

NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC MEETING

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TUESDAY,
JANUARY 25, 2011

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The meeting convened at 1:15 p.m. in Room 800 of the Hubert H. Humphrey Building, Department of Health and Human Services, 200 Independence Ave, SW, Washington, D.C. Patricia Quinlisk, Chair, presiding. Leigh Sawyer, DVM, MPH, CAPT USPHS, Designated Federal Official.

NBSB VOTING MEMBERS PRESENT:

PATRICIA QUINLISK, NBSB Chair, MD, MPH
STEPHEN V. CANTRILL, M.D
JANE DELGADO, Ph.D., M.S.
DAVID J. ECKER, Ph.D.
DANIEL B. FAGBUYI, M.D.
JOHN D. GRABENSTEIN, R.Ph., Ph.D.
KEVIN A. JARRELL, Ph.D.
JOHN S. PARKER, MD
BETTY J. PFEFFERBAUM, M.D., J.D.

NBSB EX OFFICIO MEMBERS PRESENT:

Michael Amos, Ph.D., Biosciences Advisor,
Director's Office, Chemical Science and
Technology Laboratory, National Institute of
Standards and Technology, U.S. Department of
Commerce

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

Rosemary Hart, J.D., Special Counsel, Office of Legal Counsel, U.S. Department of Justice

Peter Jutro*, Ph.D., Deputy Director, National Homeland Security Research Center, U.S. Environmental Protection Agency

Ali S. Khan, M.D., M.P.H., RADM, U.S. Public Health Service, Assistant Surgeon General and Director, Office of Public Health Preparedness & Response, Centers for Disease Control and Prevention, 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

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 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.*)

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

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

LT. BROOK STONE, M.F.S., LT, U.S. Public
Health Service, Program Analyst

*Present via telephone

I-N-D-E-X

**Call to Order, Conflict of Interest Rules, and
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P-R-O-C-E-E-D-I-N-G-S

1:15 p.m.

CAPT SAWYER: I am calling this meeting to order. I would like to welcome everyone today, to our first NBSB meeting of 2011. I would like to meet the new members to the board, the continuing NBSB members and the retiring NBSB members, ex officios and the public.

I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board. I serve as executive -- the designated federal official for this federal advisory committee.

The purpose of this meeting is to welcome six new, outstanding individuals to the NBSB, congratulate and present certificates to the six members whose teams expired in December of 2010 and to discuss the new topic of interest, the All Hazards Science Response.

Before we move into the introductions, I would like to read the

Federal Advisory Committee Act rules and overview the conflict of interest rules.

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 advice or recommendations where one or more members of their group are not federal employees.

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

With regard to the conflict of interest rules, the standards of ethical conduct for employees of executive branch document has been reviewed by all board members, who as special government employees

are subject to conflict of interest laws and regulations therein.

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

Board members must be attentive during meetings to the possibility that an issue may arise that could affect, or appear to affect their interest in a specific way.

Should this happen, it will be asked that the affected member recuse himself or herself from the discussion by refraining from making comments and/or leaving the meeting.

Public comment announcement. That's what I have to do now. We will have a public comment period today from 2:30 to 2:45, in which time there will be an opportunity for the public to provide comments.

If you are joining us by phone you will be given instructions by the operator as to how to signal that you have a comment. Comments will be taken in turn and you will be notified when 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 be better prepared to anticipate how many people we will need to accommodate during the public comment period.

To date we do not have any comments that have been registered with us in advance. 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 any public comments made, will be available on our website following this meeting.

I would like to now take roll call. We are going to do this a little differently

than we have in the past since we have a number of new members and so I'd like to go around the room in order, with the first person across from me, and if you would please introduce yourself and give some brief background about your affiliation.

DR. DELGADO: I am Jane Delgado. I am the President and CEO of the National Alliance for Hispanic Health. I am a clinical psychologist also. I have a very tiny private practice in D.C. and I am also a trustee of the Kresge Foundation and the Lovelace Respiratory Research Institute in Albuquerque, New Mexico.

DR. ECKER: I am David Ecker. I am a PhD biochemist and I work for a company called Ibis Biosciences, which is part of Abbott, and my expertise is in diagnostic instrumentation.

DR. FAGBUYI: I am Dan Fagbuyi. I am a pediatric emergency physician at Children's National Medical Center and at George Washington University. I am a veteran

of Operation Iraqi Freedom and I take care of children also.

MR. JARRELL: I am Kevin Jarrell. I am the CEO of Modular Genetics. We are a synthetic biology company. We engineer microorganisms to consume underutilized agricultural material and produce useful green, chemical products.

DR. PFEFFERBAUM: I am Betty Pfefferbaum. I am Chairman of the Department of Psychiatry at the University of Oklahoma Health Sciences Center and I am the Director of the Terrorism and Disaster Center of the National Child Traumatic Stress Network.

CAPT SAWYER: I am going to jump over to our other voting members here, starting with John Parker.

DR. PARKER: Good afternoon my name is John Parker. I am a physician. I came to the board after 39 years of a military career which ended by commanding Fort Detrick and the labs at Fort Detrick and I have been with Science Applications International Corporation

for nine years this March. My interests at SAIC and my last assignments in the Army were CBNRE defense.

DR. CANTRILL: Steve Cantrill, I am an emergency physician at Denver Health Medical Center in Denver and have been involved in disaster and WMD preparedness.

DR. GRABENSTEIN: I am John Grabenstein. I am a pharmacist and an epidemiologist. In my military career I was director of the military vaccine agency for the Department of Defense. For the last 4-1/2 years I have been the senior medical director for adult vaccines with Merck Vaccines in West Point, Pennsylvania.

CHAIR QUINLISK: Hi, I am Patty Quinlisk. I am a state epidemiologist and medical director of the Iowa Department of Public Health and I am Chair of the NBSB.

CAPT SAWYER: And while all the voting members have these backgrounds, they represent their independent expertise when serving on the board as special government

employees.

Let's begin now with Ali, the ex officios.

DR. KHAN: Good afternoon. I am Ali Khan. I am the Director of the office of Public Health Preparedness and Response at CDC in Atlanta, Georgia.

DR. KAPLOWITZ: Well, I am not George Korch but George couldn't be here. I am the Deputy Assistant Secretary for Policy in ASPR, the Office of the Assistant Secretary for Preparedness and Response.

MS. PARKER: I am Tracy Parker, I am a biodefense adviser in the Office of Health Affairs at the Department of Homeland Security.

MS. HART: Hi, I'm Rosemary Hart, I'm a senior attorney with the Office of Legal Counsel at the Department of Justice and one of my areas of expertise is Presidential emergency authorities.

COL. SKVORAK: Well, I'm John Skvorak. I am currently the Commander of

USAMRIID. I am the DoD ex officio to this committee and spent the last about 14, 15 years of my military career in medical CB defense.

DR. MICHAUD: I am Vince Michaud. I am representing NASA and I am the director of medicine of extreme environments at NASA. I am a physician specializing in aerospace and occupational medicine and I am an Air Force detailee to NASA.

CAPT SAWYER: Thank you. Now I would like to go to our phone line and the ex officios if you could -- well actually, since you don't know who is on the line I am going to ask Peter Jutro, would you like to say something about yourself?

DR. JUTRO: Yes, is the line open, can you hear me?

CAPT SAWYER: Yes it is.

DR. JUTRO: This is Peter Jutro. I am representing the Environmental Protection Agency, and I am the Deputy Director of the National Homeland Security Research Center

with responsibility for science and policy issues.

CAPT SAWYER: Thank you. Bonnie Richter?

MS. RICHTER: Hi, I am Bonnie Richter. I represent the Department of Energy Office of Illness and Injury Prevention. I am an epidemiologist with expertise in occupational health, environmental epi, and radiation.

CAPT SAWYER: Thank you. Michael Amos?

DR. AMOS: Hi, Mike Amos here. I am the U.S. Department of Commerce representative. I am the biosciences and healthcare adviser at the National Institute of Standards and Technology in Gaithersburg, Maryland.

CAPT SAWYER: Carmen Maher.

CDR MAHER: Hi, I am Carmen Maher, Commander of the United States Public Health Service. I represent Dr. Luciana Borio for FDA. Dr. Borio is the Acting Director for the

Office of Counterterrorism and Emerging Threats in the office of the Commissioner.

CAPT SAWYER: And Randall Levings.

DR. LEVINGS: Yes, I am the United States Department of Agriculture representative. I am the science adviser for veterinary services in the Animal and Plant Health Inspection Service of that.

CAPT SAWYER: Thank you. So I'd like to now turn the microphone over to Patty Quinlisk, chair of the NBSB.

CHAIR QUINLISK: I would like to welcome everybody this afternoon to our meeting and this is, as Leigh said, is our first meeting of the year 2011.

And I do notice Dr. Nicki Lurie is here with us, but before I introduce her, I would like to take just a moment to acknowledge and to personally thank our retiring members for their contributions to the National Biodefense Science Board and all of the work they have accomplished with the board.

So I would like to just read off one and acknowledge what they have done. We have two members who unfortunately were not able to be with us today: Roberta Carlin, who participated in three of the NBSB working groups and our subcommittee that focused on at-risk individuals and people with disabilities; Andy Pavia, who had extensive expertise in pediatrics and infectious disease and contributed heavily to the development of some of the viral vaccine recommendations during the 2009 H1N1 pandemic. He also served on five of the NBSB's working groups.

We also have one person who I believe is on the phone, Al DiRienzo, who focused on science and technology acceleration and made very valuable contributions to the area of cutting edge IT technology and he has served on four of our NBSB working groups.

Now we are very privileged to have three of our retiring members here in person, so as I call your name if you could just acknowledge who you are.

Jim James brought his expertise in disaster medicine and public health preparedness and contributed to five of the NBSB working groups and our subcommittee

Ken Dretchen, whose 20 plus years focused on pharmacological defense from biologic and chemical threats and has helped many of our recommendations produced by five of our NBSB working groups.

And then Eric Rose whose expertise both in private industry and medicine provided unique contributions to five of our NBSB working groups.

So on behalf of the board, thank you three, and Al on the telephone and the two who are not here today, just thank you, all of you, for the great contributions you made to NBSB.

I would now like to turn the meeting over to Dr. Nicole Lurie, who is the Assistant Secretary for Preparedness and Response, who will be making some presentations and swearing in our new members.

RADM LURIE: Great, well good afternoon everybody. I am delighted to be here. As you heard I am Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response, I very much appreciate all of your participation and commitment.

I want to welcome back our continuing members. It's great to see familiar faces and people who, over the time we have been working together, have been friends, as well as to see new faces and some old friends among those new faces. It's great to have you here Jane.

So I am thrilled. So we have had lots of changes in the NBSB as you know. It turned out that when NBSB started, we didn't really have a rotation policy because that was just one of the things that hadn't been well worked out when it started as a brand new committee.

And so we decided that it is always important and good to get new ideas and that we know that we can continue to call on people

who have provided us ideas in the past.

And so to figure out what to do, we did what every good scientist does: you draw straws. So some people wonder, so why me? It's because we decided to do it the most equitable way possible and we drew straws, and then found that we have really big shoes to fill in all of the people who are rotating off, and we are excited about our new members and the challenge that they will have in filling those shoes.

I want to also give a very special acknowledgment to members of the former disaster and mental health subcommittee for their incredible contributions over the past few years to the subcommittee, to NBSB and to the department.

I think the work that you have done over the past couple of years has really represented the highest spirit of public service and I thank you and I recognize that.

Betty Pfefferbaum, who is chair of this committee, is going to be sworn in today

as a full member, and I am delighted to say to Betty congratulations.

This is not an opportunity for me to do big updates but I do want to recognize that largely because of the work of that committee, we were able to do something very differently than we had done before, particularly in our considering of some of our responses to Deepwater, also H1N1.

But also now we are finally in the process of putting together a behavioral health CONOPS, one of the recommendations, so that we are clear, the behavioral health, mental health, whatever you choose to call it, is part and parcel of what we do to prepare, what we do to respond and a really key ingredient to recovery.

So I know that Patty just had the opportunity to recognize, though retiring, our rotating off members.

But I do have some certificates that I wanted to have the opportunity to award to those who are here and then we will be able

to send the others to those who are not. But I'll just take this opportunity.

So, first Ken.

(Awarding of certificates.)

And let me just reiterate my thanks to these three as well as to Al and to Andy for their just incredible work.

And you know, before I swear the new members, I also just want to take a moment to say how important the work that NBSB has been for me in the time that I have been here.

They obviously played, and many of you are still here, played a pivotal role in H1N1 and issues related to our response. The work on mental health is going to have a long, long life.

And then the work on countermeasures, whether it was about the business models or all of the work that many of you did, and I am looking at John and John, who are sitting here, in particular, to advise us about the medical countermeasure enterprise and how to move forward, has been so, so

crucial.

I know at times there have been questions like, "Did the work of the NBSB really matter?" and some interesting email exchanges about that.

And I know that a lot of the work on recommendations at the NBSB itself made -- were maybe a small paragraph of the Secretary's recommendations on the MCM review, but as I have said on multiple occasions, we have fundamentally changed the way we do business inside of ASPR, inside of BARDA and across the enterprise in the way FDA, NIH, CDC, our DoD colleagues, BARDA and ASPR work together.

And I don't think that would have happened without your careful analysis, thought, recommendations, both in public and in private, and I just want to say how much I appreciate all of that hard work.

And I hope that you are beginning to see some of the results of that bear fruit, and I hope that you will see many of the

results of that bear fruit as we go forward.

Now it is my pleasure to swear in our new members. I'm looking around and I see that not everyone is here.

Okay, so I am missing Georges Benjamin, but I am going to ask everybody to come up as a group so we don't have to do this one at a time.

Before I do this, I hear that Al DiRienzo is on the phone and thank you for joining, thank you for your service. We will photograph your certificate and throw it into the mail

(Laughter.)

And I hope to see you and to be able to continue to call on you, because you have been terrific. Thanks.

DR. DIRIENZO: Thank you.

(Official swearing-in of new members by RADM Lurie.)

I do solemnly swear (or affirm) that I will support and defend the Constitution of the United States against all

enemies, foreign and domestic; that I will bear true faith and allegiance to the same; that I take this obligation freely, without any mental reservations or purpose of evasion; and that I will well and faithfully discharge the duties of the office on which I am about to enter. So help me God.

RADM LURIE: So I know when I took this oath for the first time, in fact each time, it totally gave me the chills and I don't know if it does that for you, but it is really sort of an awesome responsibility.

So all of these people have been chosen through a very careful selection process. They are among some of our nation's preeminent scientific, public health and medical experts and I am really excited in working with all of you and getting your advice on new ways to move ahead, helping our country prepare to become more resilient to all hazards.

So this is the time now when I get to say, here's my first task of you, and I

think that there will be a number of them down the road and I think particularly, having seen the incredibly excellent work that this group does, I have high expectations and high hopes.

So I know one of the things that I remarked to many of you about along the way, is that at least for the three major emergencies that I have been involved in dealing with this year, over the year, last year-and-a-half -- H1N1, Haiti and the oil spill, and all of the ones that we worry about and plan for, there are lots and lots of scientific gaps in our knowledge about the underlying threats, how people deal with them, whether it be biologically or scientifically, what are the best things to do.

We confronted a lot of those scientific uncertainties in H1N1 and in H1N1 we made an incredibly concerted, scientific effort to develop this vaccine. We used the best available science, we developed vaccine quickly.

We used ours and your best judgment

about filling and finishing the 15 micrograms. We subjected it to very rigorous testing to know what was the right dose and if it was likely to be effective and if it was as safe as we could tell at the time, and it was a real triumph I think of bringing science to bear to a problem.

I think there were also, in the heat of the moment, probably lots of other questions that we should have thought to ask and answer, and in retrospect, it's always easier than going forward in the heat of the moment.

I had sort of the same experience in Haiti, looking at the response to the earthquake and recognizing that there was really a pretty urgent, almost just-in-time need for scientific and clinical information on how best to respond to many of the injuries and that that wasn't yet available.

And then with the oil spill, as we got into it, I learned that there had been something like 35 oil spills in history and

that eight of them had been studied, and that we weren't yet in a situation to be able to know whether and how bad oil and dispersants were, despite all of this experience.

And as we step back, one of the things that really struck us as we have been thinking about how to do a better job both preparing and responding overall, is that we have got CONOPS for all kinds of things. We've got checklists for all kinds of things. There are things that we do in every emergency. There's prescriptive mission assignments in every emergency.

There hasn't been, really, a CONOPS or a prescriptive mission assignment for doing the science and it seemed to us high time that we did that, and that we did that for a couple of reasons: one is to bring the best available science to bear in an acute situation, to help us manage the response for however long it's going to go on, and so that we are never in the same situation again if, whatever happens, happens again, oil spill as a case in point.

And so what we have talked a lot about is developing really an all hazards science response strategy and what I want to do is ask all of you to help advise us about what that should look like, and how it should be pulled together.

So what are the various major components of an all hazards science response? How should we operationalize that here within HHS and I recognize in the big scheme of things it's a much bigger issue than HHS but we have got to get our own house in order, I think, first.

And then what infrastructure and supporting pieces need to be put in place, so that we will be ready to go the next time? What does the CONOPS look like, what are the prescribed mission assignments?

We have already have begun as a result of thinking about this rostering scientists in each of our key threat areas, making sure we have their phone numbers, their email addresses, really basic stuff, are ready

to go, as a result of some of the work that was done with H1N1 and I know you will hear more later about some of the challenges that we face.

We are pretty far along in thinking about a national IRB and what that would look like to use in case of an emergency. We have had a lot of interaction with OMB because any time you want to collect data on more than nine people, including doing a survey, you have to go to OMB.

And there are times that they have been able to turn around things incredibly fast, and many times that they did in H1N1, and many times that things take a really long time for a whole lot of different reasons.

So we have been -- they have recently issued a new set of guidance about science, an OMB clearance process, which I think is a really important step forward.

There may or may not be more room to go there but I'd sort of like for you all to take a look at that, and think about --

what are those, those kind of key infrastructure pieces, you know, do we need prescriptive protocols? Do we need prescriptive surveys since we don't know what is going to happen next and it's hard to get people to pay attention to things that, in their mind may quote, never happen, the unthinkable, it's hard to write protocols for those things, but are there generic ideas about how to do those things?

Those are examples of the kinds of things that I think kind of are in an infrastructure bucket. So what is that infrastructure, one of those important pieces, need to look like to be put in place so the next time we have an emergency, something that we haven't had to confront before, we can harness the best available science.

But we also take advantage of and don't miss the scientific opportunities to advance knowledge in important areas and be sure that we don't end up in the same situation again.

So I think that's the end of my really prepared remarks. I am happy to entertain a couple of questions about that before I leave, but I want to thank you in advance for taking on this challenge. It's a little different than some of the other ones we have asked you to take on, but I know that you will make important contributions and I hope that along the way that you will find it an interesting and stimulating thing to do as well.

CHAIR QUINLISK: Thank you very much. I think what I'd like to do is just see if people have questions or perhaps if there are places where you would like more clarification.

Go ahead please John.

DR. GRABENSTEIN: John Grabenstein. So the charge is all hazards, and there's a lot of hazards. So are there places where -- or are there categories of hazards where you think -- are in greatest need of attention or places that you think are adequately covered

already because of past experience and we can move past that and get to other areas where you think greater attention is needed?

RADM LURIE: Well, so I think it is a great question, and I thought about this quite a bit. We can think about what science do we need to do for anthrax, what do we need to do for bot, what do we need to do for smallpox, on and on. And that would I think take us a pretty long time and be pretty tedious.

I think we can all be sure, if we are confronted with one of those emergency situations, we will want -- there are a lot of unknowns there and we will want to take advantage of that time, use that time to answer and address some of those unknowns.

At the same time, none of us know what is going to happen. We planned for one pandemic, we got another. We didn't necessarily plan to deal with the health effects of an oil spill. We got out of the blocks with a science response, for the human

health side late enough so that we couldn't get collect for example biological data while people were still exposed or immediately after exposure.

We didn't collect biological data on people in ICUs during H1N1.

So I actually, rather than think about hazard by hazard, CBRN, whatever, think about categories of some -- there's exposure meds of all different kinds. There's exposure meds for responders, there's exposure meds for the public, you know, there's set of biological events, and probably within each of those a set of generic issues that need to be addressed.

My going in assumption is that we would head up with the CONOPS that would say while you are doing whatever you need to do, while you are mobilizing your NDMS teams and sending them wherever, while you are doing these things, you are going to identify a team of scientists who are going to go off by themselves, not get in the way of operational

response, identify what are the priority issues that are to be addressed, come back and make recommendations that we can then operationalize, and that that becomes a regular operational component of response.

Now if you all had a different idea about how to do this, I'd be very open to that, but that's my own simple-minded conceptualization.

I don't think you have to go threat by threat and I think that for exposures to lots of different things, there's a generic set of things that you want to know and then there are probably specific things that you want to know, we might as well have as much of it in place as we can so that like I say, with all the response, to have 80 percent of it is stuff that we rehearse and we practice and we do and we have got that down and we have the time and energy to get in and do the rest.

I think probably the same might be the case in trying to figure out who are our best scientists available, for example. So

those are the kinds of things I'm looking for John, if that helps.

CHAIR QUINLISK: This is Patty Quinlisk. I see you almost asking three different kinds of science. One is to perhaps at this point, pre-disaster, understanding where the science might lie, where the experts might lie, how to get a hold of them, and then -- so that's before anything happens.

And then something about during events to have a method of quickly answering the key questions that need to be answered immediately for that response.

But then I also hear you saying that during a natural experiment of a disaster, there may be things that need to be learned that would not necessarily be effective or used during that disaster, but would need to be learned so that we could then better respond to the next disaster.

RADM LURIE: I think that's exactly right and I don't -- you can, again, decide differently. I think for the kind of threats

that we know about and anticipate and that this body was originally formed to help us address, we can put out calls and identify who the scientists are and figure out -- you don't need an advisory board to do that.

I think sometimes in an acute event, there's questions that certainly need to be asked. Some can be answered acutely. Some take a long time to answer. Some we in government in the natural course of things we will think to answer but sometimes it's great to have people who are not so steeped in this thing, when you know, you haven't thought about the following, and then really I think taking this cue from the oil spill, and frankly from what happened 10 years ago with anthrax.

We have got to be asking the same kinds of questions yet of -- what the bigger questions and will we have advanced knowledge so that we will have different kinds of questions, but the issue is to get out of the box quickly enough with asking the right

questions, figuring out how to answer them and a mechanism, a method to do that, so it involves people and it involves budget, it involves RFPs, it involves data collection kinds of methods, it involves thinking about different kinds of affected populations, all of these sorts of things.

And those are the things in a more generic sense that I'm hoping those three sort of linked questions, that you will help us really think through, what is the infrastructure to do that need to look like, and a probably related question is when should we mobilize it, we don't need to mobilize it with every hurricane.

But with unusual events, yes.

CHAIR QUINLISK: I believe Jane has a question.

DR. DELGADO: Jane Delgado. I have a short question. When there's an emergency, do the OMB compliance rules for line questions get put aside for you, or do you still have to go through that process?

RADM LURIE: So OMB has been really terrific at working with us to get stuff through the system quickly, okay? And we are working to get approvals to do things and there are things that are in different categories. Collecting public health commission and Ali Khan can speak to this at some length, you know, collecting public health information from health departments is different from wanting to collect information from responders, or wanting to collect information from the general population.

And each has its own set of ways forward. You know, I have certainly posed this set of issues to OMB and they are very eager to work through a way forward and they also understand, obviously, that we need to move quickly. With that said, I think different people have different ideas about what quickly is, different ideas about what essential information is, different ideas about lots of different things, and kind of in the heat of a moment, you don't want to get hung up on those

things.

So the more we can work those through in advance, the better. So in this science guidance that OMB just put out, and I know you'll take a deep dive into it, there are these suggestions about sort of more generic kinds of protocols for different sorts of things that they might be able to approve in advance and then just have you tweak little things at the end.

So things that can really shorten the process and what you get out. But I think you'll find as you start diving into this, there's lots of kind of little nooks and crannies and the more we've got the basics down so that we check the box, we say let's mobilize the science response, we all know what we are talking about, and we do it, I think the better off we'll be.

CHAIR QUINLISK: Kevin.

DR. JARRELL: So in terms of mobilizing the science response here, you mentioned the oil spill for example. So it

seems like the task here is to think about the science response in terms of human health, because an event like that affects so many things, not just human health, and I just want to make sure that that's the task. Is that correct?

RADM LURIE: I very much appreciate the clarification. That's absolutely right, that it affects human health very much. So during the oil spill, it's really interesting, 17 different federal agencies did science in response to the oil spill, and some of it is really, in fact most of it is really quite impressive.

NOAA for example, that didn't have to deal with human subjects, went out and they tagged dolphins and they looked at how they traveled through oil and was able to measure their exposure.

And then they anesthetized them with a dart gun and they biopsied them and they looked at stress markers and looked at their DNA and all of these kinds of really

amazing things that they were able to do kind of in the acute event. We can't quite get there with humans for lots of reasons, but that, I think has been quite interesting as a model.

So all the different agencies, whether it was on fish or wildlife or different ways to measure exposure or other kinds of things have been quite interesting.

During the Prestige oil spill in the '90s in Spain, people who were investigating the health effects of that actually weren't quite sure what to do about worrying about whether genetic damage happened, and so they collected specimens.

They stuck them in a freezer and when the science came ripe, 10 years later or however many years later, they took them out of the freezer and analyzed them and the science that has come from that has been quite interesting.

So there are a lot of different ways to think about this. That's what I'm

asking you to do. But yes, humans.

CHAIR QUINLISK: John Parker.

DR. PARKER: John Parker. Dr. Lurie, you have got me all excited and I'm an old man. I think this is wonderful. You know, I think it's a complex task and you know that, and one of the things that will haunt me on this task is baseline, because when the -- any agency looks at a particular environmental, shall we call it an antigen of any type, we look at them one on one, and in this particular task, we are actually looking at multiple effects on the human body and how they can accumulate during a disaster.

So getting -- an important part of this discussion, not here today, but will be how do we baseline community's health or individual health. I think that will be an eye-opener and a lot of people have kind of stayed away from that, because it really is a third rail.

RADM LURIE: I think it is a really, really important point, and I think

something that we have struggled a lot with, and are continuing to struggle a lot with.

The group that is doing the Gulf study et cetera continues to really struggle with a lot of those issues, but it's key. And you know, one of your recommendations may well look something like figure out how to advance science without knowing the baselines before you start.

I don't know what it would look like, but a great point, and I'm glad you're excited.

Well, thanks everybody. I look forward to lots more discussion and interaction and I have a growing mental list of things to ask you guys to dig into, so I am looking forward to this. Thanks so much.

CHAIR QUINLISK: Well again, thank you very much Dr. Lurie for coming, and bringing to the board a very important topic. What I'd like to now is --

CAPT SAWYER: I just wanted to acknowledge that Bruce Gellin has joined the

meeting. Thank you Bruce.

CHAIR QUINLISK: Okay. So what I'd like to do now is open up discussions of the board about the new issue that we have been tasked with, and of course any other questions, but I think now we need to start a discussion about this new topic and how people think we might start to go about dealing with this issue.

So I am going to open up for discussion. Again I would ask people if they have a comment or question, put their name tag up so I can keep track of who has got suggestions, and I'll try to get back to people in order.

And David, I believe you were the first person.

DR. ECKER: Yes, I was wondering how we might begin to coordinate our efforts with the other scientific societies, like the National Academy and the National Science Foundation. In doing a little bit of diligence on this topic I saw that the NSF has some sort

of a rapid way to fund things with very short turnaround and get things reviewed essentially instantaneously and then -- and have then money release.

And so there are other entities that are -- that have an interest in human health that have a similar charter but from discussions I have had with people, never is anything rapid or precooked and ready to go upon pulling the trigger.

And so I think some consultation with some other groups might be appropriate for us.

CHAIR QUINLISK: Okay so this is Patty Quinlisk. What I hear you saying is maybe what we need to do is get to sort of our baseline, not quite the population baseline, but sort of to have a good understanding of what is out there right now, who has been tasked with what and where we might have the biggest impact on this issue.

Because I think as we heard from Dr. Lurie, this is a very large issue and

there's lots of pieces to it and for us to be most effective, probably for us to take the piece that we have the most expertise on and nobody else really is dealing with.

So I think David, that is probably a very basic thing that we might want to do right now, ask the staff to help us identify some of those things. Is that sort of where you were coming?

Okay, Vincent.

DR. MICHAUD: I just wanted to suggest that, although the tasking is sort of a list of things that she wants or we want, that we might want to consider things we don't want, impediments to all hazards science response.

It wouldn't do us much good to have a great scientific response get stuck by jurisdictional issues once they arrive and that sort of thing.

So we -- I guess we need to think about what we don't want to have impede the process when we implement it.

DR. GRABENSTEIN: John Grabenstein.

So as I have been thinking this through, it seems like there's a couple of ways to cut it. One is to think -- some of this work I think we are being asked to do is about preparedness, about doing things ahead of an event, and then some of it is thinking about what to do during the event.

And it seems like there are -- akin to thinking about what the National Science Foundation might have a capability of doing, is what can the Epidemic Intelligence Service at CDC, what can they do, what have they done, is there a -- is this something you know, what lessons should we learn or maybe intensify.

Or, HHS headquarters' own, I think it's OPEO, Office of Preparedness and Emergency Operations, or whatever the acronym stands for. We need to know what is underway and if it is just a matter of getting a science cell attached to the responders, sort out what can be done ahead of time and what should be better planned for doing in the

event.

CHAIR QUINLISK: Yes, I think you are right John. I am going to bring a little bit of my personal experience in just to tell you, just from my own experience what happened.

Iowa, several years ago, was the epicenter of the largest outbreak of mumps that we had had in 20-some years and during that thing, because there had not been outbreaks of mumps in this country for such a long time and since the science had evolved over those 20, 25 years, we did end up having requests from a wide variety of agencies to do research while it was going on, sort of the natural experiment of having thousands of college students come down ill with mumps.

And just to think about it, we had people all the way from, as you might expect, academia, we had some of the large medical centers wanting to do genetic medical research on why some people were getting it and other people weren't.

We had economists want to do research on the cost of this. We had great support from CDC both in EIS officers as well as staff people.

We had people wanting to use GIS and sort of some of the new geographic informational services, to try to figure out if this was a tool that could help graph college students and what they did and how it was spreading.

So we ended up having people from a very wide variety of backgrounds and institutions et cetera all be very interested in something that was not that big, truly, when you compare it to Haiti or the oil spill or whatever, and yet we had just an immense number of requests.

And one of the things that we had a bit of issue was, while the event was going on, we didn't have a whole lot of time to sit down and review research applications or even to have discussions about it because we were too busy trying to get the thing stopped.

So I'll just throw that out there. We actually did end up doing I believe 10 or so different kinds of studies during the epidemic itself, but it was sort of an interesting experience for me to be dealing with a new situation and how many requests we had for research.

And some of the research was public health practice, which meant that we did not need to go through a formal IRB approval because it was necessary for us just to be able to respond to the outbreak, but some obviously was what one would call pure research purposes and required things like drawing blood on people and more invasive kind of things and those did need to go through IRBs.

So it was something that was sort of interesting, but I think the bottom line was I was amazed at how many different groups were interested and from how many different kinds of backgrounds, and how little time we had to look at what was being requested and

make judgement calls on that because we were being -- you know our time was being taken up by just trying to respond to the disaster itself.

So I'll throw that out there.

Steve?

DR. CANTRILL: Steve Cantrill. Patty, I think you bring up a very important point and that is separating the responders from the data collectors, because it's the old saying, you know, when you are up to your fanny in alligators, it's tough to remember that your initial intent was to drain the swamp.

And having been involved in events, you get so focused on the patients that you can't stand back and say, these are the data points we need to gather.

CHAIR QUINLISK: Yes, thank you, and this is Patty Quinlisk again. I must admit, one of the things we did get asked about, which was probably appropriate, was -- because we were gathering a lot of data on

each individual person who was ill, we got requests to add on more questions.

And really, that's the time to do it. You don't want to go back four months later because they are not going to remember and everything, and I just remember updating our database, in don't know how many times, and at the end of course, then we ended up with a database with some people being asked every single question, and some people only being asked half the questions and some people not being asked any of the extra questions at all, and so the database was not complete and that was an issue.

But again, that became something that I think was very difficult for us to do on the fly, even though that's the time it needed to be done because it was very hard to make the judgement calls right then and there when we had all these other things to do, and to ask our people who are out there trying to stop it, to take five extra minutes to ask four more questions was a bit problematic.

So I think you raise a good point Steve. Thank you. And Daniel.

DR. FAGBUYI: Dan Fagbuyi. So I guess from what I gather, I think we are all clear that there needs to be something done preemptively, at this time, now.

So the question is, how do we approach this all hazards. Dr. Lurie alluded to the fact that we might look at it from an exposure standpoint, but I think when we talk about all hazards, they don't fit into all -- into one box, so with that said, we have to either figure out how we are going to actually break this pie up, meaning are we looking at a category where we say maybe these are chemical related, these are biologicals, this is maybe something in a different category that we haven't even prepared for.

But then, I think we also should think about the things we have experienced before, so in the service sometimes we say lessons re-experienced, we are supposed to learn them and make it better, and if we re-

experience it, we haven't learned anything.

So what are the malefactors that we already know about, and that we anticipate can happen and what are we doing about those, I think, so we have to prioritize the things likely to happen or maybe even make that pie chart or matrix where we say these are rare, but the lethality is high, so we need to prioritize those, the most common things we need to prioritize, and then figure out the gray area. I think those are kind of some of the things we need to start thinking about.

CHAIR QUINLISK: John Parker.

DR. PARKER: Thank you Patty. John Parker. I just want to throw two things into the cauldron. Dr. Lurie talked about infrastructure and I think in this day and age, we are not looking to hire 150 government employees.

So I think when we juggle the infrastructure, we may have to take a close look at virtual structures.

The other point that I want to

throw in the cauldron is that it's very difficult sometimes to think in the future and say what would be the next disaster or what it might be, and I don't know if this will help or not, but whenever there's any construction or building in the United States of America, the contractor or the developer files an environmental impact statement.

Now that goes to EPA or to a local government, and in that, if that's done well, that's a risk assessment, and there may be some hidden things in that environmental impact statement that might give us some triggers as to what could be the next disaster or what could happen with the type of construction or the type of industry that is building something out there.

CHAIR QUINLISK: I think I am going to pause for a moment and allow anybody on line to have a chance. Do we have any comments or questions from anyone on line that are ex officios?

OPERATOR: If you would like to ask

any question, please press star then the number 1 on your telephone key pad.

CHAIR QUINLISK: I am sorry operator, we are not asking for public comments at this point. I want to know whether any of the ex officios on the board have any comments they would like to make at this point.

Okay, sounds like we don't, so Jane, I believe you have another.

DR. DELGADO: Jane Delgado. I think it's important, when we talk about baseline, to also understand the baseline of how things are currently operationalized within HHS, so that we know how things are happening, and in an all hazards science response, how we would like them to happen, so we know where we are going.

But we have to have a better understanding on where we are starting and how that occurs.

Also we can look at some good models of things and I think, not because John

is here, but the Department of Defense, after 9/11, the way they handled the Pentagon and allowing people to go back in, was very different than the way it was handled in New York in allowing people to go back in.

And those were two very different responses and one was much more considerate of the people than the others.

CHAIR QUINLISK: So this is Patty Quinlisk. What I am sort of hearing is perhaps one of the places to start is to look at seeing how a science response was done to some of the recent events and see if there's things from that that we could build on to make sort of the best practices types of recommendations.

Okay, Kevin?

DR. JARRELL: Kevin Jarrell. So our -- when we had the spill in the Gulf, since there was a reference made to the NSF rapid response grants, we applied for that funding and put together a consortium of three academic institutions that are working with

us, and just in terms of thinking about timing, and when we would like to put this science team into action, I think their response was, true to their word, incredibly rapid, if you think about how long it typically takes to receive funding for a project.

But it was about -- it was exactly two months from the date that we first contacted them until the project was funded, which is incredibly fast.

But I think that this board needs to think about, when there is an event in the future, how much time does the board feel should pass before this team goes into action, so it's a question.

CHAIR QUINLISK: Bruce Gellin.

DR. GELLIN: Just to build on some of John Parker's comments about infrastructure, I think that you have given one suggestion, you know things that are already out there, like whether or not environmental impact statements might even

have existing information, not just a model for bad things to worry about.

But the other is existing networks that you can leverage. I mean, during the pandemic experience, to be able to tap into ICU networks. It wasn't something that they were wired to do, but to be able to get a read from the frontlines about what was going on in the ICUs.

Then the next step is what specifically might you want to be looking at beyond just those observations. I think that maybe as you go through this effort, to look at the spectrum of things that are already in place, that could be brought into the fore here.

CHAIR QUINLISK: This is Patty Quinlisk, and Bruce, I think you, as you are talking about ICUs and things, I know that there were a lot of requests during H1N1 for clinical information about the people who were the sickest or even, unfortunately may have died.

And one of the things that I saw was -- it wasn't too bad, but there was not as good coordination around the people who wanted that information and we got complaints back from say hospitals saying there's now four different people asking for the same information, and that kind of thing is not necessary, obviously.

So maybe part of it is learning how to best coordinate the need for data and not have four different researchers calling the ICUs asking for the same information.

But obviously getting that information will be very important and necessary, but I wonder if that coordination might be something that could be planned for ahead of time or thought about so that the least burden possible is put onto the people who are trying to respond.

So, Daniel?

DR. FAGBUYI: Dan Fagbuyi again. So with regard to leveraging networks, which I think is a great point, I think a good

starting point would be also NIH and to reach out to them. I know they also had grants that were for real time, and that's the problem with most of the researcher networks, they are not real time.

It's more retrospective. By the time we get around to getting IRB approval, going through the process, you forgot the story and you didn't glean those data that you needed.

So I think finding that list of different networks both from the adult, pediatric population, whatever you have, and get those networks and try to bring them into this discussion and see if there is funding that can be actually already -- almost like a prepositioning of this and say hey, at time go, we expect a time that Kevin was alluding to, maybe it's 72 hours, 48 hours from the time an incident happens, your researchers should be in place, your research assistants and things like that, at least to gain the clinical and health information that we need.

From the emergency department perspective this is the same kind of issue we dealt with also.

CHAIR QUINLISK: This is Patty Quinlisk. I think Dan, you bring up something that is -- we might want to distinguish. One, there is research that basically can be done with existing resources because it is sort of part of people's jobs or they can be delegated over for a period of time to do things without needing extra immediate resources.

But then there's other research that obviously you have to have resources for in order for that research to even begin, and maybe that's something that we can also talk about, is how do we distinguish between the two and you know, see how we can ensure that resources are available for those things that can go forward without extra money, but other things that how you can get the money readily available so that there is not a delay time for that research to start. John Parker?

DR. PARKER: I feel like I am

jumping on the microphone a lot. John Parker. You know at these times in the United States, there's a significant part of the population that is not wanting government interference.

And so I think one of the things that we should wrestle with is how do we make this project for the people, by the people, rather than giving -- having them say, oh it's just another government thing coming at you.

And/or how do we reverse how they feel about the government during a disaster and immediately after that they want help, how do we transfer that to the earlier part, so they are saying we will help now so that when you help later, it's better.

DR. GRABENSTEIN: John Grabenstein. Several of us in the room have had involvement with IRBs at various points in our career, and so surely an IRB is going to want in the consent, any consent of this sort, the ability for the data source, the person, to opt out.

And yet we also know from the last 10 years or the history, that -- I'll use the

example maybe of cleanup workers at ground zero in New York City, they may well have opted out at the beginning, but if some long-term consequence is claimed, they may wish they had been involved earlier, contributed earlier, or been on a registry earlier.

So it's going to be a very interesting balancing act, but it would be get to get an IRB started in thinking these things through and obviously, public comment would be very helpful too, because it would be -- there won't be time for dispassionate public comment in the midst of the emergency.

CHAIR QUINLISK: And this is Patty Quinlisk. And I think that brings up another point. If we are trying to collect the data, the closer you are to the event, at least my personal experience has been, the more likely people are to volunteer.

You come back six months later, and maybe now they are on to the next thing and not as interested. So you get a better response the quicker.

That only brings up, I think, another issue and this is again just from my experience of working in some disasters in Iowa, is that oftentimes the people that you are trying to get information from, want information back from you.

And so you have some of the people doing double duty, trying to find out things from them, but then also acting as a conduit to information that they need at that moment to help them respond to the disaster, whatever it might be.

And that becomes, sometimes, a little bit tricky to do also, and yet obviously, might be the most appropriate and ethical thing to do, given the situation.

And Jane?

DR. DELGADO: Jane Delgado. I also want to emphasize that whatever is considered an all hazards science response, it's not just data collection.

It also means being prepared for whatever may happen based on the science that

we currently have. So what that would entail in terms of operationalizing that within HHS, outside of HHS and the infrastructures that are needed in order to make that happen, which is something Dr. Lurie mentioned.

CHAIR QUINLISK: Kevin.

DR. JARRELL: Kevin Jarrell. I also want to make the comment that in addition to collecting data about exposed populations, that that data I believe will be more meaningful if you are also prepared to collect data about particular agents, if it is a chemical agent or a biological agent, that there should be teams in place to collect that sort of, those sort of data as well as the distribution of particular materials that are involved in the incident.

CHAIR QUINLISK: And this is Patty Quinlisk, and I will just, going back to our epidemic mumps, probably the hardest thing we had was not collecting the data but getting the data entered into a computer, just an amazing burden that was.

And in fact I believe we actually ended up going to CDC and having you send us people just to enter data, which seems sort of silly, but that is the thing that was our bottleneck, so that's -- just a little sort of non-technical thing, so just thought I'd add that. Other comments?

Let me ask again for people on the phone. Are there any comments from our members who are on the phone line?

Okay. Again this is Patty Quinlisk. I think what I would like to do at this point, it sounds like people have an interest in this topic, obviously, we have been asked to deal with this topic, and the typical way in which we go about dealing with issues that we need to explore, do some research on, come back with recommendations, is to form a working group that can work outside of our meeting to try to collect information, come to some conclusions, that can be brought then before the entire board.

So I'd like to throw that piece out for discussion. How do people think or feel about putting together a working group?

CHAIR QUINLISK: Okay, so I see --

DR. DELGADO: Yes.

CHAIR QUINLISK: I see nods and everything, so I think what -- do we need to take a formal vote on this?

CAPT SAWYER: Yes.

CHAIR QUINLISK: Okay so I think what I would like to do then is -- we have a proposal for putting together a working group to deal with the issue of science response to disasters. Can I have somebody make a motion?

DR. CANTRILL: Steve Cantrill. So moved.

DR. DELGADO: Second.

CHAIR QUINLISK: We have a second from Jane Delgado. So what I would like to do perhaps is go through the roll and take a vote on this.

CAPT SAWYER: I will go around the room.

Jane?

DR. DELGADO: Yes.

CAPT SAWYER: David Ecker?

DR. ECKER: Yes.

CAPT SAWYER: Daniel Fagbuyi.

DR. FAGBUYI: Yes.

CAPT SAWYER: Kevin Jarrell.

DR. JARRELL: Yes.

CAPT SAWYER: Betty Pfefferbaum.

DR. PFEFFERBAUM: Yes.

CAPT SAWYER: John Parker.

DR. PARKER: Yes.

CAPT SAWYER: Steve Cantrill.

DR. CANTRILL: Yes.

CAPT SAWYER: John Grabenstein.

DR. GRABENSTEIN: Yes.

CAPT SAWYER: Patty Quinlisk.

CHAIR QUINLISK: Yes.

CAPT SAWYER: It's a unanimous yes.

CHAIR QUINLISK: Okay. So now that we have a working group that will be created, we need members for that working group, and I have thought about people who are on this

committee already who might have some particular expertise in some of these areas.

So, and I will tell you, when I think about this particular issue, I do think this issue is very broad in scope. I think there's a lot of sub-issues within this and therefore I think that given this issue, our experience in working with similar, very broad topics in the past, I think it would be more appropriate to not have the burden of this working group fall on one shoulder, but to ask people to perhaps co-chair. We have done this in the past where we have had large committees and perceive a lot of work.

So I think I would like to propose that we have two co-chairs for this committee who could share the burden of chairing this working group.

I don't know that we need to take a vote on that, but if that is all right with everybody, what I would like to do now is to ask for some volunteers for co-chair.

DR. CANTRILL: Steve Cantrill.

John, there's a reason you are sitting right next to Patty.

DR. DELGADO: I volunteer for this.

CHAIR QUINLISK: Okay. Jane Delgado.

DR. CANTRILL: Steve Cantrill. I volunteer with John as well.

CHAIR QUINLISK: Okay, and I believe that John has --

DR. GRABENSTEIN: I should say so out loud. Yes.

CHAIR QUINLISK: So it looks like we have three co-chairs, and I think to be honest that that might not work bad, because I think having two people who have been on the committee, or been on the board for a while, is good. But then to have some new thoughts and experience coming in, and I do admit that I do think that this is going to be a committee where we break down into perhaps sub-topics and maybe then we can have the co-chairs each sort of take the lead in a sub-topic.

So I would like to then propose to the board that we accept the generous volunteering of being co-chairs on this committee, and I think we can again just do with nods and everything. Is everybody okay with that?

Okay, now --

CAPT SAWYER: I would just like to ask that one person be designated to lead in some respects, as it's very hard to coordinate with three, so if I could have a POC for the co-chairs, that would be great.

DR. CANTRILL: I would be willing to do that.

CAPT SAWYER: Great.

CHAIR QUINLISK: Okay, so that's Steve Cantrill. Lead co-chair will be Steve Cantrill and then two co-chairs. So I think now the thing to do is to find out who else would like to be on this working group and I will start out by volunteering that I would like to be on this working group and maybe we can again go around the room and have people

say whether they would like to be part of the working group or not, and since Jane, you are co-chair, I think that's sort of a done deal. You are on it.

So David?

DR. ECKER: David Ecker. I will be on the committee.

DR. FAGBUYI: Definitely.

CHAIR QUINLISK: That was Daniel.

DR. JARRELL: Kevin Jarrell. I will participate, yes.

DR. PFEFFERBAUM: Betty Pfefferbaum. Yes.

CHAIR QUINLISK: And we will finish with the voting members.

DR. PARKER: John Parker. Yes.

CHAIR QUINLISK: And then obviously Steve and John Grabenstein are both on it also as co-chairs. So what we need to do then is see about specific ex officio members, if they would like to be on the working group also.

CAPT SAWYER: Yes, I have received emails from individuals in anticipation of the

charge to the board. We can ask around the room here, but any ex officios who are not present today or whose delegate is present and able to tell us who would be on this working group, it would be good to know.

So, we can start with Dr. Khan, Admiral Khan.

RADM KHAN: So, actually, I was going to volunteer a couple of briefs. So we put together registries at CDC all the time and I think it would be very valuable to have somebody from ATSDR come up and give you a brief on registry issues.

We also tackle with the issue of research and non-research determinations as you know very well, being the chair and from your role in Iowa, so maybe we can have someone of our science officers come up and brief you on those issues.

You may also want to consider having OMB actually, since these are so tied to the assistant secretary's issues around OMB and what needs OMB clearance, to really have

some good clarity of what needs OMB clearance, because technically, these clinical issues don't need OMB clearance.

So a lot of questions that I heard around the room had to do with clinical issues, and you don't need OMB clearance for clinical issues. We have other mechanisms to deal with clinical issues.

So it would be nice, as you sort of lay out the questions you want to ask, and what you need OMB waivers for, to understand what falls within that lane as opposed to what falls into our routine research lane.

So I'll be glad to volunteer the appropriate people from CDC to come and do those, at least first two set of briefs and you may want to consider the appropriate person to do the OMB brief.

CAPT SAWYER: Thank you. Dr. Kaplowitz?

DR. KAPLOWITZ: I know there will be a number of people from ASPR who would be interested at least in addressing the working

group and you will be hearing from Dr. Rubinson shortly and Dr. Miller from the NIH.

So I know that input from OPEO is important since they are directly involved in the response. I'll be glad to be involved since we are addressing a lot of these issues in terms of policy, anything involving behavioral health, we have expertise and I'll volunteer Dan, who is sitting right here.

So I think that we can -- I know we can pull on a lot of expertise depending on the questions that come up. This is something that we have been thinking about a great deal and Leigh has done a great deal of the background work.

So I think it's a matter of the specific questions that come up.

CAPT SAWYER: I know in previous discussions, you have mentioned BARDA, and their involvement as well.

DR. KAPLOWITZ: Absolutely, and I don't know if Robin is still here, but BARDA in terms of what they are doing with medical

countermeasures, big issue, and they have had a lot of involvement in so many of the issues with H1N1 and vaccine development.

DR. GELLIN: So I must have missed that seminar, how you get to volunteer everybody else, but nevertheless, I think that it would be useful, just given while the NVPO had some involvement with the pandemic response, I think it's probably worth -- useful to take a look at that as one which had broad implications across a number of things, and to use that as an opportunity to cross-walk that one. So I will volunteer others, including myself, to participate in that.

CAPT SAWYER: And NVPO is the National Vaccine Program Office and Dr. Bruce Gellin is director of that office.

MS. PARKER: So, I am happy to volunteer Dr. Phillips. She is very interested in this topic. And as her alternate, I will also participate and will be happy to work within the department to also engage our science and technology directorate to help

brief the committees as necessary to -- on the department's activities and any information that you may need to inform your decisions.

CAPT SAWYER: That was Tracy Parker.

MS. HART: Rosemary Hart, Department of Justice. We didn't see a clear role for us here. We do very little research. But we would like to make ourselves available to the extent you have questions or see a role for us.

We have been canvassing within the various components as to whether people want to participate and it's actually been helpful, coming to the meeting, and hearing more about the scope.

So we will continue that canvassing, but in the meantime let us know if you see a role for us.

COL SKVORAK: John Skvorak. DoD. Yes, myself, but also I mean, across the Department of Defense, there's a lot of response teams and if anything, they could at

least provide some of the gaps, help with what their processes and procedures are, but also what they wish they knew, which I think is what we are after here.

And of course, CBRNE is certainly an emphasis within the Department of Defense and post-traumatic events so, yes.

DR. MICHAUD: Vince Michaud from NASA. Yes, I'll participate. In the two named disasters NASA was pretty busy with the imaging for situational awareness and communications, so we can provide that kind of expertise.

CAPT SAWYER: I do know that CDC NIOSH also is very interested in this and John Decker is here today representing Dr. Margaret Kitt and John Howard from NIOSH. So I know that they are interested in participating as well.

And are there ex officios on the phone that would like to participate?

DR. LEVINGS: Yes, this is Randall Levings with USDA. We would be interested in

contributing.

CAPT SAWYER: Could you repeat that?

DR. LEVINGS: Levings of USDA.

CAPT SAWYER: Oh yes, I'm sorry.

DR. LEVINGS: I had some of the same concerns and mobilization teams so I could serve as liaison and get some more information for you.

CAPT SAWYER: Thank you Randall. Randall Levings. Anyone else?

CDR MAHER: Leigh, this is Commander Carmen Maher from FDA. I volunteer to serve on the work group and be the point of contact or representation if needed from CBER, CDER, CDRH and the Center for Food.

CAPT SAWYER: Thank you.

DR. AMOS: Leigh, this is Mike Amos from NIST. It's not clear what our role might be from the Department of Commerce, but you know, we have a sense of spirit, NOAA and NIST, and if, as the scope develops further, you can feel free to contact -- to include me

on any correspondence or if you think you need any help from us, just let me know and I'll work it back through our organization.

CAPT SAWYER: Thank you.

CHAIR QUINLISK: Okay. I think we have gone around. I think the last thing we need to do is just decide what we are going to call this working group. We have sort of been calling it believe All Hazards Science Response and I -- so I guess I open it up. Do you want to continue calling it that, or anybody have any better ideas?

DR. CANTRILL: Steve Cantrill. Sounds good to me.

CHAIR QUINLISK: Okay, I don't think we need to take a vote on that. So this will now be called the All Hazards Science Response Working Group.

Okay the last thing we need to do is open up for public comment, so operator, if you could please open the lines up and if we could see if we have any public comments on

any of the issues we discussed today. Thank you.

OPERATOR: At this time, in order to ask a question, please press star then the number 1 on your telephone key pad. We will pause for just a moment to compile the Q&A roster.

CHAIR QUINLISK: Okay and as they are developing the roster on the line, I'd like to see if there's anybody in the room that has public comment. If you do, please step up to the microphone and identify yourself.

MR. DECKER: Good afternoon. My name is John Decker. I am from the National Institute for Occupational Safety and Health, or NIOSH, mentioned a few minutes ago.

I think that it is self-evident to the committee, but one large categorization you might think about is the worker population, the responder work force, versus the general population.

And there's many differences

between these populations, whereby I think they probably need to be considered somewhat separately.

The other thing I wanted to mention is that about two years ago, NIOSH sponsored an interagency work group to look at responder health monitoring and surveillance, and we have put together -- we have had agencies from all over the government, about 49 representatives in all, and we will be having a public comment document available for review during the first week of February.

It's titled the Emergency Responder Health Monitoring and Surveillance. And one thing that was mentioned was baseline. I think Dr. Parker mentioned that earlier.

This guidance document talks a lot about baseline in terms of pre-deployment health screening for responders, and there's other guidance related to base information and rostering of deployers. Thank you.

CHAIR QUINLISK: We will take one more from here and then we will go to the

people on the phone. Go ahead.

DR. WHIDDEN: Good afternoon. Thank you very much for your perceptive leadership. For the last seven years, I have been working in all hazards risk assessment for the Department of Homeland Security and I am just finishing up the CIRA, the Chemical Infrastructure Risk Assessment, which is a holistic, cradle to grave approach from looking at the 17,000 and some chemical sites in the United States, and modeling the impact of that from both the clean-up through the health impact perspective, looking at the mitigation measures.

It's a very thick document and it's classified. There's a non-classified piece of it. But if you are looking at the holistic, all hazards approach, that's a very important document that you should consider, please.

CHAIR QUINLISK: Could you please identify yourself?

DR. WHIDDEN: I'm sorry. I'm Dr. Whidden.

CHAIR QUINLISK: Okay. Operator, could we now take any calls on the phone?

OPERATOR: We have a question from Marcy Rockman.

CHAIR QUINLISK: Go ahead, Marcy.

DR. ROCKMAN: Hi, can you hear me?

CHAIR QUINLISK: We can hear you. Go ahead.

DR. ROCKMAN: Okay great. Actually, I was trying to jump in for the working group volunteers and was having some trouble with my phone. I am with Peter Jutro in the EPA homeland security research office and we have worked quite a lot with various disaster infrastructures and I am not able to commit Dr. Jutro to the working group but we definitely would like to contribute some information and whatever expertise we can provide. So that was my comment for that.

CHAIR QUINLISK: Okay. Well great, we like your comment very much and thank you.

DR. ROCKMAN: Thank you.

CHAIR QUINLISK: Is there any other

comments on the phone?

OPERATOR: I show no further questions at this time.

CHAIR QUINLISK: Okay. Any other comments from the room? Okay. What I would like to do now is to turn the meeting back over to Leigh Sawyer to sort of finish up this session and to talk about our next steps.

CAPT SAWYER: Thank you. What I would propose is that the working group co-chairs decide on a timeline. I know that Dr. Lurie has actually stated in her letter, which is available on the website for the public, that she is looking forward to receiving recommendations, advice, guidance by April of this year, 2011.

We do have a public meeting that is planned for April 28-29. I think that that would be a good time. She wasn't descriptive about the details she wants at that point, so it may be that the working groups and the co-chairs will decide to parcel this in some way and I think that that should be an activity

that is conducted in collaboration between the co-chairs in terms of laying out a schedule and a plan for how to really investigate or gain detail and data to form a response.

So I would expect that the board would be ready for a presentation from the working group in April, I hope, and we will plan an agenda around that. Do you think that's possible Steve?

DR. CANTRILL: I will have to consult with my co-chairs. I think we will, if not a final report, we will certainly have an extensive progress report.

CAPT SAWYER: Thank you. Do you have any other items you'd like to discuss? At this time, this will be, from what I have heard today, the primary focus of the board. We do have other working groups that we have briefed the new members about.

Currently those working groups do not have any particular activities, and I wonder if the board wants to discuss that. We have not asked them to perform any particular

task at this time --

CHAIR QUINLISK: This is Patty Quinlisk. I think given that pretty much everybody who was on the NBSB has volunteered to also be on the working group and the very short time line we have for this very important project, I would like to propose that the other working groups that we have sort of go to inactive status at this time, to be brought back into active status should there be issues that come up that are most appropriate for those working groups, but at this point to focus our energies on the task that is before us today.

So I'll open that up for discussion.

DR. CANTRILL: Steve Cantrill. I would endorse that concept.

CHAIR QUINLISK: I don't believe we would need -- do we need to take votes on it? So just, unless I see around the room anybody who disagrees, what we will do is the other working groups will go into sort of inactive

status but be available should issues come up.

But meanwhile we will spend the next several months focusing on the new working group of the All Hazards Science Response.

Okay. I think what I would like to do is to just take a quick moment to thank Leigh and the staff members for all the work that they do. I know that sometimes that work is not always visible to all of us, but there is an incredible amount of work that goes on behind the scenes to make sure that these meetings work.

So I think that what I would like to do is have the staff stand up so we can acknowledge them. And Mackenzie, I am going to ask you to stand up first. Thank you very much for all your work Mackenzie.

And then Jomana, thank you. And Brook behind her. Again, if you haven't met them before, they are great staff and they do a huge amount of work to make sure that our meetings are successful.

CAPT SAWYER: So as I indicated, the next public meeting is scheduled for April 28-29. We do not have the location yet but typically they are in the D.C. area. Please check our website for additional information.

If you -- let me tell you, the website is <http://www.phe.gov/preparedness/legal/boards/nbsb> and you should get there. There is a little bit longer part of that.

I would like to thank all of you for attending, thank the new members, and the retiring members for being here today, for the welcome and for the final sign-off from Dr. Lurie, and thank all of those who have attended by phone and the public, thank you.

This meeting is adjourned.

(Whereupon, the above-entitled matter adjourned at 2:46 p.m.)

