NATIONAL BIODEFENSE SCIENCE BOARD

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PUBLIC TELECONFERENCE

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FRIDAY
NOVEMBER 13, 2009

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The meeting convened telephonically at 12:00 p.m., Chair Patricia Quinlisk, presiding.

MEMBERS PRESENT:

PATRICIA QUINLISK, M.D., M.P.H., Chair
RUTH L. BERKELMAN, M.D.
STEPHEN V. CANTRILL, M.D.
ROBERTA CARLIN, M.S., J.D.
ALBERT J. DI RIENZO
KENNETH L. DRETCHEN, Ph.D.
JOHN D. GRABENSTEIN, R.Ph., Ph.D.
JAMES J. JAMES, Brigadier General (Retired), M.D., Dr.PH., M.H.A.
THOMAS J. MacVITTIE, Ph.D.
ERIC A. ROSE, M.D.

EX OFFICIO MEMBERS PRESENT (or designee):

MICHAEL AMOS, Ph.D., Scientific Advisor, Chemical Science and Technology Laboratory, National Institute of Standards and Technology, U.S. Department of Commerce (designated by Willie May, Ph.D.)

DIANE BERRY, Ph.D., Chief Scientist, Director, Threat Characterization and Countermeasures, Office of Health Affairs, U.S. Department of Homeland Security

VICTORIA DAVEY, R.N., M.P.H., Deputy Chief, Office of Public Health and Environmental Hazards, U.S. Department of Veterans Affairs

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

ROSEMARY HART, Special Counsel, Office of Legal Counsel, U.S. Department of Justice

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

BORIS D. LUSHNIAK, M.D., M.P.H., Rear Admiral/Assistant Surgeon General, USPHS, Assistant Commissioner, Office of Counterterrorism and Emerging Threats, Office of the Commissioner, Food and Drug Administration, U.S. Department of Health and Human Services

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

PATRICIA A. MILLIGAN, R.Ph., C.H.P., Senior Advisor for Emergency Preparedness, U.S. Nuclear Regulatory Commission

STAFF OF THE NATIONAL BIODEFENSE SCIENCE BOARD:

LEIGH SAWYER, D.V.M., M.P.H., CAPT, USPHS,
Executive Director

P R O C E E D I N G S

(12:01 p.m.)

CAPT. SAWYER: I'd like to welcome the public, the voting members and Ex Officios to the NBSB, The National Biodefense Science Board, Public Teleconference today. I am Leigh Sawyer, the Executive Director of the National Biodefense Science Board. I serve as the Designated Federal Official for this Federal Advisory Committee.

The purpose of this teleconference is for the Board to discuss recommendations presented from the Disaster Mental Health Subcommittee, and for the Board to discuss H1N1 and seasonal flu activities, including H1N1 vaccines and antivirals, and other personal preparedness methods that may be of relevance during the H1N1 pandemic.

I'd like to begin now with the roll call of voting members. When I call your name, please respond. Patty Quinlisk.

DR. QUINLISK: I am here.

CAPT. SAWYER: Ruth Berkelman.

DR. BERKELMAN: Here.

CAPT. SAWYER: Steve Cantrill.

DR. CANTRILL: Here.

CAPT. SAWYER: Roberta Carlin.

MS. CARLIN: Here.

CAPT. SAWYER: Al Di Rienzo.

MR. DI RIENZO: Here.

CAPT. SAWYER: Ken Dretchen.

DR. DRETCHEN: Here.

CAPT. SAWYER: John Grabenstein. Jim James. Tom MacVittie.

DR. MacVITTIE: Here.

CAPT. SAWYER: John Parker, Andy Pavia, Eric Rose, Pat Scannon.

Okay. Now, I'd like to begin with the NBSB Ex Officios. If you are a designated alternate, please provide your name. Joe Annelli, Hugh Auchincloss, Diane Berry, Victoria Davey, Peter Emanuel, Bruce Gellin, Rosemary Hart, Susan Haseltine, Peter Jutro, Larry Kerr, Carol Linden, Boris Lushniak.

RADM LUSHNIAK: Here.

CAPT. SAWYER: Thank you, Boris. Willie May, Carter Mecher, Patricia Milligan, Jeff Miotke, Frank Scioli, John Skvorak, Dan

Sosin, Richard Williams.

DR. MICHAUD: Hi. This is Vince Michaud for Rich Williams.

CAPT. SAWYER: Thank you, Vince. Patricia Worthington. I think there is some interference coming in. Someone may not have their phone on mute.

MS. HART: Hi, Leigh. It's Rosemary Hart. I missed my name on the call.

CAPT. SAWYER: Oh, who is this?

MS. HART: Rosemary Hart.

CAPT. SAWYER: Oh, wonderful. I'm so glad you're on. Great. Did I miss anyone else?

DR. JAMES: Yes, Dr. James.

CAPT. SAWYER: Oh, good, Jim.

DR. JAMES: Yes.

CAPT. SAWYER: Anyone else?

DR. ADIRIM: Terry Adirim is on for DHS.

CAPT. SAWYER: Okay. I hear that Terry Adirim is on, so we have you, Terry. You will be on the speaker line in a minute.

Okay. Now I'd like to explain that

the NBSB is an Advisory Board that is governed by the Federal Advisory Committee Act. The FACA is a statute that controls circumstances by which agencies or offices of the federal government can establish or control committees or groups to obtain advice or recommendations when more than one member of the group are not federal employees.

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

I'd like to tell you about the Conflict of Interest Rules that govern this Board. The Standards of Ethical Conduct for employees of the Executive Branch document has been received by all Board members who, as special government employees, are subject to conflict of interest 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 meetings to the possibility that an issue may arise that could affect, or appear to affect, their interest in a specific way. Should this happen, it will be asked the affected member recuse himself or herself from the discussion by refraining from making comments and leaving the meeting.

The public will have two opportunities to provide public comments today, from 12:45 to 12:50. The public should only comment on a presentation from the Disaster Mental Health Subcommittee at that time. The other comments can be addressed from 1:45 to 2:00.

You will be given instructions by the operator as to how to signal that you have a comment. You will be taken in turn and notified when your phone line is open for you to speak during the public comment period.

A Federal Register notice

announcing the November 14 public meeting -- November 13 public meeting stated that any public comments could to be addressed to the Board and sent to NBSB email prior to the meeting. We have received public comment, which will be read during the public comment period. And that, of course, will be later during this meeting.

I would like to remind everyone that this meeting is being transcribed. When you speak, please provide your name. Now, I will turn it back to Patty Quinlisk.

DR. QUINLISK: Yes. Thank you, Leigh. I appreciate everybody being here today. I think we've got some great things to discuss. I think what we're going to do, though, first, is I believe that Dr. Lurie is available and is going to give us some opening remarks. Is that correct, or is she not here yet?

CAPT. SAWYER: She is still in a meeting at this time, so she is not available. So I think we should go ahead, Patty.

DR. QUINLISK: Okay. I'll just go

ahead with the overview and the goals.

As you can see on our agenda, the first thing we're going to be taking up this morning is an issue that we've been working on for a while. And I'd like to just extend my thanks to the Disaster Mental Health Subcommittee for all the work that they've done over the last year, and especially in the last several weeks, trying to work on specific recommendations for H1N1. And we are going to have Betty Pfefferbaum tell us what their recommendations are. And I believe that you, in your package, should have received information concerning those recommendations.

We do anticipate after we have this discussion with these recommendations that there will be a discussion of the Board, and then we will decide where we go from here and what we want to do with these recommendations, et cetera.

Then after the -- the first hour on the Disaster Mental Health Subcommittee recommendations for H1N1, we have asked several people to be here today to give us

some updates on H1N1 and the national activities. We're going to have some discussion on both H1N1 and the seasonal flu activity, H1N1 vaccines, the antiviral medications, and some of the other personal preparedness things that the Committee has looked at before, but things are changing very rapidly, and I believe there's some new issues there.

So I appreciate all the people who will be here this afternoon, also, to give us those updates, and they include Michael Bell, Jay Butler, Anita Patel, and Sally Phillips.

We will then have discussion after that and some public comments, and then we will wrap up and adjourn.

We do have a very full agenda this afternoon. I think what we will do, and, Leigh, just let me know if you think this sounds all right. We can go ahead and start with Betty's presentation, and then at whatever point Dr. Lurie becomes available, we'll halt that for a minute, and let Dr. Lurie give her comments, and then we'll go

back to the Subcommittee's recommendations. Does that sound all right?

CAPT. SAWYER: Yes, Patty. I just wanted to let you know that Elise Johnson joins for Boris Lushniak and Bruce Gellin has also dialed in. Has anyone else dialed in that I did not -- you did not hear a name called earlier?

DR. ROSE: Eric Rose.

CAPT. SAWYER: Sorry, who?

DR. ROSE: Eric Rose.

CAPT. SAWYER: Oh, Eric. Oh, great. Okay.

MS. MULLIGAN: Patricia Mulligan, NRC.

CAPT. SAWYER: Wonderful. Thank you.

DR. JUTRO: And Peter Jutro. I got back on. I got bounced off before.

CAPT. SAWYER: Okay. Thank you.

CAPT MILLER: Aubrey Miller, FDA.

CAPT. SAWYER: Hi, Aubrey.

DR. AMOS: Mike Amos, NIST.

CAPT. SAWYER: Thank you, Mike.

DR. GRABENSTEIN: John Grabenstein.

CAPT. SAWYER: Oh, John. Terrific. It looks like we've got everyone here. It takes me long enough to read you my intro that gives you enough to join. Thank you.

Okay. So, I believe, Patty, that we are ready to continue with the agenda.

DR. QUINLISK: Okay. Well, Betty, I believe you're on. And I appreciate you again being here to address the Board. I think what we'll do is we'll turn it back, or we'll turn it over to you to give us your update on the Mental Health Subcommittee's recommendations for H1N1. And I do apologize, but when Dr. Lurie becomes available, we may have to ask you to pause for just a second to allow her opening remarks, and then we'll go right back to you. Thank you, Betty.

DR. PFEFFERBAUM: Yes, of course. This is Betty Pfefferbaum, and let me begin by saying that on behalf of the Subcommittee, all of us thank you for the opportunity to submit a new set of recommendations today.

First, we strongly recommend that

state and local Public Health officials invite their Behavioral Health authorities in both mental health and substance abuse to meet and discuss local efforts and plans to identify their constituents, including, as you know, we're quite concerned about high-risk and vulnerable populations, and to develop steps that they can take together in this effort to address mental health concerns. We have forwarded to you a roster of current state disaster mental health and substance abuse coordinators, which was developed from materials available to us from HHS and SAMHSA.

Second, we recommend that state and local public health and behavioral health officials develop some strategies to maintain calm at treatment sites, like flu clinics, primary care settings, and emergency rooms to minimize stress on providers who are working at these locations. And we recommend that they ensure sensitivity to emotional and behavioral health needs that may arise at vaccination sites.

One successful strategy that we are

pointing out is simply to assign mental health staff to monitor waiting areas, waiting lines, and to provide a reassuring presence, convey the message that individuals' concerns will be addressed, provide basic and accurate information about what to expect when they receive treatment, and identify and intervene with individuals who experience severe psychological distress. We have also forwarded to you a fact sheet that has further suggestions that might be useful.

Third, in the interest of providing swift, accessible education about behavioral health concerns during this crisis, our Subcommittee, with the assistance of ASPR, compiled a list of specific resources pertaining to behavioral health, including resources related to death and bereavement. We have generated the list and suggest that you recommend distributing it to state public health authorities.

Fourth, during our deliberations, we recognized that significant expertise exists regarding messaging, especially among

individuals within the federal government, including HHS. And while our Committee members do have some expertise in this area, we chose to simply indicate that membership on our Committee who have expertise are willing to serve as subject matter experts, as needed, for messaging and guidance. And note that our members also have access, through various affiliations and associations, to additional experts in many areas, who also can address gaps as those are identified.

Again, on behalf of the Subcommittee, I express our appreciation to the Board for providing us the opportunity to contribute to this significant effort.

DR. QUINLISK: Okay. Thank you very much, Betty. I appreciate, again, the work you guys did, especially in the last couple of weeks going back and forth to give us very specific recommendations on what to do for the H1N1. I think that that's been very helpful for us.

I think what I would like to do now, then, is open it up to discussion from

the Board members. I guess I'll go ahead and get the ball started. This is more of a procedural question, sort of for Leigh; is that, these recommendations, the way they're written right now, they're sort of targeted at state and local. And, obviously, this letter goes up through the Secretary. I assume that these could be modified, just so that they would be directed at the Secretary to encourage state and local health officials to do these, if we wanted it in sort of a more appropriate directed format. Is that correct?

CAPT. SAWYER: Oh, yes, of course.

DR. QUINLISK: Okay. And, Leigh, I believe it would need to be modified that way. Is that my -- is my understanding correct?

CAPT. SAWYER: Patty, one approach would be for you to write a letter, as Chair of the Board, to the Secretary and indicate what the Board would like to make as advice or guidance to the Secretary on these issues.

DR. QUINLISK: Okay. I just want to make sure the procedure is correct. Well, let's see if people have questions or

comments, other than myself.

I guess I have another question. This is for you, Betty. Where you say we recommend that the public health officials invite their behavioral people to work together, is there some place where there's some - I don't know quite how to put it - when you get these people down and sit together, are there some sort of specific issues that you all identified as being the key issues for them to discuss together?

DR. PFEFFERBAUM: Well, I think, in general, we were concerned that individuals representing both or all three of these systems, in some states substance abuse is addressed by separate authority, but our interest was in having, at the state and local level, the individuals who are most closely involved come together to discuss the efforts that they currently have underway to plan for future efforts, both near term and longer term. I think it's important for those groups together to identify and address some of the needs of the high-risk populations and

vulnerable populations. And those will differ, of course, across systems, and may also differ in various locales. And then, I think, primarily our concern was to foster the joint planning among these various authorities.

DR. QUINLISK: Okay. That makes a lot of sense. Thank you.

DR. BERKELMAN: This is Ruth Berkelman.

DR. QUINLISK: Go ahead, Ruth.

DR. BERKELMAN: Yes, I really -- I appreciate all the work that's gone into this. The principals of all three are, I think, very important. I wanted to ask whether or not, and I'm not sure who best to answer this question, but where they're maintaining calm at the vaccination sites right now, I mean, this actually is more inclusive of vaccination sites, but there is a focus on them. But the vaccination sites for H1N1 that are now springing up all over, whether this is actually currently a problem that is in need of behavioral health personnel there or

anticipated to be a problem?

I guess, I thought there might have been a little bit more early on, than possibly now, but I'm just wondering if anybody has any thoughts on that.

DR. QUINLISK: This is Patty. I can say that here in Iowa, things have been pretty well, but then I'll just -- Iowans don't get that upset about things, and they're pretty courteous. But I have heard -- there was an article or something in the media last week, I believe, that someplace in the Northeast, there was actually threats of violence, and they closed a clinic. I'm not quite remembering correctly, maybe, but I think there have been places where there have been concerns, especially on the part of the health care providers.

DR. BERKELMAN: Yes. It seems like one of the things will have to be to identify those sites that are most at risk because this is probably not tenable to do at every site. Just something to think about.

DR. GRABENSTEIN: This is John

Grabenstein. As I read through that document, it was almost like good clinic practices, just keeping everybody in a happy state of mind, to belittle it a little bit. So I think there are some ways of good crowd control, good queuing processes that are at the heart of keeping things calm, in the first place.

DR. JAMES: This is Jim James. And I think all of the comments sum up some of the frustration involved with this, starting with the way the letter is addressed, which is from the federal government recommendation to the states. And then, at the same time, we try to get real specific, but we can't get too specific state-by-state. To me, the important thing was to make this one of the checklist things at the state level for them to consider, and then to operationalize in their state, as conditions require.

DR. QUINLISK: Yes. This is Patty. Jim, I think you're right. I think one of the biggest problems that the states have dealt with is that, because the supply and the demand can vary from place to place, we have

different clinics offering vaccine to different kinds of people at different times. And that, obviously, confuses the public and causes frustration. I don't know what a particular answer is to that, but I think this situation has lent itself to frustration, especially when you add on the vaccine supplies have not met the need.

DR. JAMES: Absolutely.

DR. PFEFFERBAUM: This is Betty Pfefferbaum, again. I'd like to underscore, though, the sense that we do not really expect much in the way of serious psychiatric outcomes in this venue and to underscore what was said earlier, that good clinical skills in working with people, in general, should serve in most locals.

DR. QUINLISK: Yes, but I think the media has picked up on it. There has been some people who have become very, very upset because of these issues. And I think -- I don't know if they're truly going to mental health issues, but, certainly, have been very upset about a variety of issues. So I think

these kind of recommendations are very helpful.

DR. GRABENSTEIN: This is John Grabenstein. To move things along, I'm certainly open to additional comments from my colleagues, but perhaps the procedural way to handle this would be for -- I'd be happy to make a motion, eventually, if nobody objects, that we adopt the three enumerated recommendations about inviting behavioral health authorities to meet and discuss, to distribute the methods of staying calm, and distribute the other resources, and transform it into a letter from the Board signed by Patty to the Secretary, allowing for nuances of shifting the language, as needed.

DR. QUINLISK: Yes, I agree. This is Patty. I'd like to just add one thing. One of the things that I think the -- since this is the first time in the country we've really done something quite on this scale, I guess I had a question that might turn into a recommendation; and that is, is there anyone at the national level who's going to be

specifically looking at some of the mental health issues that came out of vaccine shortages, difficulty in distribution, all of that, and looking at the issues that came out of that, and then putting together recommendations for future situations that might be similar. And I don't know if there's already somebody at the federal level planning to do that, or whether that would be something that maybe we might want to consider adding to these recommendations.

DR. PFEFFERBAUM: Dan, are you -- this is Betty. Are you aware of anything?

DR. DODGEN: Yes. This is Dan Dodgen on the line. I think it's a great question. And I think, certainly, that there are a number of efforts towards monitoring a number of different things that are happening at the point of distribution, and how vaccine is being distributed, and what the psychological impact of various aspects of this are.

In terms of there being one, first, and, obviously, my office is the office that's

responsible for coordination, but in terms of there being a point person who's just following that particular issue, unless there's someone at CDC, I would say the answer to that is probably no.

A potential answer to your question, though, Patty, is, as you know, Dr. Lurie has asked the Disaster Mental Health Subcommittee to begin thinking more and prospectively about how HHS is doing as a department in integrating mental health into our overall public health emergency preparedness activities. So there may be a way that, as we move forward, we can think strategically about how the question you raised might be addressed.

DR. QUINLISK: Well, thank you, Dan. And, to be honest, I was thinking, obviously, about the pods, and the distribution, and all that, but I think there's even a bigger picture thing here, and that's a lot of the risk communications, et cetera. Because I can't remember back in my career something quite --that's ever been done

quite this scale. And I think that there's things that we, potentially, could learn, and not only learn and put it in a book on somebody's shelf, but to truly then get it out, back out to the people on the front lines very quickly so that we can learn from this situation and make sure that next time if something like this happens, we can do an even better job, hopefully, on it.

DR. DODGEN: I think those are great points. And, certainly, the Assistant Secretary for Public Affairs at HHS, as well as the wonderful Communications Office headed by Marsha Vanderford at CDC, are doing some really great work. So maybe when we have our next Subcommittee meeting, and we talk again about this larger, how do we look at our successful integration of mental health into public health preparedness, maybe there's ways that we can think, also, about integrating what you've brought up, Patty, into this evaluation because I think those are both important issues. And I do actually think people are doing them, and what we may need is

just a more strategic way to make sure that it's being captured and presented at the right places.

DR. GELLIN: Patty, this is Bruce Gellin. Let me add to what Dan said, as well. I mean, this issue has come up in other times, as well, both internally, and the National Vaccine Advisory Committee has had a similar comment about how we capture the lessons learned. So maybe something more broadly about, as our efforts to revisit this to make sure that we learn from these, to make sure that this is one of the aspects that's highlighted. And then we can subsequently look on, and get a better sense of where this might be -- have the focal point within the Department.

DR. QUINLISK: Yes, I think that would be great. And I'd like to, maybe, suggest not only just for how well HHS and the federal level was done, but since we know that this --whatever the feds do trickles down to the state, what the state does trickles down to the locals, I don't know if there was a

plan, also, to look at the different levels and make sure that we understand how each level influenced each other before it, ultimately, went out to the guy standing on the street. So do you know if anybody's planning to do that full spectrum kind of thing, or were they just thinking at the federal level?

DR. GELLIN: I can't say what any specific plans are, but I think that you just turn it around as to say that as you go through this, as this is revisited, to make sure that you're -- to include this perspective you've just articulated.

DR. JAMES: This is Jim James, and this is going to sound a little ---, but it's really not ---. Going back to when I really was getting involved in some of these mental health things, beginning with the sniper attacks, and continuing forward from there, there is an absolute need out there to establish study protocols to get real-time data to answer the kinds of questions you're asking. I don't think anyone at CDC, or any

place else, is going to be getting into answering behavioral questions that really need to serve as the database for looking forward. And the frustrating part becomes, when you want to do a study, there is no short-term mechanism, unless one's been developed in the past couple of years, to get funding for that type of study in less than eight to twelve months, then you've lost the window.

DR. QUINLISK: I think you bring up a very good point, Jim. Other discussion? I guess, then, I would like to put forward a suggestion that in the letter that we forward with whatever recommendations we vote on, maybe adding, basically, the content of all of the discussion we had here now for these suggestions to not miss the chance of learning from this particular situation, and making sure that those lessons learned are shared and impact on our next response. So I know -- I'll see. Are there any other discussion on the letter and the recommendations from the Subcommittee on Mental Health or anything on

any other recommendations or comments?

DR. CANTRILL: Patty, Steve Cantrill. Just a minor word change, I would propose. Please replace Emergency Room with Emergency Department.

CAPT. SAWYER: Patty, this is Leigh. I wonder if we could consider perhaps addressing the issue of lessons learned in a separate letter, and that it might be more important for -- it would be important to include more than the disaster mental health issues in that letter.

DR. QUINLISK: Okay. I think, we were talking about the disaster mental health, because I do think that's one area that we do not put a lot of time and lessons learned about it. But, I agree, we could put it in a larger context. I won't have a problem with that. What do other people think?

DR. BERKELMAN: You know, one thing. This is Ruth Berkelman. I just want to add that there are a number of preparedness and emergency response research centers. There are, I think, nine of them in the

country now. I'm at one of them at Emory, but these might serve as a platform for some of this type of research. And some of it is going on with H1N1 now, but not, to my knowledge, the issue of mental health, behavioral health. It's a little bit off from Leigh's question, but I just thought everyone ought to be aware of these centers.

DR. QUINLISK: Yes, I think that's a good point, Ruth. And I know just from my own experience at the state level, we do a lot of lessons learned, but they very much focus on process, activities, et cetera, and tend not to look at some of these mental health substance abuse issues. So I guess my thought was maybe we could ensure that those -- when those things happen, that these issues are not forgotten.

DR. PFEFFERBAUM: This is Betty Pfefferbaum. We would be pleased, I think, if that were addressed specifically to mental health issues as part of these recommendations because we second the fact that it is an important issue.

CAPT. SAWYER: Patty, if that's the case, can you be more specific about the statement that should be included?

DR. QUINLISK: Well, let me just -- let me try, and then see if the other people agree. I guess, what I was wanting to do is just have some kind of a recommendation that we -- this Board believes that the mental health issues are important, and that given that this was one of the largest responses in this kind of situation that we've had in most of our careers, that we do not lose the opportunity to learn more about mental health response and lessons learned in the mental health area, and that as people go through evaluating the response to the H1N1 pandemic, that we ensure that mental health issues are looked at, included in a report, and distributed to ensure better response in the future. See what people think. That was sort of a general statement, but does that sort of address what other people are thinking?

DR. JAMES: This is Jim James, again. I think for what we're dealing with

here today, and what we're trying to accomplish in the short term versus the long term, what you outlined is what we need, and we need to move on with that.

The second issue, the more strategic one, the way you incorporate this into every day preparedness and response, I think needs to be one of the things high on the items looked at by the Disaster Health Mental Subcommittee going forward. They'll have their meeting in December, and I think really outlining a plan that includes a research, or at least a study base to start to answer these questions would be extremely helpful.

DR. QUINLISK: Okay. Well, maybe we could add that and say we need to start looking at -- as we go into the future, that the questions that need to be answered and the studies that need to be done, we've asked the Disaster Mental Health Subcommittee to look at that and come back with more specific questions that need to be answered. Other comments?

I think what I'd like to do then, I think from my sense, from what we've heard, I get the sense that everybody is comfortable with the basic recommendations from the Disaster Mental Health Subcommittee, with the addition of the comments about the lessons learned in the mental health area, and that everybody feels comfortable with that. So I guess the next thing to do would be to decide whether or not we're ready to take a vote on this.

DR. GRABENSTEIN: Yes.

DR. QUINLISK: Okay. Is that John?

DR. GRABENSTEIN: That's John.

DR. QUINLISK: Okay, John. Maybe you could, then, put forward a motion.

DR. GRABENSTEIN: All right. So I move that we transform the letter from the Subcommittee to -- for our own transmission to -- as a Board to the Secretary with Patty as signatory, and that we adopt the three enumerated recommendations, add in the effect of capturing lessons learned so that this stays as a mental health-specific letter, and

empower the Chair and the staff to adjust the wording of the letter appropriately.

DR. DRETCHEN: This is Ken Dretchen. Second that.

DR. QUINLISK: Thank you.

CAPT. SAWYER: I wonder should we have our public comment first, or -- at least, according to our agenda, we have this scheduled after the public comment.

DR. QUINLISK: Oh, thank you for bringing that to my attention. Yes. Why don't we go ahead and have the public comment before we vote. So we'll put the motion and the second just on standby for a minute, and let's go ahead and open for public comment prior to the vote. So, operator, could you open this up for public comment, please.

OPERATOR: Okay. You want all lines to be opened?

DR. QUINLISK: Well, however you do it. If they have a comment, how do they let you know?

OPERATOR: Okay. At this time, if you have a question or comment, please press

star, then the number one on your telephone keypad. Again, if you would like to ask a question or have a comment, please press star one at this time.

CAPT SAWYER: Operator, I also have a comment. It looks like we have three people queued up here, so I don't want to take too much time. The Board did receive a letter from two individuals representing the Multi-State Disaster Behavioral Health Consortium, Gladys Padro and Ashley Pearson. And it's a six-page letter, so I don't want to read it all, but I'll just briefly tell you the two points in this letter.

It is to Dr. Quinlisk. We are the newly formed consortium of 23 states' Disaster Behavioral Health Program Coordinators representing states across the nation from California to Maine, Illinois to Georgia. Today we submit for your consideration two requests, and provide one rationale, or our rationale in the discussion that follows. One, that the Board recommend to the Department of Health and Human Services direct

funding of state mental health authorities for all hazards planning and preparedness for disaster behavioral health activities. FEMA, Department of Homeland Security through the Stafford Act did some of the crisis counseling, assistance, and training program by providing funds directly to state mental health authorities for disaster behavioral health response and recovery, which includes a significant training component. With such a longstanding track record at the federal level, we believe the planning and preparedness funding should be directed to state mental health departments.

Two, that the Board appoint a minimum of two state mental health disaster coordinator members from the Multi-State Emergency Behavioral Health Consortium as full representatives on the Disaster Mental Health Subcommittee. One of their initial contributions could be to undertake a review of the important and significant work that has been accomplished by state mental health authorities in disaster behavioral health

planning, preparedness, response, and recovery, including training.

And it goes on then to provide a discussion of the rationale for the next four or five pages. This letter will be posted as part of our summary of this meeting on our website and is available to anyone who would like to have it by emailing the nbsb@hhs.gov email. And that's it on this letter.

We are ready for the first public comment.

OPERATOR: Paul Gordon, your line is open.

MR. GORDON: Thank you very much. This is Paul Gordon.

First of all, I just wanted to, I guess, applaud the Board members, all the participants, and members of state and federal agencies for all the efforts that are taking place. It's, obviously, a pretty complex and dramatic issue.

The comment I would like to bring forth, and at least propose some method of addressing it, is in talking about behavioral

issues and fear-related issues, one of the things that I think needs to at least be addressed and brought to the public's attention a bit more is some of the efforts that are taking place that are having some very positive dramatic results. And one of the things I would like to point towards is some of the results that seem to be appearing with regards to the IV-based Peramivir antiviral. We've seen some pretty dramatic instances of lives being saved. These have been reported on CBS and CNBC, and the likes. Many of you have probably seen these, so I think in this effort of trying to manage the message intelligently, convey positive things that are happening, I think some of these things need to be publicized a little bit more because there are some very positive --.

CAPT. SAWYER: Mr. Gordon, thank you for your comment. We will need to reserve that for the second half of the meeting.

MR. GORDON: Okay. Thank you.

CAPT. SAWYER: It's time for the next comment, please.

OPERATOR: Jane Bishop, your line is open.

MS. BISHOP: Thank you. First of all, I'm from Pennsylvania. I am one of the state behavioral health disaster coordinators. A number of us are on the call, and I certainly applaud the recommendations that are being made to include state mental health authorities and their disaster coordinators, along with drug and alcohol emergency responders.

I also applaud that you provided NBSB a list of the coordinators in each state. Many of us are working with our state health departments already, most without funding, however. And we've been training our disaster mental health response teams across the Commonwealth, and other people have been doing this across the state to respond to the psychosocial needs of persons who are either victims of disasters or emergencies, and in line for vaccination. So we've been doing some of this. Again, our state has been lucky enough to have some funding given to us from

our Department of Health, but most states do not get that funding. It's not direct funding from the federal government.

We are doing this, as we speak. Sometimes we'll get a call from Health where they're going to be having vaccination sites. Our teams around the state are ready to go, and they'll hand out literature on how to cope, hand out literature on how to help kids that might be stressed by this, a psychological first aid/crisis counseling approach that we have been taught by the feds, actually, through SAMHSA and the National Center for Post-Traumatic Stress Disorder. We use CDC curriculum and FEMA curriculum. And, actually, all these efforts were started close to 9/11 with the help from federal government, where we all started these positions.

So I certainly applaud the efforts to -- that you propose today, and hope that further dialogue might continue with the state disaster coordinators.

DR. QUINLISK: Thank you.

OPERATOR: Your next comment is

from Russell June.

MR. JUNE: Yes. I'm at Virginia Tech, a member of the Subcommittee, and I just really want to reinforce the recommendations that were put forth. The idea of having a mental health professional on site, whenever possible, I just think is a great one, is something that we did following Katrina and also the Virginia Tech shootings here. And I realize that this event, certainly, doesn't have the same proportion of fear and anxiety as was there, but, nonetheless, having those individuals present, I think, can be quite worthwhile.

I also just wanted to comment that Jim James's suggestion of putting more science behind what it is we're doing is an excellent one. And I'm looking forward to meeting with the Committee on, I believe, the second and third of December to follow up on that thinking. Thank you.

OPERATOR: There are no further questions or comments.

DR. QUINLISK: Okay. Leigh, is

there anything else we need to do then before we go on to the vote?

CAPT. SAWYER: No. I want to have the voting members consider whether there is anything that we'll be adding to the letter that was submitted to the Board by the Subcommittee, other than the one statement, and whether we should consider forwarding the letter or attaching the letter to a cover letter that is prepared by you to include this last comment from the Board about the learning from our current situation now.

DR. QUINLISK: Right. So we could do it either way, either take the recommendations, incorporate them into a letter, or just have a letter that has this letter attached to it.

DR. GRABENSTEIN: This is John. I would recommend -- I'm certainly happy to attach Dr. Pfefferbaum's letter, but I think we should state it in our own words, perhaps distilled, but I think we should make our own statement.

DR. BERKELMAN: This is Ruth

Berkelman. I agree with John.

DR. QUINLISK: Okay. And I believe, John, that your recommendation was that we do that, that I and the staff put together a letter and then send it to the Board members for their comments before we send it on up to the Secretary.

DR. GRABENSTEIN: That's right.

DR. QUINLISK: Okay. Any other comments on that? I think, then, we'll go ahead and vote on John's recommendation, which let me just reiterate -

CAPT. SAWYER: Patty, may I just say that if we are going to be revising the letter, and unless we can say what the letter is going to say, we will need to have that at our next public meeting and have a vote on it at the public meeting, unless you can tell me now what it is that will be in the letter.

DR. QUINLISK: Okay. Well, let me say what I think is going to be in the letter and then you can let me know if you think that that would still work. And what I see us doing is the three specific recommendations

that came from the Disaster Mental Health Subcommittee, they will retain their intent. We would just modify the language so it would say we, the Board, on the recommendation of the Disaster Mental Health Subcommittee, recommend, and then it would be the same basic recommendations. So we would be just changing the wording of how the recommendation was going forward. We would not be changing the recommendation itself. And then we would be adding on to that a paragraph talking about the issues with what I stated previously, with that type of language. So the intent would not be changed, just the language of how it's being sent forward.

Let me make sure that that is the understanding of the rest of the Board members.

DR. GRABENSTEIN: Yes, for John.

DR. DRETCHEN: Yes, for Ken.

DR. QUINLISK: Okay. So if we go forward that way, Leigh, I believe we can go ahead and vote on it now. We would not have to revote on a finalized letter?

CAPT. SAWYER: That sounds fine. That sounds like we can take a vote now.

DR. QUINLISK: Okay. Why don't we go ahead then and take a vote on John's recommendation that we go forward with these recommendations with the addition of the lessons learned, that we write a letter from the Board itself. We could attach this letter, or not, but the letter from the Board would include all of the content with the three recommendations and the lessons learned additional paragraph.

So I believe that that is the motion that's been forwarded and seconded. So I think, Leigh, if I could ask you to go ahead, and we'll do the vote on the roll call.

CAPT. SAWYER: Patty, I think I need to ask -

DR. QUINLISK: Okay.

CAPT. SAWYER: Are we also going to be including the attachment?

DR. QUINLISK: I think if we have -- I think the intent is to have all of the information in the letter from the Board, so

the letter could be attached or not attached. It would not change the letter itself that's coming from the Board because that letter would include all three of the recommendations just with the context of the recommendations changed so it makes more sense coming from the Board.

CAPT. SAWYER: Okay. I guess, what -- there has been discussion on some of our other calls, so this is why I'd like to make sure we're all clear, whether the Board would like to include, as part of their recommendations to the Secretary, the attachments that are part of the letter from the Subcommittee to the Board, which include the roster of state disaster mental health coordinators, behavioral health H1N1 websites, and resource list, the five attachments that are described in this letter.

DR. QUINLISK: Okay. And I'm gong to just -- this is my personal preference. Some of the attachments actually already come from Health and Human Services, and I see no reason to add those. I think we could, in the

letter, state that we have been given these attachments, and they are available. But, I guess, I would not automatically attach them to the letter. I think the letter would be stronger if it comes just as a letter with these recommendations and not with a lot of attachments to it. But that's my personal opinion, and I'll throw it out there.

DR. GRABENSTEIN: This is John. That's fine with me.

DR. QUINLISK: Okay. So the thing that we're voting on would be to not have these attachments with the letter specifically, but we could state that the Subcommittee provided us with these attachments, which would be available.

Okay. Then I think we are ready to go ahead and vote, Leigh.

CAPT. SAWYER: Okay. Patty Quinlisk.

DR. QUINLISK: Yes.

CAPT. SAWYER: Ruth Berkelman.

DR. BERKELMAN: Yes.

CAPT. SAWYER: Steve Cantrill.

DR. CANTRILL: Yes.

CAPT. SAWYER: Roberta Carlin.

MS. CARLIN: Yes.

CAPT. SAWYER: Al Di Rienzo.

MR. DI RIENZO: Yes.

CAPT. SAWYER: Ken Dretchen.

DR. DRETCHEN: Yes.

CAPT. SAWYER: John Grabenstein.

DR. GRABENSTEIN: Yes.

CAPT. SAWYER: Jim James.

DR. JAMES: Yes.

CAPT. SAWYER: Tom MacVittie.

DR. MacVITTIE: Yes.

CAPT. SAWYER: I know John Parker is not on. Andy Pavia, have you joined? Eric Rose.

DR. ROSE: Yes.

CAPT. SAWYER: And I don't believe Pat Scannon, are you there? No, okay. So of the voting members attending today, it is a unanimous vote of yes. Patty, are you ready to go on?

DR. QUINLISK: Sorry. I had you on mute still. Yes. Thank you, again, to the

Disaster Mental Health Subcommittee, and I think some of this discussion may provide you with some issues for discussion at the December meeting, too. And we do very much appreciate all the work you're doing and continuing to do on these issues. I do think it's an area that's too long not been as integrated into response as it probably should be.

So I'll let Betty, see if you have any final comments.

DR. PFEFFERBAUM: No. Again, thank you, though, for letting us participate.

DR. QUINLISK: Okay. And then, Leigh, is there anything we need to do before we go on to our second part of our agenda, the H1N1 updates?

CAPT. SAWYER: I think that's where we are in the agenda although we do not have our panel on yet.

DR. QUINLISK: Okay.

CAPT. SAWYER: What I can do is I can read a public comment that we received that has to do with the second part of the

agenda, unless there -- is there any other discussion points of the members?

DR. QUINLISK: Let me ask this. Leigh, has Dr. Lurie been able to join us, or she's gotten hung up?

CAPT. SAWYER: She will not be able to join.

DR. QUINLISK: Oh, she will not. Okay. Well -

CAPT. SAWYER: She sends her apologies.

DR. QUINLISK: That's all right. Please tell her that we appreciate how busy she is these days, and we regret that she was not able to join us, but perhaps we could try setting up again for a future meeting.

CAPT. SAWYER: I'll be sure and convey that.

DR. QUINLISK: Okay. Well, why don't you go ahead while we're waiting for the panel to call in, could you go ahead and read us the comment?

CAPT. SAWYER: So let me read a comment that has come in to our email box.

"Dear NBSB Committee Members: Thank you for taking this opportunity to review this comment with regard to H1N1 vaccine production information." There's a lot of noise on the phone. Please mute your phone.

On a weekly basis, the public is updated on the available doses of H1N1 vaccine for purchase by states. However, no information is publicly available with regard to the number of doses being delivered to the distributors from each individual manufacturer. This information needs to be made available to the public to provide a better understanding of vaccine production and distribution logistics between HHS and the vaccine manufacturers.

Once again, thank you for your time and attention to this matter. Sincerely, Anjelica Dortch. And she is with McKenna, Long & Aldridge Group.

This is the only comment that we have received in writing for the second hour of this meeting.

DR. QUINLISK: Okay. And maybe,

since we have time, I know there was the first -- and, I'm sorry, we are getting just an incredible amount of background noise. Could everybody please make sure you put your phone on mute when you are not speaking. Thank you.

There was the public-comment person. Is it appropriate to allow that person to continue with that comment right now, or do we need to wait until the formal comment period at 1:45?

CAPT. SAWYER: I think we can wait, Patty. I, actually, have just received another comment, and this has to do with the previous hour's session. This is from Samuel Dixon.

I appreciate the Board's work and recommendations. I am concerned that any language in the recommendations be careful not to mandate how services should be delivered. Most H1N1 distribution centers do not need claims. As they have staff appropriately trained and professional in their ability to provide intervention and referrals to clinical providers. Mental health resources are

already strained enough without asking them to provide monitoring services. And Samuel Dixon is with the Addictions & Mental Health Division in the Department of Homeland Security.

DR. QUINLISK: Okay. Thank you. I guess I think we just then are waiting for our people who are updating us. Can we, maybe, see if any of them have joined us?

CAPT. SAWYER: We can take a break, Patty; they haven't joined us. Or if there are any other questions or comments from the Board that they'd like to discuss right now in reference to H1N1, or the Behavioral Health issues we've just discussed.

DR. QUINLISK: Or we can just take a five-minute break.

DR. JAMES: This is Jim James. I'm definitely taking a five-minute break. I think I'm one of the guilty ones with background phone noise. I'm going to go find a different line.

DR. QUINLISK: Okay. Why don't we do this, why don't we take just a couple of

minutes break, but we will start back right at exactly 1:00 Eastern, which is only about four minutes from now, so please do not go very far.

CAPT. SAWYER: Okay. We'll hold the lines open here.

DR. QUINLISK: Okay. Thank you.

(Whereupon, the above-entitled matter went off the record at 12:57 p.m. and resumed at 1:07 p.m.)

DR. QUINLISK: Okay. I'd like to introduce Sally Phillips. She is from the Office of the Assistant Secretary for Preparedness and Response at HHS, and she's going to talk to us about some of the H1N1 updates. Please go ahead, Sally.

DR. PHILLIPS: Well, I wondered if it might be more prudent to find out if there are specific questions. I'm going to be talking about sort of the medical surge, the medical care side of this equation, less on the vaccine than some of the other speakers. And I wondered if it might be even more timely to find out if there's something very specific

that your Board members would want to hear about until Jay and the others get on, that I could address, rather than just sort of rambling.

DR. QUINLISK: Do any of the Board members have specific questions? Maybe what I could do, Sally, is just ask you to update us on the issues that you think are most pertinent and relevant at this time, and then we'll go to questions after that.

DR. PHILLIPS: All right. Well, I think that probably the most timely event has been the declaration of a public health emergency, which allowed us to move forward on some other provisions within the Department. And, specifically, we're experiencing the 1135 Waiver issues at the present time.

Many of you are familiar with the CMS Open Forum calls, and this week we had an open dialogue with the Medicaid, Medicare, and CHIP providers to talk about what's going on related to the provisions within the 1135 Waivers, and reviewing people's requests. You may be aware that there have been a number of

states who have submitted requests to look at the 1135 Waiver option. There have only been five that were really eligible for the review, and all five were approved, and not denied. There were many others that were withdrawn once the state regional individuals who are working with the individuals that were submitting the requests, and in many of the situations we're able to review it under current law, and were able to be resolved. And, in many other instances, people were just kind of leaning forward, trying to anticipate the need for 1135, and have been processed through to start looking at. We can't really grant them until there is a situation occurs, but I think to just clarify the process, and make sure that individuals know how quickly the responses have been, and that there won't be any major delays when the time presents itself.

All the requests have been handled within 24 hours, and I think there's been a lot of good reception. The individuals on the phone calling in with questions, were mostly

asking procedural questions on how to apply. And we had about 450 people that we were talking with this week. So, I think the -- trying to deal with what's happening at the hospitals, at the health care systems level with the increased numbers of hospitalizations has been something that we wanted very much to be able to give as much authority, and as much leeway for the hospitals to be able to respond, as possible. And, as you know, many of the issues related to that have to do with EMTALA, as they're trying to deal with the high number of ILIs coming through the emergency departments, and then some other ways to sort of flex the system.

I'm sure CDC is going to be giving some numbers here, but when we're talking about medical care, of course, we're wondering how heavily hit are the health care systems, and in what ways. And, certainly, from the emergency department standpoint, the numbers of individuals coming in to be screened through the emergency department for ILI is certainly one major area of surge. The second

of which, of course, as we know, and have heard a great deal about, are the very, very sick individuals, and what's happening with our intensive care units related to that.

The number I pulled this morning related to hospitalizations, I think this is the most current number, but my CDC friends can help clarify that in their report, 17,838 hospitalizations defined by influenza lab tests. And I'm sure they'll go into more confirmation information related to that.

There's been a lot of money sent out to help the health care systems deal with the stress. Much of the HPP program monies since 2002 have been allowed to be focused on surge capacity for our health care systems. And, of course, primarily the last 90 million supplemental was to really focus on the H1N1, hoping to support and encourage the hospitals, and the health care systems to do what they can related to PPE for their workers, to get their workers vaccinated, and then to try to look at with them any purchasing of ventilators, or respiratory equipment that may

be necessary to deal with the cusp of this event affecting the intensive care units.

I think I might stop there for a few minutes. There are a number of reporting systems that we're trying to use to monitor what's going on in the health care system, one of which, I'm sure you've had discussions prior to this, and I apologize if I'm repeating myself. HHS had in place the HAvBED, hospital available beds in emergencies and disaster system for quite some time to support evacuation and patient movement in disasters. And, in order to get a good sense of just how stressed the health care system is, the HAvBED system was enhanced, and there were new data elements put in place to be able to identify some of that system's stress so that we, at the federal level, could start looking in with our state colleagues to determine if and when there may be a need for any type of federal augmentation and support.

We've been receiving data now for a couple of months now, and we're at about 65 to 70 percent of all the hospitals reporting, and

have also done a sample across the country of the different types of hospitals to make sure that we had a pretty good representative sample, since we don't have 100 percent reporting. And I talked with the group this morning, and they were fairly confident that there is a representative sample coming in.

What we're basically finding is, peoples numbers are up, but they are managing at the present time within that surge, and not requesting or leaning forward yet to look for any type of augmentation to patient care. The only augmentation we have been hearing, there have been a few requests for help in support of the vaccination programs, but none specifically for patient care areas yet.

DR. QUINLISK: Okay. Well, thank you, Sally. Maybe what we'll do is see if any of the Board members have any questions for you.

DR. CANTRILL: Sally, Steve Cantrill. Two questions. First, on the 1135 Waivers, are they allowing them to be retroactive a couple of days?

DR. PHILLIPS: They are. They are.

DR. CANTRILL: And, also, in terms of looking at your nationwide data, do you get any feeling for how the waves are coming? I think here in Denver, knock on wood, I think we're done. We had our peak four weeks ago.

DR. PHILLIPS: What we have been hearing, and I don't have as much solid data, so my CDC colleagues can jump in here as well, is all along this event, it's been like popcorn. Some events are very, very high, and other events dying down. There are clearly areas in the country where we're on a plateau, some where it's on a downturn, and there are still other parts of the country where it's going up, and it's pretty high. So, it's still sort of disparate around the country.

DR. CANTRILL: So, no definite pattern has emerged yet.

DR. PHILLIPS: Not that I know of, no.

DR. CANTRILL: Thank you.

DR. QUINLISK: This is Patty. I've

been also starting to hear people being concerned that there's going to be a third wave sometime sort of in the depths of winter, late January, early February. I know that that's all speculation and everything, but I have heard that. I don't know if a lot of people think that, but I'm just wondering if that's something that you're prepared for, also.

CAPT. BUTLER: Patty, this is Jay Butler at CDC. Maybe I could address that, just in terms of the question of, will it happen. I think the short answer is, we don't really know. There certainly was a smaller peak that occurred in January and February of the 1957-1958 pandemic, and that was in many ways a third wave. If we are sort of peaking on the second wave now, it would actually fit with that time frame. If we look back to 1918-1919, some people would certainly say there were three waves. There were certainly parts of the country that were having disease during the spring of 1919. In fact, a trivia fact for you is the Stanley Cup was canceled

that year because of illness among some of the players.

DR. QUINLISK: All right. That's very useful. I mean -- and it's particularly useful out here in the states, just because as some of our areas in Iowa have gone down in amount of activity, coming the same time we're starting seeing more vaccine become available, and I don't want to get complacent, and not vaccinate people, especially if we think there's a possibility for that third wave.

CAPT. BUTLER: I think that's an excellent point.

DR. QUINLISK: Other questions for Sally? I guess I'd just like to ask one other question. Sally, I know that there were a lot of concerns that we really would have a massive overwhelming of our hospital systems. And while I do know that there have been localized issues for short periods of time, I've not gotten the feeling that there has been sort of some of these overwhelming problems that there was concern might occur. And I guess I'd like to know if you've sort of

gotten the same feeling, also?

DR. PHILLIPS: Well, we've certainly heard from -- many anecdotes at a lot of the national meetings that we've been attending, that if you look at the emergency departments, they're probably at about -- those that may have generally about 100, they're seeing about 300, but their surge plans that they've put into place over time are working, and they are accommodating the numbers. It's not that they aren't a major stressor on the institution, some have had to go to some alternative sites of tents on the campus to expand, using some other areas for screening, some very unique screening strategies in their emergency departments to deal with those numbers, but, at this point, they have been dealing and managing with the numbers.

The in-patient area is kind of what makes me nervous at night. Our ICUs are pretty small numbers, anyhow, and the ICU beds are not all that expandable. And even though I think they're pretty full, and they're

maintaining, there haven't been major requests, there hasn't been any stockpile requests yet that I know of, my CDC friends can join me, where people have actually had to activate that yet. But you would certainly say that, you know, those individuals that are still experiencing high demand are full, but they are managing within their surge plans that they have in place, to the best of my knowledge.

DR. QUINLISK: This is Patty. That sounds great. Have you gotten any sense of the need for respirators, et cetera, or has that with the plans, basically, been able to deal with the situation?

DR. PHILLIPS: Well, you know, most of the hospitals have spent their Hospital Preparedness dollars, and they'll up some of their own caches of them. Some of them have the contracts where they can pull in additional ventilators as part of their regular surge plans. And many of the states have built up caches that they've pre-deployed around their states from previous planning

dollars, so the states within that, I think, are working within their allocation plans that they have in place to get vents where they need to be.

Most of the hospitals that we've talked to that have had high numbers have, in fact, drawn from their own internal caches, and their own contracts that they've had, but they haven't run into indications yet that they haven't been able to get access to ventilators, unless somebody else knows something more on the funds than I do.

DR. CANTRILL: Patty, Steve Cantrill, just a comment. One of the biggest issues has been PPE. And many places have run out of N95 masks, and there's still a lot of confusion, even in the literature, about, do we use surgical masks or N95 masks, even with the IOM report. So, I think that's an issue that, in the future, I think hospitals need to -- have not really -- many have not done an adequate job of preparing for the PPE draw.

DR. QUINLISK: Right. No, and this is Patty. I agree with you. Maybe, at that,

we should go back to the panel and let them say, because I think some of them may be addressing at least part of that issue. Do you want to go ahead, Leigh, and then have the next person speak?

CAPT. SAWYER: Sure. Well, let me just more formally say that this part of the meeting is scheduled as a panel, so that there's more opportunity for dialogue and questions of each of the panelists. And now that all of them are on line, we can introduce them formally. Jay Butler is the Program Director of H1N1 Vaccine Task Force at CDC, and he will give us an update on the current epidemiology of H1N1 and Seasonal Flu, and also provide us with some topics around the vaccine distribution, and how that's going.

Michael Bell is on the line. He's Associate Director for Infection Control, and he will be able to talk to some of these issues on personal preparedness, and, possibly, the N95 masks and surgical masks.

Anita Patel is a Health Scientist in the Division of Strategic National

Stockpile, SNS, and she will be able to address issues around antivirals.

And, as we've heard, Sally Phillips is in our immediate office of ASPR, and she's given us some perspective on the medical surge capabilities of the federal government.

So with that, Jay, if you would serve as the moderator for discussion, we'll turn it over to you.

CAPT. BUTLER: Okay, happy to. Thank you, Leigh.

Let me start with the epidemiology update, or the disease status update for the week. Using the ILINet, which is based on the proportion of visits to physicians' offices for influenza-like illness in a network of single providers around the country, and then reported to CDC, we actually have had a decline in the proportion of visits for ILI, that it peaks at 7.9 two weeks ago, with 7.7 this past week, and was down to 6.7 in the report this week. And when I say this week, it really is data for last week.

Those declines actually were

consistent in all regions except for New England, so I don't want to paint an overly optimistic picture, because, certainly, sometimes there's transient downticks that then are followed by an up-tick again, but it is possible that we're near the top of the peak of this current wave of the pandemic.

When we look for variation among the states, and the state epidemiologists report 46 to 50 states are still reporting widespread, which is the highest level of influenza activity. The four states that have regional, which is the next to the highest level, are Mississippi, Nebraska, Texas, and Hawaii.

The measure of influenza illness by pneumonia and influenza mortality remains above the baseline for this time of year, and is actually in the range of normal for a -- during the influenza season. So, in many ways, what we're seeing right now is very similar to a very bad influenza season.

The major difference in the current pandemic is that younger people are

disproportionately impacted, so the number of deaths occurring among younger people is actually much greater than what we would anticipate from seasonal influenza.

You've probably seen reports of the estimates out from CDC yesterday, that are intended to give us a more complete picture of the impact of the pandemic. Recognizing that many of the -- we actually don't count cases, specifically, anymore, because most cases go without laboratory confirmation, unless they result in hospitalization or death. And even in that case, often times laboratory confirmation is lacking.

The current estimates are that there have been 22 million infections with the H1N1 influenza virus, including 8 million in children. And let me focus on children, because it's estimated that there's been 36,000 children hospitalized, and 540 deaths, which is about four-fold higher than the number that we actually have laboratory confirmation on. The total number of deaths are estimated in the range of about 5,000,

thus far.

Moving on to the vaccine program, the vaccine program as of today, has had 43 million doses available for order through the states. Just to refresh everybody's memory on the distribution system and how it works, orders are placed by the state health departments, and some of the large urban health departments on a daily basis, actually, can be more frequent than daily. They are transmitted to CDC, and then are sent to a central distributor that then ships the vaccine out that day in more than 90 percent of the instances for overnight delivery.

Certainly, the biggest challenge we've seen with the vaccine programs so far has been the supply, the amount of vaccine iterates into the pipeline has remained relatively low. And after a couple of weeks that were better, this week was down a bit, again, which certainly is very frustrating.

We've also seen a challenge with the smaller amount of vaccine, as well as some weather issues on the East Coast, that some of

the states have had smaller allocations this week, because less vaccine has been able to enter into one of the four regional distribution hubs to be available then for allocation for ordering, and we're working to address that issue as quickly as possible.

Maybe, at this point, it would be better to give people opportunity to ask questions. I don't know, Leigh, if you wanted to have any kind of brief update from Mike Bell, or Anita Patel, but they're both on the line. In fact, Anita is here with me.

CAPT. SAWYER: I think this might be a good time for the Board to ask you questions.

CAPT. BUTLER: Okay. Fair enough.

DR. DRETCHEN: This is Ken Dretchen. So, what is then the prognosis, let's say as best as you can, over the next three to four weeks in terms of vaccine distribution?

CAPT. BUTLER: Well, we are working with the manufacturers to get the best information possible. The prognosis is that

we will be getting several million doses of vaccine. The exact numbers, I'm very hesitant to speculate on. I think some of the information we've been given certainly was challenged by some of the technical problems that were encountered in production of the vaccine. We certainly would -- we want to do everything we can to support the manufacturers to get vaccine into the system so that it can be administered.

DR. BERKELMAN: Jay, this is Ruth Berkelman.

CAPT. BUTLER: Yes, Ruth. Hi.

DR. BERKELMAN: Hi. I wanted to see if I heard you right, that most children, maybe as many as three out of four children, and many young adults may have died from H1N1 have no laboratory confirmation?

CAPT. BUTLER: That's comparing the number of cases that are reported with an isolate for confirmation, with the numbers from the modeling that has recently been completed based on the best epidemiology, comparing that point estimate. So, that's an

estimate.

DR. BERKELMAN: But, if that's the case, that many, if not most children and young adults are dying without laboratory confirmation, is that -- why do you think that is? Do you think it's a reporting phenomenon, or do you think truly they're not being tested?

CAPT. BUTLER: It's a very good question, Ruth. And I'm sure you're familiar -- as familiar, if not more familiar than I am, with the modeling methodology to produce these estimates. You're also a clinician, so you are also aware that cases sometimes go undiagnosed, even when they're severe. So, I think we could speculate on a number of reasons. I think under-reporting is a very real possibility, but we would be speculating.

DR. BERKELMAN: Yes. And the reason I raise it is because I find it so high. I mean, I would have expected a number to go unreported or undiagnosed, but this seems like an extremely high number.

CAPT. BUTLER: Okay. And keep in

mind, that's the point estimate. There is a range in the model, and I'm sorry I don't have those numbers right in front of me, but that is the estimate from within the range.

DR. BERKELMAN: I guess the follow-on to that was whether or not the actual testing was good.

CAPT. BUTLER: And I'm assuming that's a rhetorical question, because I certainly can't answer it.

DR. GRABENSTEIN: This is John Grabenstein. When the Board met live the last time, we were discussing an event that hasn't had much chance to happen yet, which is for the vaccine to get to the wrong place, a place where it's not needed. In a shortage, that's a little bit unlikely, at the moment. But let's say that a place ordered more vaccine than it could use, have you refined your ability to redirect it to a place where it's needed, or is there one mechanism, or are you simply assuming that states or the big municipalities are going to realize that quickly, and get it to a place where it can

get used?

CAPT. BUTLER: We've certainly seen that happen at the state level. At least, where we're looking at pandemic so far, we don't see enough regional variation to try and do that nationally. As I said, 46 states are reporting widespread disease. The four remaining ones are only one notch down with regional levels of activity. Within states, there have been some decisions about redistribution based on the local epidemiology.

I'm aware of one instance where a very remote town actually received enough vaccine to immunize everyone within the town, because of an outbreak that was complicated by the remoteness of this area. Another state is allocating -- making sure that there's a larger allocation going to tribal and IHF facilities because of concern that American Indian populations, at least in their states, are disproportionately represented among the hospitalized cases. So, at this point, the wisest course still seems to be for the states

to be able to have the ability to make those local decisions based on their local epidemiology. It's a very good question. Thank you.

CAPT. SAWYER: Maybe we should move on to one of the other panelists, Jay.

CAPT. BUTLER: That would be fine. I'd like to introduce Anita Patel, a Health Scientist with the Division of the Strategic National Stockpile. Anita?

DR. PATEL: Good afternoon. I guess I'll follow suit with providing some history, and a brief update, and then see if there's any specific questions that I could help address.

Back in the spring, April and May, the Stockpile had deployed 25 percent of all of its pandemic influenza countermeasures that we had on hand pro rata, based on population to the 62 project areas. Those assets included approximately 11 million regimens of antiviral drugs, gloves, gowns, face shields, surgical masks, as well as respirators. In October and November, we've also shipped out

an additional 58.6 million N95 respirators, as well as an additional 535,000 regimens of suspension products.

All of those are really -- the decision to deploy those products were made based on need, as well as monitoring the supply chain for those assets to make sure that there were enough products available for the U.S. population, as needed.

We've been doing a couple of things as far as follow-up, reaching back to states to see how they're -- see what their focus is on distribution for the assets that they have received from the stockpile, as well as how they're distributing some of their stockpile, their specific state stockpile assets.

States are reporting that back to us on a weekly basis through a survey mechanism which is voluntary. So, on average, we're getting about 41 or 42 states or project areas reporting of the 62. And they provide us information, such as how many have actually looked for inventories for supplies, and what some of the locations are that they're moving

shipments of antiviral drugs, as well as PPE to.

We've also got a project that is a supply chain dashboard, where we're able to monitor antiviral drugs and respiratory protective devices that are in the marketplace. We are working with manufacturers, distributors, and retailers to gain visibility on their inventory, and to see what supplies are for those two categories of products. In addition to that, to give -- to feed into the decisions that -- of when and how the stockpile should be released, we're also monitoring the demand side. Specifically, for antiviral drugs, we're monitoring prescriptions, prescription rates, to determine if the prescription needs are being met with the current supply through the dashboard project where we see reports on. So, there is a lot going on on our end as far as supply and demand for assets, and the current inventory, and making the right decisions to make sure the stockpile is released at the appropriate time. I'd be

happy to open it up for any specific questions regarding SNS.

DR. DRETCHEN: Ken Dretchen. How are we with pediatric Tamiflu for distribution to the states? Are there shortages, or are people's needs being adequately met?

DR. PATEL: There have been limited-supply issues, especially with the suspension products, so there are three formulations for pediatrics that could be used, as far as antiviral drugs go. Those include 30 and 45 milligram capsules of Tamiflu, as well as the Tamiflu oral suspension. The oral suspension product has been in limited supply. Roche, the manufacturer, has made that basically public information, and they've been able to provide some supply to the marketplace. However, when you look at the need based on prescriptions, it's really not meeting the current requirement, so we pushed oral suspension product to states for use, and have also followed up with guidance to the project areas for them to push that down to the local level.

There are alternatives available to the Tamiflu oral suspension, and those include, again, the 30 and 45 milligram capsules. For kids that can't swallow, those capsules may be opened up and put into a sweetened liquid, such as Hershey's chocolate syrup and administered that way. There's also compounding, so CDC has been focusing on messaging towards pharmacists to make them aware of compounding as an option. We've posted the compounding guidelines that are in the Tamiflu package insert on our website, as well as it's on the FDA website, and provided additional guidance through a compounding video, and other communications directly to chain pharmacies, as well as the pharmacy professional organizations.

For the 30 and 45 milligram capsules, there are no shortages in the commercial supply chain, and that product is readily available. Roche has also pushed forward with a communication towards pharmacy partners to make sure that physicians and pharmacists are aware of that as an

alternative product. Some kids could actually take that product if they weigh over 33 pounds.

CAPT. SAWYER: Anita, thank you very much. This is Leigh Sawyer. I wonder, one of the questions had to do with resistance, and finding H1N1 resistance, to antivirals. Are you seeing any of that with your antivirals?

CAPT. BUTLER: A minimal amount of resistance. I don't have exact numbers, but not ticking up much.

CAPT. SAWYER: So, shall we move on to the personal preparedness issues?

DR. QUINLISK: That sounds good to me, Leigh. Let's go ahead and do that.

CAPT. SAWYER: Jay, do you want to introduce our next speaker?

CAPT. BUTLER: Yes. Mike, are you there?

DR. BELL: Yes, thank you.

CAPT. BUTLER: Okay. Great. Let me introduce Dr. Michael Bell, the Associate Director for Infection Control in the Division

of Healthcare Quality Promotion at the CDC. Mike.

DR. BELL: Thanks. Hi, everybody. This is Mike Bell. I'm happy to go over details of the recently updated interim guidance, if that would be helpful. There is nothing in addition to that to report at this time.

One thing that I would say sort of in prefacing this, is that we're looking at a situation where the focus on protective equipment, while understandable, is far from adequate to cover the waterfront in terms of exposure risk for health care personnel. As we look at what's happened in the past several months, it's becoming very clear that individuals who are diagnosed with H1N1 who are health care personnel have a variety of sources of exposure, and that exposure to sick patients is actually the minority of those exposures, with the majority being split between communicated household exposures, and exposures to other health care personnel who show up at work, despite the fact that they're

sick. So it's, I think, reasonable to consider all of the issues related to protective equipment, but also to bear in mind that it's a fairly weak link in terms of protecting our healthcare personnel.

I'm going to stop there and open it up for questions. I think it might be more useful to respond to your thoughts than to go further on this.

DR. QUINLISK: Patty Quinlisk. I'll add something. Just -- you're talking about the health care workers getting it from others. We found during our big mumps epidemic that that was exactly what happened, too.

I guess, I -- could I ask just, what kind of feedback are you getting from the health care workers about the issues surrounding the masks, and supplies, et cetera, and use of the procedural masks versus the N95s?

DR. BELL: So, we're seeing a variety of things, as you might expect. We're seeing fairly uniformly around the country

that there are patches of various areas where they are having difficulty to supply them both masks and respirators. The issue is interesting in the sense that, despite the fact that distributors might say that they're available, or other sources might say they exist, we find that there's a challenge when it comes to the actual clinician opening a cabinet and reaching in to find something, finding that they're not there. So, somewhere in the local supply chain, we're seeing some challenges in maintaining supplies.

The other challenge that we're seeing is that when facilities attempt to order more masks or respirators, they're being told that they're going to get a proportion of the allocation based on annual purchasing, and that any extra ordering will take several months to fulfill. And, obviously, that's not terribly helpful in the current circumstance. So, that's sort of the tone of what we're hearing.

DR. QUINLISK: Okay. Thank you.

DR. CANTRILL: Steve Cantrill.

That's certainly the situation here. In fact, when they go for more N95s, they're been put on back order, so I think this, to me, at least, illustrates an area that we probably should focus on in the future, in terms of hospital preparedness, because they clearly haven't thought through the potential demand with an epidemic like this.

DR. QUINLISK: This is Patty, again. I don't know if you have any feel for this, but what we're sort of seeing here in Iowa is that while the hospitals seem to be pretty good at using masks appropriately, and using the appropriate mask, getting people to use masks in the clinic setting, the outpatient setting is much harder. And I don't quite understand that, but I cannot tell you how many people I hear from that said, oh, I went in to see somebody because I had the flu, and the health care providers didn't put masks on.

DR. BELL: Yes, I think that's something that we're seeing not only in out-patient settings, but in a range of settings

where respiratory protection hasn't traditionally been used, not only the willingness to use the equipment, but also the infrastructure needed to use it appropriately. In other words, the training, the testing, and so on. The respiratory health program that's supposed to underlie these respirators, those things tend not to be in place in places like long-term care facilities, clinic settings, and so on, ambulatory surgical facilities, and the like. So, when we make recommendations that are mainly focused on in-patient facilities, I think we do miss the fact that patients are seen in a wide variety of settings, and standard recommendations for hospitals alone may not be adequate to guide that behavior.

Frankly, even if we make good recommendations for the other settings, the challenges still remain in terms of making sure that everyone's trained, and fitted, and so on in an appropriate way so that they can then adhere to our recommendations.

DR. CANTRILL: Steve Cantrill again. Remember we're dealing with a population of health care providers that nominally only 30 to 50 percent believe in influenza vaccinations, and that's another part of the problem, as well.

DR. QUINLISK: I want to just say here in Iowa we're over 80 percent for health care providers.

DR. CANTRILL: Patty, that's probably all due to your efforts, and I think it's marvelous.

DR. QUINLISK: Oh, I can't -- we have a collaborative here that's very active, and have been for years. But I hear your point, though, especially it just makes me mad when I hear health care providers telling their patients don't get the vaccine because the vaccines don't work. But, anyway.

DR. CANTRILL: Yes, some of us get livid when we hear that.

DR. QUINLISK: Are there any other questions?

DR. BELL: I think I'd chime in

very quickly. It's not specifically on the topic of respiratory protection. This is Mike Bell again. But if we look at the interim guidance as it was updated, there's a very intentional focus away from masks and respirators, and towards solutions that will protect individuals more broadly. And that includes focus on vaccine use, because having an immune population is the best possible solution here. But secondary to that, there are a couple of things, which I think deserve some focus before we then go on with the whole mask and respirator issue, and those are the importance of source control, and the dedication of some supplies of masks to put on coughing individuals.

If we can do a very good job of that, and then, in addition, the second thing being, ensuring that sick individuals stay home, those two things alone may have a much bigger impact than any sort of protective equipment that we talked about for routine patient care. So, just making sure that we maintain our focus on those administrative

efforts, in addition to considering supply issues of masks and respirators, I think is very important.

DR. QUINLISK: Yes, this is Patty. I think you make an excellent point. I mean, too often people focus on one thing, and maybe not even the thing that's most important, so I appreciate your comments.

Are there comments from anyone else? Okay. I guess, I'll ask Leigh, are we ready to open up for public comments?

CAPT. SAWYER: Yes, this would be a good time.

DR. QUINLISK: Okay. Operator, can you open it up for public comments, please.

OPERATOR: Yes. At this time, if you would like to ask a question, please press *1 on your telephone keypad.

Your first question comes from the line of Robert Rayl, private investor.

MR. RAYL: Good afternoon, everybody. I've got a couple of questions. One is on the emergency use authorization was given for Peramivir on 23 October. Can you

tell us how many patients have received Peramivir, and are the results good enough to allow Peramivir use as a first-line treatment, instead of after the patients are on ventilators, and in serious condition? And we are getting some news out of Israel, I guess, if you can convert Hebrew, that it's working good for them over there. I guess they got a few doses to try out. And, another question, it's a very bad situation, H1N1 crisis over in Ukraine. And I'm just wondering, what are you -- they asked for support from our government on Peramivir, would that come from the government, or would they have to purchase that from BioCryst?

And one last thing. I heard that you said Robin Robinson come on, and I'd just like to thank him for all the work that he's done in working with BioCryst and getting Peramivir in the system. And I just wondered if he could comment on what is his -- is this drug meeting his expectations so far. Thank you.

CAPT. SAWYER: I'm sorry. Robin

Robinson was not able to stay on the line, so we'll have to convey your message to him. And, Boris, are you on the line from FDA, or Aubrey Miller?

RADM. LUSHNIAK: Yes. Hi, Leigh. This is Boris from FDA. I don't have the numbers. I know that CDC is filtering the requests coming in. I'm not sure if there's anybody on from CDC that has the latest numbers in terms of requests. I don't have those at hand. They were reported to me in a report this past Monday, but I can get back to the group with those numbers.

In terms of the Peramivir use, you know, the conditions of the EUA are such that we still -- it's not a fully approved product. It's a product that had been issued the special use authorization under emergency use authorization for this specific emergency; so, therefore, the conditions still need to be met as they're set aside within the emergency use authorization provisions, which is a process that everyone needs to go through to get access to this medication. So, at this point,

even though there's more and more use of it, we still don't have the data to move it out of the emergency use authorization conditions right now.

CAPT. BUTLER: Since this is CDC, I'm going ask Anita to address the question you raised about requests.

DR. PATEL: Sure. And just to provide a little more background for those of you who may not be familiar with this; in October of 2009, and toward the beginning of November, HHS procured a total of 11,200 treatment courses of Peramivir IV from BioCryst, and we made this product available through the CDC. It's available via the SNS for distribution, and under uses Dr. Lushniak had mentioned, under the CDC EUA.

Licensed clinicians may make requests for this product through the CDC website electronic request system, and requesting clinicians are required to review the scope, the conditions and criteria for emergency use authorization. They must agree to comply with the conditions of the EUA in

order to request Peramivir.

Once we do receive the request, and once it is accepted, CDC is able to deliver product directly to the hospitals within 24 hours of the decision to ship. Currently, we've had a total of 829 regimens deployed to 533 patient requests. Some of the patients did request a 10-day regimen versus a 5-day regimen. There's a total of 93 percent of our supply that remains, so we're confident that the current supply that we have will meet the demands as they've been set forth in the last couple of weeks.

There was a question on -- actually, let me just stop there.

DR. ROSE: This is Eric Rose from the Board. I have a question. Haven't IV Tamiflu and maybe Relenza also been distributed on this EUA basis?

DR. PATEL: Those two products have not yet been -- are not yet out of -

CAPT MILLER: This is Aubrey Miller with FDA. Those are not under an emergency use authorization, though, there are -- some

of that is available through the emergency IND process on a case-by-case basis, as well.

Another point, too, the Peramivir intravenous formulation is really intended for very sick individuals while there are approved antiviral medications currently available for individuals that can take those medicines through the normal routes of injection.

DR. BERKELMAN: This is Ruth Berkelman. I want to follow up. You mentioned that you get the Peramivir to the patient within 24 hours of decision to ship. What is the average time, mean time, between request and delivery?

DR. PATEL: That average time right now is 30 minutes.

DR. BERKELMAN: Between the request from the doc and the decision?

DR. PATEL: That is correct. So, the electronic system is set up in such a way where there's very little time frame between that request and that decision to deploy. It's really just SNS confirming logistic information, and assuring that all the

conditions of the EUA have been agreed to.

DR. BERKELMAN: Great. Thank you.

DR. QUINLISK: Okay. Are there any other questions from the public?

OPERATOR: Grace, your line is open.

MS. HUANG: Hello, thank you. Can you hear me? Hello.

DR. QUINLISK: Yes, go ahead.

MS. HUANG: I, actually, have a few questions, just trying to catch some details that I think I missed. In terms of the N95 respirators, what was the number that have been released from the Stockpile, and then how many are still in the Stockpile?

CAPT. BUTLER: Yes. Anita Patel will answer that question.

DR. PATEL: The total quantity of product that remains in the Stockpile is 20.4 million respirators, and as far as what was deployed, there was a total of 27.6 deployed in the spring, an additional 58.6 recently deployed.

MS. HUANG: Okay. Thank you. And

the other quantity that you mentioned has been released from the Stockpile, was that for the liquid Tamiflu for children?

DR. PATEL: Correct. An additional 540,000 bottles, and that's -- one bottle is one regimen, was deployed from the Stockpile for a pediatric oral suspension.

MS. HUANG: Okay.

DR. PATEL: In this fall deployment.

MS. HUANG: That's your total quantity.

DR. PATEL: That was deployed in the fall, and that was in addition to the 59,000 courses that were deployed in April.

MS. HUANG: Okay. Thank you. And then regarding the 1135 Waivers, it was mentioned that there were five states that received them. Can we hear what the five states were? Is there any correlation between, like, what specific states those were in terms of the severity of the disease, at this point?

DR. PHILLIPS: This is Sally

Phillips. I can tell you the states. I don't know how that correlates with the severity of the disease. There were two requests that were approved for Ohio, one for North Dakota, and one for Montana, and one for Washington state.

MS. HUANG: Thanks so much. And then the next question, again, unrelated, but all very interesting. For the medical surge, what is the name, the official name of the system that keeps track of hospital beds?

DR. PHILLIPS: It's -- the short name of it is HAvBED, but it's the Hospital Available Beds for Emergencies -- Steve, help me out -- and Disasters.

DR. CANTRILL: And Disasters, right.

DR. PHILLIPS: So it's called HAvBED. And it's Hospital Available Beds in Emergencies and Disasters.

MS. HUANG: Oh, I see. So, the acronym is H-A-V Bed?

DR. PHILLIPS: B-E-D, yes.

MS. HUANG: Thank you so much for

all the answers.

DR. PHILLIPS: Sure.

DR. QUINLISK: Are there any other public comments?

OPERATOR: There are no further comments or questions.

DR. QUINLISK: Okay. Then I think I'll just see, are there any other comments or questions from Board members? Okay. Leigh, do you have any more issues, just reminders, or any things for the Board?

CAPT. SAWYER: Well, there are two more people, one just dropped off, to ask questions.

DR. QUINLISK: Oh, sorry. I thought she said there were no more.

CAPT. SAWYER: I think they all of a sudden popped up. Operator, are you still there?

OPERATOR: Yes. Mr. Paul Gordon came into queue. Mr. Gordon, your line is open.

MR. GORDON: Oh, thank you very much. I guess I'll dovetail a little bit on a

question and comment I made earlier, maybe just get to a particular question here. Regarding the use of antivirals, in particular IV-based antivirals, at this point, understanding is Peramivir has been released under the emergency use authorization, and I had a couple of questions.

What are the respective issues with regard to additional IV-based antivirals? And I know that IV-based Relenza and Tamiflu have been mentioned. And I ask the question maybe to -- if Aubrey from the FDA is still here, that neither of those have been through, to my knowledge, clinical trials with regards to IV-based administration. And the other question is, in our national stockpiles -- I raised the question that evidently the company, BioCryst, has got limited supplies of this Peramivir, and I'm wondering where we sit with regards to our stockpile vis-a-vis public statements from the company, BioCryst, that they're out publicly selling their inventory to other countries, and does that leave us at risk? That was the end of my question.

CAPT MILLER: This is Aubrey. I can only respond to the first portion of your question, but the -- with respect to other IV formulations, such as Tamiflu and Relenza, as you know, those are currently not approved for IV. And it is just a case-by-case basis, emergency use IND is the only current way to obtain those. We do not have a request, as of this moment, with respect to emergency use involving those formulations.

MR. GORDON: Okay. Thank you. Is there anybody that could answer the issues with regards to the national stockpile of Peramivir?

DR. PATEL: Sure, this is Anita. As far as what's currently in inventory with the Strategic National Stockpile, we are confident that we are able to meet current demand for a product. We've been working with BARDA, who's been engaging the manufacturer to assure that there is product available, if additional are needed.

MR. GORDON: Okay. Thank you. And just another question. I don't know if

there's anybody appropriate on the line. We've heard issues of shortages of some of the Tamiflu formulations for pediatrics. Has there been any discussions to expanded use of Peramivir? And I only bring this up because of a point I made earlier. I don't know, again, how many folks have seen a number of the stories that continue to crop up, and whether they're 100 percent attributable to Peramivir, or the fact that it's just an IV-based antiviral, I guess it really doesn't matter. But the stories seem to be pretty dramatic, of people coming back from their deathbed after having an IV-administered Peramivir. And I'm wondering if there's any consideration for expanded use earlier in the protocol, because I know it's pretty restricted at this point, and expanded at all for pediatric use?

DR. PATEL: This is Anita from the Stockpile. Currently IV Peramivir is allowed for use in peds, but as far as additional expansions of emergency use authorization, CDC has no additional plans at this time to make

any request to FDA for changes of our current requested EUA.

MR. GORDON: Okay. Thank you very much for those responses.

DR. QUINLISK: I think we're getting down to the end of our time. Are there any other public comments in line?

CAPT. SAWYER: No.

DR. QUINLISK: Okay. Any Board members have any final questions or comments? Okay. Then, I'll go back. Leigh, do you have anything we need to do, reminders for future meetings, or anything?

CAPT. SAWYER: Yes. We will have a public meeting on Wednesday, December 9th. That information will be posted on our website. I think it's the same time, I believe, 12 to 2. And we'll have an agenda posted, as well, at least a week before the meeting. That's it from our side, Patty.

DR. QUINLISK: Okay. Well, I appreciate the panel. Thank you all for being here today and talking to us. I just applaud all the efforts you're doing at the national

level. I just -- being a state person, I'll just say I commend all the work that's being done, and I think this thing has gone pretty smoothly considering everything. So, thank you all, again, and thank you for being here today.

Any last comments from anyone? I think then we're done for today. Thank you all for joining.

(Whereupon, the above-entitled matter went off the record at 2:02 p.m.)