NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC MEETING

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THURSDAY,
SEPTEMBER 22, 2011

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The meeting convened at 9:00 a.m. in the Sphinx Grand Ballroom of the Almas Temple, 1315 K Street, N.W., Washington, D.C., Patricia Quinlisk, Chair, presiding. Leigh Sawyer, Designated Federal Official.

NBSB VOTING MEMBERS PRESENT:

PATRICIA QUINLISK, 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.*
JOHN S. PARKER, M.D., Major General (Ret.)
PATRICK J. SCANNON, M.D., Ph.D.

DESIGNATED FEDERAL OFFICIAL:

CAPT LEIGH SAWYER, U.S. Public Health Service

*participating via telephone

EX OFFICIO MEMBERS PRESENT:

VINCENT MICHAUD, M.D., Office of the Chief Health and Medical Officer, NASA *designated by Richard Williams, M.D.)*
RANDALL L. LEVINGS, D.V.M., National Center for Animal Health, USDA*
BONNIE RICHTER, Ph.D., Office of Health Safety and Security, DOE,(*designated by Patricia R. Worthington, Ph.D.*)
CAROLE HUDGINGS, Ph.D., National Institute of Allergy and Infectious Diseases, NIH, HHS*(*designated by Hugh Auchincloss, M.D.*)
BRUCE GELLIN, M.D., M.P.H., National Vaccine Program Office, Office of the Assistant Secretary for Health, HHS
TRACY D. PARKER, R.N., Ph.D., Health Threats Resilience Division, Office of Health Affairs, DHS *(designated by Sally Phillips, R.N. Ph.D.)*
ROSEMARY HART, J.D., Office of Legal Counsel, DOJ
ANDREW FLACKS, ASPR/HHS Liaison, Office of Public Health and Environmental Hazards, Department of Veterans Affairs (*designated by Victoria J. Davey, Ph.D., M.P.H.*)
PETER JUTRO, Ph.D., National Homeland Security Research Center, EPA

*participating via telephone

ANTHRAX VACCINE WORKING GROUP MEMBERS PRESENT:

RICHARD GORMAN, M.D., National Institute of Allergy and Infectious Diseases, NIH, HHS
CYNTHIA KELLEY, M.S., Center for Biologics Evaluation and Research, FDA, HHS
ROBERT "SKIP" NELSON, M.D., Ph.D., Office of Pediatric Therapeutics, Office of the Commissioner, FDA, HHS
NICKI PESIK, M.D., Office of Public Health Preparedness & Response, CDC, HHS
PRESENTER ON PAHPA REAUTHORIZATION:

ZENO ST. CYR, II, M.P.H., Director of Legislative Coordination, Office of the Assistant Secretary for Preparedness and Response, HHS

STAFF PRESENT:

JOMANA MUSMAR, M.S., Policy Analyst, Contractor
MacKENZIE ROBERTSON, Program Analyst

PUBLIC COMMENTERS:

VERA HASSNER SHARAV, President, Alliance for Human Research Protection (letter submitted via email)
AL ROMANOSKY, M.D., Ph.D., Maryland Department of Health and Mental Hygiene (via telephone)
CLAIRE DWOSKIN
MERYL NASS, M.D., The Alliance for Human Research Protection

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

C-O-N-T-E-N-T-S(Cont'd)

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

(9:05 a.m.)

CAPT SAWYER: Good morning. I'd like to welcome everyone to the National Biodefense Science Board public meeting. The NBSB Voting Members, the NBSB ex officios or delegates, members of the Anthrax Vaccine Working Group, and members of the public.

I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board. I also serve as the Designated Federal Official for this Federal Advisory Committee.

Today's meeting will cover a discussion of the draft executive summary developed by the Anthrax Vaccine Working group, and we will hear about the status of the reauthorization of the Pandemic and All Hazards Preparedness Act.

Before we begin today's meeting, I would like to take a roll call of the NBSB Members here, and attendance on the telephone. I will call out the names of the voting members, and if you would please answer if

you're here? Okay.

Patty Quinlisk?

CHAIR QUINLISK: Right here.

CAPT SAWYER: Georges Benjamin?

(No response.)

CAPT SAWYER: Ruth Berkelman?

MEMBER BERKELMAN: I'm on the phone. Good morning.

CAPT SAWYER: Hi. Good morning, Ruth.

Steve Cantrill?

MEMBER CANTRILL: Present.

CAPT SAWYER: Jane Delgado?

MEMBER DELGADO: Present.

CAPT SAWYER: David Ecker?

MEMBER ECKER: Present.

CAPT SAWYER: Dan Fagbuyi?

MEMBER FAGBUYI: Present.

CAPT SAWYER: John Grabenstein?

MEMBER GRABENSTEIN: Present.

CAPT SAWYER: Kevin Jarrell?

(No response.)

CAPT SAWYER: Tom MacVittie?

(No response.)

CAPT SAWYER: John Parker?

MEMBER PARKER: Present.

CAPT SAWYER: Betty Pfefferbaum?

(No response.)

CAPT SAWYER: Pat Scannon?

MEMBER SCANNON: Present.

CAPT SAWYER: Now I would like to call the names of ex officios. And if you are serving as a designee, please give your name at that time.

Franca Jones?

(No response.)

CAPT SAWYER: Larry Kerr?

(No response.)

CAPT SAWYER: Richard Williams?

DR. MICHAUD: Vince Michaud for Richard Williams.

CAPT SAWYER: Thank you, Vince. Randall Levings?

DR. LEVINGS: On the phone.

CAPT SAWYER: Good morning, Randall. Mike Amos?

(No response.)

CAPT SAWYER: Patricia Worthington?

DR. RICHTER: Bonnie Richter for Pat Worthington.

CAPT SAWYER: Good morning, Bonnie.

DR. RICHTER: Good morning.

CAPT SAWYER: Ali Khan?

DR. PESIK: Nicki Pesik for Ali Khan.

CAPT SAWYER: Hello, Nicki. Hugh Auchincloss?

DR. HUDGINGS: Carole Hudgings for Hugh Auchincloss.

CAPT SAWYER: Hi, Carole. George Korch?

DR. KAPLOWITZ: Lisa Kaplowitz for George Korch.

MEMBER CANTRILL: Hi, Dr. Kaplowitz. Carol Linden?

(No response.)

CAPT SAWYER: Bruce Gellin?

DR. GELLIN: Bruce Gellin for Bruce Gellin.

(Laughter.)

CAPT SAWYER: We're glad you're here, Bruce. Luciana Borio?

DR. COURTNEY: This is Brooke Courtney for Lu Borio.

CAPT SAWYER: Hi, Brooke. Sally Phillips?

DR. PARKER: This is Tracy Parker for Sally Phillips.

CAPT SAWYER: Hi, Tracy. Lori Caramanian?

(No response.)

CAPT SAWYER: Rosemary Hart?

MS. HART: Present.

CAPT SAWYER: Kerri-Ann Jones?

(No response.)

CAPT SAWYER: Vicki Davey?

DR. FLACKS: Andy Flacks for Vicki Davey.

CAPT SAWYER: Hi, Andy. And Peter Jutro?

DR. JUTRO: Present.

CAPT SAWYER: And Patricia

Milligan.

(No response.)

CAPT SAWYER: Great. All right. Thank you. Let me go through a couple of things here. The NBSB is an advisory board that is governed by the Federal Advisory Committee Act. The FACA is a statute that controls the circumstance 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 the group are not federal employees.

The majority of the work of the NBSB, including information-gathering, drafting of reports, and the development of recommendations, is being performed not only by the full Board, but by the working groups who in turn report directly to the Board. This is the case today with the Anthrax Vaccine Working Group.

With regard to the conflict of interest rules, the Standards of Ethical

Conduct for Employees of the Executive Branch document has been received by all the Board members, who as Special Government Employees are subject to conflict of interest laws and regulations therein.

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

Board members must be attentive during the meeting to the possibility that an issue may arise that could affect, or appear to affect, their interests in a specific way. Should this happen, it would be asked that the affected member recuse himself or herself from the discussion by refraining from making comments and leaving the meeting.

We will have a public comment period today from 11:30 to 12:00. The public will have an opportunity 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 we can better anticipate how many people we will need to accommodate during the public comment period.

The comments will be limited to two minutes today, in that we expect several comments. I would also like to remind everyone that this meeting is being transcribed, so when you speak, please provide your name. The meeting's transcript, summary, and any printed documents will be available on our website. The draft executive summary is on the website now, so if you are on the telephone, you can use your browser. If you do not know our website, find NBSB and it will

take you to where these documents are available.

We will not be monitoring our email box today, so if you do have comments relevant to this meeting, you need to use the speaker line when the comment period is open, or you can send them and we'll be looking at those tomorrow.

So now I would like to turn the meeting over to the Chair, Patty Quinlisk, for a welcome and overview.

CHAIR QUINLISK: Good morning, everyone. I'm very glad to see everybody here this morning. I think we have a very interesting day in front of us. I know that the Anthrax Working Group, and particularly John and Dan, have been working very hard on the report. And of course, that's going to take the main portion of our day, is discussing that report and the issues surrounding the anthrax vaccine.

The other thing we will be doing, later on today, is getting an update on the

reauthorization of the Pandemic and All Hazards Preparedness Act. And that will happen after lunch.

So I think, with no further ado, I'm going to go ahead and introduce our first speaker, which everybody on the Board, I believe, knows. And that's Lisa Kaplowitz, who is the Deputy Assistant Secretary for Policy and Planning, out of the Office of the Assistant Secretary for Preparedness and Response.

Thank you, Lisa.

DR. KAPLOWITZ: Well, first, I want to give regards from Nicki Lurie, who always stays in touch even though she's out of the country. So thanks from Nicki for everybody's hard work.

And thanks to the Board for the recent report about scientific investigations as an integral component of disaster planning and response. ASPR is doing its best to integrate this into our ongoing work, challenging as that may be with all the budget

cuts we face. But it's very, very important to us, and especially to Dr. Lurie.

I just wanted to review for a few minutes the charge to the Board. In January 2004, the Secretary of Homeland Security determined that anthrax is a material threat to the United States. Of course, we don't know exactly what the risk is, but there is a possibility that we will face wide exposure to anthrax. And as a reminder, this isn't only theoretical. We've already had a situation where many people have been exposed to anthrax, and we would be remiss to not address this risk.

HHS has pursued a comprehensive strategy to address the threat of anthrax, has made substantial investment in the acquisition of medical countermeasures in the strategic national stockpile, both antibiotics for treatment of the entire vaccine, and BioThrax, or Anthrax Vaccine Adsorbed, AVA, which as we know is available for adults over the age of 18.

We continue to face policy challenges in the use of medical countermeasures, and especially in the potential use of AVA, should we be facing a widespread anthrax event.

To clarify some misconceptions, no decision has been made to proceed with any vaccine clinical trials in pediatric populations, but we would be remiss to not address this issue now. The American people expect that we will have discussed this and faced the challenges prior to the need for AVA in the general population.

And the infectious disease part of me wanted to remind people that anthrax is a very unusual organism. While it isn't transmitted person to person, we know that the spores can remain in the environment for prolonged periods of time, which causes us to face some unique challenges should we face an anthrax event impacting many in the population.

I understand that the Anthrax

Vaccine Working Group is still in the process of developing their final report, and I look forward to the discussion today in terms of their deliberations and input from the public.

I am also pleased that Zeno St. Cyr is going to present an update on PAHPA. We are pleased with how the reauthorization is moving forward. That will be all the way -- the bill that will come out of the Senate. And we have been partnering very closely with Congress and our partners within the federal government in terms of developing this reauthorization legislation.

And last, I want to give a welcome to Dr. Diane DiEuliis. You can stand up here. I finally have a deputy. She is Deputy in the Office of Policy and Planning within ASPR. She comes to us most recently from the Office of Science and Technology Policy, OSTP, within the White House, where she was Assistant Director for Life Sciences, as well as Social and Behavioral Sciences. And prior to that, she spent many years at the NIH, in the

National Institute of Neurologic Disorders and Stroke.

She's only been on board maybe a month and a half, and I am thrilled with having her on board. She's jumped right in. Though I don't think she fully realized what she was getting into, she hasn't shown any regrets so far, which I'm thrilled with.

So with that, I'm going to turn over the microphone to Dr. Fagbuyi and Dr. Parker -- I don't know which one of you will be first -- who will discuss the charge to the Board.

CAPT SAWYER: Dr. Kaplowitz, thank you very much. This is Leigh Sawyer. I did not call Dr. John Skvorak from the DoD in that roll call. I just wanted to give him an opportunity to indicate that he's on the line, if he is on the line. And have any of the other voting members joined the call, can you tell me? Has anyone else joined the call that's a voting member of the Board?

(No response.)

CAPT SAWYER: Okay. Thank you very much.

MEMBER FAGBUYI: Good morning. Dr. Kaplowitz, thanks for those comments. My name is Dan Fagbuyi, and I'm the chair of the Anthrax Vaccine Working Group. And my partner in crime, my co-chair, General John Parker, is here also.

I just wanted to set the tone for this morning. This is part two of our first public engagement. This is really the public meeting on it. I say good morning and welcome to everyone who took time to make it here. And for those who are on the call, thank you.

I also want to state the goals for this morning. My intent this morning -- or our intent -- is to give an overview and background of what we were tasked to do and what we have come up with. And again, I think we need to reemphasize that the Board has not made a decision today. We will not be deciding or voting on the topic at hand. We have not made a decision in general to say

that we're going to vaccinate children, or do anything.

However, the executive summary gives a good account of all the data that we've compiled through our experts, our panels. We've been working with the public engagement piece that took place a few months ago. Our intent today is to dissect the executive summary. We will go through section by section, with your comments, the panelists and the public, to put their comments on what things may need to be changed, or what issues may further need to be looked at. That is our goal for today.

After we get that, we will compile this data, revise this document, and have a final document, hopefully within four weeks from now, to be able to present to the public. I hope that kind of clarifies what our intent and goal for today is.

With that said, I'll go into the discussion. So we'll follow through the slides. I'm not a fan of death by PowerPoint,

so you'll look at the slides and you should have some handouts which summarize the issues at hand.

This slide shows the Anthrax Vaccine Working Group mission statement under the NBSB. And our charge is that the Anthrax Vaccine Group will actually identify and explore the risks and benefits of using Anthrax Vaccine Adsorbed in pediatric populations. We would also focus on the risk communication, legal, and ethical considerations and challenges throughout the continuum of preparedness and response.

We have a proposed plan that's already in place. The government has not been asleep at the wheel. They actually have plans in place, should this happen. So it's important to highlight that. In the event of some anthrax release of spores, the current plan is to ensure that AVA vaccine and antibiotics are actually made available to children and adults following the actual or potential to anthrax spores.

Vaccination under this emergency condition would actually be voluntary. And for individuals who are under the age of 18 years, they would actually require informed consent from a parent or legal guardian, under the current Investigational New Drug mechanism, the IND intended for AVA PEP, or post-exposure prophylaxis, in short.

There are a few questions that were asked of the Board, and I just wanted to give some background on that. Dr. Lurie gave us a task, and that's four interesting questions, which have been a challenge to the Board and to this group, to actually answer those.

And in our process today, we will also be looking at the responses to those questions, and if there were any things that we did not discuss, we would hope that you would chime in and give us your comments on that.

So the first question of the Board, this asks about the risks and benefits of attempting to perform an AVA vaccine safety

and immunogenicity research protocol study pre-event, before something happens, versus after an event.

The second question was regarding the challenges of administering such a vaccine under an IND, and how those challenges would actually compare with the ethical challenges and considerations that would permit us to have enough data for use under an EUA, emergency use authorization.

The third question looked at pre-planning steps: what are the things that we should actually be doing ahead of time, that the government should do to optimally perform such an investigational protocol after an attack.

And lastly, how should the government communicate the risk to the practitioners and others, families, governments, other partners, both health officials and political officials, in response to an attack.

So that was the task at hand.

Great conflicts, as you can see. There's no right or wrong answer; you look at both sides of the coin. But at some point, we have to stand up and take responsibility, and think ahead for the future of our children. This is the first time kids have been really put on the radar.

This doesn't mean that kids weren't thought about. It just means we haven't really focused a central and important issue around children. And I think this is a great step by the government, and under the leadership of Dr. Lurie.

So there were options that were considered by the Board. And option one was to conduct a pre-event research IND protocol. Option two was to conduct a post-event IND protocol. And we came up with recommendations on what the government should do.

I'm going to pause here, because I want us to go into the executive summary, to now actually put all these kinds of things together, to give a background on what we've

done, what information we have, look through that information, and see if there are any things we need to change, and get a good idea of where we need to move forward, or what things we need to change, what other things we did not think about, and opportunity for public comment for those who were unable to be a part of the initial public engagement to be able to further discuss these issues.

MEMBER PARKER: The rest of the meeting will be conducted in our place. We don't have to go to the podium unless someone really wants to go up to the podium and show us a slide or something that they may have in their pocket.

Just for clarification, the Board members and the ex officios that -- the tradition is that you tip your sign up in a vertical position if you want to speak. And hopefully, with our peripheral vision and everything, we don't slight people. And I depend on my co-Board members across the way to make sure that we know if there are signs

coming up behind us. And also on the phone, Board members, just interject to let us know that you want to speak.

The iterations of the report and of the executive summary have been numerous, and they've been well-circulated. And Dan and I are exquisitely indebted to the support that we've had from Captain Leigh Sawyer and the headquarters team. Without them, it would be nothing more than probably an adventure to the abyss.

The other thing is that Dan and I are exquisitely pleased with the number of people from various professional organizations, all interested agencies within the United States government. And people who feel strongly pro about what we're doing and those who do not agree with us have all had equal opportunity to speak to Dan and I, and the Board, so that we are not in the dark about where people sit on this situation, or how they feel about this particular situation.

And this makes us feel pretty good,

because the worst thing you can do is sit down to write a report and have no one care. And so people do care about this issue. They do care about children. They do care about the threat of anthrax. They do care about the post-exposure prophylaxis. And they do care very strongly about the use of this particular vaccine in the post-exposure prophylaxis regimen.

So with that background -- you know, Dan unleashed me here, so he has to throw the leash on me if I get out of control. But this all started -- and I encourage people to have the executive summary in front of you, because it's very, very important, as we go through the background --

CAPT SAWYER: John, I'm going to interrupt you, because you weren't really properly introduced. So people on the phone may not even know who's talking.

MEMBER PARKER: Oh.

CAPT SAWYER: This is Dr. John Parker, General John Parker, retired. And he

is the co-chair of the Anthrax Vaccine Working Group.

MEMBER PARKER: Gosh, I thought I could do this anonymously.

(Laughter.)

MEMBER PARKER: But this is -- the background of this is that we are extremely lucky to have an agency like Health and Human Services that really has a global vision of taking care of people in this nation, under all circumstances.

And yes, they work with other agencies, but when it comes down to the bottom line, the Secretary of HHS, with her very astute agencies within the HHS, really are our public health scientific resources of this nation.

And the Department of Homeland Security is very concerned about our national security. So when they respond to various scenarios, and they do what I would call studies of these different scenarios, they bring a lot of people to bear on these

scenarios, so that they're dissected well. You not only know what the scenario is, but how it might be perpetrated. What is the result of the particular scenario?

And then an analysis of the results of that, and then a secondary analysis of how, operationally, we would manage that situation. One of those scenarios was an aerosolization of Bacillus anthracis. And that was looked at very carefully, as to an unannounced attack, and then a discovery by detectors, and then a careful analysis by dispersion techniques of how those spores would be moved by air, and physical means, et cetera.

Now, remember, this is not a contagious disease. So it would amplify if it were, but this is not a contagious disease. You have to actually come in contact with the spore to be affected by this disease.

As a result of that study, a large number of people would be affected by an aerosolization, and any particular number of people that are exposed by that

aerosolization, roughly 25 percent of any given population exposed is children. Will be children.

That's a pretty good statistic on any group, when you look at any population statistics. And so with that group, they looked at the post-exposure prophylaxis for that, and post-exposure prophylaxis means "How would we manage and treat the population that was determined by public health authorities to be exposed to the spore?"

And the recommendations from various groups who have looked at that -- the ACIP, the Institute of Medicine, the CDC, the FDA -- is that the post-exposure prophylaxis regimen should be mainly focused on an antibiotic treatment for immediate protection. And that antibiotic would be determined by the sensitivity of that particular anthrax spore. And then that antibiotic would be dispersed, and people would have to take that antibiotic for 60 days.

Also, when you look at the research

that has been done in the past, it was noted that in studies in non-human primates, even though they were given antibiotics for 60 days, once the 60 days were over we saw some of the animals actually look well, and then have the anthrax disease reappear.

And studies in that particular area demonstrated that although the time you're on the antibiotics -- the antibiotics are very good for those spores who have germinated and are in circulation in the lymph nodes and the bloodstream. But some spores remain in lymph nodes and other quiet places within the body. And if they don't sporulate, or if they don't germinate, the antibiotics are not effective on the spore.

And so, when the antibiotics are over and these germinate, the person can be reinfected. And so the answer was that if we treat people with antibiotics for 60 days and, concurrently, while they're on antibiotics, give them three doses of anthrax vaccine, the initial threat of having disease is stopped,

and having been vaccinated allows the individual to have an innate -- not innate, but an immunological response to any spores that would germinate in the future. The body is capable of destroying that germinated spore, and thus averting the possibility of a secondary relapse of the disease.

Now, if an adult appears to the distribution point where the post-exposure prophylaxis is being given, we know that this vaccine has been given -- we've given over 10 million doses to adults of this vaccine, and that represents about 1.2 million people. And the safety record of the vaccine in the adult population is certainly acceptable to the Institute of Medicine and to the ACIP.

Because this vaccine is being used in a different way than it's licensed for, the United States government would offer the adults not only the antibiotic but, with consent, they would offer the vaccine under what's called an emergency use authorization, to the adult, to give them total protection.

Now, why the emergency use authorization can be used on the adults is because we know the safety and the efficacy in adults. We're just using it for a different purpose. It's an off-label purpose, but we're convinced that it's safe and useful.

But that doesn't translate for children. Because in the data of anthrax vaccine with children, it's a null and void situation. We don't know anything about the safety, and we do not know anything about the immunogenicity of the vaccine in a child. And so vaccinating a child, the vaccine would be considered a new drug.

And so the way the government would give a child the vaccine would be under what's called an Investigational New Drug protocol. However, it would be a non-research protocol. But the parent would have to consent to giving the vaccine to the child.

The difficulty there is, we wouldn't be able to sit down with the parent at the time of the exposure and give them any

background data on safety or immunogenicity, or the dosing strategy, because we wouldn't have it if we were giving it post-event and had not done some sort of a study before the event.

That's the crux of our argument today. And so if you look at the threat, with the United States government, the people that determine threat have done that. And we're not here to question the threat today. And the probability of the event? Well, we've already had one event, so the probability is not zero anymore, for sure.

And so what we struggled with in this, looking at the Secretary's four questions, is if we believe in the threat, and we believe that there may be another event, and we believe that 25 percent of whatever population's affected will need to be given antibiotics and vaccine, should we know something about the vaccine ahead of time with the children? Or should we wait and, because of the probabilities, allow the event to

occur, allow parents to have their child vaccinated, and then take a subgroup of that group and study the immunogenicity, and follow them up closely about how they reacted to the drug?

That's where we are. And the Working Group struggled with that, and the first struggle we had was actually "Well, what would be a reasonable recommendation?" And it would have been very easy to just say "Well, let's just recognize that the Unites States government -- CDC, FDA, Health and Human Services -- have taken this problem and they have gone a long way with it. And they have looked at a lot of things, even to the point of planning research exercises and looking at what they would do in an event, and how that would be communicated, how that would be distributed, and all that sort of stuff."

So our report has -- it is certainly not a critique of the United States government. We certainly don't want it to be perceived that way at all. I think we've

discovered that the arguments that they put before us on this Board are not new arguments. That they have had plenty of opportunity to discuss these things within their own agencies, and everything. And it's a very, very tough subject, and they have sort of said "Well, let's give it to Mikey, and see if he likes the cereal."

And so we looked at that. Now, just some background information, so that everybody on the phone and everybody in this room is -- and I'm probably going a little tediously here, but this is important enough that at least the people in this room and on the phone, to really engage in the discussion, needs to know exactly where we are.

Let's talk about the anthrax vaccine first. AVA is licensed, and it's licensed for the prevention of disease produced by the Bacillus anthracis. It is licensed for prophylactic use, and it is licensed for the age group 18 to 65 years of age.

Now, where is that used most? It's used in the military, because we believe that our military that are deployed in certain situations may have a higher-than normal possibility of being exposed to a biological in the event that one of our adversaries should be forced into that.

The other thing is that we have thousands of people across the country who do research with the anthrax Bacillus, and because they are working with it every day, they, voluntarily, certainly want to be immunized to the vaccine.

So if you look at the 10 million doses that have been given, those are the two major groups that are getting it. There's a small number of first responder groups that have asked for the vaccine, and there are some other small groups that have asked for the vaccine under a special immunization program. But this vaccine has never really been one of what I call a public health vaccine, where you can walk into your doctor's office and request

to be vaccinated with anthrax vaccine. In fact, I have friends that want to be, and have limited access to get it.

So the other thing about the clinical use of AVA -- we certainly know that it's safe. And the risks of taking the vaccine are outlined in the package insert, and maybe a little later in the program we could go through those risks. But generally speaking, the risks of taking anthrax vaccine are no different than other vaccines that have been offered to the public.

It is a little more reactive, perhaps, than some other vaccines, but that's about it. So we have 2.5 million people vaccinated. Over 10 million doses. And we have the Institute of Medicine saying that it's reasonably safe, and we also know that it's efficacious, not by large studies, but by studies that have been done in woolen mills, by Brachman and group, and also by our non-human primate studies.

We have not studied it in children

at all, and I explained to you before that during an emergency, the Secretary of HHS may allow the anthrax vaccine to be allowed as a part of post-exposure prophylaxis, through an Investigational New Drug protocol.

Now, the ACIP recommends three doses of the vaccine as a component with the antibiotics, and I explained why that is. And the ACIP is on record, and it has been published in the MMWR, that 60 days of antibiotics are also important in that regimen.

Now, we also know that doing research with children is an extremely difficult thing to do. First of all, if you look at the amount of research that's done with children, you will find that it's minimal. You will find that it's done under very extraordinary conditions.

Most of the research that you see with children has been on an individual basis, with oncological or cancer drugs, where children have been enrolled in very specific

protocols for their particular cancer, to test, perhaps, a new drug that may give them benefit.

May give them benefit. So most of the studies with children, even though they are extreme and small, there's always been a way of describing the possibility of benefit over risk to the child. And so because children are a special population, they have special protections and they are unable to consent on their own. We have numerous protections under the Code of Federal Regulations and other regulations that say "If you're going to use children as research subjects, you must pass through some pretty significant wickets."

And at the bottom line, the argument of risk versus benefit to the child will be a supreme piece of the argument.

MEMBER FAGBUYI: Thank you for that, John. So I guess, as we're going through this -- and John has done a great job of setting the background information. But

the intent, as we go through this, is to really dissect this executive summary. So through the discussion we just went through, if you look at your handouts that you have -- and for the people at home, from the section on the background information of the executive summary, from pages 6 through 8, are there any comments on that, out of the group here?

To quickly summarize each paragraph, there's a paragraph that talks about the license indication, the data we have available, the dilemma for children, the ACIP recommendations, and the research. So I just broke it up into categories, and we can take some dialogue and some comments. Patricia?

CHAIR QUINLISK: I just had a question. I know that we have not used this vaccine in children at all, but we have obviously used it quite a bit in the military. And I was just curious as to whether or not we have any information on differences in side effects or response rates in the different ages of the military getting it.

Obviously, there are some military, I believe, that would get it at, say, 17, 18, 19, versus some that would get it at 30 or 40. And I would just be curious as to whether we know that there's any indication that younger age had a difference in response.

MEMBER GRABENSTEIN: John Grabenstein. I'm mentally going through the list of studies that have been performed in my head, which if I had an hour I could give you a more definitive answer than what I'm going to say off the cuff.

But nothing remarkable. One of the things was that there was a little bit of a gender differential in most of the injection site reactions, and that sort of thing, which has been found with other vaccines as well. On age, the study I'm remembering most clearly was one that looked at disability evaluations, and there was no differential -- no substantial differential, I need to go back and read the whole thing -- nothing remarkable based on age in that study.

And nothing else is coming to mind, but I'll scan this list that I've got in front of me and see what I can come up with.

CHAIR QUINLISK: Well, I do understand that, for example, women seem to be more reactive and have, maybe higher particularly local side effects, et cetera. Is there any understanding of the biological basis of that reaction that would, again, in any way potentially predict some of the reactions that children might have?

MEMBER GRABENSTEIN: For gender?

CHAIR QUINLISK: I'm just saying, do we understand --

MEMBER GRABENSTEIN: Or for age?

CHAIR QUINLISK: -- the biological nature of why women are reacting differently? And is that something that could be extrapolated to children?

MEMBER GRABENSTEIN: This is John Grabenstein again. So I have an anthrax vaccine answer, and I have an all other vaccines answer. The all other vaccines

answer is, sometimes women react more and sometimes men react more, depending on the study and depending on the vaccine. And there are a couple of Review articles. But it's nothing obvious. It's nothing extremely well understood.

With regard to anthrax vaccine, body mass index has been looked at and not found particularly informative. Stage of menstrual cycle has been looked at and not found particularly instructive. And I think those are the main two phenomena that have been looked at.

MEMBER FAGBUYI: Pat Scannon?

MEMBER SCANNON: I just have a couple of remarks, one of which is, since this is a public meeting and because of the nature of the subject, I would just suggest that if we start using medical terminology, that we simplify it, to make sure that anybody listening to this -- and I've been listening carefully. I don't think we've been egregious so far, but just to be aware of that.

I think the other thing I want to say is, there have been a proposal to use two forms of response in the event of attack. One of them is the vaccine, the other is the antibiotic. And you've correctly stated that 60 days of antibiotics would be part of the regimen, and that even after 60 days there is some chance of exacerbation from spores that remain in the GI tract, or wherever they are, after that 60 days.

I would just like to point out that a person could legitimately ask "Why aren't antibiotics good enough? Give it 80 days," or whatever. And you know, I think there are a number of answers, one of which is very simple. And I don't know if anybody has had to take antibiotics for any given period of time, but if you have to take it for 10 to 14 days, which is a typical period, by about the 10th day, you know, you're forgetting or whatever, because you're generally feeling better.

Imagine giving 60 days of multiple

doses to children, in addition to yourself. And the complexity of just the administration of that kind of therapy, and the compliance, essentially for a lethal disease if it actually manifests itself, is a staggering possibility. And to leave gaps in the affected population is a concern that we discussed.

I think the other thing is, is that 60 days of antibiotics is not trivial in terms of potential side effects. Depending on the antibiotic, you can have enormous GI problems, gastrointestinal problems, diarrhea, nausea, vomiting. And there are other, more antibiotic-specific complications.

So I just wanted to emphasize and extend the comments that Dr. Parker made earlier, that although antibiotics sounds like an obvious solution, it's not, particularly given the nature of the anthrax and its ability to exist in two forms, one as the so-called spore form which is essentially impervious to most therapies, and a second,

what's called vegetative form, which is the one that actually causes the disease as it enters into the bloodstream.

So with that in mind, I think the working group and the Board has realized that serious gaps would exist in any kind of single-arm response with antibiotics. And again, I think Dr. Parker did a good job of summarizing it, but I wanted to just extend the part on antibiotics.

MEMBER FAGBUYI: Thanks, Pat. I want to seize this opportunity to invite people who are in the audience, please, if you have any comments, you can just go to the microphone. I want the Anthrax Vaccine Working Group members specifically to be able to go to the mic.

MEMBER BENJAMIN: Chairman, this is Dr. Benjamin. I just wanted to let you know that I was on the phone.

CAPT SAWYER: Thank you, Georges.

MEMBER FAGBUYI: The time for the public comment will be coming subsequently.

CAPT SAWYER: Just for clarification, there are several members of the Anthrax Vaccine Working Group that are in the audience, that if they do have comments, since they are part of this product here, they are welcome to come to the microphone, introduce themselves, and speak.

MEMBER FAGBUYI: Patricia?

CHAIR QUINLISK: Yes, this is Patty Quinlisk. I think the points that Pat made were very valid, and maybe in the background we might even want to put in -- I believe that after the anthrax letters and the people who were put on antibiotics, that the compliance rate was very low, primarily due to side effects.

And I think that might be a very valid piece of information to put in the background, just because that would be the other tool that we would be relying upon to protect people.

The other thing that I thought of that probably should be placed in the

background information, that we're all aware of but I don't know that everybody in the public is, and that is, there is no way of testing a person after an exposure to determine whether or not they have been exposed.

Therefore, when you are doing a response, you have to do it on a population basis. You cannot do it on an individual basis. And that might be an important point for the background, also.

MEMBER FAGBUYI: Thank you for that comment, Patricia. John?

MEMBER GRABENSTEIN: John Grabenstein. Based on a comment John Parker made to me at breakfast this morning, we probably should be more explicit in the background, also, about what the adverse events that are attributable to the vaccine are, and call that out maybe somewhere around page six.

My thoughts are to organize that around what's in the vaccine information

statement from CDC, and the ACIP recommendations from 2009, something like that.

MEMBER FAGBUYI: Thank you. Pat?

MEMBER SCANNON: Yes. I have one other general comment, particularly when we were listing the options. And my comment is to be, at the risk of being redundant or perhaps too simplistic, but in terms of the options that we listed, to conduct a pre-event research IND protocol, I just want to make clear that that protocol is voluntary, and would require parental consent.

That is, there is no scenario, under any condition, where it would be anything other than parental consent, voluntary in nature. And so again, at the risk of being redundant, I just want to make that very clear.

MEMBER FAGBUYI: Thank you. Any Work Group members on the call that have comments?

(No response.)

MEMBER FAGBUYI: Bruce Gellin?

DR. GELLIN: Just under the spirit of clarity, I think somewhere we should also be clear about how long it takes to get an answer when you do a clinical trial. I think that some people may not appreciate what it takes to start it up, and then how long it takes to conduct the trial, draw the blood, make sure the lab does its thing, do the statistics, validate all that, so that people don't think that you're going to get an instant answer. So again, just to be transparent about what that process is.

MEMBER FAGBUYI: Thank you, Bruce. And we'll be getting to the section on conduct of trial, and we'll add that to that. John?

MEMBER GRABENSTEIN: I was just going to second Bruce's comment, and say excellent idea. Could CDC or FDA give us an estimate to put into the paper? Because it's not a number we should invent. It's something that we should import from those most knowledgeable in the planning.

MEMBER FAGBUYI: Patricia?

CHAIR QUINLISK: Patricia Quinlisk. Just following on on that, I think again in the background, it might be worth stating that regardless of whether or not there is any pre-event study done, there will be during-event or post-event studies done. Because that would be the only way you would be able to look at certain issues, such as vaccine efficacy.

You would not be able to do that in any way in a pre-event situation, so that there will be studies done post-event, no matter what's done pre-event. So that might be a statement to make in the background.

MEMBER FAGBUYI: Thank you, Pats.

MEMBER SCANNON: You know, in the spirit of continuing on that string of remarks, I think one of the concerns, again, that the Working Group has had is that in the event of an attack, times will not be normal. And so there will certainly be serious attempts to collect that kind of information,

but the kind of information you can collect in a post-exposure setting is not the kind of information that you can collect sort of in peacetime. And I just say that with the caveat that that is a difficult task.

MEMBER FAGBUYI: Thank you. Cindy Kelley, from FDA? She was also on the working group.

MS. KELLEY: Yes, Cynthia Kelley, Center for Biologics. So I just wanted to clarify that, whether you are on 14 days of antibiotics or 60 days of antibiotics, of course the idea behind giving the anthrax vaccine is to prevent germination of spores.

It should also be clear that, even if the anthrax vaccine is approved for a post-exposure indication, and its current intended use, under an emergency use authorization for adults 18 and older, is to be given in conjunction with 60 days of antibiotics. Therefore, administering the anthrax vaccine will not shorten the recommended duration of antibiotics.

MEMBER FAGBUYI: Great point. Thank you. Thank you, Bonnie.

DR. RICHTER: Thank you. It's hard to be seen. I thought it might be helpful, and I was reading -- I read the executive summary, not the full report. But if there could be a little bit of information about the mortality -- you refer to this as a lethal disease, but there was no discussion about actually what the mortality is.

And I don't know if the mortality rates from the people exposed, whether through occupation, cattle ranches, whatever, versus -- is the mortality rate different in adults versus children?

And I think maybe it might help to put a little bit of information in it, so people understand what the seriousness of this disease is, those who are not medically inclined.

MEMBER FAGBUYI: Thank you, Bonnie. That was a great comment. And in the report, we have some of that information. In the

executive summary, we didn't put that in there, but we do have the mortality information that you mentioned.

Seeing -- oh, Steve.

MEMBER CANTRILL: Dan, just one comment that occurs to me. Given our experience with the initial anthrax event, I wonder if we should address the fact, looking at the number of people that got vaccine as part of their PEP, and those that didn't. Because I think kind of a question that will come to the mind of many is "Well, gee. A lot of people didn't get the vaccine. They only got the antibiotics, and they did fine."

Now, we didn't do the study, but I think that's something that we may want to address head-on in the background. Again, further justification of why the vaccine is necessary.

MEMBER FAGBUYI: Thank you, Steve. Voting members on the phone? Is that a mumble?

MEMBER BENJAMIN: I don't have any

comments.

MEMBER FAGBUYI: John Parker?

MEMBER PARKER: One item that for sure Dan and I were quite concerned about in a post-event study is that you're marching the children through, and they're getting antibiotics, and then at some point they're going to get vaccinated, and a subgroup of those people are going to be followed. And we're going to be looking at reactions and immunogenicity, and it's going to be a mixed thing, because now you have the variable of the antibiotic on-board, plus the vaccine.

So Dan pointed out, and we put it in the paper, that the results under those circumstances will be difficult to interpret. But if we were to do that in a pre-event setting, and look at the vaccine in isolation, we may be able to get cleaner data to be able to say "This is the right dose for this particular immunogenicity," without the interaction of the antibiotic during the study.

CAPT SAWYER: This is Leigh Sawyer. I think someone who is on the speaker line, on the telephone, you need to mute your phone, please.

(Whereupon, the phone was not muted.)

CAPT SAWYER: Could you please mute your phone, please, someone who is on the speaker line, on the telephone?

(Whereupon, the phone remained unmuted.)

CAPT SAWYER: We know who's on the speaker line, so please mute your phone.

(Whereupon, the phone was muted.)

MEMBER FAGBUYI: All right. With that said, if there are no other comments, I think we'll move on to the next section. John?

MEMBER PARKER: In the executive summary, our next section is called the proposed plan for the post-exposure prophylaxis following the exposure, and I think we've addressed that fairly well. It is

the work that the CDC and the FDA and HHS has done, essentially been described. And if you would look at that, I think you would find that it's pretty straightforward on that.

The one part of that paragraph that I do want to highlight is that when the ACIP recommended 60 days of antibiotics, and the different types of antibiotics were looked at, the National Advisory Committee on Children and Terrorism made a determination that, with children under the age of nine, it's very difficult to give them oral tablet medication.

And they went on record to say that maybe this has to be looked at. Now, I want to make sure that everyone in this room and everybody on the phone understands that Health and Human Services, through the ASPR, is looking at that, to make sure that we have a palatable form of the antibiotics that would be used.

And once that palatable form is determined, it will be put in the stockpile. Now, on some preliminary looks at those

palatable forms of some of the antibiotics that we may have to use, there's a cost involved. And once you -- if you were to put things into pediatric suspensions and everything else, you do change shelf life. So there's a lot of work being done on that. I want everybody to understand that this wasn't a flying statement by the National Advisory Committee and no one paid any attention to it. The proper authorities are looking at that very carefully.

Now, we've talked about what the proposed plans are for post-exposure prophylaxis. Is there anyone on the Work Group or ex officios who want to comment about the way we have iterated the current proposed government plan?

And it's very important to understand that it's proposed. It's not locked in concrete. It's not one of those things that's -- it's a good demonstration that the CDC and the FDA and other agencies are working extremely closely together to

tackle this program.

MEMBER SCANNON: Pat Scannon. You know, the more I think about Dr. Gellin's remarks about the time needed to evaluate a vaccine, it is probably worth, again, mentioning for those that are not used to thinking about vaccines, is that when you get a vaccine, you are not instantly protected, and that it takes time for the immune system to mount the appropriate response against the vaccine.

And different vaccines cause immunologic, beneficial response at different times. In the event of a post-exposure situation, one of the things that the Working Group struggled with is this problem of wanting that information at the very time that you need that information, and that it's not just a matter of "does it work," but in the spirit of avoiding or minimizing side effects, some vaccines have more side effects if you give more, so there may be a dose dependency in both immunologic response and side effects.

And this would precisely happen at the time when physicians all over the United States are going to be asking "Well, how much do I give to a three year old? How much do I give to a 12 year old? How much do I give to a 17 year old?"

And we wouldn't have that information instantly available in the post-exposure situation that's described in this setting. Again, that's one of the reasons we're having this discussion, but again for the point of clarity, I just thought that Dr. Gellin's remarks really emphasized that we don't have, and we would not be able to instantly get, that kind of information, if we were to wait for the post-exposure study.

MEMBER PARKER: Dr. Khan?

DR. PESIK: Nicki Pesik for Dr. Khan. Just a couple comments. One, I think that, in the report, while there's no guarantee that you can avoid serious adverse events in children, I think ACIP and AAP looked at this issue, and they concluded that

there was no reason to believe that children would be at increased risk with this vaccine in a post-event.

So I just wanted to make sure that, at least in that bullet point number one on page 12, that it's a little bit of an -- that it's not overstated, that we're at least recognizing that ACIP and AAP did reach the conclusion that there was no reason to think that adverse events would be worse in children.

But again, there's no guarantees, but I think we should at least recognize that committees have tried to address this with this vaccine. And then a couple other comments.

On page 13, regarding adverse event monitoring, I think we should be clear that we would be recommending adverse event monitoring for anyone that receives this vaccine, and all children, regardless if the parents decide to enroll, to get a blood draw to evaluate immunogenicity at the end of receiving vaccine

in a post-event study so that the children that are enrolled in a post-event study are not the only individuals that we are recommending adverse event monitoring. Adverse event monitoring should be occurring regardless of the protocol.

On the second bullet, number two, there, we weren't quite sure what was being implied here, but we're not going to be -- if you had a research study to attempt to evaluate immunogenicity in this population during an event, we certainly wouldn't be providing that information to those children or those parents, because there would be no way to be able to correlate that to -- because there's no correlative protection, you wouldn't be able to tell any individual how to interpret their individual results. So I think we do still need to do a little bit of rewording in some of those sections.

MEMBER FAGBUYI: So Dr. Pesik, I'm going to say we're going to pull back a little bit. You've sped ahead of us a little bit.

We're going to dive into those conversations, so please hold that thought, but I wanted to go back to where we were before, because there needs to be some clarity on what those comments are and where they're coming from. Dr. Grabenstein?

MEMBER GRABENSTEIN: On the train yesterday, coming down here, as I was reading through the current version of the draft, I thought to myself "Which comparison am I making?" And I realized we probably need a graphic to call out that there are two big comparisons here: the EUA versus the non-research IND, the means of large-scale distribution. One graphic. And then the data gathering mode, the before or during research IND comparison, because I think that gets at several comments that people have made about clarity and intent of what the government's intending.

And I'm starting to sketch it out, what it might look like, on this little piece of paper, and I have "Voluntary, voluntary,

voluntary, voluntary" in all of the cells.

MEMBER FAGBUYI: So we are still -- just so everybody knows where we are, we are actually on page nine, under the -- I guess we're going into the section on conduct of trials, since this is talking about the methodology and the different ways of doing that.

MEMBER PARKER: This is a good time to -- Nicki, I can only see the sign. I can't see you, see?

You know, as the Working Group struggled with this, I just want to say that the ex officio members of the Working Group have been extraordinarily with us, educating us, teaching us. If it's Nicki, Cindy, Nancy, I don't want to leave anybody out. Dr. Nelson, all the ex officios representing the different agencies, and all the people that are touching this have, at different times, played educator, advisor, making sure that we're using the right terminology.

And so bringing everybody together

to wrestle with this subject is one of those interesting experiences that very few people get to go through, and you gain a huge perspective of what a word means in one sector, where the same word in another sector means a different thing, or is unknown in a different sector.

And so struggling to get the right word into print, and to make sure that we are giving credit to the people who are actually working the problem and trying to really figure out where the gaps are, so that we can focus on that, has been an extraordinary event.

And although some of the people on the phone, especially with me, have probably thought I was fairly antagonistic at one time or another, but it's hard for an old man to be reeducated sometimes. But you all have done a wonderful job of keeping the train on the main line.

And I personally, and I know Dan does, want to thank you for the fact that

every time we pick up the phone, you're there for us. And that's been absolutely wonderful.

MEMBER FAGBUYI: Patty has a question.

MEMBER PARKER: Oh, Patty?

CHAIR QUINLISK: Patty Quinlisk. I also, in the background, and perhaps in the area of the conduct of clinical trials, I think it might be useful looking at vaccine delivery under a comparison between an EUA and an IND. I don't know that they've ever done mass vaccination programs where there were two different protocols being used and therefore you could compare the time.

But again, one of the things we are concerned about is if we did a mass vaccination response, whether we could do it on an EUA versus an IND, would that speed up the process and allow more children, or more people to be protected?

And yet, I've never really seen a comparison of the two, and whether or not it truly speeds up things. I've been involved in

ones that have been under EUA, and I know that there is a process involved that does propose some extra action, and all of that. But I don't know about the comparison between the two, and I think that might be useful in the background material.

MEMBER PARKER: Patty, John Grabenstein has worked with folks at the CDC and the FDA, and we do have a draft comparison chart. But if John could speak to that, I just wanted to verify that we have an attempt going on to graphically portray that. And John could speak to it.

MEMBER GRABENSTEIN: This is John. Correct. I took a document that CDC and FDA had drafted, and sort of made it generic to medical countermeasures in general. I'm going to turn to Nicki, and ask Nicki if I can ask her a question.

Basically, I imported the time estimates that came out of Atlanta. And I'm not sure of the source of those time estimates, which I think gets to Patty's

question.

DR. PESIK: So they are exactly that. I think they are approximations and estimates. We held a meeting with about 25 state and local public health officials that would be responsible for points of dispensing with the antibiotics, but theoretically also where the vaccinations would occur. And we asked them "This is a mark on the wall. Are you comfortable with some of these numbers?" And again, these are opinions.

And you know, I think everybody felt that they were probably underestimates, to be honest with you, that everybody in the room was pretty comfortable with what an EUA and an IND is. And as I said at the meeting, my mother would think they were two different handbags.

So I think that the general public would have questions that -- forget the vaccine, but the heck is -- you know, what is this, versus what is that? You know, you've got to get over that hurdle first. So I think

folks felt that there was probably an underestimation there, as well. And it really did bring up something that they said was very interesting. If you think about the amount of exercising we do, it almost always stops at 48 hours.

And you know, we give the antibiotics, and some of the state and local public health authorities said it would be very interesting to exercise this. Now, it would be very difficult, but nevertheless, we don't exercise the mass vaccination component of preparedness plans.

CHAIR QUINLISK: Again, this is Patty. Could I just ask, was there -- the time difference between doing the mass vaccination process with an EUA versus an IND, what was the time differential between those two processes when you compare the two? Do you remember, just --

DR. PESIK: You know, I didn't bring the most revised version, so -- I feel like we're doing a tag team here, but John, I

suspect you have it on your computer.

MEMBER GRABENSTEIN: I have it on my computer at the moment. It was a 20 minute differential from the perspective of the individual. In other words, arriving to leaving would be a 20 minute difference. And then I put in a footnote that that's -- if you have a million people to move through the line, it's not 20 million minutes. You know, you could mitigate that with lines, and group briefings, and that sort of thing.

CHAIR QUINLISK: Let me make sure I'm clear. So it was 20 minutes faster if you did it under EUA than if you did it under an IND?

MEMBER GRABENSTEIN: Correct.

CHAIR QUINLISK: Okay. Thank you.

MEMBER FAGBUYI: Skip Nelson? Oh, I'm sorry.

DR. PESIK: I'm sorry. And John, I don't know if we even had a chance to talk about this a little bit, but part of what state and locals were struggling with was,

would the parents have to go in two lines? So they would go in an EUA line and get their vaccine, and then have to go to maybe a different area to then go through the process -- and so now you really -- you know, that sort of mucks up the picture a little bit.

But like I said, I think what they were saying is it would be very interesting to try to simulate this in some fashion, with folks that really haven't heard these terms, to get a better sense.

MEMBER FAGBUYI: Skip Nelson?

DR. NELSON: Thanks, Dan. I'm with the Office of Pediatric Therapeutics at the Food and Drug Administration. I just thought it might be worth emphasizing -- I think it would be important to get some real testing of some of these time estimates, as was suggested, based on some modeling and going through that.

But the only procedural difference between the two is the need for a signature. The EUA regulations require an information

sheet. That's two pages. The IND consent document that I'm told has already been reviewed by both CDC and the FDA is two pages. So the only difference, effectively, is that you need the documentation of a signature.

So whether that's 20 minutes from the perspective of an individual moving through the line, it could be only -- I believe it was a five minute estimate from the perspective of someone collecting that signature, which may even be an overestimate. So there's not a big difference between the two.

MEMBER FAGBUYI: I think that's Dr. Gorman.

DR. GORMAN: Skip, who would be able to sign?

MEMBER FAGBUYI: Can you introduce yourself, sir?

DR. GORMAN: Richard Gorman, DMID, NIH. Who would be required to sign? Could it be any adult, or would it have to be their parents?

DR. NELSON: Well, it would be a parent or legal guardian. So someone who has the authority to consent. If you're suggesting problems if a school gets dusted, and then you're dealing with issues of -- but again, the vaccine is not an emergency.

The antibiotics need to be provided. The vaccine could follow any time during the time the antibiotics are being provided, so I don't think we're -- you know, it would be interesting to review the possibility that parents and children are separated. Having practiced in intensive care, I can understand that that can often happen. But the vaccine, again, is not an emergency.

MEMBER FAGBUYI: Okay. Any comments from our Work Group members on the phone?

(No response.)

MEMBER FAGBUYI: All right. Hearing no comments, we're going to move on to our second part of our discussion. This is a

response to the questions that the ASPR asks the Working Group and the NBSB. And that starts on page 10. So we're going to go through this in this next hour. We'll put the questions up on the board here.

MEMBER PARKER: As we go through the paper, since there was a discussion about the time intervals between the EUA and the IND, and the fact that a significant work effort has been put into a tabular form of that, is there a recommendation within the Work Group that that should be included in the report?

CHAIR QUINLISK: I think, since that is in the body of the recommendation part of the argument, then, I think it needs to be placed in the background to clarify what the argument is.

MEMBER PARKER: Okay. Just so you know where I, as one individual, felt about that, is that from the standpoint of making a recommendation, we ought not to look at time of process, per se, as a scientific criteria

to determine whether safety and immunogenicity should be determined before or after. But I agree, it's a part of the argument, and Dan and I will try to weave it in appropriately.

The ASPR asked four distinct questions for the Work Group to wrestle with. And the first question -- I think I can work that machine. And I'll put the first question up, but everybody has it in front of you.

CHAIR QUINLISK: They're working to put it up for you.

MEMBER PARKER: Oh. Oh, wow. That's neat. I love magic. You can see the first question, and it looks like a fairly simple question. It's difficult to answer in a word form. So we've gone through several iterations of how to answer these questions.

MEMBER FAGBUYI: Do you want to read it for people on the phone?

MEMBER PARKER: Oh, for folks on the phone, yes. The first question is "What are the risks and benefits of attempting to perform an AVA vaccine safety and

immunogenicity IND research protocol in children pre-event, versus after an event?"

And so we looked at that question from the standpoint of looking at the pre-event evaluation on the basis of its risk and its benefit. And as you can see in your summary, that under the risk of a pre-event evaluation, the number one thing that we put on there is that vaccination carries some risk. And we did not iterate what those risks were, but that was the risk of doing a pre-event study.

And that risk is against the fact that we would be vaccinating children in the distinct scenario of they were not at risk to get the disease, because they had not been exposed to anthrax.

So a lot of people could look at this as just isolated vaccinations of children for no apparent benefit to the individual child, just to put that in real plain language. And therefore this child, who is not at risk for anything, may in fact bear the

reactions to the vaccine, or the other risks that have been itemized in the brochure.

Now, the benefits from that --

CHAIR QUINLISK: Can we have the discussion around this one first?

MEMBER PARKER: We sure can.

CHAIR QUINLISK: Sorry, I have some things. I think that when we put here under risks -- I think we need to acknowledge a couple other things. In particular, there were a couple things that came out in the workshop that we had, and I just wanted to see if we would want to go ahead and put them here under risk.

I think -- again, I totally agree that the vaccination carries some risk. I think here, again -- and in the background you have the actual known risks in adult populations, but I think we then need to acknowledge the fact that we do not know what the true risk is in children. We can extrapolate from the adults, but that's one of the problems, is we do not know what the risks

are.

Second, I do think we need to, under that, specifically state that at this time we know of no benefit to those children. Of course, there is a potential future benefit should they ever be exposed to anthrax, that they would have immunity on-board. But that is a future and somewhat hypothetical risk.

The next thing, and I think this was one of the issues brought up in the workshop, was that if you did a pre-event study with a number of children, there are going to be, probably, children who have some sort of adverse health problems that may or may not have anything to do with the vaccine, and one of the concerns is if you would have one child have something go wrong with their health -- again, whether or not it has anything to do with the vaccine, that could adversely affect the future uptake of that vaccine, because of a perceived concern.

For example, should a child die of something, and that be potentially blamed on

the vaccine, that could adversely affect the future uptake of a vaccine during a true event. And I think we have to at least acknowledge that that is a concern.

The last concern I have under risk is, if you would go out into the public, try to do a pre-event study, I have some concerns about, one, having it truly go through a Human Subjects Review Board and be approved. As you say, there's more stringent ethics around children, whether or not that would even be approved.

And the other thing, as just a practical one, would be if it was offered, would you truly get a representative sample of children, or would you -- because of the perception of risk based on the parents -- get an unrepresentative sample of children.

And just throwing it out there, you might be able to get 15 and 16 year olds, but you might not get any children under two. And would that, then, give you a representative sample of the children?

Maybe it would be good enough, but again, I think that would be one of the risks of doing a pre-event study, is that the children that would be volunteering for a study may not be a good, representative sample of the general population, which is who we would expect might be exposed if an event truly occurs.

MEMBER FAGBUYI: Thank you, Patty. I'm going to actually call on Rich Gorman and Skip Nelson to comment on those, on Patty's comments.

DR. GORMAN: This is Rich Gorman, DMID, NIH. Talking to the design issue in your concerns, any protocol would be structured and balanced by age. Whether or not you could recruit or not, I am not in a position to predict, but those concerns would be addressed in the protocol design.

CHAIR QUINLISK: And I do understand that that would be the way you would want to do it. I just have some concerns about, again, the volunteering of

those children. There might be a difference in what children whose family might feel that they want them to participate in the study, and what children may not be participating in the study, and that giving you a biased sample.

DR. GORMAN: But that's --

CHAIR QUINLISK: And I understand you would try not to do that.

DR. GORMAN: And that's a concern that would be addressed by whoever executes such a protocol, if it is decided to do it.

MEMBER FAGBUYI: Skip, do you have any comments? By the way, both Richard Gorman and Skip Nelson are on the Anthrax Vaccine Working Group.

DR. NELSON: Just, I guess, two comments. I do agree that the broader context that John outlined ought to be described under the risks, meaning that in this case, the vaccination risk is against the possibility that the children being vaccinated will never, ever be exposed to anthrax, because there's

already a flip side.

I might just take the opportunity to make one comment that bridges, maybe, to benefits. There was a discussion in the meeting that occurred previously about the possible advantage of doing a pre-event dosing evaluation.

The point made scientifically was that we would be using immunogenicity to bridge from pediatric to adult trials, and so one couldn't necessarily do dosing studies to be able to do that bridging unless you potentially did immunogenicity studies in adults.

And so if that's an issue, then I just -- it's not my scientific area, but I would just put it on the table, that if we wanted to ask questions about whether or not we can do antigen sparing, or how we do that dosing -- do we need the same dose, et cetera -- that we may need to do adult studies of immunogenicity using those same regimens, in order to be able to establish whether we can,

in fact, bridge immunogenicity from the children to adults. Just a point that I don't think is captured under benefits.

MEMBER FAGBUYI: Thank you, Skip. Any comments from our Work Group on the line? Okay. Oh, Pat.

MEMBER SCANNON: This is Pat Scannon. I'm coming back to Patty's comments. And I think, again, it reflects -- her remarks reflect the struggles that we have as a Working Group in talking about pre-event clinical trials. And I think nobody wishes any harm to any child from any clinical study. I don't care who you are.

The question is, if there was a significant adverse event or adverse events that happened during the course of a pre-event trial, that's precisely one of the reasons you do those kinds of studies, because it would be magnified -- if it were a real problem, it would be magnified by the number of kids who would get it in the post-event without that kind of information.

And so, you know, I just say this for the people who are listening here, this is probably the fundamental pain, essentially, that this working group has gone through. It's the struggle of what a pre-event trial would -- or what might happen during the course of a pre-event trial.

Nonetheless, I think the on-balance gaining information about the safety profile and immunogenicity in the event of a real exposure would be invaluable, and it would be multiplied by the maybe thousands or tens of thousands of children who would then have to receive -- or would not have to, but would voluntarily receive the vaccine in a post-event setting.

So I think -- you know, I'm just really talking on an emotional basis, as opposed to a scientific basis.

MEMBER FAGBUYI: Fair. Any comments from the Working Group on the line?

(No response.)

MEMBER FAGBUYI: Okay. Barring

that, we'll move on.

MEMBER PARKER: Dan and I expanded the amount of time that we had for this, and we may have underestimated it even at that. So I'm going to make an assumption that everybody has a copy of the summary. And if we look at the benefits, I would ask you to take a look at one through six under the benefits.

Quickly, children who have been immunized might be protected from anthrax infection and disease should they be exposed. In the event of a public health emergency, the pediatric population could receive a dose of AVA PEP that's been demonstrated to be safe and immunogenic. In the absence of an emergency involving exposure to the anthracis, parents would have ample time to consider whether their child should participate as a volunteer in the study. Conducting the pre-event trial starting with the older children first is more likely to yield useful data than conducting these studies during a public

health emergency. Studies would be conducted in a controlled setting to reduce the likelihood of error that could result due to the haste that may occur during an emergency. Conducting the pre-event trial may afford the government the opportunity to shorten the duration of anti-microbial use -- this has not been determined -- with concurrent receipt of the AVA.

And that's kind of a theoretical benefit. And as we know, the CDC and the FDA are in discussion about the proper route of administration. And so through a pre-event study, perhaps the differences between the intramuscular route and the subcutaneous route could be worked out before an event.

Are there any comments about those bullets that we have used to described benefits, or additions?

DR. PESIK: One other thought that we had for the Board to consider is that by having data ahead of time, the communication message that you can give to parents would

help, potentially, to reassure them and allow for increased acceptance of the vaccine.

Public health officials that routinely are involved in routine childhood immunizations, and given the emerging issue of vaccine hesitancy, are rightly concerned that trying to discuss a vaccine at the time of an emergency without data would certainly lead to increased hesitancy. And we expect that parents will have increased vigilance over vaccines given to their children, even in an emergency.

MEMBER FAGBUYI: Good point, Nicki. Bruce?

DR. GELLIN: This is Bruce Gellin, HHS. I wanted to build on what Nicki said and actually come back to her other point about a safety monitoring system that will be in place to look at what the experience is, but also to acknowledge that the kinds of clinical trials that are being discussed are relatively small, primarily designed to look at immunogenicity as a correlative protection.

And that's the information you're most likely to get, so as your communication message is, how good such a vaccine is likely to be to protect you. Separately is also the understanding that rare adverse events are rare, and you're not going to pick them up in a small study like this. So reinforcing that there are other systems in place that will be looking for those, but you shouldn't expect the one in a millions to show up in the clinical study.

MEMBER FAGBUYI: Any other comments?

(No response.)

MEMBER FAGBUYI: Okay. We're going to be good stewards of our time, and we'll move on to post-event evaluation.

CHAIR QUINLISK: So if we could have question 2 projected, please?

MEMBER PARKER: If we look at the second part of this question --

CHAIR QUINLISK: I'm sorry, number one, still. I apologize. We're still on

question one, but the second part.

MEMBER PARKER: We are. But we looked at -- we just finished, sort of, risk and benefit of the pre-event study. And part two of the first question is, how does that contrast with the risks and benefits of a post-event evaluation?

And if you look at page 12 and 13, and we look at the risks of a post-event, we have essentially said that in a post-event scenario, we actually state in number one that the children could be at serious risk of adverse events, because we would not know what would happen to that population by pre-event studies.

Number two, we feel that the public health emergency that's going on would make it very difficult for our federal, state, and local agencies to be involved with getting the consent forms signed and being able to answer questions about the vaccine, so that this goes back to the IND/EUA timeframe.

And I totally acknowledge the fact

that Dr. Nelson has said, that it's two pages for this and it's two pages for that, but I have dyslexia. And to read two pages and put my signature on something actually does take some time.

And then, on the third part, as a risk, we think that in the post-event scenario, if you look at the mid-portion of number three, we have concern that there's no control group in that particular scenario, where we can actually make some sort of comparisons on that.

And we already mentioned that we are concerned that, in the post-event scenario, when we're following children that are not only given the vaccine but they've been given an antibiotic, that the data may be extremely hard to interpret, as we look at that.

Those are the risks of the post-event. The benefit would be that --

CHAIR QUINLISK: Can we do the risks first, and then do the benefits?

MEMBER PARKER: We may do the risks first. Patty?

MEMBER FAGBUYI: Comments?

CHAIR QUINLISK: Patty Quinlisk. One just general issue, when we go to the post-event evaluation, I think we need to make it clear that we're talking about post-event with no pre-event having occurred. I think, as we heard earlier, we would be doing some post-event evaluations no matter what, yet these risks and benefits are, I believe, under the assumption that there is no pre-event study done for dosing or for safety. So I think we need to just, at the very top, where it says "Post-Event Evaluation," just place a "with no pre-event having occurred," to make it just clear that that's what we're talking about.

Next, just when you talked about number two, I'm a little bit concerned about keeping this in. I understand the two pages and all of that. I'm not sure, again -- and I'll defer to CDC -- in an actual event -- and

I've been involved in mass vaccination programs -- I'm not convinced that an IND versus EUA would so significantly be different that it truly is something that needs to be in a risk.

I guess I'd like to see that. If it's truly two pages and a signature for both, I'm not sure that that truly makes such a huge difference that that should be here as a number two kind of risk. So I'd like to re-look at that and make sure that that's a valid piece to put in there.

Next, in three, I totally agree with the fact that you're not going to have a control group, except for children who do not get vaccinated, but that would be the same as in a pre-event study, too. That would be your control group, would be children who were not vaccinated.

So again, I don't see a huge difference in a control group looking at the vaccine itself, but I do think it's a totally valid argument in that the children would be

receiving the antibiotics, and therefore pulling the vaccine piece apart is a very valid concern if you only did a post-event. But I'm not sure if the control group issue in a vaccine-only is truly valid, because in both of those situations your control group would be children who are not vaccinated.

MEMBER FAGBUYI: Thank you, Patty. Pat?

MEMBER SCANNON: Yes. Pat Scannon. I did have a question that follows on from what Patty said, and that is, I don't -- I think if we're going to talk about control groups, we should probably talk about whether we're talking about negative controls or positive controls. Because are we talking about non-immunized children?

Really, a truly valid negative control, there would be a prospective definition of that, and perhaps even mock injections and so forth. If it's a positive control, coming back to earlier remarks, perhaps an adult population would be an

appropriate positive control. And there would be, obviously, some dosing. You know, all of those would be part of the discussion. So we should be deliberate in terms of how we talk about controls.

I respectfully would differ from Patty on item two, in that I do believe the difference between -- and also, I would not disagree that it should be as fact-based as possible, and I absolutely agree with that. I think the one thing that is very hard to assess is the state of parental concern in a mass casualty setting, the role of the media in stoking the fire, so to speak.

And I think, whereas in peacetime, so to speak, people can be more thinking about what's going on, I think that could break down in a mass casualty setting. And I think that was the intent of that, somehow -- and maybe it's not worded correctly, and if there's more factual information it should be included.

MEMBER FAGBUYI: Thank you. Skip?

DR. NELSON: I do agree with the

previous comments about the need to have clarity on controls. Just one other area I think there could be better clarity is this language of "non-research IND." I have no problem if we choose to use it, because I think it does send the signal that this is an IND that's very different than what we normally think of an IND, but it's still a clinical study.

It's still a clinical investigation. The anthrax vaccine would still be considered an investigational drug under those circumstances. So maybe we should add a footnote that explains what we mean by that. Because you know, one could use the phrase "bare bones IND," "stripped-down IND," you know.

Whatever, but it's still a clinical study under FDA regulations, so the "non-research" phrase is a little bit problematic. And what I've used to try to describe this is things like the general IND versus nested IND, or some kind of language that tries to make

this distinction between the two in a clearer fashion.

MEMBER FAGBUYI: So Skip wants a sexier term.

(Laughter.)

MEMBER FAGBUYI: Nicki?

DR. PESIK: The only thing I can say is that we tried to work with Cindy Kelley on the terms to avoid the confusion about the voluntary vaccination where the child is just receiving the vaccination, i.e. the non-research IND if the parents consent in an emergency, and then that other, the nested research IND, if you will, where parents would be consenting to, once their child received the vaccine, also a blood draw.

So I think we tried to do that language with Cindy, and we can maybe go back and revisit what the terms are, so as to avoid the confusion. But because what we were trying to get at -- and I'd hope, if Cindy is still here in the audience, she can comment as well -- is the IND was to obtain informed

consent, and that's it. That's all that's happening in that IND. Those children are not being enrolled in any sort of other steps following the vaccination.

DR. NELSON: I think that's fine, and if we wanted to retain that term, I would just suggest adding a footnote or a discussion about those differences. Because my concern is that the community that's not been a part of this discussion, such as the IRB community, will look at that and wonder "What is this new animal? Is this a new FDA category, if you will," et cetera. So a footnote may be sufficient to just explain some of those differences.

CAPT SAWYER: This is Leigh Sawyer. Actually, the term IND, or Investigational New Drug -- I think that has an implication that it's investigational, as well. So we have grappled with this, and we will try it again. Thank you very much.

MEMBER FAGBUYI: David Ecker? Yes, I have everybody on a special format here. Go

ahead, David.

MEMBER ECKER: Coming back to Number two, recalling some of the conversation we were having in the Working Group discussions, the argument that I found most compelling that was discussed was, it's not a matter of how long it takes to read and sign off on the paperwork.

It was, in the absence of doing something pre-event, that you would have to explain to parents that they were getting -- their child was signing up for a vaccine, or they were signing their child up for a vaccine that had never before been put into children. And it was that explanation, confusion, concern that really would drive the difference between the two.

MEMBER FAGBUYI: Thank you. Jane?

MEMBER DELGADO: Could I -

DR. PESIK: I think I have a little bit of better explanation of -- thank you to our regulatory affairs officer, who is whispering in my ears. Our CDC IRB actually

identified the IND as a non-research IND because it doesn't contribute to generalizable knowledge, and that it's only going to the direct benefit of the individual receiving the vaccine. So they considered that particular IND a non-research IND.

MEMBER FAGBUYI: That is very helpful.

DR. NELSON: Dan, if I could just build on that, because we might lose this moment. HHS regulations, under 45 CFR 46, defines research as a systematic investigation designed to yield generalizable knowledge. So it is true that the general IND may not be research under HHS regulations for HHS-conducted research, and that's why the CDC IRB decided what it did.

Under FDA regulations, it is a clinical investigation, which means an investigational product is being delivered to one person. We don't need it to be a systematic investigation to get generalizable knowledge to still be a clinical trial under

FDA regulations.

And that's a key difference, because what this means, if we get into a discussion of the IRB process, is the general IND may not need IRB approval anywhere, because it's not HHS-conducted research, and the FDA is willing to accept only one IRB approval. So that's a key point to just keep in mind.

MEMBER FAGBUYI: Thank you, Skip. Jane?

MEMBER DELGADO: Thank you. Just a couple of comments that I am increasingly concerned about. I think, with the executive summary, it really isn't an executive summary of all this. But that put aside, if we look at what we have on page 11 in terms of risk/benefits, that kind of listing should be similar to what we have here. And somehow, it is very different. It looks like the risk/benefits on page 11 was written by a very different person than the ones on page 12. As a result of that, what's on 11 is a lot more

coherent.

I'm also very concerned that in all this, that what consumers and people and parents would actually think, and want, or do, is actually sort of left out. And it is -- communicating the intent is left to item number four, later. And I think that needs to be throughout the document. Because if we're talking about risk or benefit, and we say here on 11 "Vaccination carries some risk," on page 12 that's still a risk, whether or not it's before the event or after.

So I think that there needs to be more of a crosswalk between the pre- and the post-, like in the question that was asked. And I think that's sort of missing that. Sometimes we get lost in the weeds and forget that we're part of a larger garden. So that's it. Thank you.

MEMBER FAGBUYI: Thank you, Jane. I think Cynthia Kelley had a comment.

MS. KELLEY: Yes. Cynthia Kelley, CBER. So I was just going to say that, you

know, we can all have further discussions on what you want to call which IND. In the Center for Biologics we used to call these kinds of INDs "Contingency Use INDs," but then some other people didn't understand what that meant, either. Because there is no formal wording.

The other thing I wanted to clarify, based on someone who, I no longer who made the comment, is that the AVA vaccine, whether given to adults 18 and older under an EUA or given to children under 18 under an IND is an investigational product either way. It is, and the fact that it is investigational for the purpose in which it's being used also must be explained to the recipients under possibly an EUA, as well as an IND.

MEMBER FAGBUYI: Okay. Thank you. Bonnie?

DR. RICHTER: I'm Bonnie Richter. I also wanted to talk about -- it said in the executive summary that these two protocols were being -- it was my understanding that

they are being developed, and we are not starting de novo here based on these recommendations.

So that means that there have to be consent forms that were also being developed concurrently. And I was wondering what those looked like, the difference in the consent forms, pre- versus post-, so that just is one comment.

And then the second comment about the post-event, just thinking as being a parent -- you know, you're in a coercive environment no matter what in the second event. And so even if you give pre- versus a post-event information, the mindset - if I'm going to be scared to death that my kid is going to be exposed to anthrax, if I'm in that area -- so I have a really hard time, and I don't really feel like it was addressed in the risk versus benefit, that coercive environment.

If you know you're living in -- like we did with the trial run of this. I

can't think of the name of it. But your mindset is totally different. There'll be clamoring for people afterwards that doesn't exist in a clinical trial, and somehow we have to be able to acknowledge that as a risk. And you know, you sign that consent form, it's different. It's just different, and I think that should be acknowledged here.

MEMBER FAGBUYI: Thank you, Bonnie. Actually, our Skip Nelson here also made that comment in the full report. But we'll probably highlight that here, too. Okay, barring any other comments, we'll move on.

MEMBER PARKER: We're on a little bit of a time constraint, now, because it's almost 11:00. And I have enjoyed every single comment, and I wish we could just stop the clock for a little bit, but we can't. If we looked at the benefits in the post-event setting, we see that with the threat of developing the disease, there'd be a potential direct benefit to the child of receiving the vaccine.

And at that particular time, that subgroup would be looked at, so that at some point in time, when that data was collated and put together, we would have information about the immunogenic and the reactions in case a future event would occur.

And bottom line under both of these things, the pre-event or a post-event, there would be the possibility of gathering enough data to go from an IND situation to an EUA situation, so both the adults and the children will be administered the AVA under the same regulation.

The number two question --

MEMBER FAGBUYI: Before we go to that, Nicki had some comments on this section, and also we had a comment before we went on. So I wanted to allow you to give your comments.

DR. PESIK: Well, given the time, I think you've written down the comments I had on the benefits section. The only thing I would -- one of the things that I think

there's questions about, "Okay, well if it's two pages for an EUA and two pages for an IND, what's the difference?"

Well, with the EUA, we're not necessarily providing every individual two pages. You might put them in an auditorium, show them a video, and you could basically inform a whole bunch of people and move them through the line.

With an IND, some state and local health departments may not feel that that may be the mechanism by which they want to do the informed consent process. So if you then go back down to a sort of more individual attention, or questions, you may see, I think, a larger gap in the differences.

But the actual consent forms are -- the fact sheets for both are the same length, and we're trying to keep them as simple as possible. But there are some discussions about how you can do this as quickly as possible. That's all I wanted to say.

MEMBER FAGBUYI: Thank you, Nicki.

Skip?

DR. NELSON: Just a quick comment. This is where I think we need to be clear on our use of language. So strictly speaking, the administration of the vaccine is under the non-research IND, adopting that language. The research IND in this setting, in an event setting, would actually simply be the immunogenicity follow-up.

So the vaccine administration is not part of that nested IND. So I think we just need to be very clear in our language here, in this section.

MEMBER PARKER: You know, I have to interject here that the reading of a consent form -- this comes from too many years on an IRB and chairing too many IRBs, but a consent form may read perfectly well, but the onus on the principal investigator, or anybody using a consent form, is that before that individual is asked to sign the consent form, you must have reasonable understanding that the person understood what they read.

And that's the responsibility of the investigator, whoever that may be in any case. And so the idea of reading a consent form and then signing it is one thing, but having a reasonable idea that they really understood that is another step.

Well, we don't have time to dwell. But number two, if we go to the second question, please, on the slide, we're looking at the challenges of the difference between the IND and the EUA. And I think we've discussed that. And I would invite people to please read that, and if you have a problem with that section, please let Dan and I know. It's pretty straightforward.

And then if we go to the third --

MEMBER FAGBUYI: Patty had a question.

MEMBER PARKER: Oh, okay. Patty?

CHAIR QUINLISK: I'm sorry. I just had a basic question here, when I was reading through this. And that would be -- and this is for somebody else to answer. If you did a

pre-event study, would that guarantee that you would be able to do an EUA versus an IND?

MS. KELLEY: Cynthia Kelley. No.

(Laughter.)

MS. KELLEY: That would not guarantee that. It depends on the data, and it would entirely depend on how much data we got, what the data looked like. It's a lot of factors, but no. There is no guarantees.

CHAIR QUINLISK: Okay. Then I would just say that that needs to be clarified in here, because it does make it sound like if you do a pre-event study, it would automatically mean that you could go to an EUA. And if that's not true, then I think it just needs to be clarified.

MEMBER PARKER: Agreed. I'll leave it at that. And that's why you'll see that we used the word "may." Yes. And thank you, Cindy, for being extremely clear on that.

MEMBER FAGBUYI: Rich Gorman, did you have a comment?

DR. GORMAN: Cynthia stated it very

well.

MEMBER PARKER: I'm rushing here. If people don't want me to rush, say we'll use the break up, or something. But then we go to a section called "What Pre-Planning Should the Government Have in Place to Optimally Perform the Investigational Protocol Post-Attack?"

And essentially what that question says, if we proceed with our proposed plan, what should the United States government be doing? And I think those paragraphs are pretty clear, and I would invite you to look at those and ping us if you think we could improve them, or we have said something that's derogatory in any way.

And then to go to question four -- I think question one was the pivotal, important question that was asked. But on question four, about communication of these issues with parents and pediatricians, we started off with like three pages here, and we got back to two paragraphs, to be succinct, because we didn't want to prescribe down to

the ultimate detail of how it should be put in bulletins and everything else.

And in this particular case, we've zeroed in on HHS and the tools that they have to use with the federal, state, and local officials, and using the executive branch, the White House, to get the word out.

MEMBER FAGBUYI: I do want people to really, actually, comment on this. Especially, I think, Jane, you brought up -- well, you have your badge up. So I think this is an important piece. Although this was the order of the questions, so in our responses this is the section where we tried to address some of those things.

And I think we can do much more, if you guys have some comments that may be able to help us focus on all the areas we need to, and all who need to be engaged. Go ahead, Jane.

MEMBER DELGADO: Okay. My concern is that you will get nowhere with number one unless you've done a good job on number four.

And I think part of it is that you can take the example of something as simple as the flu vaccine, where CDC has been telling people to get this, and yet the rates are going down of people getting it.

And so I think that just like you have to have information before anything going out to the public, and to parents and pediatricians, you also need to be doing that in this area, also. That parents need information before something happens, not just during, so that when the time comes, they are prepared to act in a way which is meaningful.

I also think the whole idea about informed consent -- I know that NIH is now re-looking at what they consider informed consent. It's not just the language issue or the literacy issue, but when people are under stress or scared, they're not at their best decision-making, so there are a lot of things that need to be taken into account.

And people, when they are informed, will make decisions. But you just can't

expect to inform them at the last minute. So I think the process of informing people about these concerns is something that should be ongoing.

MEMBER FAGBUYI: Thank you, Jane. Any other comments on outreach, and how we get to -- Bruce?

DR. GELLIN: I couldn't agree more with that, although I just have to correct the record that, while our flu vaccine rates aren't going up as high as they need to be, for the most part they are. It's encouraging that they are going up, so I just wanted to make sure that -- but that doesn't take away from the importance of communicating the science.

MEMBER FAGBUYI: Thank you. On the phone?

MEMBER BENJAMIN: No comment.

MEMBER FAGBUYI: Moving on --

MEMBER BERKELMAN: I was on mute. This is Ruth Berkelman. No comment, but I did want you to know that I am listening in, and

anything I have, I will share with you later. Thank you.

MEMBER FAGBUYI: Thank you, Ruth.

MEMBER BERKELMAN: But I think this has been a really excellent discussion.

MEMBER PARKER: Okay. If we could put up the slide, the options? And it's also in your document. And I would refer to the document, because you see the options in tandem nature.

Essentially, option one was to conduct the pre-event research IND protocol, and I think we've talked about this very well during this meeting. And the option says that the protocol should be complete. It says all the things that we particularly would want it to.

But the last sentence in option one is "These materials would be submitted to an IRB with the expectation that the protocol would be subjected to the review and approval process outlined in 21 CFR 50-54, 45 CFR 46.407."

Which means, essentially, under a standard review of a research protocol, all of the guts of what an IRB needs to do is under 25 CFR 50-54. But what 46.407 says, that because it's research in children and there's a good possibility that there's no benefit to the children, that HHS can convene a public panel of experts and laypeople to review that particular protocol, to advise the government or any institution doing that type of research work to do it.

The question that comes up is, on this particular option, do we need to be that finite, or could we just leave it "These materials would be submitted to an IRB," period?

And the section option is --

MEMBER FAGBUYI: Do you want to do one at a time?

MEMBER PARKER: Oh, let me -- and then the second option is conduct the post-event research protocol, which we have talked about. And then, before we go to discussion,

I just want to make sure that people get a chance to glance at the four paragraphs under the discussion.

But just so that the people listening in and everything know that at this point in time, with the draft, that the Working Group has selected option one, and recommended a pre-event protocol study. So with that, I would like people to comment about our wording in option one, our wording in option two, and on our final recommendation.

And the endpoint of that discussion will be when our chairman says "Go to break."

MEMBER FAGBUYI: All right. Steve?

MEMBER CANTRILL: John, Steve Cantrill. I would leave in the references to the different CFRs, but I would even go further. I would footnote them, and basically say what you just said. Because quite honestly, 45 CFR 46.407 is totally meaningless to me, but when you describe that it recommends that HHS empanel a public group to

hold a public hearing, that is very meaningful information.

MEMBER PARKER: Well, not to contradict your remark. I love your remark. But I just want you to know that we struggled with that, as to whether we should say "See report," where we talked about the 407 or not. But we agree with you, Steve.

MEMBER CANTRILL: Okay, that's fine. As long as I can get to the details in the corpus of the report.

MEMBER FAGBUYI: Yes. Great comment. Pat?

CHAIR QUINLISK: Yes, I just had a couple things. In option one, the last sentence you have there, about the ability to give it to people under EUA, et cetera, I think given the conversation we had this morning, that final statement would be more succinct and everything if you would just stop before that final statement.

You already say it would be available to children under EUA rather than

IND. And really, the bottom line -- you're doing this, as I understand it, is not to change it from an IND to an EUA, but truly to learn about the safety, immunogenicity, et cetera.

And you almost weaken it by double-stating that last -- I think the argument is stronger if you just stop and don't put that last sentence in. That's just my opinion.

In option two, I would just say "Conduct only a post-event research IND," again to make it clear that what you're talking about there is without the pre-event, only do the post-event.

And then the last sentence you have -- or the second to last sentence you have there, I think to say that you might learn something about the safety is incorrect. You will learn something about the safety.

I agree, it will not probably under the same kind of thoughtful, plenty of time, kind of study, but you will, indeed, learn something about the immunogenicity, the

safety, et cetera, in a post-event. It doesn't mean that you might not. You would. So I would take that might out of there. You will learn about that.

And again, take the something, so that would read "but would be sufficient to learn about safety and immunogenicity." You might say "though not to the same stringent controls as you would in a pre-event." But to say that you might not learn anything, I think, is very much overstating. You will learn something. You will have people getting the vaccine. You will be able to learn something about the safety and immunogenicity. And that's all the statements I have on that.

MEMBER PARKER: Patty, on -- I'll tell you, the comments that you made about the second paragraph under option one are really not a part of the option. But it's a comment in the executive summary.

CHAIR QUINLISK: Right.

MEMBER PARKER: But do you really feel that we should not even make comment that

perhaps the data could affect the movement of the IND to an EUA?

CHAIR QUINLISK: You already have that in the first -- you have "and could also be considered by FDA to support making the PEP available to children under EUA rather than an IND." Absolutely. You said that, and I think that's correct.

By restating it in the second paragraph, you make it sound like that is the primary and only reason for doing the pre-event, and I think that that is not. The reason you would do the pre-event is for the safety and immunogenicity of the vaccine, which, again, you stated in that first sentence.

I just think you make your argument stronger by not restating something that may or may not truly be a main reason for doing it.

MEMBER PARKER: Okay. I understand better now. Okay. Understand that.

MEMBER FAGBUYI: All right.

Bonnie?

DR. RICHTER: Maybe I'm jumping the gun here, but you already brought it up, what your recommendation is. When I read the recommendation section, could you please clarify -- I have a hard time getting through that to say "What is your recommendation?" So I think that first paragraph needs to be a little bit written with more clarity.

MEMBER FAGBUYI: Under the recommendation?

DR. RICHTER: Under recommendation.

MEMBER FAGBUYI: Got you.

DR. RICHTER: So when I read it, I still can't tell what you're trying to tell me. And if I'm having a hard time, then I think other people are going to have a hard time.

MEMBER FAGBUYI: I think that's great. In the Army, we say "bottom line up front." Be bluff, and you probably just state "This is what we're doing," and then go into some detail. Would that be better?

DR. RICHTER: Yes.

MEMBER FAGBUYI: Okay. Skip?

DR. NELSON: Just a comment on the 50-54, 407. One could, for sake of brevity, footnote the harmonized guidances that exist on the part of the FDA, as well as OHRP, which is the Office of Human Research Protections, that specifically outline what that process is and how that process would be used.

For the benefit of the Board and members of the public, briefly, the Pediatric Advisory Committee of the FDA is specifically chartered to be able to advise the FDA Commissioner, as well as the Secretary of HHS, on whether protocols that are referred for review under 50-54 should proceed. So that would occur under the FDA's sort of Federal Advisory Committee structure, with appropriate experts within that committee, including likely, in this case, Vaccine and Related Biological Products Advisory Committee, et cetera.

So that would be the process, and I

might just say I think the word "expectation" is fine. Our regulations require an IRB to make that referral, but I'll just put my own cards on the table to say that if an IRB did not refer such a protocol, they would be out of compliance with the federal regulations.

MEMBER FAGBUYI: Thank you, Skip. John?

MEMBER GRABENSTEIN: So, following Skip's comment, in option one, that sentence that has the CFR references in there, I am glad it is there. I think it should be part of there. It should be clear to everybody that going that route is not an option. If we go the option that's the top of the paragraph, the only way to do it, the only way to implement the option is to go through that 407 process.

And then, with regard to option two and Patty's comments about information-gathering, yes, information will be gathered. And then it hinges upon the availability to act on that information would be after the

event, not during the event.

CHAIR QUINLISK: I'll just disagree slightly with that. During the H1N1, we were looking at adverse events during the event. And should we have started to see problems, that would have been acted upon during the event.

And this is going to be actually a little bit slower, because we do have the antibiotics also. So there is going to be, as I understand, a little bit more of a time period for perhaps dealing with if there are adverse events, or whatever, than maybe we had during things like H1N1, where the viruses were already out there in the community, and that was the only tool we had.

MEMBER FAGBUYI: Jane?

MEMBER DELGADO: Going back to what I think Bonnie said, when it comes to the recommendation, since you have option one and option two, it would be easier if you said which option you were going to recommend. And that recommendation should also be in the

executive summary, so it's clear to people what is being recommended.

That being said, I think that we want to have a document that people can read and understand. And obviously, even something as simple as flu data -- you know, we have a disagreement here. That's okay.

But when you talk about 21 CFR 50-54, I also agree that you should make things clear to the public who are going to read this. We should make things so people understand what our recommendations are, and not have to have a playbook to know what the different things mean.

Because otherwise, it seems like we're not -- like we're trying to hide what we're trying to do. And obviously, since this is a public meeting and a public committee, we don't want to do that. We want the public to know.

And I have to say that when I read the recommendation, I had to go back to the options and say "Well, which one are we

recommending?" It should be clearer, more straightforward, to that.

MEMBER FAGBUYI: Sure. Thank you, Jane. Nicki?

DR. PESIK: So Patty, can I for a clarification? Are you, in your comments, saying that you would only envision a post-event research IND protocol if the pre-event had not happened?

CHAIR QUINLISK: No. I honestly think that, regardless of what's done pre-event --

DR. PESIK: Okay.

CHAIR QUINLISK: -- post-event there will be, I think as we all understand, there will be studies done. I think especially since, pre-event, we assume whatever study is done will probably be small, have a limited number of participants, so that you will always -- almost like you do vaccine trials, you will always do the post-marketing, or whatever.

DR. PESIK: And I also -- thank

you. I think that it would be helpful, perhaps, somewhere in the document -- and we can certainly provide a description. But I think we should be clear. We're talking about a blood draw. It has very -- it's a fairly low risk for the children, and a potential for a lot of information. Perhaps not for the current event, but for other events.

And also, that we're not talking about every child that's receiving a vaccine, but probably a very small number of children, compared to a very large exposure of children in the population.

We're talking probably a couple hundred children, and not every child would be subject to the blood draw, et cetera. So I think that would be helpful, to put it in some perspective.

CHAIR QUINLISK: And I totally agree with you. I will say, though, that if we're looking at adverse events, that would be with every child.

DR. PESIK: Absolutely. And adult.

CHAIR QUINLISK: Exactly.

MEMBER PARKER: You know, one of the -- Jane, you bring this to light in my head. Because as we were writing this -- the difference between a public document and a document that the public has access to to read.

And so I was schizophrenic, almost, from the standpoint of "Are we writing this report for the Secretary to read, and the public may read it if they want to," versus writing a public document. And I think a lot of people, like yourself, have influenced me enough that the document needs to be written so that the public can read it.

And from myself, as living most of my 70 years in the scientific community, you know, you can write a scientific document for the Secretary to read and get the recommendation, but we've really tried to make this document readable to the public.

And all the comments that have come in today, when we act upon those, we'll make

it actually more readable to the public. And I just want to share with you that I really had trouble with the fact, are we writing a document for the public or are we writing a document for the Secretary?

MEMBER DELGADO: The Secretary is part of the public. And I think that's important. And having spent many years in the Secretary's office for prior administrations, what they get is public, and therefore you want to make it so people understand it.

Otherwise, people don't trust government, and don't trust us. And I think that's part of the problem that we're facing, even on something like getting information to the public about biodefense, and the risks, and everything.

CAPT SAWYER: This is Leigh Sawyer. I wanted to welcome Kevin Jarrell, one of our voting members, to the telephone. And because we're coming on to the public comment period, ask the operator if they could ask those on the phone who plan to make public comment to

queue up.

And we will -- I'm going to return to the chair here, but I just want to make sure we can plan for the number of people who may want to make public comment. And anybody in the audience who plans to make public comment, if you could please let it be known at the registration desk. Thank you.

MEMBER PARKER: Patty?

CHAIR QUINLISK: Yes, this is Patty. I just have one last comment. We're going to rewrite the recommendation section, I understand, just to make it clarify and talk about "The Work Group recommends option one."

I think it would be worthwhile in those recommendations, however, to say "If, for example, option one becomes unfeasible because it does not get IRB approval, or whatever, that option two would be recommended."

And then explain specifically the pieces that we would expect to be in a post-event study, that we would then want to ensure

that we do immunogenicity studies, safety studies. I think that's understood, but again, to make it clear to the public, I think that that would be worthwhile to put "If option one is unfeasible, option two would be under these criteria."

MEMBER PARKER: We actually had it at one of our iterations, and took it out because there are some old guys that don't want to give anybody any leeway anyway, you know? But yes, I think your point's well made.

MEMBER DELGADO: Patty, would it be helpful as a state health person, that with option two, that we had some guidelines for people that would be helpful in a post-event?

CHAIR QUINLISK: Could you say exactly what you mean by guidelines?

MEMBER DELGADO: You know, like in an IND, you have your protocols and things like that, the data that you collect. Wouldn't it be nice if we had, for state health officials, some sort of protocol data

for them to collect and use in a post-event?

CHAIR QUINLISK: And I would expect, to be honest, in previous times that has come from CDC.

MEMBER DELGADO: Okay. So that's important, that we have that --

DR. PESIK: The future plan -- right. So the future plan is not only for the INDs -

MEMBER DELGADO: Right.

DR. PESIK: -- but for the pre-EUAs to work with FDA to release these documents, and the drafts, ahead of time.

CHAIR QUINLISK: Right.

DR. PESIK: Because some states may not defer to CDC IRB, but need to use their own IRB. So there's quite a bit of pre-planning for the post-event that would need to happen.

CHAIR QUINLISK: But you're right, Jane. All of that would need to be done, to make it -- if an event happened, to run as smoothly as we could absolutely make it.

MS. KELLEY: Yes, Cynthia Kelley. I just wanted to make clear that, whether or not one recommends doing a study pre-event, the post-event plans are already in place. We've already done all the work, FDA and CDC working together.

And they're going to remain in place until if and when you actually get anyone enrolled and are able to do a pre-event study, if in fact that's the final recommendation. So those things are ready and set to go.

MEMBER FAGBUYI: Thank you. Okay. With that, I'm going to say that we are going to go on break. All right. So it's now 11:30. We will return back at 11:40, and then we will have our public comment.

(Whereupon, the above-entitled public meeting went off the record at 11:30 and resumed at 11:44.)

MEMBER FAGBUYI: Okay, if we can start to make our way back to our seats.

CAPT SAWYER: Operator, if you can

just tell me how many people are wanting to make public comments, please?

OPERATOR: If you would like to make a public comment, please press Star-1 on your telephone at this time. Once again, that's Star-1 to make a public comment.

(Pause.)

OPERATOR: There is one person with a comment.

CAPT SAWYER: Thank you. And I understand that we have three people in the audience waiting to make comments. One of them we actually have, that they sent ahead of time, is going to be read. Okay. So we have about 30 minutes -- I think there's 20 minutes left for public comment. So if there are four people, we're going to give each person up to five minutes, but we are going to cut you at five minutes.

So we're going to begin with the first comment that was received at our email box, and one of the staff members is going to read that for the person.

MS. MUSMAR: This comment was submitted to the National Biodefense Science Board by the Alliance for Human Research Protection, and it starts off "First: absolutely no evidence has been presented to suggest the existence of an anthrax risk for American children. It is an unsubstantiated claim aimed at gaining approval for an illegitimate policy -- just as the claimed threat of Iraqi weapons of mass destruction had been used to gain support for the U.S. war against Iraq.

"Second: Anthrax vaccine efficacy is questionable: Despite being vaccinated, Monkeys Got Anthrax -- so, the vaccine's effectiveness is unproven.

"Third: Safety Concerns: the FDA-approved ANTHRAX VACCINE ADSORBED label states: 'Approximately 6% of the reported [adverse] events were listed as serious. Serious adverse events include those that result in death, hospitalization, permanent disability or are life-threatening.'" They

have listed a website for this.

"Indeed, there were 757 serious adverse event reports following vaccination of 2.5+ Million soldiers. There were 42 reported deaths.

"Gulf War Syndrome features are subjective and no biomarkers exist. Symptoms include Fatigue, Pain, Cognitive and Emotional Impairment. It can take from months to several years for symptoms to develop. Most case will probably be overlooked in children.

"Will the FDA consider and evaluate subjective signs of illness before issuing a clean bill of health for the vaccine?

"How will subjective signs of illness be identified and monitored?

"How long will vaccinated children be followed as part of the trial?

"Fourth: Why exactly did you disregard the legal-ethical prohibitions under CFR 401.07, against the use of children in experiments involving greater than minimal risk with no direct benefit?

"How can you ignore questions about how well the vaccine works, if vaccinated monkeys became ill with anthrax? Are you going to inject healthy children who are not at risk of anthrax, with a vaccine that is both dangerous and likely worthless?

"The Alliance for Human Research Protection suggests: follow the money to discover the real catalyst for the proposed unethical anthrax pediatric vaccine trial.

"Evidence uncovered by Scot Lilly, Senior Fellow at the Center for American Progress, formerly with the Senate Appropriation Committee, who examined 10-K documents filed by anthrax vaccine manufacturer, Emergent BioSolutions Inc, with the Securities and Exchange Commission:

"These documents reveal that in 2009, the company manufactured only one product and had one purchaser -- the U.S. government. Revenues in 2009, amounted to $217 million, while the vaccine manufacturing costs amounted to a mere $46 million. That

netted the company a 300% profit.

"This is astronomical: by comparison, a 2009 study of 6,00 Army and Air force contracts by the Institute for Defense Analysis found that margins on such contracts typically ranged between 9% and 10% of production cost.

"Further research by the Center for American Progress revealed that the vaccine was developed with taxpayer money by U.S. Army scientists. Yet, over the past decade, the U.S. government paid Emergent BioSolutions $1.3 billion for this vaccine netting the company over a billion dollars in profit from the anthrax vaccine whose production cost amounted to a quarter of a billion dollars.

"Read "Getting Rich on Uncle Sucker" 2010" And the link is provided.

"FDA-approved label for ANTHRAX VACCINE ADSORBED, January 31st 2002, states:

"Approximately 6% of the reported events were listed as serious. Serious adverse events include those that result in

death, hospitalization, permanent disability, or are life-threatening. The serious adverse events most frequently reported were in the following body system categories: general disorders and administration site conditions, nervous system disorders, skin and subcutaneous tissue disorders, and musculoskeletal, connective tissue and bone disorders. Anaphylaxis and/or other generalized hypersensitivity reactions, as well as serious local reactions, were reported to occur occasionally following administration of BioThrax. None of these hypersensitivity reactions have been fatal.

"Other infrequently reported serious adverse events that have occurred in persons who have received BioThrax have included: cellulitis, cysts, pemphigus vulgaris, endocarditis, sepsis, angioedema and other hypersensitivity reactions, asthma, aplastic anemia, neutropenia, idiopathic thrombocytopenia purpura, lymphoma, leukemia, collagen vascular disease, systemic lupus

erythematosus, multiple sclerosis, polyarteritis nodosa, inflammatory arthritis, transverse myelitis, Guillain-Barre Syndrome, immune deficiency, seizure, mental status changes, psychiatric disorders, tremors, cerebrovascular accident, facial palsy, hearing and visual disorders, aseptic meningitis, encephalitis, myocarditis, cardiomyopathy, atrial fibrillation, syncope, glomerulonephritis, renal failure, spontaneous abortion and liver abscess. Infrequent reports were also received of multisystem disorders defined as chronic symptoms involving at least two of the following three categories: fatigue, mood-cognition, musculoskeletal system.

"Reports" --

CAPT SAWYER: Thank you. Now we're going to go to the telephone for a comment there. Operator?

OPERATOR: Al, your line is open.

DR. ROMANOSKY: Hi, Dan and John. It's Al Romanosky from Maryland. I have to

agree -- and there may have been some further discussion on this, but I had to step out of the office for an impromptu quick meeting. But somebody had mentioned the need about putting some information about morbidity and mortality of inhalational anthrax into the draft report.

I think that that would be important, because it adds another layer of context for why the anthrax PEP vaccination is considered important, in addition to the other information about the need to identify the immunogenicity and potential side effects in the pediatric population.

MEMBER FAGBUYI: Thanks, Al.

CAPT SAWYER: Dr. Nass, are you in the audience?

DR. NASS: I am. Can I be last?

CAPT SAWYER: Oh, you want to be last? Okay. Then we have Ms. Dwoskin.

MS. DWOSKIN: My statement is not made with any disrespect for those in the positions of power here today to decide, under

pressure from known and unknown sources, the fate of children whose bodies and health may be used for profit-seeking purposes. In defense of children, it is appropriate to use the strongest, most compelling logic, language, and reason to protect those who cannot protect themselves.

I cannot see any relationship between the use of this vaccine and protecting children from an anthrax attack. Even if a vaccine for anthrax was added to the recommended pediatric schedule, there is no evidence that it would be protective against any particular strain of anthrax, or how long any supposed protection would last, given the likelihood of an attack.

If it were used as a post-event prophylaxis, it would not be effective until sufficient immunity was developed, requiring many months, whereas antibiotic treatment is 100 percent effective. How could this study possibly provide useful information for the purposes the vaccine is proposed?

After reading the materials prepared and distributed for this meeting and an analysis of the relationship between lobbying interests for the company that manufactures the anthrax vaccine and the resulting increases in proposed vaccine stockpiles in the report from the Center for American Progress titled "Getting Rich Off Of Uncle Sucker," as well as other safety studies, I oppose the testing of anthrax vaccine on children.

This is the most egregious example of the government accepting and committing expenditures to a fabricated assertion of risk with a potential solution that is expensive, unproven, and puts individuals and children in the role of guinea pigs for corporate profit-seeking interests of the worst kind, by utilizing an army of lobbyists to manipulate the regulatory and legislative processes to engineer the purchase of a product that evidence shows is more harmful than helpful.

A trial to support any policy that

would prophylactically administer anthrax vaccine to the public, including children, in the absence of any realistic demonstrated threat, is a swindle of scarce health care resources, and is economically, ethically, and scientifically unsustainable.

The anthrax vaccine has never been proven to prevent a single case of anthrax infection in a civilian setting. According to published anthrax vaccine protocols, post-exposure prophylactic administration of anthrax vaccine would still require multiple doses and weeks to build immunity, and would require the use of 100 percent proven effective co-administration of antibiotics. Therefore, this proposed pre-event trial would not be conducted under conditions that would exist if an exposure took place, or revealed the true level of adverse reactions that children could experience if required to take the anthrax vaccine with simultaneous administration of antibiotic.

Antibiotic use interferes with the

normal function of the immune system, and it would be unknown how the body reacts to the vaccine as it is co-administered with an antibiotic, and whether antibodies would be produced if an event were to occur and co-administration were recommended as treatment.

A pre-event trial would only measure the reaction to the vaccine alone, which is not a realistic measure of the results that would be required to assess efficacy and safety in the event of a post-exposure prophylactic vaccine treatment.

The investigation of white powder letters sent to D.C. schools one week after the announcement of the meeting to discuss anthrax trial on children, thereby seeming to satisfy one of the conditions of the regulations preventing experimentation on children, should be thoroughly investigated before any proposed vote on the approval of this trial.

Who on this committee will go on record to offer their own children or

grandchildren as a test subject for this trial? The approval of a trial to test anthrax vaccine in children only serves the profit-seeking motives of the company producing the vaccine, not the health of children.

I seriously doubt that this meeting would even ever be taking place if the vaccine manufacturer had remained in the hands of the government, rather than in a private company. There is no possible way to test the safety or efficacy of the vaccine on children under the conditions the vaccine would be administered. Therefore, the trial data would be unreliable, and the trial itself could cause serious harm to children who receive the vaccine.

If this trial is approved, a complete compilation of VAERS reports should accompany the risk statements that are presented to parents, to provide them full information. Resources would be better spent preventing an anthrax attack than on sickening unsuspecting recipients of a vaccine that has

a very questionable safety profile.

Testing an experimental adjuvant on children under the premise of protecting the public against terrorism appears to be a backdoor way of testing an experimental adjuvant in violation of existing regulations, which protect the public from this very type of human research experimentation.

CAPT SAWYER: Thank you. Dr. Nass?

DR. NASS: I was hoping you'd have a table where I could put my computer, but just give me a moment.

Okay. I think everybody -- my name is Meryl Nass. I practice internal medicine. I've written a Review article on anthrax vaccine that was published in infectious disease clinics, and I've given half a dozen congressional testimonies that had to do with anthrax vaccine.

This vaccine's efficacy, in adults as well as children, is uncertain. And all the literature that's looked at that has been clear that it depends on the size of the

inoculum, the strain of anthrax, and the strain of the animal that's being affected, as to how effective the vaccine is. So until you know what the attack anthrax is going to look like, there's no way for you to be really sure about efficacy. And that is very clear in the literature.

First of all, nobody really knows how many spores are going to germinate late, after the 60 days of antibiotics. One could certainly give antibiotics longer. For tuberculosis, you give them for nine to twelve months. For osteomyelitis or subacute bacterial endocarditis, you give antibiotics for four to eight weeks.

Certainly, antibiotics have side effects. There are problems with compliance. But we do it all the time. We give prolonged antibiotics. And there are no big problems with it. I do it on a regular basis.

Okay. What are the problems with the compliance to anthrax vaccine? When the anthrax letters were sent, 10 to 30 thousand

people were offered antibiotics, and many thousands took antibiotics for different periods of time, because compliance with the whole 60 days was about 40 to 50 percent.

What was the compliance with vaccine? Everybody who took antibiotics was offered vaccine. 198 people took vaccines, and almost half of those were congressional staffers who were counseled by an admiral. In England, when airmen were given the vaccine, a study looked at how many continued to take it at three or four different air force bases. Compliance, by the time you got to the fourth dose, at different airbases, was between 4 and 20 percent.

Obviously, the side effects must be greater from the vaccine than the antibiotic, to have this kind of a compliance problem. So please get your facts straight before jumping up and down about antibiotic compliance.

Another thing that wasn't mentioned today was the fact that the U.S. government has stockpiled antisera and monoclonal

antibodies for anthrax, which in the event of an emergency could be given to people who were exposed or even had become ill, and would give you the same antibodies that it would take about 35 days for your own body to develop. But they could be given IV immediately, and start to work.

It's not at all clear that there's any advantage to giving vaccine, starting at day one or somewhere like that, when you're giving a 60 day course of antibiotics. You don't get virtually any benefit from the vaccine until about day 35. And then, of course, as I said, you don't really know how much benefit you're going to get from vaccine.

Now what doctor is going to take a patient off a 100 percent effective antibiotic regimen, that worked in every case during the anthrax letters to prevent anthrax in people who were not yet sick, and rely on uncertain vaccine protection after those 60 days are over?

I mean, somebody's going to figure

out how much antibiotic you need, and the doctors are going to give antibiotics for that long. No doctor is going to be foolish enough to risk the lives of their patients on an unproven vaccine, which your own consent form admitted was unproven, your draft consent form that was discussed at the prior meeting.

The efficacy in the Brachman trial for a much older anthrax vaccine was 92 percent, and that was for cutaneous anthrax. So nobody knows about this vaccine, and no one knows about inhalation anthrax.

By the way, the serious adverse event rate to VAERS, I just checked last week, is 11 percent now. 757 serious adverse events. And according to the Military Vaccine Health Care Centers and the GAO, one to two percent of people who get anthrax vaccine suffer a serious adverse event. That's this MILVAX and Vaccine Health Care Center slide, okay?

One to two percent. Now, how are you going to call this vaccine minimal risk?

You can't do it under --

CAPT SAWYER: Thank you. I'm sorry, your time is up.

DR. NASS: Anybody who wants my handouts, please come see me after. Thank you.

CAPT SAWYER: Also, any written comments, we will include at the end of the summary of this meeting. They will be available to the public. Thank you.

MEMBER FAGBUYI: Any other comments?

(No response.)

MEMBER FAGBUYI: Okay.

CHAIR QUINLISK: Okay. Well, thank you all for all the comments this morning. And I'd like to again thank the Working Group, and particularly Dan and John, for all of their work putting together this report.

I think they've put a lot of time and effort into this, and people have come to the Work Groups and to the workshop, and certainly gotten on a lot of conference calls.

But I appreciate everybody's efforts in putting this report together.

We've received a lot of comments and suggestions this morning, particularly for the executive summary, which then, of course, would also be reflected in the whole report. So let me go back to Dan and John, and given all the comments and suggestions, what do you think your timeline is for having the next draft of this available to the Working Group? And you cannot say next year.

MEMBER FAGBUYI: So, we are in the last week of September. Actually, almost the last week. Second to last. We anticipated -- our initial discussion was that we would hope to have the draft for review, discussion, and vote, actually, within four weeks.

So if I look at the calendar, we are looking at the last week -- second to last week in October. And I would actually prefer that we just say the last week of October, and that would be either Tuesday or Thursday, so around the 24th to the 27th, the week of the

24th to the 27th of October we should have something tangible.

CHAIR QUINLISK: And are you planning on, for example, having a rewrite going back through the Working Group one last time before you bring it to the full Board?

MEMBER FAGBUYI: Most definitely.

CHAIR QUINLISK: Okay. So the month will give you time for --

MEMBER FAGBUYI: Yes, a couple of calls.

CHAIR QUINLISK: -- a draft, maybe a couple drafts, and so that you would be able to present to the Board and you wouldn't have to allow time for them to look at sort of the final draft. So I think your idea of a month probably is quite realistic.

So we are looking at the last week of October, of having probably a conference call meeting in order to do final deliberations and voting on the whole report, and of course the recommendations. Is that correct?

MEMBER FAGBUYI: Correct?

CHAIR QUINLISK: Let me just look to the Board members and see if there's any comments on that timeline, or that process?

(No response.)

CHAIR QUINLISK: Everybody is in agreement? And anybody on the phone on the Working Group or Board have any comments?

(No response.)

CHAIR QUINLISK: I think what we'll do, then, is we'll ask Leigh and the staff to put together a conference call for that last week of October, with anticipation that the Working Group will respond very quickly to any drafts that come out, and that the Board will quickly review any final draft that comes out to them in preparation for that conference call and final vote.

CAPT SAWYER: Yes. I just wanted to add the caveat that I know Dr. Lurie, I expect, will want to come to the meeting, so I'll need to check with her calendar or whoever else she may have here for her.

CHAIR QUINLISK: Okay. So that will be the next steps for dealing with the Working Group report, as well as the recommendations that are coming out of the Working Group to the Board. And just to remind you, the whole Board will be asked to then vote on the report and the recommendations prior to it being sent to the Secretary as our final specific recommendation of the Board itself.

We have a couple minutes. Are there any other questions or comments, or issues surrounding the Anthrax Vaccine Working Group, the presentation and the report?

(No response.)

CHAIR QUINLISK: Any on the phone?

(No response.)

CHAIR QUINLISK: Okay. We thought that would take about 15 minutes, but you all are very quiet. So I don't know that we have any other issues at this time, so I think then we can just go -- okay. So what we will do, then, is we will be having lunch on our own.

That ends all of the discussion about the Anthrax Vaccine Working Group report at this time, until such time as the group comes back to the whole Board with a final recommendation.

We will go to lunch at this point, and at 1:15 we will be talking about the reauthorization of the Pandemic and All Hazards Preparedness Act. So we will reconvene here at 1:15. Thank you, everyone.

(Whereupon, the above-entitled public meeting recessed for lunch at 12:08 p.m. and resumed at 1:18 p.m.)

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

(1:18 p.m.)

CAPT SAWYER: This is Leigh Sawyer. We'll be starting the meeting in just a couple minutes as people take their seats here. And we have people on the phone, still is that correct?

MEMBER BERKELMAN: That's correct.

CAPT SAWYER: Is that you, Ruth?

MEMBER BERKELMAN: It is.

CAPT SAWYER: All right. How was your lunch?

MEMBER BERKELMAN: Excellent.

CHAIR QUINLISK: Okay. I think we'll go on to our next step, and we're going to have -- and I'll probably butcher this name -- Zeno St. Cri?

CAPT SAWYER: Cyr.

CHAIR QUINLISK: Whoops. Sorry. I told you I'd probably butcher it. Anyway, he is going to talk to us about the reauthorization of the Pandemic and All Hazards Preparedness Act. Thank you.

MR. ST. CYR: Good afternoon, everyone. I'm happy to be here with you all today to give you an update on what's going on with the reauthorization of the Pandemic and All Hazards Preparedness Act. I thought that I would talk this morning about a couple of things.

First of all, the House bill that's already been introduced and has made it out of committee. That bill number is H.R. 2405. I'll talk for a few minutes about the status of the Senate bill, what's going on in the Senate with regard to a PAHPA reauthorization, and then I'll wrap up with some comments about next steps, and where we appear to be going.

First, let me share with you that in our conversations with House and Senate staffers, there were a couple of what I call guiding principles that the staffers shared with us about where they saw PAHPA reauthorization going.

First, we learned that there was pretty wide support on both sides of the

aisle, Democrats and Republicans, and in both the House and the Senate, for doing a PAHPA reauthorization bill this year.

We also were told that, given the current economic and political climate, that there was no appetite on the Hill for any big, broad legislation that provided sweeping new authorities, or that provided a number of new appropriations for any of the new or the current authorities that would be in a PAHPA reauthorization bill.

More so, they envisioned a reauthorization bill that more tweaked the current bill, and maybe filled some gaps that we had found in the five years since PAHPA was first enacted. And there might be some consideration of the non-PAHPA-related legislation, such as the Project BioShield Act that was enacted in separate legislation.

And in terms of some of the gaps and the tweaks to the current model, in that context there might be some consideration of some new authorities. But again, these were

envisioned to be small, more technical corrections. Things along that line, for inclusion in the PAHPA reauthorization bill.

There's been considerable interest, and I'm sure many of you are already aware of the interest in this PAHPA reauthorization bill. A number of entities, a number of stakeholders have provided input to House and Senate staffers on what they envision should be in a reauthorization bill. Many of those stakeholders, those communities of interest, if you will, have their own particular niches in various provisions of PAHPA.

I've listed here some of the stakeholders who now have provided some technical assistance, if you will, to the Hill staffers. Some have actually written provisions that they have wanted to be included in PAHPA reauthorization.

So with that, let me turn to talking about the House bill. As I mentioned earlier, the House bill is H.R. 2405. It was introduced by Representative Mike Rogers from

Michigan. There were two co-sponsors of the bill: Representatives Sue Myrick from North Carolina and Gene Green from Texas. The bill was introduced and handled by the House Energy and Commerce Committee. Before the August recess, the Energy and Commerce Committee held a markup of the bill, and it cleared the Committee.

Currently, the bill is being scored by the Congressional Budget Office, so that it can then go to the full House for consideration. And some of you may know that, under the scoring process, if the Congressional Budget Office determines that there are cost items in the bill, then the Committee, and ultimately the full House, will need to determine some offsets in other areas of the federal budget to cover the costs of those items that are in PAHPRA.

I've listed on this slide a number of the straight reauthorizations that are included in the House bill. Now, interestingly, in the House bill, for the

authorized amounts for each of the provisions, the authorizations are flatlined, level-budgeted for the full five years of the reauthorization.

So we've got the Pandemic Influenza Vaccine Tracking and Distribution provision, the Public Health Emergency Preparedness grant program, operated by our sister agency, CDC, the HPP program, and on, listed there in the amounts -- the Medical Reserve Corps -- those amounts listed are authorized for each of the five years that the bill would be reauthorized, 2012 through 2016.

Then there are a few -- these are some of the tweaks, some of the new authorizations that would be included in PAHPRA, in the House's PAHPRA bill. The first one is -- if it was on a test, it might be a trick question, because it's not really a new authorization.

Under the existing PAHPA bill, the Biodefense Medical Countermeasure Development Fund was authorized, but it was never funded

by the Appropriations Committee. That's the fund that would fund some of the activities in BARDA.

Under the new bill introduced in the House, the Biodefense Medical Countermeasure Development Fund would be authorized for each of the five years, Fiscal Year '12 through Fiscal Year '16, at 415 million dollars. I'll get back to the appropriations process in just a minute.

Also, this bill would now give ASPR the authority to use up to 30 percent of the Special Reserve Fund for Advanced Research and Development activities. Under the existing provisions of PAHPA, if ASPR wants to use any of the Special Reserve Fund dollars for Advanced Research and Development funding, we would have had to go back to the Congress to request that through the appropriations process, to get approval to use our funds. And we have done so for several years now, but under the House's PAHPA reauthorization bill we would no longer have to request that

permission from Congress to use those funds. We would be authorized to use a percentage of them, up to 30 percent for ARD funds.

And we found during the ED response, as well as going back to some of our hurricane response, that we had trouble paying in a timely manner some of the hospitals that contracted with, in the event, the Natural Disaster Medical System for care that was provided to some of the patients that NDMS would evacuate during emergencies.

So this bill would provide us with the authority to directly contract to pay for those services that are provided by hospitals to some of the NDMS patients that are evacuated. That's another one of the tweaks to the law that would be provided.

The bill would clarify a lot of the duties and functions of the ASPR. The intent of the original legislation was to establish ASPR as the lead federal agency within HHS to coordinate emergency preparedness and response activities. This bill would try to strengthen

that language around ASPR's role in this regard.

Another tweak to the House's bill would be that now the Secretary would be provided the authority to allow states to redeploy federally paid employees on the state payroll that might be able to assist with the response efforts during an emergency. We found particularly during the H1N1 response that a number of workers who were paid under federal grant programs -- state workers who were paid under federal grant programs -- could not move to assist the state efforts in responding to H1N1, because the current federal grant laws did not allow for it.

Under this provision in the House bill, someone who is working at the state level, who is working on one of the federally funded programs, would be allowed to temporarily move to assist state efforts: vaccination efforts, immunization efforts, or other activities related to a particular emergency. And I might add that this was a

concern that we heard from many of our stakeholders at the state level, and we're happy that this was put into the House bill.

The House bill also mandates a new Countermeasures Implementation Plan that would be required from the Department within the first six months after enactment of the bill, and then annually thereafter. This Countermeasure Implementation Plan would include a number of ASPR-related activities, and I have listed some of them there. This plan is also intended to replace a lot of the other annual reports that are required under the existing PAHPA legislation.

ASPR is involved right now in a grant alignment effort, working with our federal partners at the Department of Homeland Security, with the Department of Transportation, and a couple of others, to try to align our grants. Many of us have various grants that we provide to states right now, and other grantees -- territories, tribal organizations -- that have different grant

cycles, different but similar grant requirements.

It's a burden on the states, who are already overburdened and shorthanded, and short-funded, to meet the requirements of so many of those different grant vehicles. Just within HHS we have two very similar partner programs: the PHEP grant program and the HPP grant cooperative agreement, grant program, that we've tried to forge a close working relationship with to align the requirements for those grants.

Now we want to go across the federal interagency to work with some of our partners to see if we can't do the same with, again, Transportation, Homeland Security, on related grants. Interestingly, that effort we have undertaken administratively, but the House bill would incorporate this effort into the statute.

And there's a number of provisions in the House bill that relate to the Emergency Use Authorizations that are really in the

purview of the Food and Drug Administration. I have listed those here, but am not going to go into them in any detail.

Before I get to the Senate reauthorization, I want to go back and mention one item that I think is very important. As you know, the PAHPA expires -- the PAHPA legislation expires this year, 2011. The Project BioShield legislation is separate legislation from the Pandemic and All Hazards Preparedness Act. The BioShield Special Reserve Fund expires in 2013, but the House staffers decided to incorporate reauthorization of the BioShield program into this PAHPRA legislation, and we were certainly very happy to see that, and think that that's a good thing.

So the BioShield program originally was authorized with a Special Reserve Fund of about 5.8 billion, somewhere over 5.6 billion, thereabouts, over a ten year period. The House bill would reauthorize the BioShield program for a five year period at about 2.8

billion dollars for the five year period.

I said that I would go back and talk for just a few seconds about appropriations. I already mentioned one of the programs, the Medical Countermeasure Development Fund, that was not funded by the Appropriations Committee under the original PAHPA legislation. And every year, there's a number of pieces of legislation that are enacted by the Congress, by the authorizing committee, but when those provisions get to the Appropriations Committee, for one reason or another they're not funded.

So while the House bill sets forth a number of authorization levels for funding of the values, pieces of the bill, there's still going to be a hurdle getting over getting those provisions funded by the Appropriations Committee. So the first step here is to reauthorize the Pandemic and All Hazards Preparedness Act, and then we will work with the appropriations committees, House and Senate, to try to ensure that in this very

austere budget environment, that those authorization levels are met. We will certainly do our best to hope that those funding levels will be provided by the appropriations committees, House and Senate.

Next, let me turn for a few minutes to the Senate bill. We have been working with the Senate HELP Committee. That is the committee in the Senate that will introduce this bill, and that will need to approve it. That committee is chaired by Senator Tom Harkin from Iowa, and Richard Burr, who is one of the leading Republicans on that committee and is also the mother of PAHPA, if you will, is also very much involved in the drafting of the Senate version of PAHPA reauthorization.

The staff meets regularly on drafting the provisions of their reauthorization bill, and they've had very frequent interactions with HHS staff, our leg staff, about the provisions that will be included in their bill.

It has not been introduced yet, but

we are expecting that it will be introduced sometime soon, perhaps later this month. Certainly, we think, sometime in October. We anticipate that that bill is going to mirror the House bill, but may include a few differences. One of the differences that we are hopeful for, and that we continue to provide technical assistance to the HELP Committee staffers on is something that you all may also be aware of, and that's the Strategic Investor Initiative.

The Strategic Investor Initiative was one of the items, one of the recommendations that came out of the Secretary's Medical Countermeasure Review. It essentially would establish as a separate non-profit entity, a venture capitalist organization that would help our efforts to get more companies at the point where they would be eligible for Advanced Research and Development funding, and eventually BioShield program funding, to produce some of the medical countermeasures that are needed to

protect the American people.

We also think that under that Strategic Investor Initiative, any funding that is provided by or through the strategic investor could be used to leverage four-, five-fold, or more, investments from the private sector. Again, to help bridge the funding gap that's needed by many of these companies to move the research along for the products that we are looking for.

Once the Senate introduces its bill, we expect that they will have a very speedy markup in the Senate HELP committee. They, too, will have to have the bill scored by the Congressional Budget Office, and then we think that it'll get moved to the full Senate floor in rapid succession.

So what are some of the next steps that we anticipate occurring? Well, we certainly think that both the House and the Senate will be voting on the PAHPA reauthorization bill in this session of Congress.

Because we anticipate some differences between the bill introduced in the House, H.R. 2405, and the bill that the Senate will approve, there will likely be a Conference Committee formed, but we don't anticipate any -- at this point, we don't anticipate that there will be any protracted deliberations between the Conference Committee to work out the differences in the bill. We think that there's enough agreement on many of the provisions that -- and we certainly are hoping that the Conference Committee can do its work very quickly.

We at HHS, at the leg offices of the Department, will continue to provide technical assistance to the staff as requested, as needed. We fully expect that there is going to be a PAHPA reauthorization bill that is sent to the President to sign this session, before the Congress adjourns for the year. And as I mentioned earlier, once that is done appropriations will continue to be a challenge, given the current fiscal

environment that we are in.

And I thank you for allowing me this opportunity to provide you with an update. I'll be happy to try and answer any questions that you may have at this time.

(Applause.)

CHAIR QUINLISK: Thank you very much. That was a nice update. What I'd like to do now is open it up for questions. And Steve, I think you're first.

MEMBER CANTRILL: This is Steve Cantrill. Thank you again for a very clear presentation. I have two questions. First, in terms of the temporary redeployment of personnel, are those only full federal personnel that could be redeployed, or would that be any employee working on a federally funded project?

MR. ST. CYR: It's any employee working on a federally funded project. Just to give you a couple of examples that may or may not be real examples, but the Department funds HIV programs at the state level --

MEMBER CANTRILL: Right.

MR. ST. CYR: -- and other communicable diseases programs. We've got chronic disease programs that are funded at the state level with federal dollars. Individuals who are working on those federally funded activities, under this provision, would be able to -- or the state or local health department would be able to petition the Secretary to allow them to temporarily move from that program to working to help address whatever the emergency is that is taking place.

MEMBER CANTRILL: Thank you. That knife cuts both ways. It's a very interesting piece of legislation. But thank you. Second question, in terms of -- since the NBSB was started under PAHPA, are they mentioned at all? Will this Board be continuing?

MR. ST. CYR: The Board is not mentioned at all. But that's not a bad thing.

(Laughter.)

MR. ST. CYR: As I understand it,

under the original legislation, the authority was given to the Secretary, or perhaps even delegated to ASPR, to continue the NBSB if that is deemed necessary and appropriate. So there is no need -- the bottom line is, there is no need for any new legislation to reauthorize the NBSB. The Department has all the authority it needs right now to continue with your activities.

CHAIR QUINLISK: Thank you. I think Pat was next. And by the way, if there's anybody in the audience who has questions, after the Board is done, if we have time, we'll take questions from the audience, too. Pat, go ahead.

MEMBER SCANNON: Yes, Pat Scannon. I have a question of clarification. On slide nine, you talked about the Countermeasures Implementation Plan, and one of the items is "identifies and prioritizes needs." And I'm just wondering how that interacts with DHS's Material Threat Determinations. Is that -- I don't know, does that supersede the MTDs, or

is that independent of the MTDs?

MR. ST. CYR: It is independent of the Material Threat Determination process, and the Material Threat Assessment process, as handled by the Department of Homeland Security.

MEMBER SCANNON: Okay. Thank you.

CHAIR QUINLISK: I think John, you are next.

MEMBER GRABENSTEIN: Mr. St. Cyr, thank you very much for the detail. In slide six, you have 415 million dollars for a Countermeasure Development Fund. Is that limited to Chem/Bio/Rad/Nuke, or does that need to share space with pandemic influenza as well?

MR. ST. CYR: You know, I think it would also cover emerging infectious diseases, as well as CBRN threats.

MEMBER GRABENSTEIN: Okay. Thank you. And I'm delighted to see that Countermeasures Implementation Plan idea. That's a wonderful thing.

MR. ST. CYR: And the key there is whether or not the Appropriations Committee will fund it.

MEMBER GRABENSTEIN: Ah.

MR. ST. CYR: They did not fund it -- this is not a new fund. This fund was created under the original PAHPA legislation, but it was never funded. In the full five years that PAHPA has been in existence, this fund has never been funded by the Appropriations Committee. So ASPR, and BARDA in particular, have used other means to fund the activities that are envisioned to be funded under part of this fund.

MEMBER GRABENSTEIN: So this is a second attempt to get the appropriators to appropriate?

MR. ST. CYR: You can view it that way. The fund is being reauthorized at an authorized funding level of 415 million dollars for each of the five years of the reauthorization. We'll have to wait and see whether the appropriators will fund it.

MEMBER GRABENSTEIN: Okay.

MR. ST. CYR: We certainly hope they will.

MEMBER GRABENSTEIN: And then on slides 11 and 12, you talk about EUA authorizations and flexibility. This is something that the Board has interacted with multiple times in its history, and as I am interpreting some of your bullets, this looks like good and prudent aspects to give the Secretary more prerogatives and more ability to respond.

Are there particular pieces of this that have a story behind them, or that there is some issue that everybody clearly wants to resolve by means of these changes?

MR. ST. CYR: Let me say up front, I am not an authority on the EUA process. My colleagues at the Food and Drug Administration, I will say, are very happy with these provisions, because it gives them a lot of the flexibilities that they think are necessary in order to improve the EUA process

and allow us to use it in a way that benefits the American people during an emergency.

So just in general, I can say that these new authorities, these new flexibilities in the current EUA law, are welcomed by the FDA. And if there are other, more specific questions, I'd be happy to take those back and get an answer to those questions for you, and get that response over to Leigh Sawyer so that she can get it to you.

MEMBER GRABENSTEIN: Thank you.

CHAIR QUINLISK: Dan Fagbuyi?

MEMBER FAGBUYI: Dan Fagbuyi. Thanks for the presentation. I'm glad to see that the needs of children are being addressed in this. We'll see what happens when it goes over to the other side. And specifically, it just says "address the needs of pediatric populations," whatever that means. So hopefully, they'll be more specific on what that entails. That's one.

The second is, with regards to the ASPR, it sounds like they're trying to make

sure that the ASPR role has more teeth, and I think that's important. And hopefully they'll be able to clarify what those exact roles are, and what takes lead, especially with the other agencies that are involved.

Because I think the issue is that different agencies tend to work in silos. Everybody's working on the same thing, and it sounds like they're trying to bridge that. Hopefully, that will be addressed clearly. Thank you.

CHAIR QUINLISK: Okay. Skip Nelson?

DR. NELSON: I think Dan touched on my concern. I guess I was interested in hearing if there are any areas where the needs of children are explicitly addressed. Because I think often, unfortunately, even though implicitly we assume that it may apply to all citizens, children are often left as an afterthought in many of these things, unless they're explicitly included.

So I'm just wondering if there's

some explicit language that's been provided in different areas that would make it clear that children need to be a priority in terms of preparedness, as well.

MR. ST. CYR: There are. And certainly in this newly-envisioned Medical Countermeasure Implementation Plan that's included in the House provisions, children are certainly mentioned. There are other provisions in the bill, some of those relating to reauthorization of BARDA and to the work that it does, where children specifically are mentioned.

But I'd like to digress here for a moment, and say that this is an area that is very important to Dr. Lurie. There are some things that are being done to institutionalize ASPR's response across the preparedness and response continuum to address the needs of children, as well as other at-risk populations, both in terms of response efforts and plans that are being required by hospitals and other entities, and addressing the needs

of children during a disaster, to the medical countermeasure development process, and trying to encourage manufacturers to develop pediatric formulations of the product that we're contracting with them for.

There are a lot of things that are being done to really institutionalize the needs of children and other at-risk populations in the entire preparedness and response continuum. I know that this is an area in which we had some of these discussions with those staffers, that they are very much interested in.

And a lot of the communities of interest who have, independently of us, met with and provided technical assistance to House and Senate staffers, have also expressed their interest in this area, and their concerns in this area. So I can tell you that it has been a topic of a lot of conversations, and I fully expect that those conversations which have taken place in the Senate will continue on through the introduction of their

bill, and their consideration of their bill as well.

They may also be addressed when the full House takes its consideration of the House bill. So the needs of children certainly have been a huge topic of discussion in this whole PAHPA reauthorization process.

CHAIR QUINLISK: Okay. Do we have questions on the line?

MEMBER BERKELMAN: Yes, this is Ruth Berkelman. And in the first question, there was some attention (phone interference) developing (phone interference) public health systems (phone interference) emergency response preparedness. And that has (phone interference) funding for that early research (phone interference) eliminated (phone interference) budgets, cut budgets. And I'm wondering, is it going to be included in the reauthorization (phone interference) is it in the current bill?

CHAIR QUINLISK: Ruth, I'm sorry. You're sort of fading in and out. It was hard

for us to totally understand what your question was. Could you please restate that?

MEMBER BERKELMAN: Let me see. Can you hear me better?

CHAIR QUINLISK: Yes, that's better.

MEMBER BERKELMAN: Okay. The question is, does the new bill pay any attention, or reauthorize funding for research in schools of public health related to preparedness systems, emergency response systems? That was first authorized in the first bill, and the funding has been eliminated for next year. So I'm wondering if it's even included in the reauthorization bill.

MR. ST. CYR: Yes, in the original PAHPA legislation, that money was authorized and was administered by our sister agency, the Centers for Disease Control and Prevention. I know that in the PAHPA reauthorization bill, there is a provision that includes 160 million dollars each year for a number of public

health improvements, a number of public health capacities and situational awareness improvements.

I believe, but would have to go back and check, that a section of the bill that includes those public health, schools of public health grants, are included in that 160 million dollars. But I would need to go back and double check that.

MEMBER BERKELMAN: Thank you.

CHAIR QUINLISK: Pat?

MEMBER SCANNON: Yes, Pat Scannon. I have more of a comment than a question, but it's just to reinforce something that was said earlier by Skip and Steve. And that is, this issue of special populations has always been a concern of this Board, and as well, as I know, ASPR.

And all of the issues around medical countermeasures -- and just to point out that it's not just the pediatric population, but immunocompromised patients, disabled patients -- you know, there's a

growing recognition that people over the age of 65 may not have the same kind of responses as people younger than 65, and there's a lot more of those folks around now. And I'm not looking at you, John.

(Laughter.)

MEMBER PARKER: Watch it, sonny.

MEMBER SCANNON: So I'm just saying that I think that's going to become increasingly important in any deliberation related to medical countermeasures, and I think certainly it's something that I hope is transmitted to the staffers as part of this reauthorization.

MEMBER BERKELMAN: This is Ruth again on the line. I just wanted to add to that that there are issues beyond the countermeasures that also need to be addressed, such as the evacuations of nursing homes and other things where there were certainly problems with Irene in New York City. But just to add that it is -- countermeasures are huge, but they're not the

only issue out there.

MR. ST. CYR: And that's exactly right. And that's what I was attempting to address when I mentioned what Dr. Lurie is trying to do to institutionalize all of our preparedness and response efforts across the entire continuum of response and preparedness efforts.

It includes all of the special populations, addressing evacuations, addressing chronic illnesses that some of these special populations may need, on, up, and through the development of pediatric formulations of medical countermeasures. So it is, in fact, the entire continuum that we in ASPR are trying to address and, again, institutionalize, in statute or not.

CHAIR QUINLISK: Okay. Well, thank you so much. That was very informative, and I appreciate you coming and giving us an update on what may be happening with reauthorization.

MR. ST. CYR: You're welcome.

(Applause.)

CHAIR QUINLISK: Okay. And we have run out of time for our public meeting. We are at 2:00, so I would like to just say thank you to everyone for coming and being part of our meeting today. And I will remind members of the Board that we have an administrative meeting when this is over. I think that's it that I've got. Let me see if Leigh's got anything else.

CAPT SAWYER: I just wanted to thank Jomana Musmar and MacKenzie Robertson, who are here, if they'll stand up, for their support of the activities today.

(Applause.)

CHAIR QUINLISK: Okay. Then I will declare us adjourned. Thank you very much.

(Whereupon, the above-entitled public meeting was concluded at 2:01 p.m.)