NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC TELECONFERENCE

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FRIDAY,
OCTOBER 28, 2011

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The meeting convened at 3:00 p.m., via teleconference, Patricia Quinlisk, Chair, presiding. Leigh Sawyer, Designated Federal Official.

NBSB VOTING MEMBERS PRESENT:

PATRICIA QUINLISK, NBSB Chair, M.D., M.P.H.
GEORGES C. BENJAMIN, M.D., FACP, FACEP(E), FNAPA, Hon. FRSPH
RUTH L. BERKELMAN, M.D.
STEPHEN V. CANTRILL, M.D., FACEP
JANE DELGADO, Ph.D., M.S.
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., Major General (Ret.)
BETTY J. PFEFFERBAUM, M.D., J.D.
PATRICK J. SCANNON, M.D., Ph.D.

DESIGNATED FEDERAL OFFICIAL:

CAPT LEIGH SAWYER, U.S. Public Health Service

SPEAKER:

NICOLE LURIE, M.D., M.S.P.H., U.S. Department of Health and Human Services

EX OFFICIO MEMBERS PRESENT:

REBECCA DALEY, Office of International Health and Biodefense, U.S. Department of State (For Dr. Kerri-Ann Jones)
BRUCE GELLIN, M.D., M.P.H., National Vaccine Program Office, Office of the Assistant Secretary for Health, U.S. DHHS
ROSEMARY HART, J.D., Office of Legal Counsel, U.S. DOJ CAROLE HUDGINGS, Ph.D., National Institute of Allergy and Infectious Diseases, NIH, U.S. DHHS (For Dr. Hugh Auchincloss)*
FRANCA R. JONES, Ph.D., Office of Science & Technology Policy, Executive Office of the President*
PETER JUTRO, Ph.D., National Homeland Security Research Center, EPA
ALI S. KHAN, M.D., M.P.H., RADM, Office of Public Health Preparedness & Response, Centers for Disease Control and Prevention, U.S. DHHS*
GEORGE W. KORCH Jr., Ph.D., Office of the Principal Deputy, Office of the Assistant Secretary for Preparedness and Response, U.S. DHHS*
RANDALL L. LEVINGS, D.V.M., National Center for Animal Health, USDA
RICHARD MARTINELLO, M.D., Office of Public Health and Environmental Hazards Department of Veteran Affairs (For Dr. Victoria J. Davey)
VINCENT MICHAUD, M.D., Office of the Chief Health and Medical Officer, NASA (For Dr. Richard Williams)
DIANE POSTER, U.S. Department of Commerce (For Dr. Michael Amos)
BONNIE RICHTER, Ph.D., Office of Health Safety and Security, DOE (For Dr. Patricia Worthington)

*attendance indicated by InterCall Participant List.

PUBLIC COMMENTERS:

STEVEN FISHER
STEVEN KRUG, M.D.
ROBERT MALONE, M.D.
MERYL NASS, M.D.
JONATHAN NEWMARK, M.D.
VERA SHARAV, Alliance for Human
Research Protection

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

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

3:02 p.m.

CAPT SAWYER: Thank you very much, Operator. This is the National Biodefense Science Board Teleconference Public Meeting today. I would like to begin by welcoming everyone to the NBSB meeting.

We have NBSB voting members, ex officios or designees, members of the Anthrax Vaccine Working Group and the public. I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board and I serve as the Designated Federal Official for this federal advisory committee.

Today's public meeting will focus almost entirely on a discussion of the report and recommendations from the Anthrax Vaccine Working Group. I'm going to begin with a roll call today and I know it is sometimes difficult to get on the phone.

We may need to go back to assure that we have the voting members on the phone. I'm going to begin the roll call with Patty

Quinlisk.

CHAIR QUINLISK: Here.

CAPT SAWYER: Georges Benjamin? Ruth Berkelman?

DR. BERKELMAN: Here.

CAPT SAWYER: Steve Cantrill? Steve Cantrill? Steve may be having a hard time responding. I think he is on the line. Jane Delgado? David Ecker?

DR. ECKER: Present.

CAPT SAWYER: Dan Fagbuyi?

DR. FAGBUYI: Present.

CAPT SAWYER: John Grabenstein?

DR. GRABENSTEIN: Present.

CAPT SAWYER: Kevin Jarrell? Tom MacVittie? John Parker?

DR. PARKER: Present.

CAPT SAWYER: Betty Pfefferbaum? Pat Scannon? I'd like to ask if we could call those individuals, please, just make sure that they have the right number.

Okay. Now I'd like to ask for attendance from our ex officios. Franca

Jones? Larry Kerr? Richard Williams?

DR. MICHAUD: This is Vince Michaud for Richard Williams.

CAPT SAWYER: Thank you, Vince. Randall Levings?

DR. LEVINGS: Present.

CAPT SAWYER: Michael Amos? John Skvorak? Patricia Worthington?

DR. RICHTER: Bonnie Richter for Pat Worthington.

CAPT SAWYER: Thank you, Bonnie. Ali Khan? Hugh Auchincloss? George Korch? Carol Linden? Bruce Gellin? Luciana Borio? Sally Phillips? Lori Caramanian? Rosemary Hart?

MS. HART: Present.

CAPT SAWYER: Thank you, Rosemary. Kerri Ann Jones? Victoria Davey? Peter Jutro? Patricia Milligan? Now, are there voting members that have joined the line since I've taken roll call?

DR. SCANNON: Yes, Pat Scannon.

CAPT SAWYER: Pat Scannon?

DR. PFEFFERBAUM: Betty Pfefferbaum.

CAPT SAWYER: Betty Pfefferbaum.

DR. CANTRILL: Steve Cantrill, can you hear me?

CAPT SAWYER: Steve, now I can hear you. Thank you.

DR. CANTRILL: Okay, thank you.

CAPT SAWYER: Jane, I see you should be on the line, are you available?

DR. DELGADO: I'm here.

CAPT SAWYER: Oh, great. Hi, Jane. We've called your name and I didn't hear you respond.

DR. DELGADO: This is Jane Delgado.

CAPT SAWYER: Thank you, Jane Delgado. Kevin Jarrell? And Thomas MacVittie? Georges Benjamin, have you joined? Okay. So let me go to tell you just briefly the FACA overview, the NBSB is an advisory board that is governed by the Federal Advisory committee Act.

The FACA is the 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 a group are not federal employees.

The document, Standards of Ethical Conduct for Employees of the Executive Branch, has been received by all board members, who as special government employees are subject to the conflict of interest laws and regulations therein.

We will have a public comment period from 3:35 to 3:45. We'll have an opportunity for the public to make comments. If you're joining us by phone as you all are here, you'll be given instructions by the operator as to how to signal that you have a comment and comments will be taken in turn.

You'll be notified when your phone line is open for you to speak. I'd like to remind everyone that this meeting is being transcribed and when you speak, please provide

your name.

The meeting transcript summary and pertinent documents will be available on our website following the meeting, there soon after. And now I'd like to turn this meeting over to Dr. Patty Quinlisk, the Chair of the NBSB.

DR. QUINLISK: Good afternoon everyone, this is Dr. Patricia Quinlisk. I welcome you to our public meeting of the NBSB. I'd like to just take a brief minute to go over our agenda and the goals. After I get done we will have some brief remarks from Dr. Nicki Lurie.

Then as Leigh Sawyer said, we will go into the main part of our meeting today, which is to have the Anthrax Vaccine Working Group report. After that report is given by Dan Fagbuyi and John parker there will be discussion by the board members.

After that there will be public comment for ten minutes, from 3:35 to 3:45. After that there will be a vote on the

recommendations.

After the vote is taken, we will talk about some of the future topics for the NBSB and then whatever time is left we will have discussion on that future topics and then we will wrap up and be done by about 4:00.

So the goal primarily for today is to get through the Working Group report and to vote on that. I think what I'd like to do now is to introduce Dr. Nicki Lurie who is the assistant secretary for Preparedness and Response with Department of Health and Human Services who is with us today and wishes to give some remarks prior to the Working Group repot.

So Dr, Lurie, please go ahead.

DR. LURIE: Good, thank you and good afternoon everybody. And I will be brief because I know we have a lot to talk about.

I really just want to thank the NBSB for taking on this challenging issue about how to protect children after an anthrax

attack. In fact, I can remember coming to the board with this request and just seeing the look in your eyes as you realized what a controversial and challenging topic this was.

I want to thank the Anthrax Vaccine Working Group and its co-chairs, Drs. Dan Fagbuyi and John Parker for their thoughtful work in developing the report and to all of you who participated and provided testimony in one way or the other.

Earlier this year, as you know, the NBSB was asked to explore the advantages and disadvantages of the various strategies to perform an AVA vaccine study for children before an anthrax attack occurred and protecting children still stands, for me, among the most important responsibilities that we have as a nation.

As I listened to the roll call, I was struck by the fact that a number of the federal ex officio members didn't get on the call yet. In fact, the reason they weren't on the call is because we had our inaugural

meeting today of our pediatrics and OB integrated product team.

This is a group of federal officials who will advise across the PHEMCE about a whole host of issues related to children and pregnant women as we continue to move much more to a whole community approach to all of the issues that we face in preparing and protecting the country.

So let me thank you again. I know that this task wasn't easy. But I do look forward to hearing today's discussion. Bye-bye.

CHAIR QUINLISK: Thank you, Dr. Lurie. Now I'd like to ask the Chairs of the Anthrax Vaccine Working Group to go ahead on the report. And I would like to just second what Dr. Lurie said. I know that this has been one of the most in depth and very interesting topics that this board has taken on and the incredible amount of work that's been done by our two co-chairs as well as other members of the Working Group and members

of our staff.

I'd just like thank -- thank you to all of them for all of the dedication and the work they've put in to getting this report done. So Dan and John, I turn it over to you now.

CAPT SAWYER: This is Leigh Sawyer, I'd just like to indicate we have another ex officio who has joined us.

DR. GELLIN : Yes, this is Bruce Gellin and probably like others, they're joining or probably in the progress of dialing into this call, so thanks again.

DR. FAGBUYI: Okay. Good afternoon everyone. My name is Daniel Fagbuyi. I'm the Chair of the Anthrax Vaccine Working Group along with my co-chair, John Parker who's on the line. I'll first do a brief intro and get us to where we are.

And John Parker may have some comments and we'll dive into the meat of the matter, what we're all here to discuss.

First of all, let me be up front.

I've always been a candid person. I think when we got the Work Group together and got the task from Dr. Lurie, there were at least three main pillars, which I looked at with my co-chair and we said we would actually make sure we focus on when discussing this issue of anthrax vaccine in children.

The first thing, and the one I want you to make note of, is protecting the children, our precious gems. That's the one thing.

The second is addressing the anthrax vaccine in an open and transparent process. How did we do that? We held some public stakeholder engagements. We involved some of our subject matter experts, people who take care of children, pediatric specialists.

We involved public health authorities and a number of different entities that deal with children. But also, we engaged the media and we actually opened this up for public comment.

So the third piece was to ensure

that we thoroughly considered and discussed the ethical, legal, and regulatory issues that surround anthrax vaccine in children.

So I want to make sure that that is clear up front and that's what we're here to talk about.

What other things did we look at, how did we come up with the development of this report? Well, July 7 we had a public stakeholder engagement workshop in which we had various stakeholders at the table to discuss this issue, both public, and private entities were involved.

In that detailed discussion were raised many ethical and legal and just compassion and care for children issues, including the threat.

With that we also had another subsequent meeting on September 22, which was the NBSB Public Meeting where we actually discussed the draft executive summary report and we got some input from the public and also from our members and our Working Group.

That informed the final draft of this product. So that gives you where we are today ready to discuss the document in detail. I'm sure you all have read it, hopefully you've digested it to now come up with some key recommendations or changes, if any, to the document or issues if you are uneasy or that still need to be further hashed out and given some more thoughts, if any.

We feel that a group of members that have been involved, the Anthrax Vaccine Working Group is comprised of a group of perspicacious individuals, as is the National Biodefense Science Board. And we don't feel that we will be asked this question, to look into it, if it was something trivial. So it's obviously important.

With that said, I hope that brings you up to speed on how we got to where we are. I would like to pass this on to John Parker if you have anything to add. Otherwise we'll move on with our agenda.

DR. PARKER: Thank you, Dan. Great

summary. The only thing that I'd like to add to this is an additional person saying thank you for the participation. The participation of the ex officios, that's a terrible name of professionals in the government sector, was outstanding.

They responded with many, many comments to help us write this report. The other, just note that I'd like to make is that, if in fact, a degree of the population were to be exposed to the anthrax spores, 26 percent of that population will, in fact, be children.

And so with that statistic in mind, it was a very important letter that the ASPR, Dr. Lurie, gave to the Board, because we are very confident that we are able to take care of the adult population, but there were so many pieces of data missing for the pediatric population that it was worthy of these two to three months of debate.

Thank you all very much and I don't want to truncate the discussion.

DR. FAGBUYI: Yes, thank you, John. So this is Dr. Fagbuyi again. I think in summary we should be aware of what our Work Group has recommended to the National Biodefense Science Board. Our recommendation clearly states that HHS should develop a plan for and conduct a pre-event study of the AVA in children to include a research IND.

HHS should submit a study protocol to one or more institutional review boards and comply with 21 CFR 50.54/45 CFR 46.407, Federal Review Process.

This recommendation should be revisited if the new anthrax vaccine or other therapeutic countermeasures become available.

What's that in English for our others who are on the phone? Basically at the point we feel that this process, if it were to move forward, should undergo a process that involves a national review board that's appointed by the Secretary to look into the issues that surround the anthrax vaccine in children and specifically in talking about the

ethical issues, legal and regulatory pieces of that along with safety.

Just to lay the rules of engagement, at this time, what we'll do is go through with the voting members on the NBSB and ask them if they have any comments on the entire document and start to go name by name, because we don't have everybody here.

We're doing this via the phone. We would like to make sure we call on each single voting member if they have any comments or anything to add or issues that we need to address. After that process we will call on the ex officios and allow them an opportunity to tell us if they have any comments.

And then as you can see on the agenda, after we have our discussion, there's also a time for public comment and I'll let Dr. Quinlisk take it over from there. Leigh?

CAPT SAWYER: Yes. So I'm going to go through the list and I do recognize, because we do have a screen with the names of people who have joined the call, so I

recognize other voting members and ex officios have joined the call, so I will be capturing your name as we go through here.

So I'm going to begin with Pat Scannon. Pat, did you want to make any comments?

DR. SCANNON: I would just reinforce the effort of the entire Working Group in terms of dealing with the challenges that Dr. Lurie mentioned in her opening remarks. I think that in the end, what we were confronted with, from my perspective, is the difficulties of trying to conduct a clinical trial and accumulating the necessary information after or during an event and -- which I think set the stage for our final recommendations.

I have nothing further to add to the content of the document, but I do appreciate the real team effort that went into the construction of this recommendation.

CAPT SAWYER: Thank you. Betty Pfefferbaum?

DR. PFEFFERBAUM: No comments.

CAPT SAWYER: I'm going to skip John Parker. Tom MacVittie?

DR. MACVITTIE: Thank you very much. I as well recognize that this is an extremely controversial area that will remain so and also appreciate Pat's comments and I think the report was very well done and in depth.

Speaking from a rad-nuc component, I'm sure we're going to approach the same type of problems with any medical countermeasures for the rad-nuc community and we'll be faced with similar dilemmas.

It's a matter of risk benefit and I think in this case it's worth that emphasis. So thank you very much. I don't have any more comments on the document itself.

CAPT SAWYER: Thank you. Kevin Jarrell, I know you are not on the right line, so we're switching you now, be ready for comments in a minute. John Grabenstein?

DR. GRABENSTEIN: It occurred to me

yesterday that I've been involved with institutional review boards in research ethics since 1992 so almost 20 years. And children have always been recognized in that system as a vulnerable population.

So we have been made well aware of the special requirements to protect them. For me this decision comes down to, would I rather the first exposures occur before mass exposures or not? And I would.

I'd rather know what the response to the vaccine is before we are confronted with offering it to many, many, many thousands of children. And I think this is a case where we should go forward to write a good protocol and then give parents a goodly amount of time to consider the pros and cons and choose whether or not to enroll their child in a study ahead of time. Thanks.

CAPT SAWYER: Thank you. David Ecker?

DR. ECKER: I will only say that I wholeheartedly agree with what John and Pat

have said and don't have any further comments.

CAPT SAWYER: Thank you. Kevin Jarrell? You have an open line now.

DR. JARRELL: It's my view that in the event that it is necessary to administer this vaccine to children in the future, that if we are able to collect the appropriate data in advance that we will be able to administer it in a fashion that's safer and also more likely to be effective.

So I think when I consider the relative risk benefit of choosing to study the vaccine prior to an event or during an event, I'm certainly in favor of doing so prior. And I think the group did a very good job of laying, both sides or all sides of this difficult issue and I just want to say that I support the conclusions that are presented in the document.

CAPT SAWYER: Jane Delgado?

DR. DELGADO: I think that the work of the committee is exemplary and I support the recommendations that are made.

CAPT SAWYER: Steve Cantrill?

DR. CANTRILL: This has been a very complex issue and I would like to commend Drs. Fagbuyi and Parker, and the NBSB staff, in terms of guiding us through this very difficult issue and I do support the conclusions.

CAPT SAWYER: Ruth Berkelman?

DR. BERKELMAN: Yes, I also want to thank the members of the Working Group, especially Dan Fagbuyi and John Parker for their dedication in tackling this challenging issue as well as all of those who have contributed through workshops and public comments and other means to help us weigh this issue.

The decision as to whether to recommend testing of the anthrax vaccine in children is an extremely difficult one. The scientific counsel of this Working Group has concluded that these data are needed and I agree fully that the data are needed.

We need to know more about the

safety and immunogenicity of the vaccine as plans are developed to use these vaccines on large numbers of children in the event of a wide scale anthrax attack.

At the same time, the scientific argument collides with the ethical considerations of testing a vaccine for which there are no safety data in children and where that vaccine is not likely to have any benefit to the children in the study.

The Working Group has --

(Telephonic interference.)

CAPT SAWYER: Whoever is in the airport, could you please mute the line? Go ahead, Ruth. I'm sorry.

DR. BERKELMAN: This working group has clearly been sensitive to the ethical issues as Dan states. The issues are noted throughout this document. I'd like to add that it may be very useful as a first step for HHS to conduct a feasibility study to better understand the willingness of parents to have their children participate in this type of

study, and if so, under what circumstances. This would also inform subsequent discussion by ethicists and others involved. Regardless of whether a feasibility study is conducted, it is paramount that we assure that this issue receives formal ethical consideration.

Although we state that HHS will comply with the federal review process, I would propose that the ethical considerations be explicitly addressed in the recommendation.

And to that end, I would propose modifying the recommendation. I would keep the opening, the NBSB recommends Option 1, in light of the current HHS plan to follow the ACIP recommendation for the use of AVA for post-exposure prophylaxis following exposure to the Bacillus anthacis spores.

I would like to add to the recommendation, “this issue should be referred to a review board to formally address the ethical considerations. This board should include ethicists and public representation. If the ethical considerations are adequately

addressed," HHS -- and from there I keep it the same - "should develop a plan to conduct a pre-event study of AVA in children," and continue it exactly as it is.

That is the proposal for modification.

CAPT SAWYER: Thank you, Ruth. We've made note of that and we'll go on now to, I believe Georges Benjamin is not on the line. Is that true, Georges? Okay, so we'll now go on to Patty Quinlisk.

CHAIR QUINLISK: Thank you. And I'd like to also express my gratitude for all the people who have put so much time and effort into dealing with this very complex and difficult study or recommendation.

And I would like, as you said, I personally struggled with looking at the risk and the benefits of doing a pre-event study versus doing a study at a time when the risk of disease is imminent and the benefit of the vaccine is clear.

This has been a difficult thing to look at and certainly my background in my position have influenced how I feel about this and I do not know that I can recommend that a pre-event study is the appropriate response to this very complex and difficult concern that we have about the use of this anthrax vaccine in children. Thank you.

CAPT SAWYER: Thank you, Patty. I want to note that Georges Benjamin is trying to call in, so we're going to have to get back to him. Now I'm going to go to the, would you like me to go to the ex officios? Okay. Well I'm going to begin with those that I know are on the phone. Vince Michaud?

DR. MICHAUD: This is Vince Michaud and I agree with the recommendation and don't have any comments for the paper, thanks.

CAPT SAWYER: Randall Levings?

DR. LEVINGS: I just want to thank the Working Group and the staff for the hard work. And no further comments. Thanks.

CAPT SAWYER: Let's go with Bonnie

Richter.

DR. RICHTER: I just wanted to thank you. I think we had a very productive meeting in September and appreciate everybody had the opportunity to comment on the recommendations. Thank you.

CAPT SAWYER: Hugh Auchincloss? Carole Hudgings, are you speaking for Hugh? Okay. Let's go to Bruce Gellin.

DR. GELLIN: Thanks. You know, like everything else I do, I see this work in the context of the National Vaccine Plan. And a key element of the plan is about informed decision making.

So I want to commend the Chairs and the Board for giving us a great example of informing this very difficult decision, not only looking at the science, but taking the pulse of the public.

And I think this is going to serve us all well as a good model. Thanks.

CAPT SAWYER: Thank you. Also, I note, Carole, that you are on the wrong line,

so we'll get back to you. Let's now go to Rosemary Hart.

MS. HART: I don't have a comment, Leigh.

CAPT SAWYER: Thank you. Are there ex officios that I have missed calling that are able to tell me if they are on the speaker line?

MS. POSTER: Hi. Diane Poster for Department of Commerce, Michael Amos. No comment.

CAPT SAWYER: Thank you. Anyone else?

DR. MARTINELLO: Richard Martinello from Department of Veterans Affairs and we have no additional comments either.

CAPT SAWYER: Thank you.

MS. DALEY: Rebecca Daley calling in for Assistant Secretary Dr. Kerri-Ann Jones from Department of State. We have no comment either. Thank you.

CAPT SAWYER: Thank you. Anyone else? Carol Hudgings, are you able to speak

now? Not yet? Okay. Is Georges Benjamin on?

Okay. So what would you like to do? Let's check the time. We would like to wait for both of those people. Dan, did you want to add any comments? Did you want to address the suggested modification?

DR. FAGBUYI: I think while we're waiting for two of our other members or contributors on the line, I think there was an issue that was raised with regards to the recommendation, agreeing with the recommendation, but with a modification.

And I think in our further dialogue, we'll probably, we'll talk about how to address that if that's needed. And I don't know if, is Skip Nelson on the line? I don't believe he's on the line.

CAPT SAWYER: No, he's not on the line.

DR. FAGBUYI: Okay. So I think we'll come back to that issue to be able to kind of discuss that. Are there any other comments from anybody else on the board or any

of our ex officios?

DR. GRABENSTEIN: This is John Grabenstein, if I'm speaking out of turn, then stop me. I agreed with the spirit of Ruth's comments. If I was taking notes properly, she said, a review board. And I'm wondering if the Pediatric Advisory Committee, I think of FDA, would be that board or, so a question somebody might be researching while we're doing other things.

DR. FAGBUYI: Yes, Ruth, would you care to comment on that?

DR. BERKELMAN: It might be. I think what I'm interested in is to have formal ethical consideration; we do not have ethicists on this board. A board that has public representation and ethicists would be good to address this issue. It could be specially convened or possibly be the Pediatric Advisory Committee; I don't want to put forward that specificity. John may be right.

DR. PARKER: Dan, this is John

Parker. I've reviewed the sentence that Ruth offered and I would recommend inclusion of the sentence. I think it clarifies and kind of puts our foot on the floor about the 407 issue.

But I would recommend, subsequent to John Grabenstein's comment that we change two words. This issue should be referred to an appropriate review board. And the rest stay the same.

DR. FAGBUYI: Okay, John. Anyone else on the board or any of the ex officios have any? All right, well Carole, do you have anything to add to that? Okay.

CAPT SAWYER: Carole Hudgings? Are you going to make comments for NIH? Okay.

DR. FAGBUYI: All right, so are there any other comments from the Board members or ex officios on the line? Very phone savvy. So I'll give my opinion on that, too.

I think it is clear, we want to be transparent, we want to be open. We

definitely had some ethicists involved in this whole process and we agree. I think that's the intent of the 407 process.

And with that said, I agree with John Parker's suggestion, I agree with Ruth's suggestion. I would take the issue, what John said exactly, to an appropriate review board, and clarify that. And if there's any dissent on that, please speak now - Board members or ex officios.

All right, with that said, so I think we're clear on that. Thank you, Ruth, for that addition. We should check and make sure all our voting members and others are on the line and we can get to the public comment.

CAPT SAWYER: I want to verify that Georges Benjamin is not on the line? I don't think he's been able to join yet. So operator, could you please queue up the public comment period, please?

OPERATOR: At this time, if you would like to ask a question or make a comment, you may do so by pressing star, 1 on

your telephone keypad. Again, that is star, 1 to make a comment or ask a question.

CHAIR QUINLISK: And this is Patty Quinlisk. I will just state that depending upon the number of public comments we have, we may need to put a time limit on each comment in order to ensure equal access to the public comment period for the public. Thank you.

OPERATOR: And your first comment is from the line of Jonathan Newmark.

CAPT SAWYER: And we will be timing these just to be fair to everyone, that they'll be only two minutes. Then we have to have all people prepared to make comments. Go ahead.

MR. NEWMARK: Quick question. I'm from the Joint Program Executive Office. We're, other than HHS, the major customer for AVA.

If HHS votes, Board votes to recommend to Dr. Lurie that HHS fund a study in children, have you considered what that study would look like pre-event? I'm

particularly thinking about a reduced dosage schedule or reduced challenge, given that work is going on to reduce the schedule down from six doses strikes me that, you know, the Board has very appropriately recognized that there are all sorts of problems in doing stuff with children.

And the fewer doses you can get away with, the better. The question is, what's the minimum data that you can obtain that would satisfy Dr. Lurie's challenge?

DR. FAGBUYI: So thank you for that comment. This is Dr. Fagbuyi. I want to be clear, and I appreciate your comment. Thank you for calling in and giving that comment.

By the way, so it's HHS and DOD. With that said, the question that we were asked, the Board was asked a specific question. Do this now, ahead of time before an event or do this after, during an event?

And that's the question we were asked to address. We addressed that question. Now that's on FDA and the other agencies that

would be involved in looking at this and how they would do the study. We don't include that detail in this tasking. Thank you.

MR. NEWMARK: Thank you.

OPERATOR: Your next question is from the line of Steven Fisher.

MR. FISHER: Yes, thank you for the opportunity to speak to you again. I was looking at Page 12, Page 17 and Footnote 36 and I'd like to make a comment to several -- to that, is that the Brentwood Postal Facility, I want to be clear on that, that no vaccine was used by those employees.

Then Page 31, there's reference to some terrorist activity for use of the anthrax agent, and again we know that the terrorist attack that was used in the letters was from the U.S. and delivered by a U.S. citizen.

On Page 14 there's a statement, says that, indicates the product has been licensed to 1970, but that question was raised in federal court with Judge Sullivan and ultimately the license procedure was completed

in 2004.

In Appendix 9, we see a package insert and as I spoke to you in July about the package inserts that is currently in Appendix 9, isn't the original package insert that accompanied the anthrax vaccine.

And as you reference in many occasions throughout the report, the draft report, you depend on the Institute of Medicine and other reports that were developed in the '90s and 2000's pertaining to the use of the vaccine.

But yet, the original package insert is not included. And then another statement that's implied in the report that I am alarmed about is that you say that there's been monitoring of military personnel after the use of the vaccine, and we know that's not the case.

And Congress attempted to address that case by requiring monitoring of military personnel after the vaccine.

CAPT SAWYER: Thank you. Thank you

very much, Mr. Fisher.

MR. FISHER: Thank you, ma'am.

CAPT SAWYER: Operator?

OPERATOR: Okay. Your next question is from the line of Vera Sharav.

MS. SHARAV: I'm from the Alliance for Human Research Protection. And I'd like to remind everyone that U.S. law prohibits exposure of children to greater than minimal risk in clinical trials if no direct benefit is expected.

The only exception is a study for the prevention or alleviation of serious problems affecting the health or welfare of children. There is absolutely no evidence that anthrax is a serious problem affecting U.S. children.

The vaccine poses substantial risks of severe adverse effects including permanent disability and death. Anthrax is only one of more than a dozen biological agents that could be used by terrorists, so why all the emphasis on anthrax?

The answer is, follow the money. This initiative is not about protecting children, but rather about protecting the vaccine manufacturer's obscene profit margins. A 2010 report based on FEC disclosure documents shows how Emergent Biosolutions, whose only product is the anthrax vaccine, whose only customer is the U.S. government, has been price gouging U.S. taxpayers, raking in an enormous profit of 300 percent.

Those profits have been used for large political contributions and heavy lobby duty. The proposed trial is an unconscionable exploitation of children's vulnerability as non-consenting subjects.

The trial would expose healthy children to substantial risks of harm with no direct benefit. It is by definition, unethical. A GAO 2007 report stated that between one and two percent of vaccinated individuals experience severe adverse events which could result in disability and death.

And FDA approved label say s that

approximately six percent of reported adverse events were listed as serious, resulting in death, hospitalization, permanent disability and were life threatening.

Antibiotics are the proven treatment of choice when the vaccine's benefits are not --

CAPT SAWYER: Thank you. Operator, we need --

OPERATOR: Okay. Your next question is from the line of Meryl Nass.

CAPT SAWYER: Thank you.

DR. NASS: Thank you. I had a couple of comments. One is that I would be happy to give you all a copy of the slide from MILVAX and the vaccine healthcare centers that points out that there are one or two percent serious adverse effects from the adults from anthrax vaccines.

And furthermore, in the CDC trial, there were about seven to eight percent serious adverse events reported to FDA in the anthrax vaccine trial that has never had a

final publication.

My other point is that although you were almost unanimous in supporting this trial, the American public that's commented on the article by Rob Stein has, in the hundreds, been almost unanimously against it.

So it's interesting to see how people inside the beltway seem to think differently than the rest of the country and I think government officials might take that to heart.

CAPT SAWYER: Thank you. I suppose we're ready for the next person.

OPERATOR: Your next question is from the line of Steve Krug.

DR. KRUG: Hello, can you guys hear me?

CAPT SAWYER: Yes.

DR. KRUG: Oh, that's a yes, thank you. I actually first want to, my name's Dr. Steve Krug, I'm a pediatric emergency physician in Chicago, so well outside the beltway and the Chair of the American Academy

of Pediatrics Disaster Preparedness Advisory Council.

Numerous representatives from the American Academy of Pediatrics, which is an organization of 60,000 pediatricians and pediatric specialists were privileged to participate in the workshop this summer and I would like to, on behalf of the academy, applaud the Working Group for its excellent work.

The ethical issues were discussed rather precisely and there are ethical issues both with a pre-exposure trial as well as tying to understand the efficacy of the vaccine after something has happened.

And the members of the academy who were present at this workshop, so these are all folks who don't work for the government, were in support of the recommendations of this Working Group.

This is a very challenging question, as Dr. Lurie pointed out and several others have pointed out. The ethical issues

in the review I think are very pertinent and should be considered to be evaluated, but again, I support the recommendations of this Working Group. Thanks for the opportunity to speak.

CAPT SAWYER: Thank you, Dr. Krug. We have two more individuals lined up and then we'll have to stop after those two. Operator, the next one, please.

OPERATOR: Yes. Your next question is from the line of Robert Malone.

DR. MALONE: Hi, thank you very much. I'm a physician scientist that specializes in vaccines and biodefense and I just wanted to lend my voice to the first comment in this public series.

That if it's possible for the committee to advocate NIAID investments in dose pairing in this pediatric population, dose pairing studies for this vaccine, I suspect that that will be warranted due to the potential AE profile and hopefully might still enable sufficient immunogenicity.

That's all I wanted to say.

CAPT SAWYER: Thank you. Our next speaker?

OPERATOR: Yes, your next question is from the line of Franklin Cousin. Your line is open.

CAPT SAWYER: Okay, I guess there are no comments there? This is Leigh Sawyer. I know that Georges Benjamin is now on the line and I apologize to you, Georges, that you had difficulty joining us this afternoon.

What we had done is we went around to all the voting members and to the ex officios to ask for specific comments on the full document. This is your opportunity to provide your comments.

DR. BENJAMIN: Hi, this is Georges Benjamin. Can you hear me?

CAPT SAWYER: Yes, we can.

DR. BENJAMIN: Yes, just to point out that I think it's a very good document. And of course, I bring to the perspective the fact that I was the health officer in Maryland

when we had the anthrax letters.

And I have to tell you, this was an issue that we were very concerned about and we pondered over, so I read the document through the lens of someone who actually had to think about what we would do had we had children's exposures at that time.

So I think all of my colleague have done a very, very good job of trying to understand the risks and benefits. This is a good document, which of course, I support. Thank you.

CAPT SAWYER: Thank you very much, Operator. Our public discussion has ended and now we have all the comments from our voting members and ex officios. I'm going to turn this meeting back over to Dan, if you have further comment or John Parker?

What we're ready to do now is go to Patricia Quinlisk for the vote on the recommendation.

CHAIR QUINLISK: Yes, thank you, Leigh, this is Patty Quinlisk. What we're

going to do now is go ahead and vote for -- the National Biodefense Science Board to vote on the Anthrax Working Group's recommendations. We will do this by roll call, go person by person and at that time, please vote whether you wish the recommendation to go forward from the National Biodefense Science Board to the Secretary or you're against this recommendation going forth from the Biodefense Board to the Secretary.

So we will go through this by roll call and so I will turn it back over to Leigh Sawyer for that roll call, or for the vote.

CAPT SAWYER: Thank you, and Patty, I wanted to clarify, will that be with the modification as proposed by Ruth Berkelman and modified by John Parker?

CHAIR QUINLISK: Yes, I'm sorry. Since I heard nothing but support for that I think we will go ahead with the recommendation from words with the modification from John Parker. And maybe you should read that one more time so we're all clear on exactly where

that modification ended up.

DR. FAGBUYI: Yes, this is Dan Fagbuyi, so I'm going to read that. So the NBSB recommends Option 1, in light of the current HHS plan to follow the ACIP recommendations for the use of AVA for post-exposure prophylaxis following exposure to b. anthracis spores.

This issue should be referred to an appropriate review board to formally address the ethical considerations. This board should include ethicists and public representation. If ethical considerations are adequately addressed, HHS should develop a plan for and conduct a pre-event study of AVA in children to include a research IND.

HHS should submit the study protocol to one or more IRBs and comply with 21 CFR 50,54/45, CFR 46.407, Federal Review Process. This recommendation should be revisited if new anthrax vaccines or other therapeutic countermeasures become available.

CAPT SAWYER: So we are right -- so

the board members are going to be voting on sending the report with the recommendation forward to the Secretary. I'll begin with Pat Scannon. Do you agree? Do you approve?

DR. SCANNON: I agree. I approve.

CAPT SAWYER: Betty?

DR. PFEFFERBAUM : Yes, I approve.

CAPT SAWYER: John Parker?

DR. PARKER: I approve.

CAPT SAWYER: Tom MacVittie?

DR. MACVITTIE: I approve.

CAPT SAWYER: Kevin Jarrell?

DR. JARRELL: I approve.

CAPT SAWYER: John Grabenstein?

DR. GRABENSTEIN: I approve.

CAPT SAWYER: Dan Fagbuyi?

DR. FAGBUYI: I approve.

CAPT SAWYER: David Ecker?

DR. ECKER: I approve.

CAPT SAWYER: Jane Delgado?

DR. DELGADO: I approve.

CAPT SAWYER: Steve Cantrill?

DR. CANTRILL: I approve.

CAPT SAWYER: Ruth Berkelman?

DR. BERKELMAN: I approve.

CAPT SAWYER: Georges Benjamin? Georges?

DR. BENJAMIN: I approve.

CAPT SAWYER: Patty Quinlisk?

CHAIR QUINLISK: I disapprove and I oppose this recommendation going forward.

CAPT SAWYER: Thank you. With the one disapproval, this is a majority decision and the recommendation appears to be ready to go forward. Do you agree, Patty?

CHAIR QUINLISK: Yes, I do. Okay. I believe that Dr. Lurie is on the phone. Dr. Lurie, did you want to make additional comments?

DR. LURIE: Sure I will. And, you know, thank you again to all of you for your work around this. Obviously the NBSB has voted to transmit these recommendations to the Secretary and I know that the board understands this, but I want to be sure that everybody listening and on the phone also

understands that the Board is an advisory body and as such that its recommendations are simply that, but they're really not binding in any way.

We all very much appreciate the thoughtful and hard work. This is a really complicated issue and I think you've just heard more from the comments today just what a complicated issue is it. And from reading the transcripts of the other meetings, we know that others are also grappling with many of the related important issues.

About both anthrax and about protecting children in general the board's work is very helpful to us and are clearly going to consider it along with the other information and perspective, including ongoing planned, dose baring studies in adults.

Over the coming months, I very much appreciated the discussions about the ethical issues and concerns. As the committee pointed out, those are also ones that we take extremely seriously and need to continue to

consider as part of our deliberations, which remains a really complex area.

And we look forward to receiving the recommendations of the group. It probably won't surprise any of you to hear that we're not ready to make a decision at this time, but that we will continue to have dialogue with you and keep you posted and informed as we go forward. Thank you.

CHAIR QUINLISK: Thank you, Dr. Lurie. I appreciate your comments and wish you luck in the future in continuing to deal with this very complex and difficult topic.

DR. LURIE: And I want to just say I look forward to continued work with the NBSB. I'm hoping that the next thing I ask you to do is going to be a lot easier and I indeed expect that it will. You guys have just been a terrific group of people to live with.

CHAIR QUINLISK: Well thank you again, Dr. Lurie, and I'd like to again thank not only the Working Group but the incredible

work of the Chair and Co-Chair and of course all the background work including late night work done by the staff of the NBSB to ensure that this report was complete and responsive to the Working Group.

So thank all of you very much, too, for all of your time and efforts in this report. I think, then, Leigh, unless we have something else, I'd like to go on to discuss some of the future topics.

CAPT SAWYER: Yes, that's good.

CHAIR QUINLISK: Okay. As you know, this ends one of the topics that we have been asked to deal with, but of course, the work of the NBSB does not end. We have several topics that have been brought up at various times during meetings.

And so what I would like to do is bring those topics back up and have a very brief, I think, discussion on this, or if we don't have time for discussion, at least to bring it up and have people start thinking about these issues to discuss at our next

meeting.

So there are six issues that have been brought up to the NBSB. The next one is the 2012 PHEMCE Strategy and Implementation Plan. This is something that I know we've talked about previously in the past but this is something that I believe we are going to be asked to comment on the future.

And Leigh, maybe I could ask you to maybe talk about that for just a second?

CAPT SAWYER: I don't have much information. I think it has been something that Dr. Lurie is considering the best way to obtain input from the NBSB on the progress and completion of the 2012 PHEMCE Strategy and Implementation Plan.

And I think the opportunity to actually formally present that to the board was not available at the time of this meeting, so that may be coming.

CHAIR QUINLISK: Okay. Thank you, Leigh. Also, one of the issues that we have talked about among the board is how to plan

for unknown threats. I think that's been discussed and I won't clarify any further here.

The next one, again, is one that we have brought up at previous meetings and that is the National Strategy for Development of Diagnostics.

The next one, again, is something that has come up multiple times and that's the eHealth or social networks and communications issues, particularly around responding to events or specific disasters. So that is Number 4.

Number 5 is integrating the countermeasures research portfolio, again, I believe that this is something that is of particular interest to several people on the board and it has been brought up to us.

And the last one is an issue that comes up, particularly in context of other things, and that's Community resilience in the face of a disaster or an attack.

So I'm looking at my clock right

now and we have a couple of minutes. I would like to see if any Board members have any comments to make on any of these six or on other issues? So at this time, could I open it up for discussion among the Board members?

DR. FAGBUYI: Hi, Patty. This is Dan Fagbuyi. The issue of an unknown threat I think is germane to our work and very interesting and important and has implications for pediatric and adult populations but also around in different areas. Rural, urban, different segments. So I think that's a crosscutting issue that should be addressed, so I would push that up as a priority issue.

And that obviously the PHEMCE Strategy 2012 is another piece. So I think those are the two top issues that I would move up.

CHAIR QUINLISK: Thank you, Dan. Other comments from members?

DR. PARKER: Patty, this is John Parker. I agree with Dan. I think that issue should be on the top of the list, but because

we have talked so much and we've heard many officials talk about the building resiliency across the nation, I think that a report should be developed by the Board on developing resiliency of our American public.

CHAIR QUINLISK: Okay, thank you, John. Other comments?

DR. JUTRO: Are you taking comments from ex officios now?

CHAIR QUINLISK: I would be glad to take comments from ex officios also. Please go ahead.

DR. JUTRO: It's Peter Jutro.

CHAIR QUINLISK: Hi, Peter.

DR. JUTRO: I'm also enthused about that one. I would, and I agree with what both previous speakers have said, especially John's comment on the resilience. But I just wanted to ensure that it has to be broader than just medical.

CHAIR QUINLISK: Okay, thank you for your comments. So yes, now if there are comments from Board members or ex officio

members, please go ahead. Okay. Hearing none, what I think, since we really are running out of time, I'd like people to take those possible issues, think about them and we will do, obviously further discussion of those at our next meeting, which does bring us up to the next meeting. Leigh, could you give us a little bit of the information about the next meeting?

CAPT SAWYER: Yes. Our next in person public meeting of the NBSB is scheduled for January 12, 2012. It will be held in the Washington D.C. area. It's currently scheduled to be a one day meeting and we will make that information available both through our Federal Register notice and on our website.

We'll also send things out through our email list. And I would just like to thank the NBSB staff, Jomana Musmar and MacKenzie Robertson for all of their help and thank all of those participating in this call today.

CHAIR QUINLISK: Okay, thank you, Leigh. So everybody get that date on your calendars and then unless we have any other topics or issues, Leigh or anyone?

CAPT SAWYER: No, that's it.

CHAIR QUINLISK: That's it? Okay, well then we're right on time. I believe we are wrapped up and I hope to see everybody in January and again, thank all, everybody, for all of their work, both on the meetings that we are having and in particular for this meeting, all the work done on the Anthrax Vaccine Working Group.

Thank you all and have a great weekend. Bye-bye.

OPERATOR: This concludes today's conference call. You may now disconnect.

(Whereupon, the above-entitled matter was concluded at 4:00 p.m.)