report,

but just to challenge whoever it is that implements this at some point in time.

And that is, I've thought a lot about the collection of data and the people who are the collectors. And I think that's very well handled in this report.

I think as the implementers of this report move forward, I think a lot of attention has to be given to the people from whom the information is being collected, as I guess the people who are busy surviving whatever the disaster may be and their attention span be much more related to the present than the future. And there may be ways to collect information that minimizes the impact on their concerns about survival. And I think one example that I saw, and I must admit I was taken aback by it, but there was an article in the Wall Street Journal a couple of days ago about using the social media like Facebook to collect information on a clinical trial, a human clinical trial.

And it was informational in nature.

And it got a lot of criticism, apparently. But nonetheless, it just opened up a whole range of thinking that I had not really given a lot of thought to.

People are more and more use to things like Twitter and Facebook. And I really do think that some of these -- and it is mentioned in the report. I'm just saying it as a point of emphasis.

I think the other comment is that we tend to think of a disaster as a point event. Patty quickly pointed out that, you know a flood can start in Iowa but end up in Missouri or other places. We've also saw in Japan the tragedy of tsunami disaster turning into a nuclear emergency.

And so thinking about this in terms of having a flexible responsiveness would be absolutely critical because we don't know the direction any given disaster might go.

And so, again, I don't feel that these comments need to be incorporated into the report, but I just wanted to point those

out as this is the kind of things that need to be considered once the report is turned over.

Thanks.

CHAIR QUINLISK: Thank you, Patrick.

Are there any other comments from Members of the Board? Okay.

DR. CANTRILL: Steve Cantrill.

In talking with several folks that have reviewed this, there was I think an area that maybe we didn't deal with enough, and that is local IRBs. And to deal with **this, what I would propose, this is not a** change in a formal recommendation, but it would be in addition to the corpus of recommendation number eight. And it would be a statement "That the integration with the community should extend to local academic communities with the intent of streamlining local IRB approval to scientific investigations when indicated." Just to bring that to the fore that the PHERRB may help us a great deal at the federal level, but we may still have some

issues at the local level.

CHAIR QUINLISK: And I have just -- I have a question not dealing with IRBs that often when there's a national thing and you get a national IRB out of CDC or something like, how does it affect, say, a local academic institutions, IRBs? Are they mandated to have their own IRB? Can sometimes they ride on the federal IRB? I don't understand quite the interactions between those levels when you're dealing with IRBs, and I don't know if anybody here does.

Do you want to -- okay?

DR. PARKER: Unless there's legislation that empowers the PHERRB, or the Federal IRB to overrule and have ultimate authority, then the CFR that controls the IRBs or sets down the guidelines says that there must be specific coordination with sovereign entities. And since states are sovereign entities, at least the state has to be coordinated with.

And then within that state if

individual organizations are actually going to execute the research, say, Iowa University if they're going to execute it, their IRB would also have to take a look at that. And they have the choice. The chairman of that IRB can look at it and especially if it's minimal risk, expedite the review by just the chairman saying "It's a minimum risk protocol and we allow our institution to be a member of the collection of data."

So the coordination is kind of important because -- let me give you two examples.

The law says IRBs must be involved if there's research and a human being's involved. Now the involvement of the human being can be an interaction with no intervention, okay? An interaction is a minimal risk; that's questions, things like that.

If there's intervention, like the use of a NIA array or something like that, that escalates the level of the whole thing.

But to be careful, you know there should be a function of coordination among IRBs. And then at a federal level the other thing that's in the regulations says that if I'm the chairman of the IRB at the University of Iowa, I have the right to say we advocate to PHERRB, okay, and they are going to be responsible for this investigation.

CHAIR QUINLISK: I just know at the state we often defer to CDC has an IRB and we're doing some kind of national project, we defer to their IRB as being sufficient to have oversight, and therefore we do not do another one at the state level. Now some states may, but we do not.

But it was always sort of interesting to me that it was apparent that even when there's things going on between different universities, that often each university had to have their own IRB which then slowed things down considerably because it depended upon the schedule of that university's IRB to the point where sometimes

the research then just wasn't done.

DR. PARKER: And we see that at the national level where the Department of Defense, you know grants huge amounts of money either by contract or other vehicle and there is human research done on that. And just what you said, Patty, the timing of the Board. Because if the DoD Board sees an inadequacy or wants a change in a sentence --

CHAIR QUINLISK: Yes.

DR. PARKER: -- and it gets back to the university, and they just had their meeting yesterday.

CHAIR QUINLISK: Right.

DR. PARKER: And they can't address it for 30 more days. And then they address it, and it misses the meeting at the DoD level.

CHAIR QUINLISK: Right.

DR. PARKER: It drags out months.

CHAIR QUINLISK: Right.

DR. PARKER: It can be terribly so. It's really important to have the coordination of the chairman --

CHAIR QUINLISK: Right.

DR. PARKER: -- to advocate quickly and say you're the Board.

CHAIR QUINLISK: Yes.

DR. PARKER: Okay.

CHAIR QUINLISK: Yes. I think that's very interesting.

Daniel?

DR. FAGBUYI: Dan Fagbuyi.

Actually, I think John Parker highlighted exactly what I was going to say.

Nationally when we do especially studies through our networks in research, and I think something that came up during our process during the Working Group meetings we did ask these questions, and the issue of liabilities, who wants to be the "IRB of record." And that's the big deal.

So in that case, that would be the PHERRB would have to have agreement in place with that institution, the local institution.

Other ways of going around this, I mean when I say "going around," I don't mean

illegally, but working through this is where institutions actually agree there's a set protocol that's already done, be the national level, PHERRB puts that out, and says "Okay, we're pushing this down to the institutions." And with the chair involved, but they have some disagreement, let's say it's blood draw there's an intervention in this, "Well you can only draw 3 CCs, that's what we allow, or five mLs of fluid." At our institution three is the max. They have an understanding that the protocol can be modified to a degree without effecting the end result of the study. So, those are some of the ways to go about that.

CHAIR QUINLISK: Thank you, Daniel.

John Grabenstein?

DR. GRABENSTEIN: So I agree with everything that's been said the last couple of comments.

Steve, back to your sentence of addition, I think it would work in cities like Denver but I think it misses some of the smaller, like the town where I grew up. And

so your sentence started with local academic communities something, something, something. And I think it needs the local academic and medical communities because my hometown has a state university and a community college, but it doesn't have a teaching medical hospital or an academic medical center. So I just think you want to be a little broader.

DR. CANTRILL: Thank you. Added.

CHAIR QUINLISK: Let me ask again if there are Members on the phone line who have any comments? And you guys don't have anymore?

Okay. Go ahead, Pat.

DR. SCANNON: As a follow-up to John's remarks, people may or may not be aware but there are an awful lot of clinical trials going on in this country and much of it is reaching out to community hospitals. And there may be a way to facilitate your comment, John, that more and more clinical trials are going on. And so there may be an ability to take advantage of that as part of getting

smaller communities that don't have as many formal IRBs in place. So just worth pointing that out.

CHAIR QUINLISK: I'll see if there's sort of last call for any comments from Board Members either in the room or on the telephone.

Okay. Seeing none, I think what we will do is go on to the public comments.

I would ask that people in the room if they're going to make a comment, to please come up to the microphone and state your name and affiliation before you make your comment.

And we will do the in-room first, and then we'll go to any comments on the telephone.

So, let me open up right now for any persons in the room from the public who wish to make a comment.

Okay. Seeing none, Operator, could we please open it up to any public comments from the telephone line.

OPERATOR: At this time if you

would like to ask a question, press star and the number 1 on your telephone key pad.

And there are no questions at this time.

CHAIR QUINLISK: That was a quick 15 minutes of comment.

Okay. So seeing that there are no more comments, the next thing is to go to the public vote of the recommendations.

And I guess, could I ask, Steve, one more time to remind us what are the two additions we've made this morning so that when we vote on this we will be voting on what we were given in our package this morning and including the two comments or modifications that have been made this morning.

DR. CANTRILL: Right. We have two additions. One is to the body of the actual recommendation number six. And that would read: "There should also be an independent review of the benefit versus the net loss of the effect of the Paperwork Reduction Act on a timely emergent scientific response with

consideration of possible approaches for remediation."

Then the second addition is to the body of number eight, not the recommendation itself, but stating: "The integration with the community should extend to local academic and medical communities with the intent of streamlining local IRB approval to scientific investigations when indicated."

CHAIR QUINLISK: This is Patty Quinlisk.

Can I ask, maybe this is getting too nitpicky, do we need to say "academic, medical, and public health local"? Because in some communities in Iowa there is no medical or academic, there's only public health. And I'm just trying to be inclusive, and I'm wondering if that would be an appropriate time to add it.

DR. CANTRILL: Not a problem. So it will now read "local, academic, medical and public health communities."

CHAIR QUINLISK: Okay. I'll ask

one more time if there are any comments?

John, go ahead.

DR. GRABENSTEIN: Yes, sorry. I'd like to have an understanding that we're empowering the staff to fix any grammar or spellings they might identify in the course of getting the silly thing ready for publication.

CHAIR QUINLISK: Yes, I think that's a given, but we'll just make sure everybody understands that we will be making any minor grammatical changes as needed to ensure that the integrity and the understandability of the report remains intact.

Okay. Well, seeing no more comments, I think we'll go ahead with the vote.

Oh, I'm sorry, yes. We have to have a motion.

DR. CANTRILL: I move the adoption of the Working Group report "Call To Action: Include scientific investigations as an integral component of disaster planning and

response. I move the Board vote in favor of approval of this to further it.

CHAIR QUINLISK: Do I hear a second?

DR. FAGBUYI: Second.

CHAIR QUINLISK: Daniel Fagbuyi has seconded it. Okay.

I think can we just do a unanimous, or should we go through?

CAPT SAWYER: Since we have some of our Members on the phone, I'd like to go around with a roll call here.

CHAIR QUINLISK: Yes.

CAPT SAWYER: If you vote in favor, please say yes or no.

Patty Quinlisk?

CHAIR QUINLISK: I vote in favor.

CAPT SAWYER: Georges Benjamin?

DR. BENJAMIN: Yes.

CAPT SAWYER: Steve Cantrill?

DR. CANTRILL: In favor.

CAPT SAWYER: Jane Delgado? She hasn't joined us.

David Ecker?

DR. ECKER: Yes.

CAPT SAWYER: Dan Fagbuyi?

DR. FAGBUYI: Yes.

CAPT SAWYER: John Grabenstein?

DR. GRABENSTEIN: Yes.

CAPT SAWYER: Kevin Jarrell?

DR. JARRELL: Yes.

CAPT SAWYER: Tom MacVittie?

DR. MacVITTIE: Yes.

CAPT SAWYER: John Parker?

DR. PARKER: Yes.

CAPT SAWYER: Betty Pfefferbaum?

DR. PFEFFERBAUM: Yes.

CAPT SAWYER: Pat Scannon?

DR. SCANNON: Yes.

CAPT SAWYER: That vote is unanimous.

CHAIR QUINLISK: Thank you very much, Leigh.

CAPT SAWYER: There is one additional item that I think the Board may want to address. Previously the Board has

sent recommendations, to the Secretary. Since we have a charter that's been amended recently to include the Assistant Secretary, I think that there should be some deliberation and discussion about who should receive these recommendations.

CHAIR QUINLISK: Okay. And maybe, Leigh, I could ask what would be sort of the most appropriate and expedited way of sending them? Do you have a suggestion to send them to both people or --

CAPT SAWYER: I think it's really up to the members of the Board. The request came from the Assistant Secretary. It has been based on the charter that all of the recommendations went to the Secretary. Of course the Assistant Secretary for Preparedness Response, Dr. Lurie has addressed many of those recommendations.

In this case, Dr. Lurie did make the request of the Board.

So it's entirely up to this Board.

CHAIR QUINLISK: I think I'd like

to maybe make a suggestion that since in the past it's been our custom to send it to the Secretary, could we send it to the Secretary with a CC to Dr. Lurie so she would get it at the same time?

DR. FAGBUYI: I second that.

CHAIR QUINLISK: Okay. I think what we'll do then is we'll formally send it to the Secretary, but Dr. Lurie will be CC'd on it so she gets it at the same time.

ASSISTANT SECRETARY LURIE: Well, let me just thank you all again for your incredibly hard work. I'm very excited about this, and excited about moving it forward. I very much appreciate the advocacy of the Board for this and the passion with which you've embraced this issue, as well as comments from some of the ex officio members and their support as well.

It will probably come as no surprise that we're trying to work some of these issues through the interagency process. I think you're aware of the fact that during

Deepwater, 17 different federal agencies conducted some kind of scientific investigation. That it's been extremely challenging to get all those data in one place and on a common platform that the investigator community of any kind can use them. It would be nice to avoid those kinds of situations in the past.

We've just been dealing with a nuclear crisis in Japan, again, where multiple agencies have been involved. Where I think the agency collaboration coordination, for the most part, has been very, very good. But again, sort of calls for a bit of a whole of government scientific response.

It did strike me in making this request initially that I need to get my own house in order, or our own house in order some before we started reaching out across the interagency. And also to be sure that regardless of what happened we could get some things moving. And so I think this report from those perspectives is very, very welcome.

But I think the suggestion of presenting this work to OSTP and working with colleagues and EPA and other agencies is a very welcome one, and we'll continue that. I think many of us see the need pretty acutely.

And thank you again for all of your hard and continued work.

I know you're going to have a robust afternoon.

And I appreciate the opportunity to listen this morning.

CHAIR QUINLISK: Thank you very much for coming, Dr. Lurie. We always enjoy having you with us.

And I guess I just again want to say what Dr. Lurie said, and just appreciate again all the work that went into this report. I think that you've come up with a very good report. And I look forward to seeing the impact of the report as we go forward in trying to deal with these emergencies and disasters.

And that is the end of our morning

session. I believe then we were going to be reconvening here at 1:15 this afternoon. And again, remember we will hear from Dr. Richard Hatchett first and then second later on this afternoon we'll be hearing from George Korch.

So, we will see everybody back at 1:15. Thank you very much.

(Whereupon, at 11:45 a.m. the meeting was adjourned, to reconvene this same day at 1:32 p.m.)

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

1:31 p.m.

CHAIR QUINLISK: We can get started now.

I would like to introduce Dr. Richard Hatchett who is the Chief Medical Officer and Deputy Director of the Biomedical Advanced Research And Development Authority. And he's going to talk to us this afternoon on reflections on rejoining ASPR.

So, thank you very much.

DR. HATCHETT: I'm sorry to have to get started -- and I'm going to use George's slides.

Unfortunately, I have a 2:00 appointment back at HHS, so I'm going to have to run. So I apologize to those of your colleagues who are not in the room, but I needed to go ahead and get started.

I didn't choose the title of my talk, I don't think. And Dan was saying it sounds like what I did last summer.

But thank you for the invitation to

come. It's great to be back here with you.

I actually approached the request to come and offer some reflections from a variety of perspectives. First, as someone who is coming back to ASPR after many years. I left the predecessor office in 2004.

Second, as a longstanding PHEMCE stakeholder and critic of ASPR and BARDA, in some ways, hopefully a constructive critic but as someone who has been thinking a lot about how we support medical countermeasures development.

An finally, as one of the instigators and chief enthusiasts of the PHEMCE review and the NBSB review.

ASPR is a much, much bigger place then when I left it. I think I was something like employee No. 15 and there were probably fewer than a 100 employees when I left.

It was established, as many of you will remember, as the Office of Public Health Preparedness in November of 2001 with D.A. Henderson as the first director. And in

preparing my remarks, I actually looked back at D.A.'s first congressional testimony from December 5, 2001 and it makes for striking reading in many respects.

In some ways our concerns haven't really evolved all that much from the main pillars that he laid out of surveillance, emergency preparedness and response and medical countermeasures development.

I was amused, if that's the right word, by his one sentence description of the regulatory process and its optimism, and I'll quote. "When all the clinical, chemistry, preapproval inspection, manufacturing, labeling and other issues have been adequately resolved, FDA will approve the application." Voila. Simple as that. He described the then and actually still ongoing efforts to create a recombinant protective antigen anthrax vaccine and the important role of a new enterprise called the National Pharmaceutical Stockpile.

He was testifying before the FDA had promulgated the final version of the

Animal Rule before the Bioterrorism Preparedness, Bioshield PREP and Pandemic and All Hazards Preparedness Acts. Before there was a Department of Homeland Security. And before SARS, before Hurricane Katrina the H1N1 pandemic, Haiti and Fukushima Daiichi.

He spoke exclusively of the threat to biological and chemical terrorism. The focus was exclusively on domestic security. Pandemic influenza had not yet assumed the important role that it would assume in later years. And radiological and nuclear threats were not on the agenda.

So in coming back to ASPR, I am returning to an organization that has been tempered by almost a decade's experience and one that has grown substantially in terms of its personnel, mission and understanding of the challenges that it faces.

I think the biggest single surprise that I've had, I would even call it an experiential shock, is just how intense things are in the environment at ASPR. Not just in

terms of how much is going on from a policy perspective, and a lot is going on both internally and externally, and not just with respect to what seems like an unending string of operational distractions such as the all hands on deck response to the Japan earthquake and unfolding nuclear disaster, but in terms of the exposure and scrutiny that we are subjected to at ASPR. And remember, I'm offering this perspective having come from the White House. I had no idea that I was leading sheltered existence on the National Security Staff. But by comparison it is.

If it is not Congress, it's the White House. If it's not White House, it's GAO. If it's not the GAO, it's a stakeholder group or a think tank. And if it's not a stakeholder group, it's the press. The scrutiny is just relentless. And managing all of that accountability, all of those audiences at the same time and still finding time to think and think strategically is proving to be quite a challenge. I just do not recall it

being pitched at quite that level when I was at the predecessor office before.

While serving at the White House, I devoted a good deal of my attention once the pandemic subsided to the issue of enterprise transformation, and that's what I'd like to spend most of my time talking about.

I was convinced that the vulnerabilities the pandemic highlighted coupled with the timing of the change in Administrations afforded us a, what was probably a once in a decade opportunity to effect meaningful coordinated change in our business model for developing medical countermeasures. And the PHEMCE review of last year seized that opportunity really to the fullest proposing a series of new initiatives as well as administrative and managerial reforms that have the potential to fundamentally alter the environment within which medical countermeasures development takes place.

I'm actually not going to review

the proposals because I assumed that most of you are somewhat familiar with them or have heard about them, but I will say that it was the opportunity to contribute to their implementation that brought me back to ASPR and to BARDA.

Let me pause to make two important points about the PHEMCE reviews that cannot be overstated. The first is that the PHEMCE review while transformative in intent and substance, does not represent a rupture with the past. If anything, it is putting the system that we put in place on steroids with the hopes of achieving medical countermeasures at lower cost and more rapidly then we currently do.

The second is that the initiatives that it proposes cannot -- cannot substitute for the market guarantee provided by Project Bioshield.

With the benefit of hindsight and eight or nine years of practical experience we can see that it was naive to think that the

authorities and funding provided by Project Shield would, in and of themselves, solve our medical countermeasures problem. Project Bioshield and the special reserve fund succeeded in providing a market guarantee, but it did little, per se, to make countermeasure development easier. The expedited authorities that the Project Bioshield Act provided were extended to NIH notwithstanding.

The result is that we have spent the years since Project Bioshield was established coming to better understand our private sector partners and the challenges they face and in making improvements to our model for partnering with them.

The PHEMCE review and the initiatives that it proposes can and should be viewed as a culmination of that process. And the good news is that Project Bioshield, the market guarantee, is working and not just working, but working well.

We have the eight procurements for the Strategic National Stockpile, of course.

But I don't these actually make the case as well the development of our pipeline. BARDA now sponsors somewhere just shy of 60 contracts for CBRN medical countermeasures development and we are literally overwhelmed with white paper proposals and with TechWatch requests, TechWatch requests for meetings.

BARDA has received nearly 350 white papers in response to its CBRN in innovation BAAs. And we have conducted more than 200 TechWatch meetings with industry since 2008. And the pace of requests has accelerated dramatically this year.

What do I make of this? Well, I have yet to encounter a company whose business model stops with advance development contracts. Companies are coming to BARDA in order to develop products and in order to sell them, and they are voting with their feet. It's the market guarantee that is working and it will, should and must remain a core pillar of BARDA's business model.

Having said that, medical

countermeasures development is still hard. In aiming to make it somewhat less hard, the PHEMCE review represented many things:

It was a statement about strategy;

It was a re-envisioning of the public/private partnership;

It was an endorsement of the enterprise as an enterprise as the appropriate frame of reference for decision making, and;

It represented a commitment to improve program management and administration.

I'd like to spend the last few minutes of my talk talking about the last of these, about our commitment to improving program management and administration. This can be a dry topic, to put it mildly, a topic that only a bureaucrat can love, but it is extraordinarily important.

Initiatives to improve program management don't have a lot of marquee value and they don't necessarily get a lot of play outside their originating organizations.

I was paying attention, I thought,

and I was surprised by how much BARDA and ASPR have done to implement changes when I arrived. My guess is that you have probably heard quite a bit more about the big budget initiatives, the Centers for Innovation and Advanced Development in Manufacturing, the FDA Regulatory Science Program, the Strategic Investor then you have about these other more prosaic, but crucially important efforts to transform how we do business.

The first improvement that I'd like to talk about is actually the engagement of our leadership. A little more than a year ago, NBSB put out its report "Where Are the Countermeasures: Protecting American's Health From CBRN Threats" that called for enhanced leadership and accountability, greater synchronization of effort across agencies and disciplined teamwork by senior officials. Today I can report that we have made progress on all of those fronts.

Dr. Lurie, Dr. Hamburg, Dr. Frieden and Dr. Fauci are fully involved participants

in the new Enterprise Senior Council. I've been in this game since 2002, and I don't recall any previous set of agency leads engaging so directly or so collaboratively in the management of the Enterprise.

This Administration has been tested by a unique set of medical and public health challenges over the last two years: The pandemic, the earthquake in Haiti, Deepwater Horizon, the Fukushima Daiichi disaster and these events have established benchmarks for leadership and collaboration that are carrying over into the day-to-day management of the Enterprise, which is a good thing.

The example in engagement of our leadership makes it easier to cultivate and maintain an organizational culture that takes an Enterprise perspective where the challenges and tradeoffs involved in the development countermeasures and in the maintenance of the Enterprise are concerned. This is a constant challenge, obviously, but I can say that we are making progress.

The NBSB report also called on ASPR to refine the HHS acquisition structure and metrics to make our medical countermeasures programs more accountable.

ASPR, as you probably know, has been reorganized. Among other changes, the Acquisitions Management Contracts and Grants Group, or AMCG, was carved out of BARDA and is now a freestanding component of ASPR reporting to Dr. Lurie.

In pulling AMCG out of BARDA, the ASPR was able to consolidate all of ASPR's contracting staff in a single office while in ensuring a proper level of separation from program staff and from the source selection authority. In parallel with this reorganization, AMCG has introduced a number of processes to improve the contracting process.

First, it has implemented a QA/QC program which its calling the Procurement Optimization Program that tracks proposals through the decision process and automatically

alerts the senior program officials when any stage or set of stages exceed pre-defined time limits.

Second, AMCG and BARDA are now structuring contracts so that they contain multiple milestone-based options. And it has introduced a formal decision gate process borrowed from DoD that allows for wide ranging input from subject matter experts prior to exercising these options.

Third, in conjunction with the implementation of this decision gate process, BARDA and AMCG have piloted the use of in-process reviews both to the assess progress at the designated milestones, as well as on an ad hoc basis to investigate significant deviations of cost, schedule or performance.

The last administrative improvement I want to mention is BARDA's ongoing initiative to improve portfolio and project management. We will shortly begin a story that will map work flows and business processes within BARDA with the goal of

implementing a common work breakdown structure and industry standard portfolio management system across all of our contracts. This will result in a common set of metrics being applied across our entire portfolio of investments and a better real time flow of information to executive decision makers.

Over time, adopting such management tools will allow us to establish standards and track the performance of individual contracts against BARDA and industry norms, which will in turn enable us to take appropriate action at an earlier stage of the development process to rectify any evolving problems. And where mediation doesn't work, improve our ability to fail small and fail fast.

I began by sharing my impressions about how much things have changed since I was last part of the ASPR. And I've told you a little bit about where we are right now. We've come a long way, indeed. And looking at our experience over the last decade, I would say that we can discern five phases of the

Enterprise's evolution.

There was the pre-9/11 phase, which was really sort of the dawning consciousness of the awareness of the threats we face. When we created the National Pharmaceutical Stockpile and the Bioterrorism Preparedness Program at CDC and issued our first award for a modern smallpox vaccine.

There was the phase of extreme urgency following 9/11 and the anthrax attacks which culminated in the bipartisan passage of the Project Bioshield Act in July of 2004.

There was a phase of what you might call adolescence during which efforts were made to implement Project Bioshield and some very important and painful lessons were learned culminating in the debacle of Hurricane Katrina, the cancellation of the VaxGen contract and the passage in December of 2006 of the Pandemic and All Hazards Preparedness Act.

The next phase was the phase of what I would call young adulthood which began

with the creation of ASPR and BARDA and included the publication of the PHEMCE Strategy and Implementation Plan, and the creation of the HHS and DoD integrated portfolio for CBRN medical countermeasures. This phase culminated with the experience of the 2009 H1N1 pandemic and Secretary Sebelius' and the President's call to transform the Enterprise.

This brings us to the current phase which I would say began with the publication of the PHEMCE Review last August, and might be called the phase of maturity. This phase has been, and will be characterized by:

A clear-eyed analysis of the lessons learned over the past decade;

By a maturation in focus on continual quality improvement of the PHEMCE Business Model and Organizational Structure;

By an enhanced attention to unknown threats and the development of broad spectrum and rapid response capabilities;

By an emphasis on long-term

sustainability. and;

By a redoubled commitment to vigorous public/private partnerships.

It's a terrifically exciting time to be coming back to ASPR and joining BARDA. I think the new initiatives that the PHEMCE Review calls for will actually be transformative in their effect.

Even as our concept of mission has evolved and expanded to include addressing unknown threats, emerging infectious disease, the looming threat of antimicrobial resistance and the development of rapid response capabilities I think our prospects for success have never been better.

I feel deeply privileged to have been offered the opportunity to help lead the Enterprise forward, and I very much appreciate and wish to thank you for the invitation to come speak to you.

(Applause.)

CHAIR QUINLISK: Thank you very much.

DR. HATCHETT: I can probably stay for like one or two questions.

CHAIR QUINLISK: Oh, you're so gracious.

Okay. Quick, anybody got a -- oh, John. John's got one.

DR. GRABENSTEIN: Richard, I think America is absolutely privileged to have a true public servant like you. You've done remarkable things everywhere you've gone in government. And I thank you as a citizen for your contributions.

I'm glad to hear of the maturation. I'm glad to hear of the contracts and the white papers and the TechWatch meetings and the cupboard still doesn't have a lot in it. So I had 25 years watching the pharmaceutical industry and now I have five years in it, and I never realized how complicated it was until I got inside.

DR. HATCHETT: Yes.

DR. GRABENSTEIN: And our report is the road is long and complicated, or something

or other. You know, so you need to pace yourself because you're in a marathon, but the scrutiny, the intensity, the drive has to stay because success is the license to product. And so I would hope your metrics would be licensed products, and FDA and others will disagreement, EUAs or pre-EUAs, is fine with me, as your metric for status, for readiness.

DR. HATCHETT: No. I think that is very clearly the ultimate metric and everything else in a sense represents just a process metric.

My point in citing the number; having a TechWatch meeting isn't success or having a white paper proposal come in is not success.

I think what that illustrates is that companies, small innovative companies primarily, are willing to come to the table given the existence of a market guarantee. The market guarantee, as I was saying, does not make the process of developing drugs any easier. It doesn't reduce the barriers along

the way, the bumps along the way. And that was the central theme of the PHEMCE Review is what can we do as an Enterprise to sweep those barriers out of the way, to increase the flow, the throughput, as it were, to the point of licensure.

I mean, we will certainly -- this will take years before we know if these investments are correct. But I think one very important thing is that the PHEMCE Review ended up calling for something over a billion dollars in initiatives. And of that billion dollars or so, only a $100 million of that, the Strategic Investor Proposal right now would flow out into companies. The rest of that is investment in fixing our side of the equation and turning us into better partners, not just grantors or contract awarders but full partners at the table in figuring out how to untie this knot.

So, point well taken.

CHAIR QUINLISK: Well, thank you very much. And appreciate you taking the time

to come and talk to us today and giving us your insights, even though they were quite reflections on going back.

DR. HATCHETT: Well, they were. These are all the things that I had.

CHAIR QUINLISK: Okay. Our next speaker -- well, we did have time on our agenda for a few minutes of discussion, but since unfortunately we ran over and Richard's not able to stay any longer, I'm not sure. Are there things people among us wish to discuss on what Richard just said? Okay.

Probably then just go on to our next speaker, and that's George Korch.

Oh, I guess I should ask about the phone. Poor George, now you've gotten up again.

Let me ask if there's anybody on the phone who has got a comment?

Okay. George, please.

George is the Acting Principal Deputy of the Office of the Assistant Secretary for Preparedness and Response. So

you're going to be talking to us about addressing the pediatric population's access to medical countermeasures.

DR. KORCH: Yes. Thank you very much.

I apologize for not being present for a couple of -- at least one of the last meetings as an ex officio. But as you see in the slide, first slide, anthrax vaccine in pediatric populations. I should stop and ask right now and ask what are your concerns and questions.

And I know that in your packet you have received a request letter from Dr. Lurie with regard to this. So, why now? Why is the issue an issue that has been on our minds and plans, or in our hopes and dreams basically for a while, why now and what is it that we view? How do we view this issue and what are we asking the Board consider in term of helping us think through this particular set of problems?

Well, a quick outline for what I am

going to be talking about today. There aren't a tremendous amount of slides. I think this is more of an opportunity for exchange of ideas, but to frame up the issues and then see where it is that the Board thinks this set of questions or this issue sort of leads. But I'm going to start with events that have happened over the recent months.

Not unusual, and going back over the decade, one of the favorite tools around here to probe at where we find gaps in our capabilities and our response, our current planning are in exercises, tabletop exercises and broad exercises that are held at a national level.

Recently the Department held its very first National Level Exercise or senior officials exercise. Generally these are held by other federal agencies like Department of Homeland Security. And what we were asking was: What happens in an anthrax event 72 hours thereafter from the time of the event? Most of the exercises that had been run up to

this point in time will generally look at what's your immediate response? What can you bring to bear as a function of the need to instantly respond and to at least stabilize the situation?

But once stabilization, in a sense, occurs, what are the downstream consequences of this particular type of an event? So in this exercise which was run at first at local levels, this one will take place as an exercise that took place in the Bay Area of California. So on the western side of the Bay, as you'll see in a moment. But the event was an anthrax release occurring during daylight hours on a Thursday. And the ultimate first identification occurs about 72 hours into this whole process. So that gives you a timeline for the amount of turnover or turnaround time from the point of release to a point where an actionable result happens. And that actionable result, BioWatch Actionable Result then stimulates a whole series of downstream consequences.

And once the emergency in this particular exercise was declared, the Mayor and the Governor declared their emergencies with their jurisdictions, the Secretary of HHS declares a public health emergency; that frees up a whole lot of -- she's got a number of authorities under that which allow for use of various funds and other response methods. And the President, of course, declares the San Francisco Bay Area a disaster.

And in this particular exercise, fortunately, we have a very successful, highly successful deployment of the necessary drugs or antibiotic countermeasures from CDC through the PODS, the points of distribution system such that within the period of just several days all ten day regimens of antibiotics are distributed to about 7.2 million people in the Bay Area. So, this represents a timeline for this particular exercise.

Now, I'm giving you this as a function of putting you in the mindset for why does a question of immunization even arise?

So, you have the distribution, initial dispensing of the PEP, the postexposure prophylaxis for drugs. And then the next question starts:

What do we do for the next tranche of antibiotics that are going on out?

What does the city look like with regard to habitability?

What decisions are going to be made at the local level with regard to abandonment of the city or stay in place, shelter in place?

And some real hard questions and some real hard issues discussed with the City of San Francisco. They had representatives in this particular engagement, representing the Office of the Mayor and Public Health, the Bay Area Public Health community and the State of California Public Health community offering their perspectives describing what in their minds would be their response. And for the most part, very, very adamantly at the level of the city and the local it was we will not

abandon the city, we want to remain here. Federal Government do what you need to do in order to ensure that that is a viable option.

So as you see here, almost all assumptions in our response were for best case. So at a minimum, we're starting there at the best possible juncture. And we then get a chance to look at in this particular model what is the area that is affected. And as you can see there on the San Francisco Bay side going all the way down to Western Bay into Santa Cruz and at the Silicon Valley the coloration that you see in the chart, and it probably shows up fairly well. But in the dark area that just really covers the area under the X, this is the zone right in a city where about 50 percent of the population would have received the lethal dose. And the population that's point based on the modeling is about 49,000 people receiving a lethal dose.

Down wind of that for a period of some miles, 24 kilometers down wind, about 15 percent of that population under the

assumptions in the model are seen with a lethal dose.

And then two percent of the population in the lighter yellow would receive a lethal dose. And a lethal dose is a function not just of the number of spores inhaled, but other possible effects of age, et cetera.

So this gives you at least what a potential health impact would be in this population and the confounding -- I'm not presenting it here, but some of the confounding issues in this particular model were that way down in Sunnyvale and down at Fremont we would have the detector devices and even sampling that happens with an occasional hit of anthrax spores. And so confusion with regard what is the actual area of contamination. Where were people during the period of release and what level of the population is really affected, knowing that while the City of San Francisco is approximately 700,000/800,000, the Bay Area

itself constitutes about 7 million total population. And so all the counties and the surrounding area are all at equal concern.

And when we go and look at what the surface contamination looks like from this particular event, we can see that approximately 19 or 58 square kilometers, a population of 301,000 are in what is considered that highest surface contaminated area. And then as you move down the coast, smaller and smaller doses as the cloud is dispersed.

So from this a whole series of discussions then began. We will touch on the discussions and how rapidly that the area could be cleaned up. But suffice it to say that under the best of circumstances it would be weeks, months, probably many, many months to be able to do a triage and a cleaning up, and also the fact that we really don't have great data right now on what reaerosolization looks like, what a how clean is clean dimension looks like. And so scientific

realities aside and, hopefully, part of the outcome of these exercises at the National Security staff level are to generate those datasets as well that are necessary so we can go back in and start making some population health discriminating projections.

The rest of it becomes well, what does the Federal Government have now at its disposal to help the populations? Well, certainly you know that we have in the Strategic National Stockpile sufficient antibiotics both doxycycline, ciprofloxacin as well as a couple of other medical countermeasures, but those two primarily to allow for an additional 50 days of coverage with antibiotics. So we would be able to provide to the 7 million people of this population if all 7 million needed it, a full 60 day supply of those antibiotics. But staying on antibiotics for 60 days is not an easy task, especially considering the fact that we have a range of populations in this particular area and people make decisions

about when they are going to stay on or not stay on, or come off antibiotics.

So, this is just for your -- it's not eye candy, but it is a projection of what would the situation look like in terms of hospitalizations, our projections based on exposures. And so this is a county-by-county representation of what populations that would require hospitalization.

What you really want to look at are the bars that are black, as in San Francisco. That is the delta of cases that would not have available beds. And across the entire San Francisco Bay Area, that very last set of histograms, shows you that within a short of period of time, within ten days, based on what we know the available bed spaces in the San Francisco Bay Area right now, we'd be looking at a pretty dire situation. But that's at ten days. By 90 days it's even a lot worse, mostly because at this point in time we probably have people who have decided that they didn't need to take their antibiotics,

other cases are showing on up. The length of time it may take to treat single cases, especially for those individuals that have the highest degrees of medical care and medical need. And, of course, there are other discussions about what we do with the medical surge and the ability to remove people from this particular area or off-load patients to be able to then treat patients elsewhere.

An interesting sidebar to this was the question of how do you take people out of this "contaminated area," movement of all sorts of goods into and out of the contaminated or the hot zone becomes problematic, such that the Department of Defense insisted that any ambulances coming out of the zone, and we don't even know where the boundary of the zone is, would have to be decontaminated before they would take a patient and put it on an airlift or an airframe to move that patient somewhere else. So you can start seeing the complications here with regard to looking at the long term

sequelae of a particular event of this sort.

And this, again, just shows you in a numeric fashion, in fact it's symptomatic, recovered and then mortality figures.

Now, against that backdrop the question emerged: Well, people are going to be living in the San Francisco Area for long periods of time and we have uncertainty with regard to what it might mean in terms of environmental contamination; does vaccination become a paradigm or a potential solution to living long-term in an area of what one might consider risk? Risk only in the sense that we don't have enough information to tell them it is or isn't definitively.

And so the problem of definition really starts from this point. I've just presented a scenario that suggested the possible need for a vaccine program for this population that will continue to live in what we will call a contaminated area.

There is no pediatric safety or immunogenicity or efficacy data for any

vaccine related to anthrax, certainly not for AVA or for any vaccine that domestically that we know of.

During the time of an emergency there is, therefore, no anthrax vaccine because we do not have the data that can be administered to this population under anything other than a research protocol, an IND protocol. And, of course, while this is all happening we have emergency use authorization or we would have the data and therefore, we have a pre-EOA package and we would imagine that under the emergency declaration we would have instantly the ability to use this vaccine under that declaration for the adult populations.

So the situations where mom and dad, grandma and grandpa can come on in, but anybody under the age of 18 we have a completely different logistical circumstance if, in fact, we can even provide the vaccine under that particular set of contingencies. And, of course, this complicates operational

response and it hugely complicates public messaging: What do you tell people and who is going to be asking the series of questions about why are my children not allowed to get this vaccine now with the level of deaths that you're seeing, with the hospitalizations hat you're seeing and with what might probably be described as complete chaos locally?

So, that's just a setting. It may never happen. We hope it never happens. And it could be a scenario that looks completely different from what I've just described, but it is a scenario. And against this sort of consideration with this backdrop, the ASPR requested that we look at development of a strategy toward the rest of the problem. It actually predated the exercise itself, but he exercise certainly brought a fine point to it.

I will tell you that over the recent several months, largely through the initiative of CBER. And they're not here today, but largely through the initiative of Karen Midthun and folks at CBER, they started

to seriously take on the question of how could we approach the development of protocols to look at the pediatric population, the administration of anthrax vaccine in pediatric populations.

Historically this has been at least discussed or debated I think in ACIP. And there has been a recognition, for instance, of the National Commission of Children in Disasters that we have done precious little with regard to any of the CBRNE medical countermeasures and trying to address pediatric and other at risk population needs. And as a matter of fact, in last year's "Where Are the Countermeasures," this body also pointed out the need to look at the at risk populations.

So, the discussions right now between FDA CBER, with NIAID, BARDA and CDC participating are asking the possibility of how we develop clinical protocols and what would the timing of those protocols be? So what conditions or data would be needed for

instance to look at or pertain to a pre-event protocol? So gathering data tomorrow without any possible threat on the horizon that we know of. And this has a whole range of issues, largely around the risk benefit related questions. What are the ethical constructs that would permit or would at least argue for such a clinical study?

And then one could say, well certainly as soon as the event happened we'd all be clamoring for action and to do something. So what would that dynamic look like? Administering this vaccine under an IND research protocol. Even if we were to do so, you know is it possible to structure a protocol in a timely fashion that would give us the necessary information and data relative to the 60 day time period when prophylaxes is happening? And once we've had that, is the all clear signal suddenly up? You've lived through the PEP, antibiotics, you no longer have to worry about the data, or is the data not going to be fresh enough to be able to

then use the vaccine in the pediatric population under an EUA?

Would you conduct a clinical trial at the location where all the events are happening? There's going to be enough logistical challenges there. Does that give you the opportunity to maybe look at another location? Because now it's no longer theoretical risk.

Of course, we deal with the real question that Richard Danzig put in front of us of what's the reload phenomena look like if you're able as a terrorist to demonstrate a tremendous impact? And that's, you know what they do is in their name of their title, their job description is perfect. It would not be beyond reason to think that if I could do this in one city, I could have another impact of the same nature in another city. That would be a real advantage, I think.

And then finally things that we're asking ourselves or what data would we consider? As long as we're doing this, at

that point in time it's no longer theoretical. Maybe we're no longer looking at a postexposure prophylaxis event, but maybe we're looking at a general use protocol which is a pre-event, which is basically the five shot protocol that is the current protocol used for AVA as opposed to the postexposure prophylaxis protocol, which is a three shot regimen I think done over a period of 30 days?

So, those are some of the questions that we're asking. You know, if you can generate the data for the General Use Protocol (GUP), you certainly have enough data for a postexposure prophylaxis protocol.

And there may be other constraints at this point that we just don't see. And just for your information, and actually this is a little bit of my own homework for myself in case you're not familiar with pediatric and clinical protocols, they follow the form mostly of adult protocols with some notable exceptions. And I would point out that the real issues are in the level of anticipated

benefits relative to the risk.

So with children we are much more cautious. There should be and there must be some specific benefit to the child in that particular protocol that you are attempting. And so if there's a greater then a minor increase over minimal risk? Is there a question about reasonable opportunity to understand, present or alleviate a serious problem affecting the child's health or welfare?

This entire list here actually comes from the flow chart if you look at the FDA section 21 CFR 50.51. This is the flow chart that one must consider in conducting a pediatric clinical trial. And they do categorize the clinical trials in several different fashions. So, sort of the least stringent or the most benign falls under Section 50.51 where the clinical investigation really does not involve anything greater then a minimal risk.

When the danger or the risk starts

getting racketed up a little bit more, the next section considers greater then minimal risk but representing or presenting the prospect of a direct benefit to that subject.

Next if there is no direct benefit to that subject, there is still the opportunity to conduct a clinical trial where you're looking for generalizable knowledge about the subject's disorder or condition. Presumably that subject then has that disorder or condition.

And then lastly, when none of these others pertain, then we're asking about an opportunity to understand, prevent or alleviate a serious problem affecting the health, welfare of children. So, that's the most stringent of all, the 50.54. And a study under 50.54 requires basically the Commissioner of the FDA to consult with an advisory panel in specific disciplines; science, medicine, ethics, education and law to be able to help pass judgment as to whether the protocol should move forward. And, again,

a series of conditions, and I've highlighted the one I think which is the important one to focus on, not that there any less important, they're all important. But reasonable opportunity to further understand, prevent or alleviate the serious problem affecting the health or welfare of children.

So with that as a backdrop, these were the questions that we posed to the NBSB in the letter. And from the perspective of the expertise what are the risks and the benefits of attempting to perform this vaccine, of any vaccine safety and immunogenicity research protocol in children in a pre-event versus post-event situation?

What are the challenges for administering this vaccine in your mind under an investigational new drug research protocol during an event?

And how would these compare with the ethical constraints or considerations that we have right now?

Any Latin scholars in here? Do you

know what the future pluperfect look like? I remember having to conjugate in the future pluperfect.

Future pluperfect is being in the past and pretending you were in the present looking forward again into the future. It was a really weird set of phenomena. Would that I had known that, you know, and you can translate from Cicero or something. But that's essentially what it would be.

If you put yourself in that future place and say "Gosh, I wish I had done this back now when I had chance," that's sort of one of the constructs for thinking about this. Can we think of this in terms of a benefit to a future population based on the fact that the event hasn't happened, but when the event happens we would have wanted to have known that information?

What preplanning should the U.S. Government have in place to then optimally perform this where we to need it at the time? So what ideas might you all have for having

something then on the shelf that one might be able to use so that when the event happens we are prepositioned to be able to take advantage of that?

And then most importantly I think, this last bullet would be to gather and assess the considerations of reactions from the stakeholder communities on how the U.S. Government should: (a) communicate these issues with parents, with pediatricians, public health officials and of course political officials before and in response to an attack?

And then finally, your recommendations on these and how one should proceed.

So, like I say, I can go back to the first slide and say what are your questions and comments?

CHAIR QUINLISK: Thank you very much. That was very interesting and sort of thought provoking, which I think it's supposed to be. So what I'd like to do now is open it

up for any questions or comments.

DR. CANTRILL: George, thank you.

Would we have access to slides? I think you have some very thoughtful points that we need to look at in depth.

And I would see there are multiple groups that serve the government in terms of vaccine knowledge and experience. Are you going to be approaching them as well, or what do you think the NBSB has to offer?

Actually, we have a fair amount of expertise in that area, but not as much as maybe some other organizations.

DR. KORCH: Well, we've thought about other organizations that would have eyes on this subject. VRBPAC would be one as a possibility. But VRBPAC is asking some very specific protocol issues when a protocol comes about.

There's the Pediatric Advisory Group that the Commissioner has. And certainly were there to be a protocol that goes forward to the FDA from a sponsoring

organization, it is very likely at that point that we would expect the Commissioner to put this in front of that group for an assessment, again, of their view of the ethics but within the framework of informing the Commissioner as to whether this protocol should go through.

ACIP has tackled the issue in a completely different way, and so as we thought about the advisory boards that are out there, the one that whose whole focus is on the issues of biodefense and the intersect between product development and these communities, this was the natural place to go for this particular sort of need.

John, sorry. You had a card up.

DR. PARKER: George, at the base of the whole thing to take off the obvious question is, is the threat real? And, you know --

DR. KORCH: If I were to say yes right now, I mean would that change?

DR. PARKER: Well, the important part of that question is that we don't have to

poke at that, okay? So that we can say that the United States Government says the threat is real, then we can take off from that point. I think that's important because there are, as you well know, many factions who believe that the different administrations have used a fear factor here, and that could complicate our process.

DR. KORCH: Now, John, your point is, again, this is where the future pluperfect comes in perfectly. But you're right, there is no definitive ability to say this is going to happen at a certain point in time. The best that we can rely on is, and you'll have some opportunity tomorrow I think in some briefings to have a flavor for what the level of threat is in this particular area but in a general sense.

I mean, if you're just to look at the general information, the chatter that you see, there are only a couple of pathogens that are sort of the universal gold standard, and this is one of them.

And so one of the real questions becomes: If this was one of the gold standards and it was not something you were prepared to think about and work through, then why did we invest anything in any of the requests that you had for medical countermeasure?

CHAIR QUINLISK: And that was John Parker.

Georges, I think you're next.

DR. BENJAMIN: Hi. Georges Benjamin.

Having lived through both the anthrax letters and then our attempts to vaccinate people with smallpox and recognizing the pros and cons of giving adults anthrax vaccine and all the other challenges around the anti-vaccine, I would pose that probably this Board could answer those questions. But the real functional questions are deeper in the list of questions you asked, such as, at what point do you give a kid the antibiotic? And then do you vaccinate them?

I would argue that I can't conceive of too many situations where we would pre-vaccinate kids?

DR. KORCH: Yes. No, I think that's right.

DR. BENJAMIN: Right?

DR. KORCH: Yes.

DR. BENJAMIN: So with that in mind, probably the real questions are, you start with antibiotics and you vaccinate early right after exposure.

DR. KORCH: Yes.

DR. BENJAMIN: I'm assuming an effective vaccine which has some risk, as all vaccines do.

DR. KORCH: Yes.

DR. BENJAMIN: And maybe to put it in a more functional model, in other words who do you vaccinate and when? I think the really intriguing question is the one you asked about once you've had a release, you know who else are you are vaccinating?

DR. KORCH: Right.

DR. BENJAMIN: And how is that decision made?

DR. KORCH: Right.

DR. BENJAMIN: And do you put those kids on antibiotics or do you vaccinate? And, you know we had all those same questions here in Washington, D.C, Maryland, Virginia, in fact nationally --

DR. KORCH: Right.

DR. BENJAMIN: -- after the anthrax letters. And it might make more sense for us to think through an algorithm of all of those questions and actually let somebody else answer the safe and effective questions, would that make sense?

DR. KORCH: Well, to your point about using the vaccine in any sort of per-event; using the vaccine, i.e., preparing populations. We don't have that as a national strategy for any of our populations, aside from the military. Military is the only population right now, and there might be somebody here who is very familiar with that

program that you can ask about.

DR. BENJAMIN: But you uncover a plot. You've got a list of cities that you know are about to be hit.

DR. KORCH: Well, that would be the ideal. And under those circumstances we'd have a whole lot of other things.

But I think to get to your point of knowing that you have the opportunity if you've got the data, the safety and the immunogenicity data collected beforehand, allows you then to not have sort of a dual track of how a logistics campaign or vaccination campaign would be conducted if the decision was made to vaccinate. So there are several decisions here.

And what you're really hoping for is to at least put children on par, on parity with adults. The adults are going to be able to come on in and under an EUA without all of the necessary steps that have to happen in a clinical protocol.

DR. BENJAMIN: Yes. But I'm not

sure. I think what will happen is, is that if you know what the dose is for kids --

DR. KORCH: Right.

DR. BENJAMIN: -- they're going to get it. I mean there's going to be demand for it and we're going to give it to them.

DR. KORCH: That is probably going to happen, but it's off label.

DR. BENJAMIN: No, absolutely.

DR. KORCH: It would be hard for the population -- I mean, the government controls basically the supply of the vaccine. It's not commercially available. So it's a little different circumstance.

We would deploy the vaccine. We would probably deploy it with certain conditions.

DR. BENJAMIN: No, I understand.

DR. KORCH: And since children would not be under a EUA status at that point, you know -- and these are discussions that we actually had with the Mayor of San Francisco's representatives. Of course you can do that,

but you're setting yourself at risk for a whole series of other things if in fact the event if the vaccine were proven to not be safe for children. Okay. So that's why we collect the safety and efficacy data -- not efficacy, but immunogenicity data when we can.

But your point is very well taken. I think your very important point is the algorithm of questions and what then naturally flows, and how many of those are things that you feel comfortable that the Board says we have an opinion on this and others that, you know that's deferred to the FDA as far as a clinical design or something like that.

And I noticed that Dan probably wants to respond as well, Dan Sosin.

CAPT SOSIN: Yes. I just wanted to clarify a point that may have slipped by in the way George described the use of vaccine. The postexposure protocol which includes antibiotics today, includes vaccination. So it's not just folks who decide to remain in a contaminated area.

The current protocol is designed around the longevity of spore viability within the respiratory tract and the potential risk that even after 60 days of antibiotics the initial exposure could produce disease. And so the protocol is both antibiotics today, antibiotics for 60 days and vaccination in that postexposure protocol.

DR. KORCH: Sure.

CAPT SOSIN: You know, it's one thing to say, you know start them on antibiotics and move them out. And leaving kids in there is irresponsible because we don't have any way to protect them long-term. But we would giving vaccine to adults. And we would be addressing children under a different mechanism.

DR. KORCH: Right. Thank you.

CAPT SOSIN: Today the plan is an IND and how do we implement such a protocol in the midst of a response.

But I just wanted to be clear that the intent today is that everybody who had

been deemed to be exposed would be vaccinated as well as antibiotics.

DR. KORCH: Yes. Thanks for the clarification.

DR. CANTRILL: Dan, one question. In terms of the Amerithrax issue, how many people that were treated with antibiotics, a course of antibiotics then went ahead and received the vaccine?

CAPT SOSIN: Yes. George, you may be more familiar with the data.

DR. KORCH: It's a complicated story. Yes, very low.

Yes, the real issue there was of course we put a lot of people on antibiotics a lot, probably people that had no exposure level at all. And the point of retention of spores, the animal data at this point suggests that they can reside in the macrophages before they asporulate for periods of many, many weeks. And that's what we're trying to avoid.

CHAIR QUINLISK: Okay. That question was asked by Steve Cantrill.

DR. KORCH: I think Dan.

CHAIR QUINLISK: Dan and Kevin. I don't know which one of you were first. Kevin?

DR. KORCH: Kevin.

CHAIR QUINLISK: Go ahead.

DR. JARRELL: I'm not an expert on the anthrax vaccine. So how effective is the vaccine in adults?

DR. KORCH: We know that -- well, true efficacy, i.e., the ability to understand whether -- I can answer this from an animal model standpoint.

In primates, individuals that have received at least three doses but probably you could extend that to the first two doses, but at three doses are protected against fairly high levels of exposure, ten to the 6th spore, I believe. So about a million spores. So that's many, many LD50s. They could be protected against 2,000 or 3,000 LD50 levels with the vaccine.

DR. JARRELL: I have another

question. So I think still globally anthrax naturally is sometimes transmitted from livestock to humans. So do you know anything about how frequent that is? I know it's not frequent in the United States.

DR. KORCH: Right.

DR. JARRELL: But what's on my mind is there an area where this happens frequently enough, you know that it's reasonable to consider vaccinating people who are naturally exposed? Or maybe this is so rare that that's something that we should not consider.

DR. KORCH: It is not that rare. It is not common, but we see outbreaks in Africa frequently. I myself know that -- in fact, I got a picture on my cell phone of a patient from the country of Georgia. You know, it's an agricultural problem.

But again, the question is in juvenile population if where you're going, is there a place where endemic disease is such that you can gather some efficacy data, or at least use it to gather safety and

immunogenicity data as a prelude to the belief that you are providing a benefit to a population.

DR. JARRELL: Correct.

DR. KORCH: There are populations. Of course, at that point you'd probably want to do that not just in pediatric population, but in the pediatric and the adult populations since this would be a community-based approach. I mean, if you're thinking about it in those terms.

CHAIR QUINLISK: Daniel, I think you're next.

DR. FAGBUYI: Dan Fagbuyi.

George, I just want to say thank you for bringing this up. Definitely this is a topic near and dear to my heart.

I think to answer part of your question also, in other states where soldiers deploy such as Iraq we saw lots of cases anthrax, cutaneous, and those are my first experience of seeing actually cases of that while we were in the field. And so areas

where we also occupy, or at least help protect when we're doing our civil military part of our operations would be a great avenue.

DR. KORCH: Sure.

DR. FAGBUYI: Because we do public health, we immunize kids there. That may be an avenue to consider.

The other part is, yes, with regards to forward deploying some of these countermeasures, and I know we're talking specifically about vaccines, but we need to also look at the lessons we have learned or we experienced in the case of H1N1 where there were vaccines then, available vaccination was available to families later, albeit the threat may have waned or there was dissatisfaction that people didn't get access to it initial. But there's some people who still won't take the vaccine no matter what.

DR. KORCH: Sure. Yes.

DR. FAGBUYI: And I would argue that also we need to get stakeholders' input and specifically to end users ahead of time

before we start making the decisions. Because if we find out that a great number of people are not in support of the vaccines or without engaging them in this kind of dialogue so they understand the complexities of it, I think we won't really get anywhere. We may have something developed, but it might be something that they would use, or they would be upset and not really understand no matter which way we go.

DR. KORCH: No. I appreciate those points. And you're absolutely right.

I think a lot of these things are contextual because if we were suddenly in a situation right now, if today or over the course of the last couple of days we started to see thousands of deaths in the area that were attributable to a specific known etiology and if it were anthrax, your calculus as a parent or as a person would change dramatically.

If, you know, you could see yourself at 90 miles an hour speeding head on

into a truck and hadn't put your seat belt on, you're probably thinking now would be a good time to do that. But people still don't do that either.

So, of course, there will be populations that have decided for whatever reasons that this is not something that they choose to do. But I think one of the questions that we put before ourselves and before the Board are: We have tools that we know are effective as responsible federal officials or responsible public health officials how do we provide the wherewithal and the access, and what can we do to remove barriers if those barriers are not otherwise there for some rational explanation?

CHAIR QUINLISK: Thank you.

Patrick, I think you're next?

DR. SCANNON: I want to extend Dan's thoughts. Because I think there are several levels in this specific, an AVA vaccine and pediatrics. Obviously, vaccines children, there are a lot of people, and not

an insignificant number of people who believe that vaccines, all vaccines are bad. But there also is a lot of transference of information about one vaccine into another vaccine and they assume that's the way it is for all vaccine, like vaccinia, for example.

And I think there's another layer, and that's anthrax. And I think there's a lot of misunderstanding about anthrax as a disease because people all they know, it's just something terrible.

So, I think under the second bullet one of the key challenges is going to be education and figuring out ways to educate if at all possible in advance. I don't know how feasible or practical that is, but asking a parent who is anti-vaccine in the middle of an emergency to change their mind could be disastrous. And so I think education of the American people, and we need to back up and say let's assume this isn't going to be the only vaccine we ever do. We need to do this with, you know what are the more general

things we need to educate the American people about emergency vaccine use.

So, I think we need to take into account the mythology of the disease, what people think they know about vaccines in addition to all the specific things about just giving vaccine.

DR. KORCH: Oh, you know there's a rich urban legend, but there are some central pieces of information that at least scientifically we know. And then from there it can and it does, and you've seen it and we all know about it. And we are really, again, not necessarily trying to solve the vaccine issue at large because there are many other much more important public health vaccines on a daily basis that are there, again, in the interest of protecting individuals again disease.

Anthrax has a very special place in the bio-defense constellation in that unlike many of the other diseases that we talk about, none of them present with this long range area

of denial possibility. All of the rest of them are fairly labile. It's one of the reasons, in fact, area of denial I will bring it back to Dan's point or the point made earlier about the longevity and the latency period of the spores even internally.

And so as you think about well where are the problem populations that we'd have to think about as we go into it, i.e., the people that have a problem with vaccines in general, what about that other side of equation? The parents who believe in vaccines and who say "You mean you have a vaccine and I can't give this to my children because you haven't collected what? The safety and immunogenicity data? Explain that to me."

CHAIR QUINLISK: I'd like to just take a minute and see if there's anybody on the telephone, any Members on the telephone who have questions.

OPERATOR: At this time if you would like to ask a question, please press star one.

CHAIR QUINLISK: Okay. I think we'll go on to the Members then. Dan, go ahead.

DR. FAGBUYI: Another part of that is with regards to parents understanding that you have something available for them but not for their kid, grandchild, niece, whoever it is, we have to think about surge in that case also. Do you really think people are going to respond to public health work to the hospital, to wherever when they know, oh, this has hit the fence, so to speak, and my child might not be able to get this. And what are we going to do? They'll panic, they will be outrage, there'll be outcry. And how we get people to respond and engage in those circumstances also is another issue that we have to look back in terms of our response.

CHAIR QUINLISK: Georges?

DR. BENJAMIN: Yes. Back to Patrick's point about messaging. The other issue here is that most of the other children, childhood vaccines we try to fundamentally

achieve not only protection but herd immunity.

DR. KORCH: Right.

DR. BENJAMIN: That's not an issue, right?

DR. KORCH: No.

DR. BENJAMIN: So I think that's a difference in message that you may not want to take those vaccines, but your child will not be protected because your neighbor got the vaccine.

DR. KORCH: Yes.

DR. BENJAMIN: And I think that does change the message a great deal and affords the opportunity to have a broader discussion of it.

DR. KORCH: Good point, Georges.

CHAIR QUINLISK: And Kevin?

DR. JARRELL: Are there specific examples with safety where a vaccine has been found to be safe in adult populations but then unsafe in a pediatric population?

DR. KORCH: The vaccine that I can think of was maybe the -- I don't know if the

rotavirus vaccine was found safe in adults. In children, it made it actually into a -- it was post-marketing when they discovered the issue with intussusception. And that vaccine was pulled from the market based on a fairly large -- I mean, it went all the way through phase 3 safety trials.

DR. JARRELL: But it does not fulfill that, the number of adults who got that vaccine, it was inadequate to test that question.

DR. KORCH: For protection, yes.

DR. JARRELL: For safety.

DR. KORCH: For safety.

So, I don't know of any. I don't know of any vaccines, and I should. I don't have that information.

DR. CANTRILL: But the example may still be valid. Because intussusception is very rare in the adult population.

DR. KORCH: Yes.

CHAIR QUINLISK: John Grabenstein, I think you're next.

DR. GRABENSTEIN: George, I'd like to run through a couple of your alternatives.

DR. KORCH: Yes.

DR. GRABENSTEIN: So it's not possible to have an EUA for anthrax vaccine for children. That would be an FDA choice?

DR. KORCH: Yes.

DR. GRABENSTEIN: And I'll point out that a vaccine that is probably like anthrax vaccine is tetanus toxoid, and the dose of tetanus toxoid for a two month old infant is the same as he dose of tetanus toxoid for an NFL football player.

DR. KORCH: Yes.

DR. GRABENSTEIN: So, the other alternative is to not do anything now, wait for Dark Zephyr to come true, or something like it, and then go implement an IND for children in the field starting on days -- oh, by the time we got the protocol together, day 10 if everybody works 24 hours a day?

DR. KORCH: Yes.

DR. GRABENSTEIN: Something like

that. And FDA would probably want it to be done under current good clinical practices standards.

DR. KORCH: I will not answer for FDA .

DR. GRABENSTEIN: I can't expect them not wanting that, right? And the PHERRB might the IRB, but maybe not.

DR. KORCH: Could be.

DR. GRABENSTEIN: And so if typical standards apply, this would be a 25 or a 30 page consent form for the parents to be taught and read?

DR. KORCH: Again, I can't answer for the FDA. We have had discussions about that and whether that is the case or not, I think they do bow to the pressures of expediency, okay.

Again, I cannot answer for FDA, but you're thinking along sort of the framework of what's the next step, what's the next step, what's the next step.

DR. GRABENSTEIN: So the normal way

to do an IND in children would be to progress in stages through ages. So you might do teenagers first before grade-schoolers, then toddlers, then infants, right?

DR. KORCH: Could be.

DR. GRABENSTEIN: And you might need a month for each of those groups, maybe two months for each of those groups, progressively, iteratively?

And so you'd need to keep the little kids on oral antibiotics, suspensions, for eight or ten months before you got to the data in the youngest age groups?

DR. KORCH: Again, I think we've run out of data after about 60 days of longevity of spores in the animal models that we know of. I don't know if we've run anything further past that, but my recollection is --

DR. GRABENSTEIN: A hundred days is what I remember from the monkey data.

DR. KORCH: Yes. I'm trying to remember that. I don't --

DR. GRABENSTEIN: I've got hundreds

in my basement.

DR. KORCH: Okay. Yes.

DR. GRABENSTEIN: I mean the data's in my basement.

DR. KORCH: Right. If you got the monkeys --

DR. GRABENSTEIN: Not the spores or not the monkeys.

And you'll only be able to do the clinical trial in a limited number of sites who can adequately achieve the proper education and consent for retaining and blood draws and all that. So, how many children are in the San Francisco Bay Area?

DR. KORCH: Children represent about 25 percent of the population.

DR. GRABENSTEIN: More than a million?

DR. KORCH: More than a million.

DR. GRABENSTEIN: So while the few dozens or hundreds of kids are in the clinical trials, the other million are waiting for the answer?

DR. KORCH: Under that particular scenario, that would be about right.

DR. GRABENSTEIN: Okay.

DR. KORCH: I mean, again, operating under what we have as the current belief of what the requirements would be for a protocol.

DR. GRABENSTEIN: Okay. That's all. Thanks.

CHAIR QUINLISK: I think this brings up the --

DR. KORCH: My cross-examination?

CHAIR QUINLISK: Yes.

DR. KORCH: And I noticed I followed only answered the question that's being asked and repeat the question if you don't understand it. Right. Okay.

Thanks, John. Great questions.

CHAIR QUINLISK: But I think this brings up just how complex this really is and how many different issues will need to be looked at if we get into this.

I would like to ask if there is

somebody from FDA who would like to respond to that question? We might have somebody on the phone.

MS. MAHER: This is Carmen Maher.

CHAIR QUINLISK: Hey, Carmen, great.

MS. MAHER: I'm filling in for Dr. Borio and listening to the discussion. And I want to say that there -- you know, Steve has been actively engaged with HHS on this issue. And we're talking about using an IND mechanism and scenario, we're talking about a streamlined IND. I doubt you would be looking at a 30 page informed consent.

There is dialogue and more on that. So within the constraints and within the circumstances, we're definitely going to be reasonable.

DR. KORCH: Yes. Thank you, Carmen. I did not want to speak for the FDA. And you don't have the slides in front of you. I do have a bullet that says that discussions are underway with CBER, NIAID, BARDA and CDC

to look at the development of potential clinical protocols. And now that you've been on the phone, CBER has looked at what do we do to streamline all this. How do we most effectively look at what happens in the face of a real critical need. So, yes. But it's not done yet, John. We won't have the definitive, you know, Mrs. Peacock in the dining room with the wrench. Remember the game? Okay.

CHAIR QUINLISK: Okay. I understand there is somebody on the phone? Okay. Please go ahead.

MS. KELLEY: Yes. Okay. Can you hear me, this Cynthia Kelley?

CHAIR QUINLISK: Yes, go ahead, please.

MS. KELLEY: I'm with CBER. So let me think of how many of the questions I can address. Starting back with the question: What was the efficacy of the anthrax vaccine? The anthrax vaccine was licensed in 1970 based on the Brockman clinical trials of which it

was shown to be 92.5 percent effective.

DR. KORCH: Against cutaneous.

MS. KELLEY: No. Against both. Cutaneous and inhalation.

DR. KORCH: Okay. All right.

MS. KELLEY: If you read the final rule. Okay.

DR. KORCH: That's right.

MS. KELLEY: With regards to John's remarks. Yes, we have bee working with CDC and NIAID and Dr. Korch on the issue of possible protocols.

DR. KORCH: Exactly.

MS. KELLEY: John, we have no intention whatsoever of there being a 20 to 30 page informed consent. Our idea is to streamline it down significantly.

The other idea is if we can't get some data in children for efficacy pre-event, then -- or for safety and immunogenicity, sorry. Then there would be a "research protocol" nested within the IND protocol of which persons under 18 years of age would be

administered the AVA vaccine along with the 60 days license to antibiotics. So it's not that we would be denying children whose parents actually wanted them to have the vaccine. Access to the vaccine while we did a little IND research protocol during an outbreak, everyone would be offered the vaccine under an IND with a streamlined informed consent. And then there would be a nested research study, hopefully, of which we could get some of those parents who wanted their children to have the vaccine to volunteer for some safety follow-up, it's a blood draw or whatever, in order to gather the information to hopefully allow at some point in time either in a long drawn out emergency or in a future anthrax event, to be able to give it to children under an EUA, because we gathered the data.

DR. KORCH: Thank you, Cynthia. I was very happy to hear your voice on your phone because I didn't want to, again, characterize what CBER was thinking without CBER being present.

MS. KELLEY: Thank you. That's fine, George.

CHAIR QUINLISK: Okay. Thank you, George.

I think we'll take like one more question, and David, I believe that you've got your thing up.

DR. ECKER: David Ecker.

I guess you kind of come to the conclusion based upon what we just heard, that there's the most likely outcome of the scenario was that children would get it under the circumstance. And in anticipation of circumstances like this and others that may occur in the future, is there any scientific approach that could be taken to try to get data for vaccines and then extrapolation from children that we maybe should be thinking about or doing for this kind of a thing when it will come up again and again?

DR. KORCH: Yes. Great point, Dave. You are asking the question. We're using a specific example, and how generalizable is

this? What should we be thinking?

And there are two ways that I can think of this and certainly that is maybe this is the catalyst or the crystal that allows for the opening or the opportunity for then considering these other follow-on countermeasure or we now have an example to go by.

The other way, of course, is to try to generalize it at first and hen apply it specifically here. And I would if I'm being pragmatic, I think the former is the right approach. Because everybody loves an example. Hopefully, it's not a bad example. But everybody loves an example to start with. And this one, because I think we're taking on an issue that as we think of these types of risks in chem, bio, rad, nuc, this is one of those game changing sort of issues or game changing sort of scenarios. And so in order to at least think that you want to be prepared for what might be some of the worst, this would certainly be one of those types of

circumstances.

But I take your point that this at least provides an opportunity for asking what happens next, and next, and next and how does this get applied across the other needs that happen in pediatric populations.

And I know we have several pediatricians here on the panel. I guess that was accidental.

CHAIR QUINLISK: Okay. Well, thank you very much, George.

DR. KORCH: Thank you.

CHAIR QUINLISK: Appreciate all the interesting issues you brought up for us to think about.

DR. KORCH: Great. And we can get you those slides. Steve, you asked for the slides, yes?

CHAIR QUINLISK: Okay. What I'd like to do now is, as you saw, we have the letter asking us to look at some of these issues around the anthrax vaccine. We've just heard a presentation about some of the issues.

So even the public part of our meeting is coming to a close, what I would like to do is ask Members of the Board that those people who are interested in continuing looking at this, and perhaps doing something such as setting up a working group to address this issue, to please stay after this meeting.

So I think we're coming to the end. I'm going to ask Leigh, I think we've got a few minor things at this point and then we'll be done.

CAPT SAWYER: I'd especially like to thank Dr. Steven Cantrill for the work that he did on the Working Group Report, and that the Board has deliberated on today.

I'd like to thank the voting members for attending and participating by phone. The ex officio members, the members of the public that are here and participating by phone.

The All Hazards Science Response Working Group. And in particular the most important part, the NBSB staff who are the

three lovely ladies over at the wall. MacKenzie Robertson, could you please stand. Lieutenant Brook Stone and Jomana Musmar.

(Applause.)

CAPT SAWYER: The next public meeting of the NBSB will be September 22nd and 23rd, 2011. So we look forward to seeing everyone at that time.

CHAIR QUINLISK: Okay. I think then unless there is any further issues, we are adjourned. And I look forward to have the interested Members stay after.

Thank you very much, everyone. And we'll see you in September.

(Whereupon, the above-entitled matter was adjourned at 2:57 p.m.)