

**WORLD TRADE CENTER HEALTH PROGRAM
SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE (STAC) MEETING
November 3, 2016**

**THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION**

**NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
WORLD TRADE CENTER HEALTH PROGRAM**

TENTH MEETING

SCIENTIFIC/TECHNICAL ADVISORY

COMMITTEE (STAC) MEETING

November 3, 2016

The verbatim transcript of the
Meeting of the Scientific/Technical Advisory
Committee Meeting held on November
3, 2016, 9:00 a.m.

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PARTICIPANTS

(alphabetically)

ROSEMARIE BOWLER - COMMITTEE MEMBER
TANIA CARRÉON-VALENCIA, PhD – NIOSH
KIMBERLY FLYNN - PUBLIC COMMENT
MRIDU GULATI, MD - COMMITTEE MEMBER
ROBERT HARRISON, MD – FORMER COMMITTEE MEMBER
JOHN HOWARD, MD – ADMINISTRATOR, WTCHP
CATHERINE McVAY HUGHES - COMMITTEE MEMBER
VAYLATEENA JONES - COMMITTEE MEMBER
RACHEL LIDOV - PUBLIC COMMENT
MAX LUM - SENIOR ADVISOR, NIOSH
MICHAEL McCRAWLEY - COMMITTEE MEMBER
STEVEN MARKOWITZ, MD - COMMITTEE MEMBER
ANNYCE MAYER, PhD - COMMITTEE MEMBER
GUILLERMINA MEJIA - COMMITTEE MEMBER
PAUL J. MIDDENDORF, PhD - DESIGNATED FEDERAL OFFICIAL
LILA NORDSTROM - COMMITTEE MEMBER
JO POLETT - PUBLIC COMMENT
DORI REISSMAN, MD – ASSOCIATE ADMINISTRATOR, WTCHP
WILLIAM ROM - COMMITTEE MEMBER
MARGARET RYAN - COMMITTEE MEMBER
MICKI SIEGEL DE HERNÁNDEZ - COMMITTEE MEMBER
GLENN TALASKA, PHD - COMMITTEE MEMBER
ELIZABETH WARD, PhD - COMMITTEE CHAIR-PERSON
MARC WILKENFELD, MD - COMMITTEE MEMBER

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WELCOME AND ADMINISTRATION

DR. MIDDENDORF: Well, good morning, everyone. As most of you already know, I'm Paul Middendorf and I'm the designated federal official for the World Trade Center Scientific/Technical Advisory Committee. I'll deal with a number of administrative issues at the front end of our meeting today. First is the exits. Best exit to use if you're here in the building is the one that I'm pointing toward on the left over there. You go through that and go through the double doors, and immediately outside the double doors, turn to your left and there's a set of stairs there that will take you down and out of the building. If there's an emergency where we need to evacuate, that's where you should go. Different kind of emergency, if you need to use the restrooms, instead of turning to your left and going toward the stairs, go straight down the hall and restrooms are on your right. Also want to point out that other than water, food and beverages are not allowed to be consumed in this room. This is a very nice space and we want to continue using it so please pay attention to this rule. They don't have to let us come here, and if we abuse our privilege, they may take it away from us. So please, only water here. For people on the committee, if you need to drink something other than water, you can use the space over here to my left.

It's been our tradition to spend a few moments at the beginning of each of our meetings in silence to remember those who were killed in the attacks on 9/11 and also those responders and survivors who have since died because of those attacks, as well as others who have been killed in or are suffering from terrorist attacks around the world. Today I'd like to add one more person to our remembrances. Tom Aldrich recently passed away. Tom has been a member of the STAC from the very beginning. He was also very involved in providing treatment to those exposed, and studying the health effects associated with 9/11 attacks. So, his professional contributions have had a substantial impact and on a personal level, he will also be missed. So please include him in your thoughts during these moments of silence.

[Moment of silence.]

Okay, thank you. I want to remind folks that we currently have an announcement out soliciting for new members for next year. That announcement is available on the committee's website for anyone who's interested. If you are interested in nominating someone, including yourself, please visit the committee's website to find the information on how to nominate someone. And for someone here in the building, we do have a flyer at the front table; you can pick one up there as well. I'd like to extend a warm welcome to each of our committee members, both current, former, who have graciously agreed to share their time and thoughts with the committee on independent peer review and the policies and procedures for adding conditions to the list of World Trade Center-related health conditions. We're looking forward to hearing everyone's thoughts and ideas. I also want to

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extend a warm welcome to those of you who are on the phone. We very much appreciate your interest in these proceedings. For those of you who have signed up to provide public comments, they are scheduled to begin at 10:45 this morning and that's Eastern Time. Those of you here, what I'll ask you to do is to come up to the podium here in front of us when I announce you; and for our public commenters on the phone, when your turn comes, you will need to follow the instructions on turning on your line to open it so you can be heard in the meeting. The next thing on our list is to do a roll call. So let me pull that up. Rosemarie Bowler? I believe she will be joining us around 10:30 so we'll wait for her. But in addition to just announcing that you are here, let me know if there have been any changes in your conflict of interest. So just let me know whether or not anything has changed on that front as well as letting me know you are here. So Rosemarie will be joining us around 10:30. Mridu just sent me an email. She probably went to the Javits Center so she'll be here shortly. So when she arrives, I'll ask her the same questions. So Catherine Hughes?

MS. HUGHES: Here. No change in conflict.
DR. MIDDENDORF: And Val Jones?
MS. JONES: Here. I retired from Mount Sinai (inaudible @ 5:26).
DR. MIDDENDORF: Okay, so new new conflicts—
MS. JONES: No.
DR. MIDDENDORF: Potential conflicts of interest. Okay. Steven Markowitz?
DR. MARKOWITZ: Here. No conflict.
DR. MIDDENDORF: Annyce Mayer?
DR. MAYER: Here. No conflicts.
DR. MIDDENDORF: And just I've got you—how is it hearing us? Can you hear us fairly well?
DR. MAYER: I can, except it sounds like maybe somebody sitting next to the telephone is moving papers.
DR. MIDDENDORF: Okay, we'll move the phone just a little bit.
DR. MAYER: Okay, thank you.
DR. MIDDENDORF: And Mike McCawley?
DR. McCAWLEY: Here. No conflicts.
DR. MIDDENDORF: Guille?
MS. MEJIA: Here. No conflicts.
DR. MIDDENDORF: Lila?
MS. NORDSTROM: Here. No conflicts.
DR. MIDDENDORF: Bill?
DR. ROM: Here. No conflicts.
DR. MIDDENDORF: Megan?
DR. RYAN: Here. No conflicts.
DR. MIDDENDORF: And how well can you hear us?
DR. RYAN: Breaking up a little bit but it's better now.

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- DR. MIDDENDORF: Okay. And Sheela Sathyanarayana is not going to be able to make it. And Micki Siegel de Hernández?
- MS. SIEGEL DE HERNÁNDEZ: Here. No conflicts.
- DR. MIDDENDORF: Glenn Talaska?
- DR. TALASKA: Here, no conflicts.
- DR. MIDDENDORF: Liz?
- DR. WARD: Here, no conflicts.
- DR. MIDDENDORF: And Marc Wilkenfeld?
- DR. WILKENFELD: Here, no conflict.
- DR. MIDDENDORF: Okay. I'll just remind folks that we do have copies of our agenda in the back, and for those of you on the phone, we are putting the agenda on the web, but it's also on the committee's website. So with that, I will turn it over to our chair, Liz.
- DR. WARD: Hi, I'd like to extend a warm welcome to the members of the committee and greetings to the new members, and also the members of the public who are joining us today. We'll get started with an introduction from John Howard.
- DR. HOWARD: Thank you. Can I be heard on the phone okay?
- DR. MIDDENDORF: Annyce or Megan, can you hear?
- DR. MAYER: Yes.

INTRODUCTION TO THE MEETING

- DR. HOWARD: Okay, great. Thanks for that sound check. Good morning and welcome, everybody. On behalf of everybody in the World Trade Center Health Program, I want to express my appreciation and all of our appreciation to each of you for the time that you take to come to our meetings and to be responsive, and also to everybody on the telephone. I'd like also to welcome all of our new members. To Micki, who has been a stalwart from the very beginning and now is on our committee, thank you very much. To Dr. Wilkenfeld, to Dr. Gulati, and to Dr. Sheela Sathyanarayana. I think I got that right. But she's not able to be with us today to check my pronunciation. Third, I want to thank the two workgroups that we formed, that you all formed last meeting, one for the peer review workgroup and the other for the policy and procedures for adding non-cancer conditions. I want to thank the members of that workgroup that have worked since June to develop recommendations for the full committee today.
- And next, I wanted to tell you a little bit different sort of meeting that we want to start here today. We put on the agenda informational time for Dr. Reissman to update you on the research portfolio and how the Program disseminates the results of that research to program members, to clinicians and to other stakeholders. And what I would like to do for this meeting—and carrying over to other meetings—is to ask you to offer your individual views about the research directions and dissemination, after hearing those presentations. There is no specific charge; it's not formal. You don't have to develop a consensus together. You don't have to take up votes. But we're interested in what your individual

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perspectives are. As you know, we've done a lot of consensus type voting on various issues, and it really hasn't allowed each member to bring their own experience to topics. So we're going to start today with Dr. Reissman's presentation.

And then I did want to give a note about the STAC's role and how STAC recommendations and guidance are utilized by the Program itself, and especially for new members. The statute that we all operate under requires that the administrator seek recommendations from the STAC in four areas.

The first is to review scientific and medical evidence, and provide the administrator with recommendations regarding additional eligibility criteria, but only if the administrator decides to modify the current eligibility criteria. So that's not something that the committee does *ab initio* but only when asked.

Secondly, the purpose of the STAC is to provide the administrator consultation regarding the research conducted or supported by the Program, and we did that in one of our past meetings as more of a consensus kind of activity where we asked for you, as a group, to vote. Today, we're asking you to listen to Dr. Reissman's presentation and offer your individual views about research, because it is a really critical part of this program, and I'd like to hear more of your thinking on this issue.

The third area is to provide recommendations regarding the identification of individuals to conduct independent peer review. Now, this is a new requirement in the reauthorized Zadroga Act. It wasn't in the original act. And this is one that we charged the committee, as a consensus body, to develop a recommendation for the administrator on, and that is one of the subjects of today's meeting.

And then the fourth is to review and evaluate program policies and procedures used to determine the issues of adding a health condition to the list. We did that, as you'll recall, a couple of years back and our esteemed chair led us through a number of meetings on adding cancer conditions to the list, and I thank her again for that. And that is an example of that, of the administrator saying I want your consensus view on whether I should add a particular condition. We haven't done that since that large effort, but it may happen in the future, and that is a consensus-type activity where you all have to get together and offer a recommendation as a group. The statute permits, but it doesn't require, that the administrator seek a recommendation from the STAC regarding potential additional conditions, and that is what we talked about when we did cancer. Also new to the STAC requirement in reauthorization is to look at the policy and procedures for adding non-cancer, which is what you all are going to be doing today.

The very important responsibilities for the STAC regarding program decisions do have broad implications for the Program, for the members of the Program, and for the administration of the Program overall. The World Trade Center Health Program is also in the position of having two unique steering committees, the

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Responder Steering Committee and the Survivor Steering Committee, and those are statutory roles where we receive input from stakeholders to facilitate the coordination of monitoring and treatment programs for enrolled members, and those are ably chaired by Dr. Melius and Kimberly Flynn. The Zadroga Act established not only the STAC and the Steering Committees as vehicles for specific types of input for the Program—valuable input. It also established a range of oversight functions performed by other government bodies. The Act specifically requires review by the Office of the Inspector General as well as the Government Accountability Office. It's my view that the Program also enjoys, what I would say, an abundance of additional oversight: policy and budgetary oversight from Congressional Authorization and Appropriation Committees; management oversight from the Office of Management and Budget in the Executive Office of the President; management oversight from the U.S. Department of Health and Human Services; and from the Centers for Disease Control and Prevention. All of these entities ensure that the Program complies with a host of legal, administrative, budgetary, regulatory requirements for spending taxpayer money wisely.

I sort of wanted to contrast, you know, what the role of the STAC is in providing advice on important matters, as distinct from oversight. You know, I sort of think my ideal of advice is, you know, somebody who's on the committee saying, either as an individual or as a group, you know, I would suggest that you do this, I have an idea that may help you here; as opposed to oversight, which usually goes something like tell me exactly what you did and I'm going to write you up if I disagree with what you did. The two are really very different kinds of functions, and the Program really needs all of you on the STAC to be able to, as physicians and scientists and responders and survivors, to give us your views that will help us, as opposed to being yet another oversight body. We have a lot of oversight but you only have one Scientific/Technical Advisory Committee. So we really value your advice.

So, I just wanted to say that we're going to try to involve each of you as individuals more than we've had in the past, in terms of ideas that you may have where we present you with a presentation like the one we're going to do today that Dr. Reissman is going to do. Again, we value each and every one of you coming to these meetings and being able to take not only these formal recommendations that you'll hopefully make today on the two issues of peer review and adding non-cancer conditions, but also as we introduce additional topics for you to individually comment. So thank you very much. Have a great meeting. Unfortunately, I'll have to go to Albany around 11:00 so I won't be here in the afternoon, so have a great meeting. Thank you.

DR. WARD:

Thank you, Dr. Howard.

DR. MIDDENDORF:

Okay. I just want to recognize that Dr. Mridu Gulati has now joined us. Thank you

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very much. And I also need to ask you whether or not there has been any change in your conflict of interest since you last filled out the forms.

DR. GULATI: No, there has not.

DR. MIDDENDORF: Thank you.

DR. WARD: I did want to ask if any members of the committee have questions about Dr. Howard's presentation. I think he covered a lot of ground in terms of the role of the STAC, and I know some of the members are new, so if anyone has any questions, you know, we can open them to Dr. Howard's response or other members of staff who are here. Yes, Guille?

MS. MEJIA: Oh, I'm sorry. So maybe—it's just a recommendation that since there is the STAC and then there is the Steering Committees, that every so often, we might be able to get an update as to what the Steering Committees are discussing and what, you know, some of the recommendations are, so that everybody is on the same page.

DR. WARD: Thank you. Any other questions or comments? No one from the room; does anyone on the phone have a question or comment? Okay then, we'll move on. So the first topic of discussion is the recommendations from the policy and procedures workgroup, and that will be presented by Steve Markowitz.

POLICIES AND PROCEDURES WORKGROUP REPORT

DR. MARKOWITZ: So I have this little microphone in front of me. Does that work? Good morning. So let me just give a little bit of background, particularly for the new members. Last meeting, we discussed, at the request of NIOSH, a document that is entitled "The Policy and Procedures for Adding Non-Cancer Conditions to the List of World Trade Center-Related Health Conditions", and hopefully you have looked at this document so you are aware of what NIOSH plans on using to look at non-cancer conditions. There is a companion document that addresses cancer, but this is specifically about non-cancer conditions. And you may need to read it a couple of times to really absorb it.

We discussed this document last meeting. I think, actually, we developed a recommendation in relation to this, but we also decided to think about it some more, and then formed the workgroup to consider the issues, because they are actually quite complicated. So we have the workgroup, which I think we met once by phone, perhaps twice. Once? Twice by phone, and then we also had a consultation with NIOSH. We developed a one-page document that was sent to you by Paul, and so you should have it. But I think it probably would be beneficial if I read it so that we—it's not very pithy recommendations; it's more like a statement about how we view these issues and what NIOSH should consider. Before I read it though, let me just, I guess, summarize what the policy and procedures say, which is that when an issue arises around non-cancer, whether by petition or through NIOSH, that NIOSH has a Science Team that considers—does an initial screening review really of that candidate health problem, and

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comes to an initial determination about whether it's likely to be World Trade Center-related, at which point a decision is made by the administrator whether there is likely to be sufficient evidence, in which case the issue moves forward to a more deliberate, more in-depth process conducted by the NIOSH Science Team; or information is insufficient really, or it weighs in against relatedness between World Trade Center exposures and the condition, in which case then it doesn't go any further. For issues that go further, the NIOSH Science Team then looks at a range of studies, mostly epidemiologic studies from World Trade Center research, and then comes to a determination and makes a recommendation or advises the NIOSH administrator, who decides whether to go forward with a rule regarding adding a new condition, a World Trade Center covered condition, and that then goes to a formal Notice of Proposed Rulemaking process. At the time the rule is developed, then these procedures describe that the public has an opportunity to comment through the normal Notice of Proposed Rulemaking process that is governed by an act larger than NIOSH I think, and also that there is an opportunity for scientific peer review in parallel with the rulemaking process. So the point being that prior to the rule, all of the thinking and decision-making is internal to NIOSH, and it's after the decision whether to go forward with the rule that there is additional either public comment or scientific input that enters the process.

I think I got that right but if, Liz or someone else, if there's some correction to that summary, please set me straight. Okay, okay.

So I should add that this is—and this is very important—that this process is driven by a timetable, a very compressed timetable which really ties the hands of NIOSH in what it can do and by what time. And I don't exactly remember the timeframe but it doesn't really accommodate the normal kind of deliberate decision-making that is customary by other federal agencies, for instance the National Toxicology Program or others, in really looking hard at a full range of scientific literature with relation to a particular exposure and its relationship to World Trade Center conditions or any exposure. So that compressed timeframe is very problematic and it's beyond the STAC or NIOSH at the moment to do anything about, so we need to live with that. Liz?

DR. WARD: I just wanted to interject that I think perhaps the intent of that short timeframe was to allow for timely decisions, and so the timeframe was well-intended but it poses difficulties for the kind of scientific—you know, time-consuming scientific review that agencies often undertake.

DR. MARKOWITZ: Okay. So this procedure, looking at candidate conditions for non-cancer and whether they might be World Trade Center conditions is really a balancing act between the scientific basis for the decision-making and compliance, really, with statutory requirements regarding timeframes and the like. So we recognize that that is a balance, and a difficult balance.

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So having said that, let me read what we wrote so that then we can discuss the document, or I can give you perhaps a little bit more background. So the workgroup—I'm reading now, for those of you on the phone—the workgroup is concerned that the proposed procedures for the World Trade Center Health Program administrators' response to a petition to add a condition to the list of WTC-related health conditions include public comment and peer review only if the decision is made that the condition should be added and a Notice of Proposed Rulemaking is published in the Federal Register. We believe that the most important time for the administrator to receive scientific and stakeholder input is before he or she determines if the evidence is sufficient to propose to add the health condition to the list of World Trade Center-related conditions. We recognize that the constraints of the timeline required for the administrator's decision in the Zadroga Act would make it difficult, if not impossible, to obtain public comment and peer review before the decision. The workgroup suggests that the administrator consider the following opportunities to expand the scope of scientific input into the process of petition review.

One, the NIOSH Science Team should include experts with a range of relevant expertise including, at a minimum, a clinical medicine/epidemiology exposure assessment and industrial hygiene. These are the core disciplines that are needed to address elements of the specified policy and procedures for adding conditions to the list of WTC-related health conditions, including biological gradient, plausibility, coherence and exposure qualifications. If possible, NIOSH should also consider creating an ad hoc team of discipline-specific experts, external or internal to NIOSH, that can readily assist the NIOSH Science Team in the review of additional proposed conditions, including psychiatry, cardiology, rheumatology and others if needed.

Two, the Program should consider whether the mechanism of a Scientific and Technical Advisory Committee teleconference or other mechanism could be used to solicit external comments when a petition is likely to advance to the World Trade Center Health Program Science Team assessment phase. We see this as distinct from a formal request by the administrator to the STAC to make a recommendation on a petition, but rather as a mechanism to allow an opportunity for public comment and benefit from the scientific expertise and knowledge base of the STAC.

Three, the policy and procedures for non-cancer conditions describes three potential phases of the NIOSH Science Team review of scientific evidence. One, the initial review, which is on page 2; two, a fuller assessment, page 3 and 4; and three, if "modest support" is found, a supplemental assessment of additional scientific literature, on page 5. This supplemental assessment is limited to epidemiologic studies of 9/11 agents, with specific emphasis on the relevance of exposure conditions. It would be important to give the NIOSH Science Team

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some flexibility in the range of scientific studies they review, by adding at the end of section IV.B.1.d on page 5 the phrase "...and additional knowledge based on peer-reviewed scientific studies that they deem highly relevant."

So that's the end of the reading. So we should look at these and discuss them one by one. I can just give you a little bit of back—let me start off with one, give you a little bit of background. The policies and procedures don't identify who is on the NIOSH Science Team, and so there was no real specification of the kinds of things that the Science Team would look at and the experts they would have look at those scientific studies. And so we thought it would be useful actually to specify what some of those core disciplines should be, and we list them here.

And then the question was how rapidly NIOSH could get expert opinion on areas other than those that are directly covered by the NIOSH Science Team. There would be need, depending on the condition, to have ready access to experts beyond general clinical medicine or beyond the particular knowledge area of the industrial hygienist who is on the science committee—Science Team, excuse me—or the epidemiologists who are on the Science Team. And so what we're trying to help is create a framework where NIOSH could get that expertise on a rapid basis. Now, one thing we learned from NIOSH is that actually, they do have some of the access within the federal government, and so that's why we specifically say that this ad hoc team of experts, internal or external to NIOSH, recognizing that they can be from within NIOSH, they can be beyond NIOSH within the federal government, or they can be from the outside world. And then we specify some, begin to specify some of the disciplines or specialties that should be included. So that's what that first item is about.

DR. WARD: Yes?

PARTICIPANT: Thank you.

DR. WARD: Sorry, just to interrupt. I should—one of us should say your name before we talk.

PARTICIPANT: Okay.

DR. WARD: Because that way, the transcriber can make sure he gets the speaker's name correctly.

PARTICIPANT: Okay.

DR. WARD: Thank you. I forgot to say that in the beginning.

DR. MIDDENDORF: We also—

PARTICIPANT: Shall I say my name?

DR. WARD: Use that.

DR. MIDDENDORF: Use that.

DR. WARD: Yes, and as the meeting progresses, so that we can keep track of who wants to speak, just raise your tent card so that we don't miss anyone. But we've got you.

PARTICIPANT: Okay. I think certainly getting additional advice to the NIOSH team is quite important. I guess my question is how rapidly could that be accessed, both internal and external, during that timetable if you're trying to actually gain

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information outside? Because it seems one of the main issues is how efficiently—the time constraints that are involved in the process. So I don't know if there's information based on other NIOSH groups where they're able to externally obtain information from other sources. How quickly is that—how quickly can that be obtained?

DR. WARD: Paul or Dori, would you like to comment?

DR. MIDDENDORF: Or Tania.

DR. WARD: Or Tania?

DR. CARREÓN-VALENCIA: Good morning, I'm Tania Carreón-Valencia and I'm on the NIOSH Science Team. I'm an epidemiologist. And yes, we can get expertise. We have done it before for adding other conditions within NIOSH or outside if we need to. We sometimes consult with other federal agencies. That, we can do that.

DR. WARD: Yes, and actually on the other team, which was talking about the process for identifying peer reviewers and the qualifications of peer reviewers, which we'll discuss later, one of the ideas that we had is if we had assembled a group of potential peer reviewers with lots of different expertise, that group could conceivably also represent a pool of people that NIOSH could choose to bring in to give advice before the decisions are made. Because those people, depending on the mechanism, ideally those would be people who self-nominated as being interested in serving in a scientific peer review role for NIOSH and they would already be vetted, and perhaps could be called in at various stages of the process if needed.

DR. MARKOWITZ: Other comments?

PARTICIPANT: It's Micki.

DR. MIDDENDORF: Oh Micki, I'm sorry.

MS. SIEGEL DE HERNÁNDEZ: This is Micki. One of the expertise that I think is needed for the initial stages regarding exposure assessment is specifically World Trade Center-related exposure issues as opposed to just in general, dose response exposure kinds of things, because I think that that—the policy also speaks to that later on about the strength of the association and I think that that's something that's also much harder to have internally within the agency.

DR. MARKOWITZ: So let me actually ask, are we voting—are we going to end up voting on this one page? In other words, in terms of agreeing on the language.

DR. MIDDENDORF: I think the way it is, this is the workgroup report.

DR. MARKOWITZ: Right.

DR. MIDDENDORF: So it stands on its own. What the committee will do is discuss the issues in there and see if there are specific recommendations it wants to make to the Program. So we'll pull out the specific recommendations and vote on those.

DR. MARKOWITZ: Okay. Other comments?

DR. GULATI: Yes. This is—

DR. WARD: I'm sorry, I need to help—your name?

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DR. GULATI: Mridu.

DR. WARD: Mridu, thank you.

DR. GULATI: Yes, yes. One more question, and I am sure this has been addressed before, but if it's deemed that there is insufficient evidence at a certain point to make a decision to go on to rulemaking, what's the process of either reintroducing that condition or saying we're going to table this for a certain period of time and coming back to it? How is that done?

DR. MIDDENDORF: If insufficient evidence is found, a new petition could be filed. In fact, that's happened several times. New petitions can be filed and the Program will reevaluate to see whether or not there's any new information to address it. Or at some point, if the administrator feels like there is a reason to address it, he could introduce it at his own discretion.

DR. GULATI: So there is no—there is not a category that said we can't make a decision at this point but we want to look at this in one or two years? The entire petition has to be reintroduced again for all these situations?

DR. MIDDENDORF: Yes, there would have to be a new petition to do it, or the administrator would have to decide to do it.

DR. WARD: Any other comments or questions? Anybody on the phone? Oh Lila, sorry.

MS. NORDSTROM: Going off that point, is there a way to make a recommendation that there be a mechanism by which petitions that have been, you know, that have been sort of deemed that they don't have enough evidence can be more easily introduced or put off to consider in a couple of years? Is that something that we're able to amend? Is that something that seems feasible?

DR. WARD: It's a good question. I mean, the petition process is actually, I think, fairly straightforward. Essentially, you write a letter to NIOSH.

DR. MIDDENDORF: And provide a medical basis.

DR. WARD: And provide a basis. So I don't know that it could get easier than that. But, and certainly I imagine, as time goes on, if a condition has been reviewed multiple times, obviously there is going to be a greater level of knowledge about that condition and presumably, you know, there could be increasing evidence, so.

DR. MARKOWITZ: Other comments or—yes?

MS. MEJIA: I'm sorry, Guille here. I just have a—in terms of number one, I know at the last meeting, we talked a lot about transparency in terms of how—what does the process look, how do these reviewers look at the research. What communication does NIOSH give to these peer reviewers? And if you're putting together an ad hoc, obviously that's a concern too. So how do you address transparency adding an ad hoc group, and would the Science Team then be able to put that information out prior to a rulemaking? Whatever the findings are, either the Science Team or the ad hoc group. Is that something that would be put out there for consideration as part of the public comment period before rulemaking occurs?

DR. MIDDENDORF: Yes, the findings of the Science Team are put out in a Notice of Proposed

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Rulemaking. So the bases for making the decision are all laid out there. Or if it's decided not to go forward, there's also an explanation of why it was decided it didn't meet the criteria for adding the condition. So all that is explained in a Federal Register Notice or a Notice of Proposed Rulemaking.

DR. MARKOWITZ: Other comments, questions? So let's look at number two. Liz, you want to discuss this a little bit, the background for this, or the thinking about this, number two?

DR. WARD: Right, and I think, you know, in relation to what Guille just said, during our last meeting, we talked about transparency. There was a desire on the part of many members of the STAC to ensure greater transparency to that deliberative process before the rulemaking was determined. And I think, you know, on the subcommittee we really talked in pretty great detail about the requirements of the timeframe and the process, and realized that that is really a difficult thing to build into the process. And so we talked about, you know, making kind of a general recommendation that the Program consider whether there are opportunities for selected petitions that really—you know, where there's more evidence, where there's more controversy or you know, where something's been deliberated on before and you know, the results are less clear—to bring in a process which would allow for a little bit more external comment and expert comment. And one mechanism we suggested was perhaps involving the STAC through a teleconference if the timeframe permits, and that's the difficulty. NIOSH is operating under a lot of constraints, including the constraint that any of our meetings must be announced in the Federal Register six weeks before the meeting. So it's just pretty, it's pretty tricky to make—you know, NIOSH really would have to make the decision six weeks before to allow us to have a teleconference. And I think that one of the other hang-ups for that solution is that the STAC really has been convened only to make a formal recommendation on adding a condition or on research, but not just in the venue of giving an opportunity for NIOSH to hear comments from the individual members of the STAC and from the public. And so this might be a different way of using the STAC, and the Program has to decide if that meets with all the requirements of the laws which establish the STAC. So we wanted to make this as a gentle recommendation but recognizing that, given the timeframe of the process, it may be hard to build in the level of transparency and open discussion that might be ideal, especially for the harder cases. I think in some of these cases, the petition comes in and there's very little direct evidence, and so it wouldn't make sense to call a meeting of the STAC. But in the cases where there is more evidence or evolving evidence, there are insights in the public comments, and external science comments might be much more helpful, especially if it's a close call. Steve, did you want to...?

DR. MARKOWITZ: No. Comments? Guille?

DR. WARD: Yes, Guille?

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- MS. MEJIA: You know, I like that recommendation. I think, you know, it is different from what the law expects the STAC to act, but certainly there may be opportunities for the STAC to maybe listen in on the specific finding of a research that may come into play later on when we formally, you know, come together to look at a recommendation—a petition. So I certainly would strongly support that, your recommendation.
- MS. NORDSTROM: Thank you.
- DR. MARKOWITZ: Comment? Oh, Micki?
- MS. SIEGEL DE HERNÁNDEZ: I also, I support this recommendation. In thinking about some other situations where—standard-setting for example—there are often, there are sometimes opportunities where an agency is just asking questions, looking for direction, and some advice from the public. In this case, it would be from the STAC or some combination of the public and the STAC, in terms of things to consider, so not necessarily weighing in on peer-reviewed studies but being able to make some suggestions about other studies that might be pertinent, other areas that should be thought about, you know, clinical assessments that might be brought into the picture. And I think that this is a time to do that because the administrator will then have to decide does this go to the—after that 90 days, does this now go to the STAC or is there enough evidence for—
- DR. BOWLER: Hi, good morning, this is Rosemarie Bowler joining in.
- DR. MIDDENDORF: Thank you, Rosemarie.
- DR. BOWLER: Thank you.
- MS. SIEGEL DE HERNÁNDEZ: Because at this point, the administrator has to decide where this is going. Does it go forward? Does it need more information or will there be some proposed rulemaking? So I think having that opportunity to bring some ideas to the Science Team would be very important.
- DR. WARD: Thank you. Yes, and I think the idea was not to say it should be done every time, but it should be done in cases where it would be useful.
- DR. MARKOWITZ: Other comments? Yes.
- DR. WARD: Yes, Mridu.
- DR. GULATI: I also support the recommendation. I think it also allows NIOSH to more fully use the expertise of the STAC in multiple ways.
- DR. MARKOWITZ: Any additional comments? Anybody on the phone? So let's move on to the third, really, recommendation and this is about the nature of the scientific evidence that is used in the decision-making regarding adding a new condition as a World Trade Center covered condition. And here, the attempt is to encourage NIOSH or really to develop language which permits NIOSH to consider a somewhat broader range of scientific evidence beyond what's currently described in the policies and procedures. So just to remind you, if the additional science—the initial Science Team review of NIOSH finds modest support and then a more deliberative or more deeper investigation into scientific literature is then pursued, what the

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current policy and procedures specify is that the Science Team will look at epidemiologic studies that involve 9/11 cohorts but, in addition, epidemiologic studies that involve the agents that were involved with World Trade Center exposure. So they can move beyond the World Trade Center literature to look at a broader epidemiologic literature, but that, in relation to the agents that created the exposures at 9/11. And our feeling was that there could be some scientific literature broader than that that involved human studies that were not epidemiologic, that involved animal studies and, to some extent, laboratory studies as well, that could be relevant to the questions that NIOSH addresses, and that the Science Team should have the flexibility of considering that additional information. We didn't want to go beyond that and mandate that they have to look at that additional information, the reason being is that that takes a long—that could take a long time and would not really fit into the schedule permitted NIOSH to make a decision. By way of analogy, comparison, the National Toxicology Program looks at, for potential carcinogens, they look at the relevant literature, all the relevant literature, and come to decisions about whether a particular agent causes cancer or not, and that process takes probably at least a year and a half and maybe even longer, and has many components. It's a good process but it's not doable here and it's not, probably, even appropriate here. So we couldn't really go for that kind of recommendation but on the other hand, if there is relevant information from studies other than the epidemiology of World Trade Center cohorts or WTC agents, NIOSH ought to be permitted and encouraged to take a look at those other scientific studies. And that's what this is about.

DR. WARD: Lila?

MS. NORDSTROM: I just wanted to, and I, I think, expressed this to the subcommittee because I was on it, but I think this is one of the most vital recommendations, specifically for, you know, we've spent a lot of time in the past on this committee talking about where there are research gaps in the body of 9/11 research. And so I think that this—

DR. MIDDENDORF: Excuse me just a second.

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Whoever's on the phone that's moving around or rattling papers or whatever, please put your phone on mute. Thank you.

MS. NORDSTROM: In any cases, I think, you know, we speak a lot about research gaps on this committee and so I think that this is an important way to ensure that those research gaps don't influence the types of conditions that get covered moving forward because then there may never be research on a lot of future conditions. So specifically, I think, from the perspective of the survivor community—and I would assume also the responder community from those of us that are reps for those communities on this committee—I think that this is like an especially vital concept.

DR. WARD: Thank you. Guille?

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- MS. MEJIA: Just a comment, because Steve, it sounds like this recommendation is similar to a motion that we voted on in June, right? So I think the motion read, “To the extent feasible, the administrator and peer reviewers should consider scientific evidence beyond 9/11 studies, including epidemiologic, toxicological and mechanistic...”—I can’t even read my own handwriting—“...studies when relevant.” So there’s really no deviation there in terms of what we—the motion we made in June to what this is saying, right?
- DR. MARKOWITZ: I think you’re right about that actually.
- MS. MEJIA: Okay.
- DR. MARKOWITZ: I think, you know, this speaks a little bit to the rationale and proposes some specific language, but I think in substance, it’s no different.
- MS. MEJIA: Okay.
- DR. WARD: I think it’s—there’s a subtle, subtle difference which is this one, the earlier one used the language “to the extent feasible” and this one is saying “that they deem highly relevant”. And I think the point was not to say you have to beat the bushes and do a comprehensive literature search, but really, it is really going to be a question of scientific judgment and (fairness @ 51:50) of approach. And we didn’t want the NIOSH folks to feel like they had to go back to the mechanistic or toxicological literature, which isn’t feasible, and most likely would not lead to anything productive, but that if there was—if they identified a body of literature that they really thought was highly pertinent, we wanted to encourage them and you know, encourage them to be allowed to pull that evidence in. So it’s almost this same. This one may be just slightly more permissive in a way, trying to encourage the NIOSH Science Team to use their scientific judgment and not kind of leave them open to criticism that they haven’t done the breadth of review that some folks might think they should do in a particular case.
- MS. MEJIA: Thank you.
- DR. WARD: Is that reasonable to say?
- DR. MIDDENDORF: Yes, and I think it’s right.
- DR. WARD: Yes.
- DR. MIDDENDORF: I’d just remind everyone, please pull the microphone up close and speak into it so that the people on the phone can hear you, as well as the transcription.
- MS. JONES: Yes, I totally support these particular approaches to finding any additional, what do I say? What I think about is the fact that we’re talking about human beings and we’re talking about their families, and so we’re talking about other ways to identify other illnesses, etc. in terms of getting this individual help. So I totally support this, and I think it’s always important to remember what we’re actually talking about because this sounds very scientific but there is a human element that these particular conditions affect an individual as well as their family. And I think wherever we can support people that went out there on that mound day after day, or lived or worked and went in and out of their apartments day after day, that we

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should. So I thoroughly think that anything that improves upon what we find and basically the findings that help the individual and their family, I think we need to do it. So I thoroughly support all of these approaches that I think would assist individuals and their families in dealing with conditions from that individual or family going in and out of their apartment or to work every day.

DR. WARD: Mridu?

DR. GULATI: I think this addition is also obviously an important one. I'm wondering, with looking at the first recommendation on there, if there is a way to—in making this process more efficient by using some of the ad hoc and other external resources to actually review that extra body of evidence to ease the burden or to make the process more efficient on the direct NIOSH team. And I assume that's what's happened also in the past. Or possibly happened in the past.

DR. WARD: Do you want to comment on that, Paul?

DR. MIDDENDORF: Yes, the one point I would make is that it's very difficult for the Program to go outside simply because of the time constraints. I think the workgroup was able to actually look at the specific timeframes, and there's a 90-day timeframe by which, from when the petition is received, by which it has to be published. And about half of that time is spent by working with the Science Team, getting the literature, reviewing the literature, making an assessment. So there's really only about 45 days. The rest of it is administrative time taken up by reviews by HHS and OMB and people like that. So the biggest issue there I think is the timing and making sure that the specific expertise is available to be able to get outside information. That would be difficult, because you don't know what the petition is before it gets there. Finding exactly the right person or the right persons who have that knowledge can be difficult. It's not something that you can set out ahead of time usually.

DR. WARD: And I think one thing we should remember, and Paul will make sure I'm getting this correctly, is in the case where there was a petition for a condition where there was a fairly large body of evidence, some really complex issues, the administrator always has the opportunity to, you know, to use the mechanism of referring that determination to the STAC, which does prolong the timeline, which does allow for a more comprehensive review of evidence. So there are, there is at least one alternative mechanism that can be invoked when the body of evidence is large or complex, or there is a really strong need to review. Kind of like what happened with the cancer petition. I mean, there, it was obviously a very complex issue and even the STAC had, I think, 90 days to—no, we had longer than that.

DR. MIDDENDORF: 180 days.

DR. WARD: We had 180 days and even that was really challenging, but that mechanism does also exist.

DR. MARKOWITZ: Any further—

DR. HARRISON: This is Bob Harrison. I just want to let you know that I've been on the phone.

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- DR. MIDDENDORF: Thank you, Bob.
- DR. HARRISON: And I also wanted to let you know, because of my schedule this morning, I will have to leave in about 15 minutes.
- DR. MARKOWITZ: Okay, so I think if—are there further comments? Then I assume we're going to vote on the recommendations in relation to this after the public comment period.
- DR. MIDDENDORF: Yes.
- DR. MARKOWITZ: Right.
- DR. WARD: I think that's good. I think we should go immediately to Bob and so we can get discussion about that recommendation while he's on, and then we can have further discussion and voting. So Bob, the floor is yours.
- DR. HARRISON: Yes, thank you. Are you—hang on a sec. Are you able to hear me?
- DR. MIDDENDORF: Yes, I was just going to ask the same thing. Can everybody, all the committee members hear?
- PARTICIPANT: Yes.

INDEPENDENT PEER REVIEW WORKGROUP REPORT

- DR. HARRISON: I do have trouble hearing you. It's a little faint and muffled for most of the conversation. I'll do my best. So I was the chair of this small but excellent independent peer review workgroup subcommittee and I want to thank my co-committee members Liz Ward, Glenn Talaska, Rosemarie Bowler, Anthony Flammia and Catherine Hughes. We had two meetings, and developed a set of guidelines for the independent peer review workgroup, and I have those in front of me and I assume, Steve, can I assume that everyone has those in front of them?
- DR. MIDDENDORF: Yes, we have them on the screen, Bob.
- DR. HARRISON: Okay, thanks. Thanks, Paul. And of course I also want to thank Paul for coordinating the meeting of the workgroup. I just want to highlight a couple of points here on each of the items. First of all, in terms of the qualification and professional characteristics of the peer review group, we advised—and this is the last sentence of that paragraph—that these individuals should have scientific background in relevant disciplines, and we had considerable discussion re in forming this pool of peer reviewers that there be no so-called exclusionary criteria. Inclusionary criteria would be their medical and scientific background and expertise relevant to the World Trade Center health effects and hazards, but that aside from that, that there be no a priori exclusionary criteria for forming that peer review pool.
- The second is that, in discussion of conflict of interest and confidentiality issues relevant to this peer review pool, that the identity of the reviewers would be made available to the public after the review is complete, and that would be with their comments and responses, but we would not attribute the specific comments and responses to each of the individual peer reviewers. The idea here is to allow them the latitude to give their peer review comments without attribution, similarly to the peer review journal process.

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The third is that, in the selection of peer reviewers for these petitions, we recommended that the NIOSH World Trade Center administrator has overall responsibility to ensure that the process is balanced and gives an unbiased scientific review, and that the selection of peer reviewers be made by NIOSH. And then finally, within that paragraph, you'll see that we also recommended that these peer reviewers might be useful in the process as a consultant to assist NIOSH, and that—to give NIOSH flexibility, the retention of an outside contractor with specific guidelines would be helpful.

So those were the major points covering those three areas, and certainly happy to answer any questions about any of these issues or process.

DR. WARD: Any questions or comments please. Steve?

DR. MARKOWITZ: So Bob, it's Steve Markowitz. I'm curious, on the last one, why you mention that NIOSH could consider retention of an outside contractor. Why did you specify that, a mechanism whereby they would be able to contract with peer reviewers?

DR. HARRISON: Steve, you were a little faint there but I think you were asking me the question about the mechanism for selecting an outside contractor?

DR. MARKOWITZ: No, no, no. Bob, is this any better?

DR. HARRISON: No, it's still really difficult to hear you. I apologize.

DR. MARKOWITZ: Well, okay, let me just repeat the question and maybe—why did you specify that they might consider retaining an outside contractor?

DR. HARRISON: Okay, I was able to hear you now. Thank you. That was simply because of the issue of flexibility within NIOSH, if NIOSH thought it was necessary to implement the provisions of this process. We just, I guess our group didn't see any disadvantage or problem with NIOSH considering that.

DR. WARD: Apparently, it's something that some of the other federal agencies have turned to, and has some advantage of kind of distancing the internal science program staff from the selection of peer reviewers. But we just—so I think Paul had mentioned it in the discussion as an option and we just wanted to say if NIOSH chooses to do that...

DR. HARRISON: Yes.

DR. WARD: That that would be fine with us. Catherine?

MS. HUGHES: I don't have a mic.

DR. WARD: Oh, darn.

MS. HUGHES: Sorry. Do we, following up on Steve's question, even though I was on this subcommittee, do we need to vet the contractor? How is the contractor vetted?

DR. WARD: Well, I mean, again, certainly we should debate whether folks want to talk about that. I do think, you know, it reminds me a little bit of what John said earlier about us not being an oversight committee. I mean, if we feel that that's an important recommendation from an advice point of view, but yes. We can have some discussion about that. Okay, Guille.

MS. MEJIA: Thank you. My question is simply the pool of peer reviewers, are they only

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specifically for a petition that is being considered, or would the pool of reviewers also assist the administrator who decides not to come to the STAC for a recommendation on a petition?

DR. WARD: I think during the committee meetings, we discussed the possibility that the pool could serve a dual purpose, and we discussed some processes that could be used to develop a pool of peer reviewers, for example, an open call to people who might be interested in serving as peer reviewers so that their credentials and their expertise could be gathered in advance. And then when NIOSH got ready to need their help, there would be a pool of people already available and vetted. But we didn't make a specific recommendation in that regard because we were really just considering what the qualifications should be and what the process should be for choosing peer reviewers, not additional uses that the peer reviewers could be...

MS. MEJIA: If I just maybe—only because it does clearly specify petition. So we're going to just limit it to that?

DR. WARD: That's a good point, and as we develop our specific recommendations, we'll be developing more concise language and we might want to be sensitive to that point. Yes, Micki?

MS. SIEGEL DE HERNÁNDEZ: So a few things. One, I think the peer review process, the formal peer review process, it's my understanding that that is what would have to happen at the point that the administrator is making the recommendation, a formal rulemaking, making a recommendation to add a condition, which is different than what we had been talking about before in terms of adding additional expertise, having an ad hoc group of people—

DR. WARD: Right.

MS. SIEGEL DE HERNÁNDEZ: For adding additional expertise. I have comments on two of the recommendations that are here. The conflict of interest and confidentiality, I actually don't believe this recommendation goes far enough in terms of transparency. I don't believe that a summary of peer reviewer comments is sufficient. I believe that both the peer reviewer names and the full set of comments should be made available, and I do think that there is a difference between the purpose of this peer review and a peer review journal process. That's does this study warrant being published in a journal, which is different than this, which I would consider just in the OMB document as an influential scientific assessment that has direct impact on whether or not the Program will cover a condition, on the lives of the people who are already and have been suffering from that condition for quite some time before it got to this point. And so I think in that regard, as the OMB document recommends, that availability to the public should be the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' reports and the agency's response to the peer reviewers' reports, which is what the administrator would do after that process is done anyway. So I don't think that this goes far enough, and there's discussion and there's, you

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know, obviously the agency has some flexibility there, but I think that it's not quite as transparent for that particular piece.

I would also, I'd like to see in a recommendation that the pool, in discussion with the pool of peer reviewers, that there is the opportunity for input from other sources, from the STAC, we have World Trade Center, we have clinical experts at the various clinical centers, and they have already done a lot of outreach for various topics and have another pool of experts. There are steering committees. So it's still NIOSH, it's still the administrator's decision, obviously, who ends up being in that peer review pool, but I think it should be opened up early on and work can start on that. We know that there are some areas that are moving forward even as we speak.

DR. WARD: Well, Bob, before we hear more discussion from the STAC in the room, would you like to reflect on those comments?

DR. HARRISON: Yes, thank you. I think I'll reflect and then will have to go in about five minutes. So I think there are a number of the committee who are there who will be able to carry on. On your first point—let me address the second point first because I think it's a little bit easier. We discussed that specific issue and our intent was that, in forming the pool, that we have no exclusionary criteria. So as long as they have a relevant background and experience, and that includes individuals who have participated in some manner, shape or form on World Trade Center research projects, so as this discussion continues, that was a very important issue that we wanted to address. We wanted to be sure that there was no conflict of interest on the part of that individual, because they might later be applying for grants or research funds if a condition were added or somehow might have a conflict. But we decided, for the very reason you pointed out, that that person or persons might have a lot of expertise and experience and we didn't want to knock them out of the box. So, on that first point you raised, my sense is that our committee might agree with you, and our intent was to include that person.

On your first point, which was about the attribution, the transparency question, we've also talked a fair amount about that, and I would just say that I think we wanted to balance the ability to get a really good pool of peer reviewers with the sense that if they were a peer reviewer and their comments were made public, that it might limit the pool of good peer reviewers because they may feel like they're going to be making comments and they would then become public or subject to—I don't know how to put this but conflict or pressure in making results public. And I don't, frankly, know if that's a true and real concern but I think that was some of our feeling, that if we put out the word to try to get really good peer reviewers, it might be, frankly, easier to say, well, you know, your comments will be shown to the public for everybody to see, but you might be freer, in a sense, if you are anonymous. So I think that was the intent, and I'll leave it now open to the rest of the committee if they recall any other pieces of that discussion.

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DR. WARD: Yes, Micki?

MS. SIEGEL DE HERNÁNDEZ: So I wasn't on the committee. I don't know if you want to just wait for committee comments first? Okay, okay.

DR. WARD: Well, I think since this is an important issue, it would be good for you to speak (inaudible @ 01:13:56).

MS. SIEGEL DE HERNÁNDEZ: So, I mean, I understand that reluctance or that there may be some peer reviewers who are reluctant. I don't know that it would be most peer reviewers when it's made very clear that this is the process. And you know, I'd also like to point out that the STAC is in this same position. The STAC may get charged—for example, cancer, which was a very difficult and complicated decision—charged with adding that decision, adding that condition and all of the comments at the committee are, it's transparent, it's a public process. There are transcripts that are produced so every person, every person's comments during the discussion is available to the public. And then there is a document that the STAC produces that is also available and committee members are known that, from the STAC, and everybody, we all realize that that is the case as these discussions and decisions are made going forward. So I think that peer reviewers, those who are involved in scientific study, are used to putting their thoughts and ideas out there, and I think that that should just be something that goes along with this particular process, again because of how important the outcome is. And if there—if a petition then is denied, I think that it provides information both for investigators going forward, for the public going forward in terms of how additional information might be attained. And I think that it's imperative for this process really.

DR. WARD: Thank you, and Steve?

DR. MARKOWITZ: So yes, it's an interesting question. You know, I am prejudiced towards transparency but my question really is does it matter whether Doctor X made this comment and Doctor Y made a different comment, whether we really need specificity. I think the identity of the reviewers should be made public. I think the reviewers' comments should be made public, and that's—I think that's what's called for in this recommendation although I'm not quite clear because of the issue of the summary of peer review comments. But I don't see really the benefit of why we would need to know, what does it add to the process to know that a particular person made this comment and a different person made a different comment. If we know, in general, or if we have the names of the peer reviewers, if we know their expertise and if we know their comments, and we judge the merit of those comments based on those comments, with some understanding of the background of those people, why do we need to—maybe Micki, this is not what you're asking for, but why do we need to know that Doctor X made a specific comment as opposed to the other peer reviewer?

MS. SIEGEL DE HERNÁNDEZ: So I think that as a compromise, if the comments in full were provided, with the names of the peer reviewers, that that might be a compromise. I was—

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here it talks about a summary, and so attribute—summaries just don't work when you're really getting into the weeds about the science behind these diseases. So I could support that, Steve.

DR. WARD:

Mike?

DR. McCRAWLEY:

Yes, this is Mike McCawley. I will add confusion to it though.

DR. HARRISON:

(Inaudible @ 01:17:54) the committee, by the way. And wish you all well.

DR. WARD:

Thank you, Bob.

DR. HARRISON:

All right, thanks.

DR. MIDDENDORF:

Thanks for all your work, Bob. Very much appreciated.

DR. HARRISON:

All right, bye. Bye.

DR. McCRAWLEY:

Just to add confusion, I can see, however, a circumstance where it is necessary to know who made a specific comment. Having been with too many groups of scientists for too long, people will tend to speak outside their discipline, and it becomes important to know whether you're getting a comment for somebody who's speaking within the discipline the comment is pertinent to. And so in some cases, it might be, in fact, important to know who made the comment because you might get people speaking outside their discipline and you want to know was this made by somebody who's an expert in this particular field or are they just commenting about something that they're thinking about?

DR. WARD:

So thank you. We need to break on time because we need to be back at 10:45. We'll continue the discussion immediately after the public comment period. The cafeteria on this floor is closed so if anyone needs anything, there is the snack bar on the first floor. So we need to allow time for people to get down there and get back. Thank you.

[Break.]

PUBLIC COMMENTS

DR. MIDDENDORF:

Okay. So we are now starting the public comment portion of our agenda. Each of our public commenters have signed up on a first come first serve basis. Each of them will have up to five minutes to present. I also want to point out that you do have the option to make written comments to the docket to this committee. The docket number is 248-F and information on how to submit comments can be found on the NIOSH docket webpage.

So the last thing to do before beginning the comments is to make sure the commenters are aware of the redaction policy for public comments. The policy is in the Federal Register Notice for this meeting and on the committee's web page. The policy outlines what information will be kept and what information will be redacted before it's posted to the docket.

So with that I'll invite our first public commenter, Kimberly Flynn. Come up to the podium.

MS. FLYNN:

Thank you. I'm Kimberly Flynn and I make these comments on behalf of the World Trade Center Health Program Survivor Steering Committee which I chair.

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We appreciate the opportunity to address the STAC on all of the peer review issues that are being discussed today. The peer review, as has been pointed out, will be a key element that either builds scientific credibility for giving determination or diminishes it. We endorse the June STAC recommendations and we very much appreciate that these recommendations recognize that meaningful input from the public is proper and essential.

The public must have the opportunity to nominate experts for the pool of reviewers. The peer review must be disclosed to the public whether or not the administrator proposes rulemaking. And the public must have the chance to comment on the review. In addition, we agree that the list of peer reviewers should be disclosed as well as all peer review comments, not just a summary. And we're going to make an argument for comments to be attached to the individual that provided them.

Speaking as one of many community stakeholders who observed peer review panels deliberate equality or validity of WTC-related environmental health policies, programs or science from assessing the quality of the EPA's WTC Test and Clean Program to the role of aspect ratio in asbestos toxicity, we strongly question the need for all review comments to be de-identified. And I want to point out that reviewers felt free to express their scientific opinions even when they fully recognized that the community would be opposed to those opinions, number one. Number two, not everyone knows the background of reviewers. And often we would hear a comment in the peer review and then we would go off and investigate the background of the reviewers. And finally—

- DR. BOWLER: I'm sorry. Could you repeat that last statement you made? I couldn't hear it?
- MS. FLYNN: Oh, I'm sorry. So when the community observed these peer review panels we would hear a comment and then we would go on and investigate the background of the reviewers. We would explore their work. And we wanted to know, you know, if anyone's—
- DR. WARD: Can we hold the comments until the noise stops?
- MS. FLYNN: Okay. Sorry.
- DR. MIDDENDORF: Just a moment. Hello?
- MS. FLYNN: It might be Rachel.
- OPERATOR: Hi, this is the conference operator for Paul Middendorf.
- DR. MIDDENDORF: Yes.
- OPERATOR: Thank you. Did you need to join your line back into the conference?
- DR. MIDDENDORF: Yes please.
- OPERATOR: Thank you. I'll join you now; one moment.
- DR. MIDDENDORF: Kimberly, if you'd like to start over you may or if you'd rather—
- MS. FLYNN: Well, I'm not going to start over from the beginning because—
- DR. BOWLER: I'm back there, back joined in. Because I don't want to leave the line when nobody is around. So I'm back and I have the agenda, Paul. Thank you. It didn't come

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through from the other person so I now I gather we are to the public comments, is that correct?

DR. WARD:

Yes.

DR. MIDDENDORF:

Yes. We've already started. Thank you.

DR. BOWLER:

Thank you.

MS. FLYNN:

I mean, also, I don't want to get like all theoretical here but science is not a disembodied activity. I mean, it is not the case that there is some platonic truth that individual scientists are articulating. But, in fact, it is what the scientific community says it is. And there are many different perspectives. And it is helpful, important and rightful for the public to know whose perspectives are being expressed.

So, again, in essence, all of the deliberations that the community observed in the World Trade Center context all concerned people's post disaster health. And the community had the right to observe the proceedings. We support the same principle for peer reviews that will not literally be held in public view. The burden should be on those who oppose the full measure of transparency to establish why any measure of secrecy is warranted. And we're going to also say that it's not just in the community's best interest that we have transparency but it is the case that the government's best interest is not served by saying to the public, "Trust us." And we'll give an example. A few years ago the Survivor Steering Committee raised questions following a research awards process. And we learned that WTC pediatric research proposals were being reviewed by a study panel devoid of pediatricians. So we don't think this was deliberate, obviously. I think our point is that it takes a village, right? It takes stakeholders, the experts, the government all having the full set of facts to gather in order to ensure the integrity and the robustness of a process.

So, just very quickly, we obviously agree with flexibility on the issue of which literature is deemed relevant for review. We agree with the emphasis both workgroups placed on assembling the right expertise. And, while we would agree that now exclusionary criteria should be applied, I think, especially if a peer review panel is small in number, it's absolutely essential that experts with the specialties relevant to the petition also have backgrounds in environmental and occupational medicine and research. An expert with an appropriate specialty but without the right kind of background may not be able to effectively link illnesses to exposures and that's really what we're talking about here.

So now I'm going to shift to a different STAC charge which the STAC took up nearly a year ago, that of developing recommendations on children's 911 research needs. After a robust STAC dialogue with meaningful input from the community, the STAC approved 12 recommendations. The Survivors Steering Committee has endorsed those recommendations and is in ongoing dialogue with NIOSH on those recommendations that are priorities for the community.

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Dr. Howard remarked this morning on the unique and uniquely valuable role of the STAC. And we indeed believe that the STAC should have an ongoing role in the issue of how children's 9/11 research needs are addressed. Engaging the STAC in an ongoing dialogue with respect to the implementation of its recommendations on children's 9/11 research needs is in the community's best interest—we think it's in the STAC's interest as well, we think it's in the government's interest—for the STAC to track and comment on how its recommendations are being acted upon. We request that NIOSH commit to holding a STAC meeting early in 2017 at which progress toward addressing children's 9/11 research needs is a major, if not resolved, topic.

Thank you.

DR. MIDDENDORF: Okay. Thank you, Kimberly. Our next public commenter is Rachel Lidov who is on the phone. Are you there, Rachel? Hi.

MS. LIDOV: Hello.

DR. MIDDENDORF: Rachel, are you there?

MS. LIDOV: I am.

DR. MIDDENDORF: Okay. I'm going to bring the microphone over and put it next to the phone so that people can hear you. Okay.

MS. LIDOV: Can you hear me better now?

DR. MIDDENDORF: Yes.

MS. LIDOV: Okay. (Inaudible @ 00:10:05) community and again I thank you for including me and giving me this opportunity to speak. I am speaking to you, obviously, again today on behalf of the parents whose children were exposed to the World Trade Center disaster at Stuyvesant High School on 9/11/2001 and also on behalf of the children in Lower Manhattan.

Following 9/11 from the very beginning we saw that the government and public health authorities were eagerly supporting mental health studies. As many of you recall, we were frustrated that there was an implicit and explicit assumption that the sole impact for the children would be psychological. Federal and city agencies (inaudible @ 00:10:50) children out of harm's way after 9/11, and they did not want to gather any evidence that there were still health consequences from the agencies' failures to protect children's health.

I will remind everyone that the first survey of the WTC Health Registry asks about dust cloud exposures only. In public hearings and in the press they were pushing the notion that children who lived and went to school downtown somehow magically escaped harmful chronic exposures.

I believe that by now it is clear that more than 20,000 children in Lower Manhattan have not. You have heard from us frequently. We know the disaster has psychological impact. Believe me, we have lived with our kids and are well aware. And there are many excellent studies which have and continued to investigate those impacts. But we also see a range of physical health impacts some of which

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are respiratory and have been examined and some of which are not. We still want to know more. Are these conditions related to WTC exposure? Are there WTC conditions that are specific to those exposed as children? We've looked at the deteriorating health of many of the responding population. And while we fully understand the different exposures (inaudible @ 00:12:11), we also take into account that children's bodies were still developing. Therefore, it is with some urgency we still ask whether the children exposed in Lower Manhattan are at risk for developing similar WTC-related conditions, whether there are early signs that might be detected and whether anything can be done to prevent (prolonged @ 00:12:35) disease. Fifteen years later we are still not seeing where are the studies, where is the portfolio of physical health studies comparable to the large and growing portfolio of mental health research.

Finally, if we are to continue to work together it must be obvious that we need an above board, scientific peer review process for decisions to add to the list of WTC health conditions that are covered under the Zadroga legislation. Specifically, there is, one, there should be full transparency. And that includes public input into who is on a given peer review panel. Two, the complete list of reviewers for a given deliberation must be released publicly. And, three, all peer review comments must be provided to the public. A summary of comments alone does not meet the standards of transparency. We need you, the experts and the STAC members of the STAC, to stay on the case. We want you to be part of the dialogue about whether and how the STAC's strong recommendations are being acted upon. The first step in this would be to schedule a STAC meeting early this coming year where children's 9/11 research needs is the major focus. Fifteen years is a long time to wait. I'm certain you agree that we don't want to be establishing such a delay as a precedent responding to disasters.

Thank you very much.

DR. MIDDENDORF: Thank you very much, Rachel.

MS. LIDOV: Thank you.

DR. MIDDENDORF: And we have one more public commenter, Jo Polett.

MS. POLETT: I'm Jo Polett, a downtown resident and a member of the Survivor Steering Committee. Just picking up on points made by several panelists earlier, I'd like the STAC to request a report from NIOSH on the background materials provided to peer reviewers. And that would include peer reviewers for NIOSH funded research grants. Assuming that peer reviewers are receiving background materials, I'd like the STAC to review those materials and provide input as members see fit.

Thank you.

DR. MIDDENDORF: Okay. Thank you very much. That's the end of public comment period. Very much appreciate the thoughts and input of the public. And the STAC always finds them to be very valuable and considers them while they're making their deliberations.

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DR. WARD: Thank you. And I think it makes sense to just continue our discussions on the peer review recommendations. And we'll go to Bill, Lila and Mark.

DISCUSSION OF WORKGROUP REPORTS

DR. ROM: I just wanted to make a comment on what John Howard initially challenged us with which was a petition to add a non-cancer condition called autoimmune disorders. And that struck me as something that is really difficult to define. So, first of all, I second almost everything that is in Steve Markowitz's report and the peer review report. I would add an expert consultant, because I'm not so sure I know what an autoimmune disorder is. I think I know what polymyositis is. I think I know scleroderma. I think I know lupus. And all of these are sort of autoimmune disorders. So we are probably getting to the point for the World Trade Center conditions to be more accurately defined. And definitions require some expert consultation. And most of these conditions come with autoantibodies or antinuclear antibodies. So they have a blood test to them which also have promise with both sensitivity and specificity. And also clarity, because there are many different types of antinuclear antibodies and many kinds of autoantibodies. And autoantibodies may appear many years before the condition becomes ripe and they may increase over time.

So an expert consultant would be very helpful in educating the peer reviewers and the scientific committee of NIOSH on precision of what autoimmune or some of these conditions might be and help with coming up with a definition. Because if I wanted to learn about an antinuclear antibody I'd want to contact or call or speak to the person who invented it and who could really tell me what this thing means. And so I think that the word "expert consultant" would be very helpful. And this is advise that is not, say, in the literature. This is an expert consultant that would come to the deliberation and explain things and provide their expertise. So I think we're getting into some of the challenges of clinical medicine which is beyond just what's in the literature and reviewing scientific literature. So I think we need to keep that in mind when we think of expansion into non-cancer conditions or entities.

DR. WARD: Thank you. Lila?

MS. NORDSTROM: I had a question actually but first I also wanted to endorse something that Kimberly said, which is that I think it is important that the experts on the peer review panel have some sort of environmental or occupational health background so that they are able to sort of, not just speak to these diseases or illnesses, but also just connect them to exposures. And but my question was specifically regarding this sort of question we're talking about, about the peer review transparency. Is there a precedent for doctors refusing to participate in things like this if they are named? Is this a concern that we're actually like basing this off of? Or what is the concern that we're basing this off of? Because I'm not sure I quite understand why this would be necessary. I think the most transparency that is

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- feasible would be best but I'm also...I don't understand the precedent for why this is in here in the first place.
- DR. WARD: Well, I can speak to it from my perspective. I think in many scientific circumstances, like if you submit an article to a journal, both the names and the identities of the reviewers is generally confidential. And that's kind of to ensure that people contributing to the review process can do so and not be concerned about personal retribution or conflict with their peers. I think it varies. Obviously for a lot of regulatory processes if you have a committee meeting and it's an open meeting then the identity of the people is known and what they say is known. So there's a lot of variability in how this is handled.
- DR. MIDDENDORF: Paul, did you want to speak to that too?
- DR. MIDDENDORF: Just to say that there are many times people will not have any problem giving their thoughts and opinions whether their names are being identified or not. But there may be situations where, if the scientific community were to know a specific thought or idea came from a specific individual, the individual may have a tendency or a preference not to express themselves as fully and thoughtfully as they might. In other words, they might hold back to the purpose of not contributing specific comments to specific individuals sometimes allows that individual to more fully express themselves. So it's really an attempt to get all of the information without the person holding back. That's the reason for not asking or not attributing specific comments to specific individuals.
- DR. ROM: I might make a comment that someone by the name of Hillary Clinton said that rough and tumble politics in academics was...and in the church were, the worst of all politics. That was before she ran for President.
- DR. WARD: Mark?
- DR. WILKENFELD: Okay. Hi. So I've been listening to the discussion or peer review and on transparency and it's a discussion in this room and it sounds to me like a very academic, almost theoretical, discussion. But I sit in a room with patients and many times...many, many times, I've had patients that suffer, that are sick. They know their condition that they suffer from has been petitioned and they know it's been denied. And they ask why. Okay? And I tell them whatever I know from what I've read. But I really think that the more information you give them, the better they're going to feel. Okay? And the more sense it's going to make. What I'm trying to say is that it's one thing to discuss it as an abstract phenomenon, "Should we do this?", "Does it really matter, Steve, whether 'Dr. A' said 'this' and whether 'Dr. B' said 'this'?" It doesn't matter. Very little of this matters unless you're the sick patient. In which case you want to know everything that happened that has the doctor telling you, "You're not covered. I'm very sorry."
- DR. WARD: Glenn?
- DR. TALASKA: I guess I have a question for Dori. And I think this discussion is predicated on what happens and what do you anticipate will happen in the peer review. Do we

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know the process that will take place yet? My point is this oft times in a scientific peer review, for the grant program, for example, reviewers will have a discussion around the table but then will provide written comments that could be attributed to "Reviewer 1, 2 3 or 4" whoever they are. Is that the intent of what's going to happen with this peer review? And that would make some difference because an open discussion with a transcript is much different than what you would want to provide in writing and attribute to you individually.

DR. REISSMAN: So, for those on the phone, this is Dori Reissman, Associate Administrator for the World Trade Center Health Program. There's no foregone conclusion as to what we're doing here today.

DR. BOWLER: Very bad reception.

DR. MIDDENDORF: You have to speak closer.

DR. REISSMAN: How about now? Is that better?

DR. MIDDENDORF: Yes.

DR. BOWLER: Yes. Thank you.

DR. REISSMAN: Okay. Sorry about that. At this point there's no foregone conclusion about what's going to happen with peer review. At this point you guys are deliberating on a particular recommendation to us and we will be considering that and trying to figure out the best process for us to go forward; balancing the tension between the agreements that reviewers have had in the past about, if they've had agreements on anonymity, to preserve the ability to fully express their opinions and whether or not there's a need for transcripts on all comments or not. It's really not determined yet. So I'm anxiously listening and thinking as you speak.

DR. WARD: Thank you. Steve is next and then Micki.

DR. MARKOWITZ: So I'd like to just return to this issue of attributing specific comments to specific peer reviewers because the peer review process occurs in a different setting. So if you consider, for instance, grant review and if Bill Rom is sitting on a grant review committee and is reviewing John Baum's grant and, let's say, Bill Rom thinks that there's some real weaknesses in that grant and writes those down in his peer review comments, and John Baum's grant doesn't get funded, and then learns that Bill Rom made those comments, which undermine his getting funded. So we probably wouldn't support attribution in that setting because it's a small world and it can give rise to undesirable things. So there's an instance in which we probably would protect the privacy of those peer review comments.

On the other hand, you can imagine a different kind of peer review, let's say, where it's not attached to a particular World Trade Center Health Program or any health program. It's an in general review of whether "Agent X" causes cancer without clear, immediate ramifications, actions that are then based on that decision-making. In which case if the peer reviewer comments are specified to particular peer reviewers it's probably okay because there's no particular... It doesn't lead to any untoward or undesirable outcome.

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So here we're talking about peer review simultaneous with a proposed rule. The administrator has proposed that a World Trade Center health condition be added, or excuse me, a condition be added to the list of the World Trade Center health conditions. The administrator has made that decision and then goes out for external peer review. We think that's how it's envisioned at the moment. So now you're a peer reviewer sitting there looking at this and you're asked to give you dispassionate scientific opinion about the literature relevant to this decision that's been made knowing, frankly, that it has an immediate consequence. There's a whole community of people who are going to be covered or not covered for this particular condition. So that, if you're the scientist and you honestly believe that, frankly, the science doesn't support that connect, that's your belief, and then you write down your reasons for that belief, you could risk being an unpopular person or you're expressing an unpopular opinion, that unfortunately means that some people...well, if it's influential, may mean that some people don't get covered for that condition but that's your honest scientific opinion.

And I think that the condition should be created where we allow and promote that kind of thinking and sharing of thoughts in order to receive a real expert peer review. And to do that I think you need to disconnect the individual comments from individual people's names, even though, yes, they make the written peer review comments, not a summary but the comments themselves public, simply not attach them to the individual. Because you want that freedom, you want that real dispassionate opinion in on the process of decision-making.

DR. WARD: Thank you. We'll take Micki then Glenn then Val, and then Mike.

MS. SIEGEL DE HERNÁNDEZ: Okay. I actually have some procedural questions I guess for Dori in just thinking about some of these policy issues apart from the identification of peer reviewers. But the timeframe that you have in the documents is very clear in terms of once a petition is received, the 90 days, if the STAC is brought in how much time the STAC has, and then how much time the administrator has to decide whether to put in a proposal for rulemaking. But then there's no timeline after that that I have been able to see. So, at the point that there is a proposed rulemaking which would also be the start of a peer review process as well as a public comment period, are there hard and fast deadlines for that process and the final decision, the final determination, by John Howard?

DR. MIDDENDORF: Yes, there are no hard and fast requirements. The dates and the time periods that are given in the policy and procedure are those that are in Zadroga. So those are hardwired into the process. The Program moves as quickly as it can beyond that. Once we get there, there's rulemaking out. There's at least 30 days for comments. Then it has to come in. Once those comments are received then the Program has to respond to those comments, it does so in writing, puts them on the website. And in fact, I would point to the acute traumatic injuries and COPD on the website that the peer reviewers are identified. Their comments are provided,

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specific comments and the specific responses to each of those comments. All that is provided. But as far as the timeframes there's nothing in Zadroga that requires things. The Program does move as quickly as it can afterward.

DR. WARD:

Glenn?

DR. TALASKA:

I'm persuaded by both sides of this actually. In the grant situation reviewers are known but their comments are anonymous. They're assigned the study section. The supervisor assigns the reviewer who is thought to have most relevant scientific knowledge as the primary reviewer. There's a secondary, and perhaps a tertiary, reviewer. And then the rest of the committee, who is supposed to have read the grant also, then weighs in and also scores the grant. But the people are initially selected for their scientific expertise which takes a little bit of what Dr. McCawley was saying out of the picture about somebody who's outside of their field talking. So, if you do select the reviewers from the point of view of what they really know about the subject, then it shouldn't be as... The potential for somebody talking outside of their field would be lessened considerably. And that may be part of the procedure that NIOSH may consider.

DR. WARD:

Val?

DR. BOWLER:

I would like to add something from my experience in reviewing and in right now responding to reviews from a proposal I put in. And I think it goes back to the initial step of who gets selected to be reviewed, that this is not a person who is sort of far out on one side and wouldn't be necessarily respected by most of the scientists in that particular field. And I think that wouldn't happen anyway. And then, in my case, getting the reviews, I've found them actual very helpful and appreciated, the reviews, and incorporate all these comments and suggestions to make my proposal better. And that's sort of the whole idea, is unless someone's proposal is so far out that they wouldn't be invited to send it back. Now, in terms of revealing who the people are, really, it doesn't matter to me. I can tell by the review if the person knows my subject area or not. So the scientists would know that. And I think that is a good protection. I do a lot of article reviews as well and it's good to be able to be free. I can even apply it to some of the clinical reports I have to write about. One that I'm having to deal with now, as an example, of whether the particular person, a high level person, has dementia or pseudo dementia. Well, after testing her neuropsychologically I don't find that at all. It's neuropsychological. And that, of course, a person may not like to hear that but if it's presented in the right way it could be very helpful. And that's sort of how I see that, no, she has worries about getting dementia because several of her...mother, grandmother had it and so on. So she doesn't have to worry, at least right now. The results show she doesn't have it. And I can apply this to the grant reviews, if there are flaws in there that we... There's always something to make it better. Most researchers will use this and it's not necessary to have the name of the person. It's all contained in the review of

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what that person thinks. And if we respect that they know our area and are sufficiently qualified then I have no need for it. I mean, I wouldn't want the name. It's better I know the whole system, that we have to be free as scientists to give our independent opinions. And it always goes back to who gets selected in the first place. And, you can assuming, by going through these criteria we've established, independent scientists will be selected and the public can review what they've said. If something is really far off they could comment. So that's from my experience applying what we've been talking about and whether to reveal the name/the identity or not. But I think it's not necessary.

DR. WARD: Thanks, Rosemarie. Val?

MS. JONES: Yes. What I was going to say somewhat goes back to what—

DR. BOWLER: You're breaking up again. Please.

MS. JONES: Oh, okay. What I was going to say is I think that what the issue becomes is not the person's name but their expertise. So what might be somewhat a balance would be, not to have the person's name, but to have their expertise. Because we're talking about epidemiology or clinical medicine or industrial hygiene, so rather than state their names, state this is their expertise in terms of—

DR. BOWLER: Exactly. I was trying to suggest that. You said it well. And maybe if this is stated to the public in sufficient detail, if somebody questions a review, that's maybe how it could be handled; that we could then state why a person was chosen because of their particular expertise and just discussing it briefly.

DR. WARD: Val, did you want to continue?

MS. JONES: That was really all I wanted to say, is that I think that just to state the person's expertise rather than their name. I don't think their name is really what we want to basically consider. What we really want to consider is what is their particular expertise. Because you have a variety of expertise here so that, that, I think might be one kind of a compromise in that you would know the person's expertise.

DR. WARD: Thank you. The next speaker is Mike.

DR. McCAWLEY: Yes. Let me address a couple of things. So our experience as scientists—

DR. MIDDENDORF: Mike, a little closer, please.

DR. McCAWLEY: Our experience as scientists is first of all with publishing papers. And when we get reviewers there's an editor that's a go-between. So the editor in fact knows the identity of who's commenting on what. And we have the chance, in fact, to question the reviewer's comments because occasionally you get something that's a little off the wall. And the same thing is true in grant reviews. There is a program official.

And I can give you one of the off the wall examples that happened to me. I put in a grant for autoimmune effects of silica, got back a review that said we've done enough studies on silicone and we don't need to do any more. That was from a presumed expert from a panel at NIH. So these things can occasionally happen and the Program official or the editor in fact can step in. We need that kind of

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position if we're going to keep the reviewers' names anonymous from their reviews themselves.

So, yes, if you know something about their expertise and if somebody is sitting there going, that was probably marginal to this person's expertise, this particular comment, because I know who made the comment, I know what their background and expertise... You won't be able to keep it anonymous if you really give the person's expertise with their name and a CV and then say, "Oh, this comment came from the industrial hygienist." Well, you know who that is. So you may have to say if you want to keep it anonymous there's got to be some interlocutor there that performs the job of the editor or the Program official. And in that particular case you can then say, "Well, we see that there's probably marginal comment here by this reviewer. You can hear what it was but you might want to take it with a grain of salt." and that way be able to better inform the public and get to that level of transparency that people want.

DR. WARD:

Thank you. Guille?

MS. MEJIA:

I just have a few comments about what everyone has said so far.

DR. BOWLER:

You're breaking up.

MS. MEJIA:

So I just wanted to give you my two cents. So I think attributing a name to a comment is not as important as what is being said. And I think that's very critical. The other thing is that we have to consider the time constraints that Micki raised. There are some time issues here. And I think that people should feel free to voice their concerns or to put out their findings without feeling that there's going to be some retribution.

In terms of what Mike said about having reviewers outside of the discipline, I hear what you're saying but I think also you can be a jack of all trades and master of none. Right? It doesn't necessarily mean because you don't have initials behind your name that you're not as qualified as somebody who has those initials. So I think we have to be considerate of that. And if we're looking at using a multidisciplinary approach then that's something that has to be considered. You just can't have a pool of expertise for one area. You've got to look at the entire scope.

Finally, I mean, I wouldn't know a good reviewer from a bad reviewer if one was standing in front of me as a member of the public. Right? But I have a lot of faith in the administrator in that they will put enough weight on the comments and the findings of these reviewers, alongside of what the findings and the comments are of the scientific team, to really come up with a decision on a petition or on whether they're going to consider a new condition or not.

DR. WARD:

Thank you. We're up to Lila.

MS. NORDSTROM:

I just wanted to sort of make a point that maybe applies more broadly to how we're thinking about this which is just that this isn't a traditional peer review process that happens solely in the scientific community. This is something that the

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public has an enormous stake in and that those of us that aren't medical experts, who have to do the research, essentially, who won't necessarily know just the name of the doctors and their expertise, who won't necessarily have that information at hand. And I think Rosemarie talked about how she could often tell whose review it was on the basis of their review. That's not information the public will have when they look at these recommendations. But the public has a huge and immediate stake in the results of these recommendations.

And so I think one thing for us to just keep in mind is that this is happening, not just within the small medical community, but as a part of a public service to people outside of it who also want to be able to kind of see these reviews, understand whether there's bias in any of these reviews, understand what the background of the reviewers is. Because it has an immediate impact on the lives of either them or their cohort or their constituents or whatever it may be. So that's, I think, something worth considering as this is maybe a little bit distinct from a traditional peer review process.

DR. WARD: Thank you. Micki?

MS. SIEGEL DE HERNÁNDEZ: So again, I'm in favor of the names of the peer reviewers being made public. And I want to go back to something Kimberly said about it being a way to also ensure the integrity of the process. And I think that it does... There are more benefits to the Program, there are more benefits to all of us who are concerned about 9/11 health to patients who are sick and have concerns, and to NIOSH, to have that be a public process. I would have more faith in knowing that there are experts, knowing who the experts are, even if those experts say, "No, we do not believe that there is sufficient evidence at that time." if I understand who those people are and what their expertise is, in the same way that we have discussions here and we may want to have a condition added. But, with the expertise that's on the STAC, when you raise points, say, "Okay, I understand that that's not the time." And I think that there are more benefits to having that information made public for both the Program and also for the general public by doing that.

DR. WARD: Mridu?

DR. GULATI: So I just wanted to make two points. I think one was raised before. I think in terms of the peer review process, I think where you would certainly want when you're reviewing, or doing a peer review, to have that open dialogue we talked about, was there going to actually be an open dialogue between the peer reviews, wasn't sure what the process was. Because during that process you want there to be freedom to actually develop the opinion. But what you might end up putting on paper is going to evolve based on that discussion. After that process, I think there's been so much transparency in this entire process in terms of who are on committees, I am concerned that just to have one place where this would be the only space in this process where we're trying to disconnect when the reality is the comments are going to be out there—which I think should be, because it think it's

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more effective than a summary—I think ultimately it’s going to be linked back. I know it’s not so easy for the public, necessarily, to link it back as it is for the scientific community but ultimately it will happen. And, if you’ve been transparent in the entire process with the World Trade Center to begin with, I think that the best we could do potentially is to provide reassurance to the peer reviewers that your opinion will be respected even if it is a difficult one.

DR. WARD: Thank you. Marc?

DR. WILKENFELD: Yes. So in thinking about peer review—and again, I think this is why you need more transparency than you do in a journal situation—when we have our studies and our papers peer reviewed for publication we get the peer review comments and then we answer them. Right? And everything is fixed in the end, usually. Usually the paper winds up being accepted, we say, “Thank you so much. Those were really good points. We fixed it now.” I don’t understand how it works in this peer review situation. A patient, or an academic, or a scientist, or a doctor, or a public member puts in a petition. It goes to peer review and peer review says, “No. This condition will not be added because of ‘X, Y and Z.’” And then the process ends. Correct? Is that...?

DR. WARD: Let me interject here because you’re coming into these deliberations part of the way through.

DR. WILKENFELD: Oh, I’m sorry. I don’t—

DR. WARD: No, but it’s good because I think that’s really one of the hardest things to understand, is the process and where the peer review falls. So basically a petition comes in and there’s the internal process within NIOSH where we kind of can either stop early on, it’s there’s really no basis or very little basis, or it can continue. And at some point the decision is made either this is a condition that the administrator feels he can support adding the condition or not. If he can support it then the Federal Register Notice happens. And if he does not support it then there’s a Federal Register Notice saying that the petition was considered and it was not decided to move forward. And so the peer review comes after the decision to nominate it for a new condition under the World Trade Center Program. And at no point in time does the STAC become involved unless the administrator decides that he would like input from the STAC. So that’s just the clarification. So the peer review doesn’t say yes or no, the peer review only comes into place when the decision is made by NIOSH that it should be proposed as a covered condition.

DR. WILKENFELD: But the peer review could decide then that it should not. The peer review could recommend that it should not.

DR. WARD: Essentially, yes. The peer review would either say, yes, it should or it can raise questions and possibly say it should not.

DR. WILKENFELD: Right. Okay. So that was what I was trying to say. Maybe I wasn’t saying it very well.

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DR. WARD: No, I just wanted to make sure everybody understood the steps because that's important.

DR. WILKENFELD: I know. Yes. So but when the peer review says, no, it's not, then that's the end of the story. Right?

DR. WARD: No.

DR. WILKENFELD: Or it isn't? Well, what happens when the peer review says no?

DR. MIDDENDORF: Well, if the internal review determines that there isn't enough evidence then the administrator publishes a Federal Register Notice saying, no, there isn't enough evidence here. If the administrator says, yes, there is enough evidence to move forward to add this condition, only then is he required by the Zadroga Act to ask to go and publish a Notice of Proposed Rulemaking. And it's at that point that peer review is requested.

DR. WILKENFELD: Right. And if the peer review—

DR. MIDDENDORF: The peer review will come back and whatever the peer reviewers say will be evaluated by the administrator. It's like STAC; it provides advice. It doesn't make the determination or the decision. The peer reviewers will provide advice and the administrator can alter his decision or modify his decision, if he choose too, based on that advice.

DR. MARKOWITZ: But then when the Notice of Proposed Rulemaking is made. the administrator has decided that this condition should be considered World Trade Center-related. I mean, so that administrator has made that decision and now it's setting in process what he needs to do for the rule and then the external peer review occurs, just to be clear.

MS. HUGHES: I have a question.

DR. WARD: Okay. Okay, Catherine and then Micki.

MS. HUGHES: It seems to be that there's a consensus generally that there's more information on the decision to be provided rather than a summary. And the sticking point is whether the people on the panel are tied to their comments. And, not being a medical expert like the people on this panel, with the people on the panel who would actually say you weren't on the STAC, would that prevent you from participating in that review? Would you feel comfortable, the medical doctors on this committee?

DR. TALASKA: It might.

MS. HUGHES: So Glenn says it might. Steve?

DR. MARKOWITZ: Well, I would participate because I'm going to call it the way it is, but whatever.

MS. HUGHES: Bill?

DR. BOWLER: It's breaking up.

MS. HUGHES: Bill? Would you participate on the peer review if your comments were attributed to you if you weren't on the STAC and you qualified for it as a possible...?

DR. ROM: Absolutely not. The peer review has to be confidential.

DR. BOWLER: Good.

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MS. HUGHES: Okay.

DR. WARD: Okay. Marc?

DR. ROM: Period.

DR. BOWLER: It's very good. You wouldn't get reviewers to do the peer reviews. I mean, if it's done well, the name shouldn't matter.

DR. WILKENFELD: It's like being a ventriloquist, I hate to disagree with my mentor but I would. I think you have a reputation for calling things the way they are and I would. I know a lot of people wouldn't but I would be okay doing it.

MS. HUGHES: Michael?

DR. McCAWLEY: Well, I said when I originally commented on this that I was opening a can of worms. And I can see both sides of this. I know there are lots of people who would not comment if their name was right there on the comments. And they're probably some good people. I would comment on them . I've always felt like anything I was going to say I should say in public.

DR. WARD: So you could possibly lose 50 percent of the pool of possible—

DR. McCAWLEY: You could lose some percentage. I don't know what the percentage would likely be but, yes, it's almost certain that you're going to lose some percentage of the pool.

DR. WARD: Okay. We've got three more folks who fit the category. Mridu?

DR. GULATI: I see both sides to it. I think that you're going to lose a pool. I think in the ultimate comments that you're going to submit and write you're going to be a little extra careful about how you word it. And perhaps that just means you're more vigilant and careful in what you word. And that might be a good thing but—

DR. WARD: Annyce?

DR. MAYER: I hope I'm going to be addressing the issue because it really is getting more difficult to hear. But I think the question is if my name and comments were going to be made public would I participate on a review panel.

DR. MIDDENDORF: That's accurate.

DR. MAYER: Okay. And my answer is it depends. I would be concerned that this represents a departure from the way that these are normally conducted. And I would be concerned about its inhibiting not only my comments but the comments of others. So I think it's unlikely that I would feel comfortable participating where line-by-line my comments that are made in discussions would be (inaudible @ 00:55:25) yes.

DR. WARD: Okay, Megan?

DR. MIDDENDORF: Megan?

DR. RYAN: Can you hear me?

DR. MIDDENDORF: Yes.

DR. RYAN: Yes. I've had a little bit of breaking up too. But I agree, especially with my prior colleague's comments. I think I would feel very intimidated to be honest as a peer reviewer unless I thought my opinion completely agree with the majority. And then I'd be like, okay, share my name. But if my opinion did not agree with the majority

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I would feel inhibited to share my honest views. And so, again, I concur with the idea that peer review that has been scientifically in our history is better done anonymously. And people who are familiar with peer review know there's a degree of rigor and professionalism that goes into that review, that what the obligation is on them. They're really not hiding behind that anonymity there of being allowed to be honest while still being very professional and rigorous.

DR. WARD: Thank you. Guille, you had your hand up. Did you...?

MS. MEJIA: Yes. I'm sorry. Maybe it's because my blood sugar levels are going down but I just have a quick question. You expressed/you spoke about the process in terms of where the peer review comes in. And you said it was done after the administrator makes a decision to include a particular condition. But I just wanted to go back to the workgroup report, because I think that needs to be a little bit cleared up because if you look at... It talks about when a petition is received. It really should, then, say "when the administrator has made the decision." And that's in the first paragraph as well as in the third paragraph. Again, it takes about "at the receipt of a petition for adding a condition." So just so that where everybody is very clear, that will clarify when that review process takes place.

DR. WARD: Good. And there's kind of a point of clarification here. These are the workgroup reports and we have to ask Paul if it's okay that if somebody makes a correction to the report can we modify the report to reflect that correction, or do these need to stand as they are and then, of course, the committee will, from the committee reports, we will take the reports and we will frame recommendations that the STAC will vote on. But if a correction is made to the workgroup report it would be, I think, appropriate to make that correction even as a note. But—

PARTICIPANT: Right. We've peer reviewed the workgroup step.

DR. WARD: Okay. So Guille has just raised the point that the wording of the workgroup report may be misleading or incorrect. And I would like to be able to make that correction in the workgroup before...even if it's reflected as a comment rather than just leave the report stand with an error. And then we have the ability as the committee to reframe the more concise recommendations from these reports as we so choose. And of course that error will not be carried forward in our recommendation.

DR. MIDDENDORF: Yes, I think the best way to handle it is the workgroup reports stand as the workgroup reports. If there are inaccuracies that the committee wants to correct we can put a note on that report and repost it, the revised report with the notes, not changing the workgroup report.

DR. WARD: Marc?

DR. WILKENFELD: Yes. No, I was just going to say that that's—and thank you for clarifying for me before because that was—actually how I read it and how I took it and that was the text of my question.

DR. WARD: Sorry.

DR. WILKENFELD: So, and then I got confused because of what you said, Dr. Ward, because it

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- seemed to conflict with this. So what you said is the way it works and this isn't accurate actually. It's not on receipt. It's after the administrator makes a decision. Right?
- DR. MIDDENDORF: Okay. And I need to make a clarification here. The administrator proposes to add a condition, it doesn't make a decision to add the condition. He proposes to add it. And then later on, after all the comments are in, peer review, stakeholder comments, he'll look at the whole issue again and then make a decision.
- DR. WILKENFELD: Right. Right. But the peer review is not at the beginning, not upon receipt.
- DR. MIDDENDORF: No, it is not upon receipt. That's all internal.
- DR. WILKENFELD: Okay. Thanks.
- DR. WARD: Right. So we will correct that, for the record, in the workgroup report. Mridu?
- DR. GULATI: So just to clarify, I mean, how many peer reviewers are we actually talking about for doing...? I mean, is there a grade. are they graded and then overall...? I mean, I'm just trying to understand because if you have three or four peer reviewers and only one doesn't like it or doesn't agree and then the others are...how is all the information if you get different peer reviews incorporated?
- DR. MIDDENDORF: Yes, the policy as its currently written states that there would be three peer reviewers who are requested. And they'll have 30 days to provide their peer reviews. That information is all looked at by the administrator and science team. They go through it all and evaluate it and make specific responses to it. And that is all used by the administrator to make a final determination.
- PARTICIPANT: I have a question, and continuing sort of on the prior question and on your question. So there are three people that have to agree to be on this peer panel and some areas that this committee addresses are a little esoteric. So, like, how large a pool can you even choose from to get those peer reviewers, generally? I just don't know the depth in some of these medical expertise areas.
- DR. WARD: Well, the workgroup did not get into... We kind of... I was on both workgroups so I get confused which is which, but I think we did have the sense that it would be really desirable to put out a broad call for potential peer reviewers. That would allow for the public to nominate people. It would allow people to self-nominate. You could put out some information about what would be required by the peer reviewers, once it's decided whether the peer reviews would be anonymous or not. The call for reviewers could state that information. And, really, at that point in time you would want to, I would think, define the scope of expertise that you'll looking for in peer reviews, which would be very broad. And I think that might be the most efficient method for NIOSH to use because then they could have a giant database with the reviewers and the areas of expertise. Conceivably a petition can come in on something where we don't have reviewers or there are no reviewers with the expertise and you'd have to deal with that on a case-by-case basis.
- So, does that answer your question?

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- PARTICIPANT: Sort of, yes.
- DR. WARD: It's kind of like the STAC. I mean, when the STAC was established it was determined that there would be a certain number of people with each type of expertise, except on a much broader level. The call would be even broader. Yes?
- DR. GULATI: I think it's a good point. I guess I wonder for certain subspecialties, for example, rheumatology, how many—in terms of associating environmental exposures, what your pool is there. I think for certain disciplines. it may be a little bit easier. But if you're looking for an occupational or environmental background then in some of the specialties it might be a little bit more challenging.
- DR. BOWLER: You're breaking up.
- DR. MIDDENDORF: Okay. I want to make one other clarification. The term "peer review panel" has been used numerous times. There is no intent to use a panel. What the administrator will do is ask for individual advice from three peer reviewers. If we were to ask for a panel to come together and begin discussing it that starts to move you into Federal Advisory Committee territory and would become a huge burden.
- DR. WARD: Yes, Micki?
- MS. SIEGEL DE HERNÁNDEZ: Again, just thinking about timeframes from the start of receiving a petition until when a final decision is made, I think the idea of NIOSH beginning to form a pool of peer reviewers would be something that's advisable. I think that there are some topics that I think we can feel pretty confident petitions will continue to be raised. For example, autoimmune disease, we know that there are other studies that are going on. Because the one that was presented was not sufficient because it was only one 9/11 study. And so I think that, as much of that that can be done ahead of time for a topic that we know we're pretty clear that the various groups are working on, it would be very helpful rather than waiting for the administrator to decide that, to propose that, and then have to start that process at that time, which is an open-ended timeframe.
- DR. WARD: A person from the public would like to make a comment. Jo, would you like to come to the microphone?
- MS. POLETT: So I listened to the discussion and there was a period of time that I was persuaded that names and comments did not need to be attached. But as the discussion proceeded I became very uncomfortable and I'm quite convinced now that they need to be attached and that, I mean, people/experts who are making decisions about people's lives and their dying and their deaths, need to have the intestinal fortitude to have their names attached to those expert opinions. And like your colleagues might not like them is not important. Thank you.
- DR. WARD: Thank you. So let me just see if I can sum up where we are. There are several things. There's one thing that I think that I haven't heard anybody speak against,

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is that rather than providing a summary of the peer review comments I think we're all in agreement that we would like to see the actual comments along with the NIOSH responses. And I think we're also in agreement that certainly the names of the peer reviewers should be given.

I think where we have the biggest split or different opinions is, is whether the specific names should be attached to the specific comments. And I have to say that, I mean, several people have said this, I think there are very good arguments on both sides and so it may be that we'll have to have a vote and have a split vote. I don't know that we're going to come to a full consensus on this matter. But I think we can talk about what we'd like to say.

I mean, I didn't speak when we were going around the room but I think my feelings are pretty close to what Jo said, probably more eloquently than I could say, that this is an important decision and you shouldn't take the responsibility if you feel that providing an honest opinion is going to inhibit your review. And it is going to be tough for some people but that's how I'm persuaded. I think there's so much at stake in these decisions and there's so much need for the people who are affected to understand what the basis of the decision was that I'm leaning that way. But I certainly can see that there's very strong arguments on both sides.

DR. MARKOWITZ: I think there was another area that we agree on which was that the identity of the reviewers and their areas of expertise.

DR. WARD: Okay. And also—

DR. MARKOWITZ: That's in the middle paragraph under the—

DR. WARD: Yes. Yes, I agree. And actually I wanted to make sure that we capture Bill's point and maybe that'll be a separate recommendation. Because I also think that's very important. As individual conditions get nominated there is going to be a need to clarify what conditions are being talked about. And I think that was an excellent recommendation so I want to make sure we get that on the record even though we haven't had much discussion about it. Because I think everybody just nodded their heads and said, yes, that's an excellent recommendation.

So I think at this point maybe we can actually go to the point of actually making some specific motions on the recommendations. But I want to make sure first of all we feel like we've really covered the topic of the most difficult question, of whether we should recommend to NIOSH that the individual comments of the reviewers be attributed to individual people. I think we've had very excellent discussion on the topic. And I thank Micki for raising it.

DR. MIDDENDORF: We're at about the noon hour now. When we come back, because of travel restrictions, we're going to have to listen to Dr. Reissman's presentation on research at that point in time. I'd like for her to have an opportunity to present and have a short discussion with her, getting, as Dr. Howard requested, individual thoughts and ideas from the STAC on that. But as soon as she is finished I'd like for us to return to this discussion, begin crafting recommendations and voting on

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- them. And then when we're finished with that, Dr. Lum would then talk a little bit about his efforts within the research area in research translation.
- DR. WARD: Right. And I'd like to remind us that we still have to go back to the other workgroup's recommendations and make sure we do some wordsmithing and get some concise recommendations and vote on those as well. Maybe that's something we could work on offline during the lunch period.
- Lila?
- MS. NORDSTROM: Can we also at some point discuss the idea that was presented in several of the public comments to sort of further our involvement in figuring out how the pediatric research guidelines are being implemented and maybe talk about the meeting that they suggested for that?
- DR. MIDDENDORF: That would be up to the administrator to bring that to the STAC, not for the STAC to decide for itself.
- MS. NORDSTROM: Oh.
- DR. WARD: Okay. Thank you. So we'll adjourn for lunch and ask that everyone be back by 1:00?
- DR. MIDDENDORF: Promptly at 1:00.
- DR. WARD: Promptly at 1:00. And sorry for all those who were counting on eating lunch in the cafeteria and will now have to go outside because the cafeteria is closed. Okay.
- DR. MIDDENDORF: See everybody at 1:00.
- [Break.]
- DR. WARD: Can all the committee members take their seats? We'd like to begin. So our first speaker after lunch is Dori Reissman.
- DR. BOWLER: So we should have the slideshow open for Dori Reissman, right?
- DR. MIDDENDORF: Yes, that's correct and we're waiting on an equipment malfunction, to try and get the microphone to work.

RESEARCH UPDATES

- DR. REISSMAN: How about that? It's better? Okay, perfect. All right, so good afternoon. I met you a little bit earlier, but I'm Dori Reissman. I'm the Associate Administrator for the World Trade Center Health Program. And what I'm doing this afternoon is giving, especially those of you who are new to the STAC, a little bit of an orientation about the Program, and the interaction between stakeholders and the Program as it pertains to generating information for research, and where that research then goes to try and inform our providers for clinical care, and also how we try to socialize that research.
- So the first thing I really wanted to go over on this slide—oops, there we go, it's very sensitive—is stakeholder engagement. We have a variety of ways that you heard about earlier today where we have a steering committee for responders and we have a steering committee for survivors. Both of these steering committees are statutory-required committees that are not federal advisory committees. That's where we hear input. It's where the people receiving care from the Program are

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able to talk to the providers providing the care, which is our Clinical Centers of Excellence. Often our data center people also attend that because a lot of the questions that come up require some kind of analytical response from data that's been collected in the clinical arena. We also have you, which is the federal advisory committee, otherwise known as the STAC. We have research grantee conferences, which one will be occurring not next week, but the week after, probably in this very room, where we have these I think twice a year now for all the NIOSH-funded research for the World Trade Center Program. And the purpose of having those conferences is a way to mix up the scientific information with other scientists, and if stakeholders come to that meeting, they also ask their questions and they're able to talk more informally with some of the scientific experts. Within our contract arena, because all the care that we deliver within this program is done through contracts with Clinical Centers of Excellence, we meet with them as well as the data centers on a weekly basis at what we call the medical forum. And with our new solicitation, we're going to be starting up an analytical or scientific forum, which is, again, more about mixing up what the clinical observations are with data analysis so that we can do program improvement. And the last part is what I've asked Dr. Lum to present on either after me or later today, which is how does the information we generate from this program in the scientific realm get disseminated? What is subject to research translation? What does translation mean and how do we socialize it?

I wanted to give those of you who are new to the committee a little bit of a history lesson. We began in this program, as it was authorized by the Zadroga Act of 2010, we started in July of 2011, and with research funded at that point, the initial research agenda was mirroring what was required within the statutory mandate, and that was how do we research the diseases that are involved with the adverse exposures that happened on 9/11? So we took the language of that and said, well, that's characterizing World Trade Center related disease because there was already a compendium of diseases that were listed for coverage. We already knew about the ones that are listed here, which for those of you on the phone, would be chronic rhinosinusitis, obstructive airways disease, interstitial lung disease, gastroesophageal reflux, and various mental health conditions like post-traumatic stress disorder, depression, and anxiety. So we already knew that these diseases had been related to the World Trade Center events and they were part of the coverage paradigm that we started the Program with in 2011. And that program was a continuity program on the backs of a public assistance program for medical monitoring and treatment that was done by the similar centers. The other part of that was what additional science did we need to do linkage in order to do what you were talking about earlier today, which was how do you link 9/11 exposures to health conditions that we weren't covering so far? Was there enough of a scientific evidence to suggest that new conditions might be covered?

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Cancers as a category was the big one that came up. I think it was in 2012 that we actually had a rulemaking to add that and that was with the great assistance of what happened here at the STAC and a lot of other work that was done by scientists within NIOSH. Another one that you've heard a lot about so far is autoimmune disorders, and Dr. Rom earlier made actually a very useful suggestion about some things that we might want to do in scientific colloquia to try and bring us to a same-page definition and explore things that are kind of merging the boundaries of medicine right now. So those are some areas that we know are on the verge.

We expanded our agenda in 2016, which was this past cycle's research announcement, and with that, since we knew at that point we were reauthorized for a 75-year horizon, that's a very different thing to start thinking about than a 5-year horizon. That means that, you know, it's not that the mandate for what we could study actually changed, but how we would study it, what it really meant, how we interpreted that could change. So what we were talking about was now you have people with chronic conditions, some of whom seemed to not follow the textbook in how diseases progressed or how they responded to traditional treatments, and the other things that are happening in our environment have to do with how healthcare is delivered in this country and the changes that are happening with national legislation. So there's health service research and questions about value-based care for chronic disease, rather than fee-for-service models that we currently pay for our care by, but we need the research in order to develop the evidence to say a different model would be necessary.

In addition to that, there's lessons for recovery. While there's lots of lessons for response, that comes from the literature, much of the literature that's already been produced by the funded research and the efforts of the scientists and medical clinicians that actually run the clinical centers and the data centers. But the lessons for recovery have a lot more to do with, well, what have we done for people who have had such a massive traumatic exposure at a certain point in their lives? What happened to them from an ability to work? Many people went on disability, other people had a change in the nature of the kind of work they were able to do, and the reimbursement strategy of the new work might not have been at all similar to what they had before, et cetera. So there was a lot of financial burdens and a lot of questions about how things might be handed down over time and how that affects the family function.

Psychological resilience for disaster responders is another area because we've learned that some people were much more resilient than others, but why? And what could that contribute in terms of teaching, education, preparation? That comes from the studies of trajectories, if you will, of mental health responses to some of the questionnaires on our monitoring exams as well as additional types of data that are collected when people propose research. Biomarkers are being

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added into that now and some epigenetics.

In addition to that, the biggest criticism we heard from the scientists all along was that there's no comparison group to the study. You're only studying the people who are sick, so how do we know that they're sicker than the general population or a comparable population? How do you know what's attributable? So we really needed to invest more in what could we enumerate, if you will, as a good comparison group? And one of the current studies funded this round in the firefighting arena is looking at some cohort studies that they can compare to and try and up the ante on the research scientific integrity.

In addition to that, as we are all moving forward in time, aging is a part of that and there have been some preliminary findings among the cohorts that we treat that suggests there may be some changes consistent with premature aging. So is that real? I mean, that's kind of a big factor. We all get older. We all have things that happen as we get older. We have a genetic history that comes with us. We don't know the gene-environment mix. We don't know what it means. And how do we look at that from a Clinical Center of Excellence model? Excellence in the very beginning of our program had much more to do with exposure assessment, occupational or environmental health exposures, but as we go forward in time, it has a lot more to do with what does it mean to grow older and have these conditions and have the interactions, and is there any point of intervention? The last one—it's not last because it's last on the priority list, it's just last because I wanted to emphasize it, and that's the health trajectories for children exposed to 9/11, and I know there was some attention to that earlier today, and I'll speak a little bit more about that in a minute.

You always love logic models because those of us engaged in science and program like to torture ourselves with getting everything on one page, especially when you can't read the writing anymore. So hopefully the copy that you have in front of you is a little bit more legible than the one I have before you on the slides here. But what I wanted to try—I've spoken to the STAC before about the logic model underpinning our program, and it's a program model, but it also is a focus on how we do our science, and how we bring that into findings, and how we take those findings and try and move those products out to make a difference for the population that we are treating and seeing, and to make a difference for future readiness for disasters. So the purpose of this logic model is to show you that the inputs have everything to do with the people who were directly affected and everything to do with all the entities that we fund and even those we don't fund who contribute to the activities of research. Those activities include getting funding announcements up and going, and all the rigor involved in that and the administrative burdens that are involved in that, being able to fund technically meritorious research which is based on a review panel which you all had quite the discussion about earlier, and that research is then conducted hopefully in a highly

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quality manner with integrity to everything that they're doing, and the findings are then shared in our research grantee meetings, and then published in peer review literature. And the hopes of getting these things into the peer review literature is to do everything that we talked about earlier about being able to make informed decisions based on evidence, whether or not we're including a new condition or whether or not we need to modify a program or think about a benefit, and how we advise people in the future about disaster preparedness. So I'm not going to go over every aspect of that. That's not my job today, but I'm happy to answer questions at now or a future time or later about the logic model itself.

I'm using this diagram, especially for those of you who are newer, where this is a highly simplified illustration of the Program. To get that actually into legible boxes like that was a feat of simplicity, and you know anything simplistic is truly complex underneath. So, you know, we're the World Trade Center Health Program at NIOSH. We administer the Program. Underneath that we put out contracts for Clinical Centers of Excellence, so there's seven of them in the greater New York area. We have a nationwide provider network that we also fund through a contract to provide care outside of the greater metropolitan New York/New Jersey area. We have data centers for three different cohorts, for a firefighter cohort, general responder cohort, and what we call the survivor cohort, where information from an initial health evaluation and medical monitoring that occurs after that on a periodic basis is stored. That information is the information that we call health surveillance in our program. The data center should be looking at that piece of information in a fairly frequent and rigorous way to see if there's trends suggesting the emergence of a new problem that we hadn't anticipated or to do a better job at linking problems that we were starting to see, but didn't have the evidence to really act on from a program coverage standpoint. The bottom box, the support service contracts are all the other types of vendors we have to hire in order to run a federally-mandated healthcare entitlement program. And then there's the rest of you in the Program members box and stakeholders. This particular diagram is really to show you the flow of information. So when a clinical provider is seeing one of our program members for an initial health evaluation or a standardized monitoring evaluation, the data they collect in that exam is then sent from the top box to the left, the health data—I guess it's, yes, your left, looking at the slide—and it goes to the data center. And the data centers are then storing and maintaining that data in a research quality data set. They have data sharing agreements that they're required to maintain and implement where external researchers can then come in and say, "Well, I'd like to look at X, Y, or Z and propose some research," and they work collaboratively to obtain that information. Sometimes they collaborate themselves on a research project. On the other side, on the right side, are claims data. This is information that arises from the payment for services rendered for healthcare. So you might say, well, why would you want

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to have claims data? Well, healthcare service research really needs to look at the costs of episodes of care. What does it cost to treat respiratory disease or the types of respiratory disease? How does the initial phase of cancer differ from somebody whose cancer has become under good control and it's quiescent? To the very nasty end-of-life phase which is typically very expensive as somebody's trying to hold on, but losing the battle.

This particular slide is really talking about our extramural research projects and the focus areas on here are talking specifically about the number of projects that are funded, and respiratory disease being 15, adult mental health: 13, cancer: 10, and World Trade Center youth is 7, et cetera. You can read those. In all of this, I would like to mention that the youth studies, especially from the survivor population who've expressed a lot of interest and frustration in not getting this better studied, there's a great deal of mental health work being done in the youth studies because some researchers were very proactive early on and were able to get study populations underway when they were easy to enumerate at the time. Unfortunately, what has happened since then is that people have, you know, dispersed as they got older. Fifteen years have gone by, so young children are teenagers or young adults now, and as we know, they don't tend to stay home or they'll come back later, but meanwhile they're not so easy to locate and they're not so easy to pin down for research. The only way that we had access to them from program resources was through our World Trade Center Health Registry investment, which was with the New York City Department of Health and Mental Hygiene. And in that particular effort, which was started with ATSDR back in 2002, I guess, right? In 2002, I think it was awarded and they had their recruitment done then. It was an extensive effort to recruit, but unfortunately, at the time, that recruitment only led to enrolling about 3,068 children under the age of 18 as of 9/11, but even with that, by the time they launched their first Registry survey in 2003 to 2004, already 556 of those children were over 18. So, you know, it was a moving target to begin with. And now we're dealing with 81% of that cohort being at least 18 years of age, so they've aged into adult. So when I hear that we really want pediatric studies, it's something where you have to think about the time lag. So we may have missed the window at this point for the development changes that you may have been able to identify prospectively, but there may be opportunities to identify things that are happening now that might represent derangements of biological systems that are not overt clinical disease, and I understand that to be a particular area of interest to the survivor cohort. So what we're trying to do with that now, we've approached the New York City Board of Education. That's been a difficult row to hoe, as I'm sure many of you can appreciate. It's been a lot of years since these records were even looked at and I'm still waiting to hear back from our contact with them from last spring as to whether or not we have legal permission to move forward by their board. I would

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view that that's not promising, but, you know, if it were possible to work with them, we could identify schools that were in areas that were considered hotspots and schools that might have been in areas that were not so hot, and you could try and recruit people from that type of attempt. That would be more of a feasibility study. We're currently in discussions with the Survivors Steering Committee about this and we're in discussions with the 9/11 Health Registry about this, not to use the members of the Registry, but to use the connections of the Registry because it's another city department that could be quite helpful in trying to unearth some of the records or link things that might help us enumerate the population. If we were able to do something like this, the arrangement for that would be a stakeholder engagement, so we very much appreciate the need for hearing it directly from the people who were affected, knowing where pockets of things happened that were never recorded. So those kinds of things are definitely part of the future.

Okay, let's see. This next slide is to just demonstrate the number of research projects and the funding. I believe that the 91 is not quite correct. This actually—it's around 66 million of extramural funding for individual research projects, but when you add the Registry funding in, which is also research, then it tops over 100 million, so please disregard the 91. And I believe Dr. Lum will probably have a similar slide that's incorrect that way, so we'll correct that and post the right thing online. But this is to show you the way in which we tried to divide the projects so that all the money didn't go out the door immediately before you knew necessarily hotspots that you needed to research. In the Registry project, while that is a larger funding, that's a \$7 million funding per year, what happens there is it's a platform where a number of collaborators come to work with the data that's collected through waves of questionnaire data. And studies spin off of that, and they've been working very closely with us on our logic model to achieve the priorities of the Program.

This is a Registry slide just to kind of show you that there have been a number of waves of research that have already been done. And this is online. They have a renovated website and my understanding is its usability is much improved, so I encourage those of you who are curious or even scientifically inclined to go have a look.

In terms of our research portfolio, you can find information for that portfolio on the various websites I've provided here. The logic model and explanations of all the boxes are actually online through—that direct link will take you to it and it's about a four or five page document that can stimulate more questions, I'm sure. And our research grantee proceedings are also posted up on our website. Our current research funding announcement is up on that website. And I don't know, is Max going to be talking now or later? A little later?

DR. MIDDENDORF:

No, now.

DR. REISSMAN:

Now? Okay. So he's going to continue a little bit more about the gateway and the

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work that he's been doing there, and I'll turn this over in a moment. But before I get there, I just wanted to alert you all to something that I think was in a handout. It looks like this, a Medscape handout, that's informational for you. If you want to go on Medscape and find these particular provider continuing medical education programs that we put together with our collaborators in the Clinical Centers, they're really excellently done. And the beauty of it all was that, by partnering with Medscape, we really had reach, so the ability to educate providers across the country who might see only one or two of our cohort at least had a reference place to go to learn a little bit more about centralizing their understanding of the scope of the disaster, the nature of the problems being seen, and a bit about how decisions were made, especially with the cancer decision, which isn't listed on here, but it is a part of this handout. So I encourage you to look at that because I really think that's a tremendous success story.

So this is my last slide and, you know, the purpose of this one, you know, I attribute this slide to Dr. Lum because this, I think, shows you a little bit of his creativity and certainly his perspectives, and a little bit of my perspective too on the bottom-left, which was—you know, you used to know how to do everything the way it used to be, and then social media came around, and all the rules changed, all the ways in which we do work and we learn about things changed. So I hate to be a dinosaur, but I've become one. So with that, I'm going to introduce you to Dr. Lum.

DR. LUM: You're a dinosaur in learning, as we all are. This is why I didn't want to show it live, Paul. It'll take forever. I've got screenshots, that I'll show you toward the end, of our new website we managed to put up for the World Trade Center, so we don't integrate it too much with (inaudible @ 00:27:19) site. But it's always a hazard in this room to show it live because of issues.

DR. MIDDENDORF: You should probably speak more into the mic.

DR. LUM: Okay. I can give you a little story while we're waiting. When I actually had a real job at NIOSH, I was the Communication Director for 15, 16 years before I attempted to retire and John said, "Well, we have this World Trade Center project. Maybe you can help us out with some communication issues," and I'm more than happy to have been doing that. But when I first came to NIOSH, and Google was just setting up really, but had been up for a while, I thought, oh, this is great, I'll type in NIOSH and just see what I get—right?—in Google. This was 1999. So I typed it in and up came, "Do you mean OSHA?" So I knew we had a problem with at least search engines. If you're going to OSHA, you'll never find our stuff. You may eventually get to where we are, but... So that really began a kind of a soul searching about, you know, exactly how search works and how can we benefit—search engine optimization? So we'll talk a little bit about that.

Just a kind of an overview, we are interested in making, I think, our research more social, meaning we're looking for different audiences, not just science audiences.

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But nevertheless, science audiences are very important for us in terms of what we're doing with the number of research projects that we have. So we worked with WebMD, as Dori said, to see if we could pull what we know into a CME activity for physicians, and we have been doing that for a while. There are four discrete modules on WebMD from easy to more complex. They get credit, physicians get credit for it. We've had 43,000 physicians take this training. Now, that doesn't mean 43,000 individual physicians because it's a four-person package. We asked, you know, WebMD to tease it out for us, but they said they don't do that, so we're thinking there's a significant number of people certainly outside of New York that took it, maybe 5,000 or 6,000 as far as we can see by looking at the URLs. And we think that's—we did ask the question at one point, you know, based on what you've learned in these modules, will you make changes in your practice? And the pulmonologists came back and almost 40% of them said, "Yes, we will make changes." Now, we don't know what those changes are. That's our next question, right? Come back in a couple years and say, "You mentioned that you were making changes. What changes did you make in your practice?" This is what I think Dori's trying to get at is this research-to-care, how much you really changed—how much impact do you have in terms of the way that research is working with care?

The other part of this is expert opinion through the peer review process. We're certainly reaching a lot of folks that way. Bibliometrics is—I don't want to really talk about it—it's the scientific—you know, how much a particular research article is being circulated, but we can collect that data and we do collect that data. But really I want to talk about what we're doing socially to increase research and engagement and impact. And again, research does go to a larger audience than just a clinical audience.

This is the error slide that I copied from earlier slides that Dori had, but the point is that we have a significant amount of research programs to look at, 57 plus what's in the Registry, so we can take those as they come online, as they go into peer review. We certainly have a nice group of research proposals, research published articles that we can follow and track. We're using, you know, the traditional outreach methods, you know, like the principal investigators meetings that are being held on a quarterly basis, and many of you I think have attended those meetings.

And when we talk about research, there is a mixture of folks in the audience from the research universities as well as from our partners. Our partner outreach activities now are focused mainly on these four top partners now – FealGood and 9/11 EA and VOICES and NYCOSH. But I want to say something about the community boards. We haven't really involved them in the push for our research, but we have talked to them in terms of the importance of monitoring and medical care that we offer, and they've been very helpful. And then of course the steering

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committees. So it's not that we give up on traditional meetings. We go to meetings, we talk about the World Trade Center, we are encouraging our researchers to go to international meetings and talk about the research they're doing.

And then we are planning what we're calling a research-to-care availability conference in September at New York University. We haven't signed a contract at this point, but I think that's where we're going to do it. In the morning, we'll be talking about research. We'll have our researchers come in and talk in a quick way about the research they're doing. And in the afternoon, we'll sit down at the tables and work with people that are interested in a little bit more one-on-one, and we'll divide this up probably by areas of research, so people have a chance to interact one-on-one. It's not that our partners haven't been doing this. We know they have been. NYCOSH recently held a very, very good meeting where they've had presenters and then they had research presenters and then people in the audience asking questions. But this will be a more one-on-one focus, and researchers and their PIs and maybe the co-PIs asking questions directly about the research that they'll be talking about in the morning. So we look forward to, again, working with NYCOSH and Kim in getting this agenda set for this meeting. And then we have a more social approach which really, for me, has been a total learning experience, I think, but pretty early on when I was at NIOSH as the Communication Director, I said, "We have to really get into social. We have research, we have 500 peer reviewed journal articles a year, you know, we need to get out this research and we can use Twitter sites and Wikipedia and some of these YouTube sites to disseminate our information." Strangely enough—and we've been pretty aggressive with social media at NIOSH thanks to John's ability to let us do some things—is we have the largest Twitter site in Washington, D.C. We have 350,000 people that follow us on Twitter, which when you think about EPA and FDA and even NASA, you know, it's kind of amazing that we have such a large following, but we do. It is a bit of firehose because we do three or four tweets a day and they might be from construction, from agriculture, also for World Trade, we do send out information that way. But just to point out, the fact is that, if we are beginning to think about—and I think in the next 90 days, we'll have a WTC Twitter site as our research becomes, you know, available now. And if we tweet about our research on our site, we are reaching 350,000 people, and then considering the re-tweets that occur from our partners, we probably are reaching close to half a million people. So in terms of reach, that doesn't mean they're opening it, that doesn't mean they're opening the site, doesn't mean they're looking, but we do know who opens and we do know how long they stay on the site and look at it, so it gives us another way to push out information, I think, in terms of social media. And that's just the Twitter site. We have a blog at NIOSH. We don't have a WTC science blog, but we're thinking about doing that also. But

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the point is, when the universities have a research program that they're putting out and they're putting it out on social media, there's no reason why NIOSH shouldn't come in and also be a part of that, to send it out to our groups, to make it more social and get it in the social sphere.

I know you can't read this. I just had to make a screenshot of it to remind me to talk about Wikipedia. In 2010, I had a really bright student in one of my classes at G.W., and I said, "Would you like to come work for us in the summer editing Wikipedia with some of our information? I want to test this out as a possibility." And he was really quite a good guy. He really knew—he was a good editor, and so we started editing Wikipedia. I think we've made about 2,000 edits on Wikipedia. But in 2013, Wikipedia became the number one driver to the NIOSH website, other than the search engines. So this kind of triggered a thought about how important Wikipedia is in terms of reaching people, and we're not talking here necessarily about reaching scientists either. It's a broad range of people that use Wikipedia. If people are going to Wikipedia for information, shouldn't we be on Wikipedia? I mean, my kids would call this a "well, duh" moment, okay? I mean, can we control Wikipedia so that it's not going to be slopped over and can we control what we put on? Yes, there's plenty of controls on Wikipedia. We've been out, we've talked to the foundation about this at their home office, and they said, "You're the first federal agency that ever visited us here," and I said, "Well, we're a science agency and we want to do this right. You need to help us with this and you need better metrics so we can convince people that we should be doing Wikipedia edits." And they have been more than gracious in working with us to understand how these particular edits work.

But for example, how many videos—this is the World Trade Center health site, okay, basically, that if you pull it up, this is what you get. What would you guess are the visits in the last 60 days? What would be your assumption of visits to this site? You know, it's been around a long—it's not very detailed. Maybe 500? Would that be a good visit—? 1,000? The numbers are 3,000, 3,000 in the last 60 days, okay? And that's on a site that doesn't really talk about specifics. It talks about a general approach to what we're doing. It doesn't talk about a particular cancer issue. It doesn't talk about a particular GERD issue.

So what we will be doing in the next 90 days is taking what World Trade Center research we have that's been published and finding a place for it on Wikipedia. And if there's no place, we'll create a page for it, and we'll monitor that, and figure out what the views are, the reach of that is, and what the engagement is.

Wikipedia is not considered social media by most of the gurus of social media. It's very social because, when you put things up, somebody comes on and says, "Well, wait a minute, you forgot this or you need to add this or what does this mean?" You have that all working behind Wikipedia, so it's a very social and engaging site, so you can engage people who eventually put information in the

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resources sections of these pages. You can get them to come to conferences, that's the theory anyway, and to be more engaged in the research that we're doing.

So the whole idea, I think, of the immediate benefit of social is that we use these social sites that are already created like YouTube, Facebook, Twitter, and blogging, in this case, just as an example. And just to go back to YouTube for a minute, one of the things that we've asked all the researchers in the World Trade Center Program to do is to give us a one-minute video about what you're doing. What are you doing? What problem are you solving? How did you solve it? And why do we care? All right? These are one to one-and-a-half minute videos. I thought we may have a problem convincing people to do this. It's been great. Frankly, it's understandable, it's not Academy Award quality, but it's absolutely excellent because, in one-and-a-half minutes, they can explain directly to the person that's viewing exactly what their research is about. Then when we talked to Wikipedia, we said, "How come we never see any videos on Wikipedia?" and they said, "We don't know. You can put them up." So we will put videos also up on Wikipedia, and Wikimedia Foundation will be providing us the metrics so we know how many hits we have and how long people stay and, you know, if that's a good thing to do. I think it will be. We've had some earlier studies that the numbers are pretty significant, much better than putting them just on YouTube, because they're related to the research. They're right next to the research. So maybe there's only five people that need to know that at that particular time, but they get the information and they can understand it. So the theory is, obviously, you know, these sites, like our Twitter sites, have other people that follow us, so you get huge reach. And eventually, I think what we will go back in doing for Twitter, particularly, is to take a small sample and ask people what they're doing with the information. You know, I think that's phase three probably, but, you know, why not? We can do this through SurveyMonkey, it's not going to be that difficult, and it'll be—again, I'd like to go back to those pulmonologists that said they're going to make changes and ask them what they actually did in a couple years. Did you make any changes? What did you make? How did you change your practice? So social media is great, but you have to have a landing site. You can't send people—you know, there's always a link on social media, so you just can't send people to a site that's junky, you know, or it's complicated. So we approached our mothership, the CDC, and we said, "Look, we need an exception to make a site more friendly than the rules that you provide us allow. If we have to use your content managing strategy, you know, we're going to be tied up for years, we're going to have to have a contractor. Let us go and do our own site and you can check it if you need to, but give us some authority to do that." And they did, which is the miracle of the summer of 2011, I think. But they let us develop our own site, so the landing site that we've created—and I'm going to just show you this

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basically in these screenshots. This is live and I'll give you the link, so we'd ask you to go in and take a look at it. But right here—is this not working? Okay. So you can search by researcher, you can search by site, you can search by basically—by a whole bunch of keywords. There's a hundred keywords that we've managed to pull out, mainly by looking at how people have been talking about World Trade Center research from the newspaper. And, you know, people don't type in "respiratory disease". They might type in "dust", okay? What dust research are you doing? So we want to make it easy for people to find out the information. So basically, you go to the next page, you want to look up your research project, there will be a prompt or prompts, you can search by individual researcher, you can search by site, you can search by the name, or you can just scroll down through all of them until you find something you're interested in. But again, I think if you type in, for instance, "Luft" here, Ben Luft's studies, you just want to know Ben's studies, you get those from the individual researchers. Or if you want, let's say, information about respiratory disease—or let's just type in "dust", you get all of our respiratory studies here. You may go down to the last column there and you see that that's Dr. Bergman's studies and really that's the one you're looking for, you're kind of interested in that, so you type in his name, obviously, and you go to the bottom there, the number two site, you click on that, and you get his site. And here you have a description of the research, you have research questions, the research objectives that they were asked to deal with—Travis asked them to define the research questions—and the video, okay, so you can click on the video, you can see a one-minute summary of what this research is about. You scroll down and you have a more complete—you have the other contributions, expected impact. It'll be nice to go back and look at the expected impact at some point and see how close they came to what they thought would be the impact. And then you keep scrolling down and you get Bergman's high school graduation picture there. And I think the key thing is we've been able to put his email and his phone number. Now, it's not his mobile phone, but it is a place where you can get in touch with him, it's the department's phone number in most cases, but again, it's that connection. I really want to know more about this. Could I maybe contact the researcher and maybe he could speak to my group about this particular research? So they were open to this and we decided we would add the email and an appropriate phone number. So I just have a few more slides here. And if you want to search by researcher, this site is in beta test, so we have yet a lot of things to do, we have other—about half of them, videos to add to this. We're going through clearance at the moment. We're going to add CVs for the researchers. We're going to be able to search by university because somebody asked us that when we asked them to look at our site. So it's a site in progress, but I think we're on the right track here. So if you type in—you only want to know, let's say, Adriana Feder's research, it comes up with her research studies and where she is and

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how she can be reached. But we're going to put in, I think, CVs here because they provided them already. It's no reason why we wouldn't put them up.

So all this is good, but how do we know—how do we measure all this? I mean, we're doing so much social. How do we measure social? We go back and, again, you know, all of the 56 and also the Registry studies are on this site. And the way we're doing this is something called Altmetrics. And the first time I heard about Altmetrics was from the National Science Foundation, when they were requiring PIs to come in with an Altmetrics score. I didn't even know what that was, and that was just really based on how social what you're doing is, you know, in terms of you're asking us for money and how much are you connected in a social way? And I thought, gee, this is interesting, we need to explore this for NIOSH. So there's an organization called Altmetric.com, and we have a small contract with them, and what they're doing is—let's go back to Bergman's study—is they're putting that little donut up in the right-hand corner, and that tells us, by merely looking at it, what the reach of this particular—the social reach is of this particular site. And the colors each mean—the color blue is Twitter, the color red is I think newspaper articles, and yellow is blogs. So we know by looking at it that this has some extensive Twitter engagement and maybe that's created by us, maybe that's created by the university, but we would be able to see how social they are by looking at that score. If you have a score over 20, you're really in the top 95% of what is social on social media. And this is the way it's scored, I'm not going to go into this, but you can score it with—the publishers actually score this, so it's not like we are scoring it and there might be some changes. This is the way it's scored when the document is published, and Altmetric is going to check this for us, so we know the scores are correct. There's one study that we had, it was the cancer study from the fire department that got a score of 900, but it was all red, the circle was all red, meaning we got tremendous newspaper coverage across the country for the study, but we didn't get much social connected to that study. So this is DSR, this is one of our divisions, I just said, "Well, I'll pull up some of the research and see what it looks like," and each one of those, when I look at it, tells me a little bit about the social engagement plus the numbers, but these are real research projects that our Division of Safety Research has, and we'll eventually be able to do this with all of our World Trade Center, so you can pull them all up—I think this will be a good way to talk about social and it also gives us a way that—what we need to do in terms of our blogging and how do we make it more social and more out there?

Just a last slide to talk about—and Kim reminds me of this all the time and it's really important because the problem is, you know, a lot of the research is behind a paywall. That's when people want to go and they want to see the complete study, you know, they want the complete study, they don't want the abstract, they have to pay for it. If it's Elsevier, you have to pay \$40. You know, if you're a library,

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you may wind up paying \$500 for a subscription for the journal. So with the law, I guess the assumption here, which is unreadable, I think, is the copyright provisions for the government is you have to do this. You're using public money; it has to be publicly available, the whole study has to be. Within a year, it has to be publicly available. And we're going to assure that that happens, so people will be able to go to the website and really get the complete study on the website. We haven't had any problem with that, but we have to pay for it, but we can put those issues in the grants that we do allow, but we've got to check and make sure it's being done.

So my questions for you, please—I will send you or have Paul send you the link, and if you would look at this—realize it is a beta test—what do you think's missing? What's confusing? Are there content gaps? What's working maybe that you actually like? We've been getting some very good replies about what we need to use as keywords, so people, what they call—what we think might be respiratory, really people are looking for dust research. So please take a look, and you can send it directly to me or back to Paul, and we'll certainly take a look at that during this test period. Please follow us on Twitter. Be one of the 350,000 people who follow us on Twitter. Thank you.

DR. WARD: Thank you. Are there any questions for Max or Dori?

PARTICIPANT: Yes, I do. Both of your presentations were wonderful, I want to say. Thank you very much. So I have a couple questions. One was about the donut, like, it seems like it gives the same weighting to a personal. private Facebook post as maybe an acknowledgment in the New York Times, which might have an afterlife. So since you're into metrics and weight and scales, I just wanted to know how you're going to address that. But I still have another question after that.

DR. LUM: If you get something in the New York Times, that's the highest score you can get, okay, or the Wall Street Journal, that's eight points. We didn't make this—and we're going to discuss this with Altmetric.com, but we didn't make this theory, see. If you do a Facebook post, you get a quarter of a point, that's all you get. But why don't I see any quarters on the donut? I don't see any 4.3s or—the reason is they move it to the nearest one, okay? So essentially you get one, and you can't get one for 15 Facebooks, but if somebody retweets it, you'll get another.

MS. HUGHES: Okay, thank you for the clarification, okay.

DR. LUM: Yes, and the measurements are still—to me, I think Wikipedia ought to be more than three points, frankly.

MS. HUGHES: Okay, again, it depends on the individual or the Facebook, you know? So my other question was on page two. Community boards, I don't want you to forget about community boards, having been on the chair of the community board for the last 4 years, and vice chair for 6 years, and on the community board for almost 20 years. The good old-fashioned approach of talking to people in a public setting where the local press is there a couple times a year is really important. And I don't

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want you all to forget about it because the survivor group and the responder group, those are closed-door meetings, and it's amazing how you think people have heard some of these topics a hundred times, and they still don't know all the resources that are available to them. So I don't want you to give up on public meetings such as a community board where the press might be there as well.

DR. LUM: Well, that comes from you talking to me at the NYCOSH meeting and mentioning that we did not mention it at the NYCOSH meeting, so I think your point's well taken.

MS. HUGHES: Okay, thanks.

DR. BOWLER: I have a question, please.

DR. MIDDENDORF: Yes.

DR. WARD: Okay.

DR. BOWLER: Actually, probably that's for Paul. We have had these wonderful meeting bound booklets for every one of the meetings before, and I wonder, are you planning, like, this last wonderful slide show and the others, to produce one of those meeting programs so we have that as well, or is that not planned?

DR. MIDDENDORF: Yes, we do have the booklets here and we can mail one out to you.

DR. BOWLER: Oh, please, that would be very helpful. Thank you. And thank you, Dr. Lum.

DR. WARD: Micki then Lila.

DR. BOWLER: It's fascinating. There's lots of good research material to look into.

MS. HUGHES: So Max—

DR. LUM: Yes.

DR. BOWLER: Maybe if I may ask one other question. The survivor group, I gather there's nothing for the tower survivors, as such. Is there or is the survivor group the tower survivors?

DR. REISSMAN: Hi, this is Dori. If you're asking whether or not the survivor group means only the tower survivors, no, it does not. The survivor group was defined in the Zadroga Act as people who were in the wrong place at the wrong time or lived in an area that was defined within the act. I can't, off the top of my head, really redefine that for you out loud, but it would be people who worked locally, who went to school locally, who happened to be passersby in the area where it was defined as an exposure zone.

DR. BOWLER: Thank you. So there's nothing for the tower survivors, as such, that you know of?

DR. REISSMAN: The people who escaped from the towers would be considered survivors.

DR. BOWLER: Yes, yes, they are in that group.

DR. REISSMAN: So they are a sub-part of the total survivor group.

DR. BOWLER: Thank you.

DR. WARD: Micki?

MS. SIEGEL DE HERNÁNDEZ: So Max, I like the way that you're looking at lots of different ways to get the research information out there and I find the metrics kind of interesting. You know, I'm always also thinking about the utility and who's using the information,

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and so there's the scientific community and how that might reach the scientific community and how that might be used. But also I'm wondering, for the people who are actually sick, right, so for responders and the survivors, what ways that you've thought about or will be thinking about in the future to make sure that that information is actually usable for them. It's one thing to see how many hits you might get on a particular site, but what does that mean for a person? You know, people respond to newspaper articles and we get questions all the time about, well, what does that mean? And I'm not really sure how you can separate that out when you're looking at these kind of numbers, but...

DR. LUM:

No, yes, actually you can separate it, but I think it's an important question because, like, let's just take Wikipedia. I'm assuming that the huge amount we get, the 3,000 that came in 60 days to that site, you know, you could take a sample of that and you could go back out, if that isn't too intrusive—I don't know if that's intrusive. We're really going to have to think about that and say, "Look, we noticed you came on the site, you looked at this. Would you answer these three questions? You know, was it helpful for your medical condition? Was it helpful for information?" I don't know of another way—we haven't done that and I think I'm a little bit concerned about doing it, but I think at some point we really do have to get down—maybe we do that at a meeting or something, some kind of community meeting, we just get 9 people together, 20 people together, and just talk about it. We'd really be open to some ideas on that, but I think we can go out and ask people what they did with the information. Was it just general or medical? Maybe that's—I don't know, is that too intrusive? I don't know. That's really your call.

DR. WARD:

Lila?

DR. BOWLER:

I just have a comment to that. Along that line, for those of us who are not—those of us researchers who have not had funding as of yet, to try to get funding is not an easy thing. When I tried—I'm particularly interested in the tower survivors after having worked in the past with the police responders, but the tower survivors, there were 1,700 in the wave three, and there's no organization, and then I also—and I looked into who the employers were of the various levels of the towers, and I was informed that I could not contact any of these employers because it might potentially identify a participant in the WTC Health Registry, and that really cuts out a huge amount of potential funding of some very good work that could be done. So that's, you know, one concern. I think the tower survivors, as such, are, you know, to me, a fascinating group and I'll be planning on sending in a revised proposal, but no one has written very much about them. So it's one concern I have, because certainly when we look at future terrorist attacks, there will be other buildings where non-responders will be impacted as much as the tower survivors. It's very clear to anyone, having gone down the stairs, that was tremendously—and then having people dying right and left on the various floors must have been hugely traumatizing, and yet nothing much has been done for them. So I tend to

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- work in that area.
- DR. WARD: Thanks, Rosemarie. Lila?
- MS. NORDSTROM: Oh, did you need to respond to that?
- DR. REISSMAN: I just wanted to say, in brief response to that statement, the Injury Center at the CDC had funded research on the evacuation from the towers, and there was some extensive funding that had been done at the time. I don't know exactly what got published offhand, but the researchers were located at Columbia University, if that's helpful.
- DR. LUM: Dr. Gershon, Robyn Gershon did that.
- DR. BOWLER: Yes, Robyn Gershon has published, but that was just on the evacuation methods, but nothing in terms of long term mental health effects or cognitive effects, nothing.
- DR. WARD: Okay, Lila?
- MS. NORDSTROM: I had a question going back to the social outreach that we were talking about before. It's sort of connected to Micki's question because I had initially sort of wanted to ask who, besides the medical community, you envision using this research and how? But I also thought, in the event that you find that this research is of interest to people outside of the medical community who were maybe impacted by the events, do you have the ability to use this site to also help connect them to other resources? Is that allowed? Are you able, if you do find that through this kind of social outreach, which oftentimes—I mean, you know, that's certainly how my group interacts, that's how a lot of younger survivors interact. Do you foresee the ability to help connect them to the World Trade Center Health Program site or some of the other social media accounts associated with this work that provide resources and things like that?
- DR. LUM: Yes, that's what it's all about, I mean, that's what social media is all about, is the linking of those things. I'm thinking the people that—just off the top of my head, the people coming to Wikipedia probably aren't scientists, maybe 20% are, but let's say they're not. They're trying to look for information, they have a hotlink of whatever we put up, there may be three hotlinks, if you're interested in monitoring and medical implication here—if you're interested in another group, there's a resource section. You know, the hotlinks are very important. They'll be on the World Trade Center site, not on the NIOSH site, because this is easier to control it, but then we have to know who else is—in fact, I asked someone, I think, about what their social media is at their university, you know, Marc, I guess it was, I asked, "What do you do when you have a research—what do you do socially?" Because we should be linked because that's where—but I think we might be a little bit away from that point because we don't even know what those connections are right now.
- MS. NORDSTROM: Sure, thank you.
- DR. REISSMAN: Actually, I'd like to follow that up, Lila. If there are concrete suggestions about

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- what people would—how they should link up, that's a way for us to actually explore feasibility and, you know, restrictions we might have as a federal government, but it's fascinating and we don't know how to play in this arena yet.
- MS. NORDSTROM: Yes, and I think that's something that—I mean, my group specifically is very social media based. We do a lot of outreach that way, but I think that's something that certainly we could be in continuing touch about because, you know, we've spoken about web accessibility and things like that with other sort of elements of the Program in the past. It's, I think, worked out really well.
- DR. LUM: And we get a point, right?
- MS. NORDSTROM: Right.
- DR. LUM: We get all that. Yes.
- MS. SIEGEL DE HERNÁNDEZ: So I really want to applaud your efforts in doing this outreach. I think it speaks to the whole issue of transparency, you know, in general because I don't think there's any other agency that does this or a government agency that puts out as much as you're trying to put out now. And it also speaks to the issue of access, which everybody should be able to access some of these research papers. But the one question I have is, in terms of looking at the navigation tools on that website, will you be able to post how researchers can access the data centers? Because that's very critical in terms of being able to get that information from the data centers, so that they could then begin to think about the various research proposals that can come out of that because, you know, it expands the pool, I guess, of researchers if you give them that opportunity.
- DR. LUM: In other words, make linkages to the data center and the reason we would do that is?
- MS. SIEGEL DE HERNÁNDEZ: Well, how do they go about getting—you know, if I want to study the women EMS workers, you know, how do I go about getting that information as a researcher, you know, to facilitate it?
- DR. LUM: I think that's a really interesting thought. I wish I'd thought about it, actually, before you mentioned it, but I think that's really important. That would be, I would say, on the front page you would have, you know, "how to collect data" or "are you interested in—" You know, that would be—but there's no reason why we can't populate something that makes sense there, but I think I like that idea, actually.
- MS. SIEGEL DE HERNÁNDEZ: Then the other question I have—Dori, you mentioned three data centers. I'm only familiar with the fire department and the one that Mt. Sinai handles. Who handles the survivor data center?
- DR. REISSMAN: The city also has...
- DR. LUM: HHC.
- MS. SIEGEL DE HERNÁNDEZ: Oh.
- DR. MIDDENDORF: Can you use the microphone?
- DR. REISSMAN: Thank you. New York City Health and Hospitals has the data center, although, remember that that is primarily a treatment program, so the information that might

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be in that data center is not as robust as the information that would've been available through the responder program that was monitoring regardless of whether conditions were found or not.

DR. WARD:

Mridu?

DR. GULATI:

In terms of the social media, I was curious, currently are you—because you oversee such a—are connected with such a large program, are there any efforts to kind of coordinate with some of the other centers that are involved, specific centers and their social media pages as well? And then I guess I'm wondering, for each of these currently, are you trying to cater each one of the different social media websites to a particular audience? Because that's a lot of work, it sounds like a lot of work, which might involve some coordination with some of the centers that may actually already be up and running.

DR. LUM:

That's a perfect question. That's what I asked Steve at the break, I said, "What are you doing with your research from your center or from your university? How do you—if you somebody publishes something, how do you—do you have a communication person? Do you put it on your Twitter site?" We don't know that. We are going to find it out, but we don't know exactly, although now I know what Steve's center does. But basically we want to link, you know, because he has a target audience, for instance, he's put videos up on a publisher's website about the WTC information that he, you know, has published, but he has videos on the publisher's—we should be linking. You know, but that's clinical, you know, and I think we're allowing—once we understand what the group's link outreach is, then we know what that group's focus—like, I know what your outreach would be and we would be able to categorize it, I hope, I think.

DR. WARD:

Catherine, then Micki then—yes.

MS. HUGHES:

Again, I have two more questions. The first one is do you ever find anyone editing the Wiki page with inaccurate information once you've posted it?

DR. LUM:

Geez, I thought I could get away without that question. In the old days—I don't know about you, but when I heard about Wikipedia, I thought it was the dumbest idea I ever heard of in my life, you know, because every crackpot nutcase is going to put something on there. And maybe that was true in the early years, but there's so many controls now that, if we do a page, okay, if we edit a page and somebody comes on that page and changes something, we know it in an email, "This page has been changed." We have to monitor it. We go in and we look, and usually it's helpful. You know, it might be another resource that somebody's added. They usually don't mess up the site. But I created a site called "rollover protection" site, it was for tractors, the first one I ever did, it took me days to do it on Wikipedia, and somebody came in there—and it was ROPS, rollover protection safety, but I had ROPS as the title, and somebody came on that site and put a whole paragraph on the Belgian painter, Félicien Rops. You know, I mean, because they weren't thinking, I guess, and so I just simply moved it to another page and put a

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- link there. That's the kind of stupid stuff that happens, not somebody using bad language. I mean, our research is not open to the things that you would find on a political or something or, like, you know, maybe climate change. I wouldn't want to monitor that site.
- MS. HUGHES: Okay, that's good to know. And then my second was in terms of the modules, are you going also down, like, the medical degree? Because sometimes the most important person that you might actually see might be the nurse or the x-ray, because I just remember when I had pneumonia, it was the x-ray technician that found it, you know, so I just want to make sure that other parts of that network aren't being forgotten about.
- DR. LUM: Actually it was for medicine and nurses, the original one, then CE and CME, for the original piece we did. And we're migrating all that to CDC's site because we want to take control over it, and so we then looked at pharmacists and some of these other areas, so that gets to your question. We'll see what we have to do to—every September, we'll make a major push on this particular CME activity, CE activity.
- DR. WARD: Steve?
- DR. MARKOWITZ: So I have a question for Dori, actually. So on your expanded agenda, I noticed one of the things is the question of premature aging, and so at the American Journal of Industrial Medicine, we got a manuscript about this and it struck me as a very emotive term, premature aging, and it's a little—and potentially alarmist. So I was a little surprised to see it on the expanded agenda, so what are we talking about? For instance, if a person—if PTSD is a known effect of 9/11 and there are cognitive dimensions to PTSD, and there may be some overlap with some of the cognitive impairment that some people get as they age, I wouldn't consider that premature aging; I would consider that a cognitive component to PTSD. So what is circulating? What's meant by that?
- DR. REISSMAN: There's been some preliminary findings by the Stony Brook group who is a Clinical Center of Excellence, and they've been funded by the National Institutes of Health and the Institute of Aging, and been working on grip strength, cognitive, ability to do some of the other physical tasks like getting up, core strength, getting up, sitting down kind of things, easy tests that are tests that have to do with overall conditioning and things that change with aging. So one can ask, is it deconditioning, is it aging? You know, you can parse that, but I believe the reason that the NIA was interested in funding that was because it had important potential implications for how primary care is delivered, things to be looking for, and things like that. I certainly didn't intend to be alarmist by using a provocative term and I appreciate you actually pointing that out.
- DR. BOWLER: I have a comment to make about this. I became very interested in there were three questions of the Registry, we asked people if, in the last seven days, they had concentration problems or memory problems, and at the last meeting I know I

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commented on people who reported that, it was at that time stated they had cognitive impairment, and that's really not at all possible to state if just someone thinks they have concentration and memory problems, that they have indeed cognitive impairment. And I followed this up by looking into validation of self-reports, and in fact I have a paper that is just now in the last stage of clearance at the EPA that I did because I had several towns in Ohio where I had both these kinds of questionnaire items, concentration—concentration and memory problems. Most of us ask those questions. And then I also had already a neuropsychological screening battery, and just like the literature shows, there's hardly any correlation between self-report of having concentration and memory problems, and that is what I was able to repeat in our Ohio data. It's much more related to depression, to anxiety. It doesn't actually mean they have it, so that's an interesting byline to PTSD, and in fact PTSD, in the DSM-5, they added on cognitive issues. But we have to be, particularly as physicians—and that's why I was encouraged to publish this work—we have to be aware it doesn't really mean they indeed will score and have these problems, so it's good to be aware of that and more work certainly should come of it.

DR. WARD: Thank you. We're actually coming to when we need to break, and I know Dori and Max have to leave, so if we could get the last two comments from Micki and Lila, I think then we'll have to move on to the next part of the agenda.

MS. SIEGEL DE HERNÁNDEZ: I just had something for you to put on your to-do list, Max, as you move forward with this and think about linkages both to other resources, but also as a way to further the outreach efforts, so keep the unions on your list, besides the Programs that NIOSH funds for outreach, those particularly in the responder program and also a percentage of the survivor program, those are our members. And so I think there's more to discuss, not here, but more to discuss at a future date.

DR. LUM: All right. Can I call you—

MS. SIEGEL DE HERNÁNDEZ: Absolutely.

DR. LUM: The specific...

DR. WARD: Lila?

MS. NORDSTROM: I think my question can be held off for another conversation.

DR. LUM: It's nice to meet you, Lila, after all this.

MS. NORDSTROM: Nice to meet you, I know I—

DR. LUM: You're a fellow traveler—

MS. NORDSTROM: Yes, exactly.

DR. LUM: So I didn't know you would be—thanks for all your...

MS. NORDSTROM: You're welcome.

DR. REISSMAN: (Inaudible @ 01:16:06).

DR. WARD: Yes, of course.

DR. REISSMAN: I just want to respond to Dr. Bowler's comment because there is actually, there

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are some studies that we're currently funding that have to do with cognitive decline where I don't know whether or not specifically they're going to tease apart the relationship of confounding effect modification or risk factor attributes to cognitive decline versus mental health issues, whether they be depression, PTSD, or whether or not there's neurological issues that might be going on and interfering. But there have been clinical observations made by the clinicians within our Clinical Centers of Excellence that cognitive decline seems to be a little bit more prevalent than they expected, and as a result of that, it generated our interest in funding that kind of research.

DR. BOWLER: Which group is doing that and has anything been published on it?

DR. REISSMAN: Offhand, I can't remember who got funded. I have a feeling it's Mt. Sinai, but I don't quite recall.

DR. BOWLER: Thank you for the comment.

DR. WARD: Yes, and thank you, Dori and Max, it was really helpful to have your presentations. And we'll take a break now for... Come back at 2:45. Thank you.

[Break]

STAC DELIBERATIONS AND DEVELOPMENT OF RECOMMENDATIONS

DR. WARD: We're ready to begin. We need to go over all the recommendations that we'd like to make. Paul has very kindly put them together in a Word document so that we can go through them. We also had a suggestion that rather than trying to condense the recommendations of the workgroups into a shorter form, we just go with the way they're written up now so we don't have to do wordsmithing, reduce the numbers of words, and those will be the final—the finals of those will be the recommendations that we put forward with conceivably some additional recommendations. So the first thing Paul has up on the screen is the recommendations that we agreed to at the last meeting. So we thought it would be important to review those as the background for our discussions today. So we can read through—I'll read through them. First recommendation was, "The peer review and public comment should be sequential so the public commenters have access to the peer review comments." Number two, "For any condition for which the administrator determines there is modest or substantial support for adding it as a WTC covered condition, the administrator should secure external peer review of the determination." Recommendation three, "Any written peer review should be made public whether or not the administrator determines to propose rulemaking." Recommendation four, "To the extent feasible the administrator and peer reviewers should consider scientific evidence beyond 9/11 studies including epidemiologic, toxicologic, and mechanistic studies when relevant." Recommendation five, "The administrator should develop and implement a process to solicit from the public recommendations of scientific experts to perform peer review." So essentially what the workgroups are coming forth with is an elaboration and

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more detail on the specific recommendations. And as we go through and discuss the recommendations we do have the option to go back—as we discuss our recommendations from today we do have the option to go back and say, well, this kind of overrides a previous recommendation or not depending on what we'd like to do. This is one recommendation, number four, that kind of overlaps with the text that's in our new recommendation. So we can either decide we'd like to strike number four and just keep the new recommendation or leave them both in and let the administrator decide. Yes, Steve?

DR. MARKOWITZ: Steve Markowitz. I just want to make a comment about that. At the June meeting we passed these recommendations. I don't know whether we actually delivered them to NIOSH or not, but as we go along in future meetings we will make recommendations. I'm a little concerned about meeting six months after we passed a series of recommendations and refiguring those recommendations. I can understand a little nuance explanation, but I can't understand—I'm not saying you're proposing this, but to revisit them with the idea of significantly amending them leaves us open to a kind of unwieldy process in the future where we make a recommendation how long is it going to be good for? Until the next meeting when we reconsider it. So some clarity around that.

DR. WARD: That's a good point from my perspective. I mean, I think we pass these recommendations and we had even a different group of people at the table voting for them. I think we can, you know, easily let them stand and then, in many ways, our newer recommendations just clarify them and the administrator can take that into account. I think that's a good point. Okay, then, so we can move on and discuss the recommendations we talked about today. I will say as we go through I think for the most part what we have written is really we tried to reflect the consensus of the group in making modifications as well as clarifying. There's still the one point where we don't have consensus as a group. So we will have the opportunity to think about that as we go through it. But I think everything else, you know, there was really no significant disagreement. So we'll just go through them one by one. And we have one additional one that we wrote up based on the discussion. So if we want to read through them it might be good if somebody who can see them—can you see it well enough to read it?

DR. MIDDENDORF: If I sit here. "A pool of peer reviewers should be formed by NIOSH that can be drawn upon when a petition is received. Peer reviewers should be individuals with background and experience in relevant occupational and environment research and/or clinical practice; this includes epidemiology, mental health, toxicology, and occupational and environmental medicine. These individuals should demonstrate publications in areas relevant to World Trade Center health effects and hazards, and other disasters. In forming this pool, we advise that no exclusionary criteria be applied."

DR. WARD: I'm sorry I didn't see this earlier, but we need to change the language again so

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- that we don't say "drawn upon when a petition is received." It should be "drawn upon when a peer review is required." So with that amendment is everybody comfortable with that?
- PARTICIPANT: Yes.
- DR. MARKOWITZ: This one dovetails with recommendation five. I guess my question is should we add the recommendation five here and say that there should be public input into the solicitation—into the recommendations of scientific experts or do we just let five stand, is the question.
- DR. WARD: Well, that is a good question. So we're really making two separate sets of recommendations. Do we need to repeat that, Paul, do you think?
- DR. MIDDENDORF: I think they can stand alone. One is about soliciting public input and the other is about qualifications.
- DR. MARKOWITZ: Okay. So we can leave it there.
- DR. WARD: Yes. So shall we vote on these as a whole or do we need to vote on them individually?
- DR. MIDDENDORF: No, we'll vote on them individually.
- DR. MAYER: This is Annyce. One other question. In addition to relevant—areas relevant, would that include other relevant exposures?
- DR. MIDDENDORF: I'm sorry, Annyce, I'm going to put the microphone over so everyone can hear your question.
- DR. MAYER: My question was in addition to areas relevant to World Trade Center health effects and hazards, if that would include other relevant exposures.
- DR. WARD: Well, the phrasing now is in "other disasters." We could either replace "disasters" with "other relevant exposures" which is a bit broader than "other disasters."
- DR. MAYER: Yes.
- DR. WARD: That might be better.
- DR. MIDDENDORF: Just for the record Annyce agreed with that.
- DR. WARD: Okay. So, Paul, do you want to make that...
- DR. MIDDENDORF: Give me the wording you want.
- DR. WARD: Strike "disasters" and make it "other relevant exposures." So is everyone—any further comments on that paragraph?
- MS. MEJIA: I don't know. I like the word "disaster," but it could be manmade or natural disasters.
- DR. WARD: We could just put—we could keep disasters in—comma "disasters and other relevant exposures." That would be one.
- PARTICIPANT: I think you should probably include "other relevant exposures" also because it may not occur in the—a disaster.
- DR. WARD: Include both. Yes.
- DR. MIDDENDORF: (Inaudible @ 00:09:48) disasters and...
- DR. WARD: Yes, I think that captures that.
- DR. MIDDENDORF: Yes. Any other discussion?

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- MS. MEJIA: One of clarification. So we're just looking at this one paragraph. We're not looking at the conflict of interest or the other two paragraphs?
- DR. MIDDENDORF: No, just this paragraph.
- MS. MEJIA: I just want to be clear. Okay.
- DR. MIDDENDORF: Yes, we're going to do these individually.
- MS. MEJIA: Thank you.
- PARTICIPANT: I think we accept this recommendation.
- DR. MIDDENDORF: Okay. Let me read it again. Okay, we had a motion?
- DR. MARKOWITZ: Yes. I second.
- DR. MIDDENDORF: And a second from Steven Markowitz. What we're voting on is: "A pool of peer reviewers should be formed by NIOSH that can be drawn upon when a peer review is required. Peer reviewers should be individuals with background and experience in relevant occupational and environmental research and/or clinical practice; this includes epidemiology, mental health, toxicology, and occupational and environmental medicine. These individuals should demonstrate publications in areas relevant to World Trade Center health effects and hazards, disasters, and other relevant exposures. In forming this pool, we advise that no exclusionary criteria be applied."
- PARTICIPANT: I'm sorry, I just thought of something as a friendly amendment, that some wording to the effect that the pool should also be dynamic in that it's not just a set pool that NIOSH—you know there aren't ten people and that's it for the pool, but it can be added to as time goes on.
- DR. WARD: So maybe the wording, if everyone agrees...
- PARTICIPANT: I have just a clarification question of my understanding. I thought there were just going to be three peer reviewers selected. Is that the...
- DR. WARD: So I think the concept of this is that there be a solicitation, an open solicitation for people to volunteer for being peer reviewers. So there might be a pool of 20 to 30 to even 50 people who say, "I'm willing to serve a peer reviewer," and in a diverse area of expertise and then when NIOSH comes to the point where they have a petition and they decide to move forward with a rulemaking they search, essentially, that database of volunteers to identify—who will have already been somewhat vetted and whose expertise they're already aware of in order to identify the peer reviewers for a specific condition. And the idea for that would be that they don't have to start from scratch. They have a group of people who've already said they're interested and then have documented their expertise in particular areas. And I think the idea of it being dynamic is very good. We had talked about reconfirming with people on a yearly or every other year basis if they were willing to continue, but certainly there could be a periodic solicitation for new volunteers so that the list can be continually refreshed.
- PARTICIPANT:** What I was thinking was that as new conditions may be explored. for example, this issue about aging. That pool may not include a relevant expert or a condition

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that might be considered in the future so there has to be the ability to add to that group.

DR. WARD: Yes. And I think the other point, which I think is understood, but maybe it should be more explicit is, it's not like we're saying NIOSH has to be restricted only to this group. If something comes up that there's no expertise in the group you go outside, but it's really a matter of feasibility by identifying people easily during the time period that they have, and so it's not restrictive.

PARTICIPANT: If we could be a little more explicit about what you just said I think that would be good because I wasn't sure whether that was what was meant or not because we had talked about it, but I wasn't quite reading it into the words that we had.

MS. HUGHES: Catherine Here. Maybe at the top of the page you put that one sentence in describing what you just said, Liz.

DR. WARD: Maybe the second sentence of the paragraph could read something like "This could be done by an open solicitation in which individuals could nominate themselves or be nominated as peer reviewers." Maybe. Period. Because we don't need to get too much into the mechanics. Comma, "a process which could be repeated annually" or "biannually to allow as needed."

PARTICIPANT: I like the word "dynamic" although maybe it's—"is to create a dynamic pool of peer reviewers should be formed and maintained."

DR. WARD: Right. That's good.

DR. MIDDENDORF: What do you mean by "dynamic?" You can read several ways "dynamic."

DR. WARD: I know.

DR. MIDDENDORF: Lively.

PARTICIPANT: (Inaudible @ 00:15:55).

DR. WARD: I have to play an instrument.

PARTICIPANT: I don't know the meaning of this.

PARTICIPANT: All right. It's just, it's a nice word.

DR. WARD: I think the wording captures that.

PARTICIPANT: Will you use it in the future recommendations?

DR. WARD: And then we could include a sentence just to be clear, you know, that NIOSH would not be restricted to these individuals. I mean, other individuals could be selected as peer reviewers if expertise—if NIOSH determines that the expertise is not available within the pool. So other persons could be chosen as peer reviewers based on similar—based on their expertise if appropriate reviewers are not found within the pool. Okay, so does that capture everything that everyone wanted to add?

PARTICIPANT: I'll accept that amendment.

PARTICIPANT: Good.

PARTICIPANT: I second the acceptance.

DR. MIDDENDORF: Please use the microphone.

PARTICIPANT: I'll accept that amendment.

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PARTICIPANT: I second that.

DR. MIDDENDORF: Okay. So the proposal at this point is, "A pool of peer reviewers should be formed by NIOSH that can be drawn upon when a peer review is required. This could be done by an open solicitation by which persons could be nominated, a process that could be repeated periodically. Peer reviewers should be individuals with background and experience in relevant occupational and environment research and/or clinical practice; this includes epidemiology, mental health, toxicology, and occupational and environmental medicine. These individuals should demonstrate publications in areas relevant to World Trade Center health effects and hazards, disasters, and other relevant exposures. In forming this pool, we advise that no exclusionary criteria be applied. Other persons could be chosen as peer reviewers based on their expertise if appropriate peer reviewers are not found in the pool."

DR. WARD: So my only question is we need to say that they could nominate themselves because right now it says "by which persons could be nominated," which implies that someone else might nominate you. Do we need to add the clarification "or nominate themselves" or is that...

DR. MIDDENDORF: I think if you leave it the way it is then self-nominations are acceptable.

DR. WARD: Okay, that's fine then. Okay. So I think we're ready for a vote.

DR. MIDDENDORF: Okay. We'll do a roll call vote.

DR. ROM: Can we do a voice vote; everybody in favor?

DR. MIDDENDORF: No, I need to have it in the record. Rosemarie, yay or nay? Rosemarie, are you on? Okay, I'm not hearing anything from Rosemarie. Mridu?

DR. GULATI: Yes.

DR. BOWLER: Yes, I'm voting to approve.

DR. MIDDENDORF: Okay. Thank you, Rosemarie. That was a yes.

DR. BOWLER: Thank you.

DR. MIDDENDORF: Catherine?

MS. HUGHES: Yes.

DR. MIDDENDORF: Val?

MS. JONES: Yes.

DR. MIDDENDORF: Steven?

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce?

DR. MAYER: Yes.

DR. MIDDENDORF: That was a yes. Mike?

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille?

MS. MEJIA: Yes.

DR. MIDDENDORF: Lila?

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill?

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DR. ROM: Yes.

DR. MIDDENDORF: Megan?

DR. RYAN: Yes.

DR. MIDDENDORF: Micki?

MS. SIEGEL DE HERNÁNDEZ: Yes.

DR. MIDDENDORF: Glenn?

DR. TALASKA: Yes.

DR. MIDDENDORF: Liz?

DR. WARD: Yes.

DR. MIDDENDORF: Marc?

DR. WILKENFELD: Yes.

DR. MIDDENDORF: Okay. It's 15 yeses, 0 nos. Okay. So the motion passes.

DR. WARD: So our next one which we may want to think about changing the title for if we use the titles because it really goes beyond conflict of interest and confidentiality, but this is the one where we really have a split view. And so what Paul suggested is we—essentially we have it written so that it can either say “with attribution of specific comments to specific reviewers” or “without attribution of specific comments to specific reviewers.” Our suggestion is we vote on one, and then if that vote doesn't pass we vote on the other one. So, but first we should look at the specific language which has not changed very much.

PARTICIPANT: If I could, I suggest that a change to it where we—I think we all agreed on...

DR. WARD: You have to look at the one of the screen, not the one in the book because some of it we've edited a little bit.

DR. MAYER: This is Annyce, and I apologize if this was said and I didn't hear it. Did we say how many people are going to be on a given review panel?

DR. MIDDENDORF: Yes. Annyce, would you mind repeating that, please?

DR. MAYER: Was it said how many people would be on a given review panel?

DR. MIDDENDORF: What is in the current policy and procedures is three.

DR. MAYER: Three.

MS. HUGHES: Did you want to add three? Because people may not go back to that tome of rules and regulations or that could change.

DR. WARD: I don't think so, because I don't know that the STAC would agree. I mean, I don't know that we—the recommendation of three is not coming from us. It was something that NIOSH—was in the NIOSH—it's in the policy and procedures.

DR. MIDDENDORF: It's in the policy and procedures. Less than three.

DR. MARKOWITZ: Of the three that we...

DR. WARD: Oh okay, Steve?

DR. MARKOWITZ: So I think in line three where it says, “The identity of the reviewers...,” I think it was the sense that we would add after “reviewers,” “...and their areas of expertise.”

DR. MAYER: Yes. Definitely.

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DR. MARKOWITZ: And then the other piece was in the next line, the next line it says the words “summary of the peer...”

DR. WARD: No, they took that out.

DR. MARKOWITZ: It’s been removed. It says, “...with review comments.” I think that should say “written review comments.”

PARTICIPANT: Agreed.

DR. WARD: Okay. Good corrections. Micki?

MS. SIEGEL DE HERNÁNDEZ: And responses, is that referring to NIOSH’s—NIOSH responses? Okay.

DR. WARD: Yes. We can clarify that. So we can take a motion to vote if we’re ready to...

MS. JONES: What do you have? Is it with or without or...

DR. MIDDENDORF: With attribution. With.

DR. WARD: That’s what we’re voting—well, we have to vote on one or the other. You can propose to vote on the “with” and then if that doesn’t get a majority then we’ll vote on the “without.” Micki?

MS. SIEGEL DE HERNÁNDEZ: Just in looking at the construction of the sentence we might want to take the Program’s responses and put it another sentence because that’s always going to be with attribution. Right? That’s always going to be the administrator; will provide responses.

DR. WARD: The second part specifically refers to specific reviewers. So I don’t know if it’s necessary to move it out.

DR. MIDDENDORF: Micki, see how the attribution refers only to (inaudible @ 00:24:53).

MS. SIEGEL DE HERNÁNDEZ: Okay. Yes. Okay. I take that back then.

DR. WARD: Guille?

MS. MEJIA: I’m sorry, I’m a stickler for Robert’s Rules. So somebody has to make a motion to accept our recommendation. So can I make the motion?

DR. WARD: Yes, that would be wonderful.

PARTICIPANT: We can’t.

MS. MEJIA: For recommendation number seven, but with the word “with” on it.

DR. MIDDENDORF: What I would suggest we do is let’s do a quick raise your hand if you want it to say “with.” And that way, then it’ll tell us which one we need to do.

DR. WARD: We can have a straw poll.

DR. MIDDENDORF: Just a straw poll.

DR. WARD: Guille is saying no to the...

MS. MEJIA: No, I’m sorry. If you’re going to follow Robert’s Rules you follow it all the way. You don’t make (inaudible @ 00:25:40).

DR. MIDDENDORF: What we will do then is we will actually make a motion on that.

MS. MEJIA: So the maker of the motion chooses which one it is, and then they could vote yay or nay.

DR. MIDDENDORF: We’re just suggesting a way to save time, that’s all.

PARTICIPANT: I second her motion.

MR. JONES: And that was “with.”

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MS. MEJIA: "With." Now you could have comments.

DR. WARD: Is there further discussion before we take a vote? I think we're ready for a vote.

DR. MIDDENDORF: Okay. The recommendation reads, "NIOSH should develop a transparent, written Conflict of Interest policy for selection of peer reviewers, to ensure that bias can be minimized in the peer review process and the outcomes of the review achieves maximum credibility. The identity of the peer reviewers and their areas of expertise should be made available to the public after the review is completed along with written review comments and the Program's responses with attribution of specific comments to specific reviewers." Okay. So, Rosemarie? Yay or nay?

DR. BOWLER: Yes.

DR. MIDDENDORF: Mridu?

DR. GULATI: Yes.

DR. MIDDENDORF: Catherine?

MS. HUGHES: Yes.

DR. MIDDENDORF: Val?

MS. JONES: No.

DR. MIDDENDORF: Steven?

DR. MARKOWITZ: No.

DR. MIDDENDORF: Annyce?

DR. MAYER: No.

DR. MIDDENDORF: That was a no. Mike?

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille?

MS. MEJIA: No.

DR. MIDDENDORF: Lila?

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill?

DR. ROM: No.

DR. MIDDENDORF: Megan?

DR. RYAN: No.

DR. MIDDENDORF: Micki?

MS. SIEGEL HERNANDEZ: Yes.

DR. MIDDENDORF: Glenn?

DR. TALASKA: No.

DR. MIDDENDORF: Liz?

DR. WARD: Yes.

DR. MIDDENDORF: And Marc?

DR. WILKENFELD: Yes.

DR. MIDDENDORF: Okay, 8 yeses, 7 nos. So the motion passes.

PARTICIPANT: Can we vote on the "without?"

DR. MIDDENDORF: There's no need to. This motion passed.

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- DR. WARD: Well, it's possible somebody might vote differently, but they would have to be very illogical. So we'd have to have a very illogical person there maybe.
- DR. ROM: The vote was rigged.
- DR. WARD: No, I think honestly this is informative. The vote's recorded. I think it's really informative no matter which way it went. I think it's going to be obvious to the administrator that there were mixed feelings about this, and thankfully the administrator was here for most of the discussion on this point. So he has heard the perspectives on both sides and I feel very lucky because we don't often come to a decision that's so difficult and it's nice that he heard the full discussion. So I think this reflects, either way—had it been 7/8 or 8/7—it really reflects the feelings on the committee, and I think it's the important thing. (Inaudible @ 00:28:56).
- DR. MARKOWITZ: I think votes really do matter, especially next Tuesday. I said I think votes really do matter, especially next Tuesday.
- DR TALASKA: I have to agree with that.
- DR. MIDDENDORF: Can we vote on it? There are a few changes we made to it.
- DR. WARD: Right. So should we read through the new ones?
- DR. MIDDENDORF: Yes.
- DR. WARD: I can read it. "The WTC administrator should be responsible for ensuring that the peer review process and reviewers are balanced and expected to give an unbiased scientific review. The selection of the peer reviewers should be made by NIOSH with consideration of the subject matter relevant to the petition. The peer review pool may be useful to NIOSH to identify consultants to assist NIOSH with their initial scientific review of the evidence supporting the addition of a condition. NIOSH may consider, if needed, the retention of an outside contractor (with specific guidelines developed by NIOSH) to select the peer reviewers and coordinate the review." There's one minor editing, it should be "a condition" on the third line from the bottom, not "conditionS." So are there any suggested revisions to that recommendation? Would anyone like to make a motion about the recommendation?
- DR. MAYER: This is Annyce and, again, I apologize if this was said before, but if you could help me understand that last sentence. Could you help me understand an example of when NIOSH might need to consider retention of an outside contractor to do this?
- DR. MIDDENDORF: When there have been particularly contentious policy documents, NIOSH has decided that it would be beneficial to distance itself from the peer review process and has elected to contract with another organization to develop the peer review of it. And NIOSH, obviously in the contract, provides a lot of specifications about how it should be done and what information it needs. That leaves it up to the contractor to actually identify and work with the contractors. It's largely a distancing effort.
- DR. MAYER: Okay. Thank you.
- PARTICIPANT: I move to accept.

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PARTICIPANT: Second.

DR. WARD: Any further discussion? Okay. Ready for vote.

DR. MIDDENDORF: Okay. Since we don't have changes I don't think we need to reread it. Okay, Rosemarie?

DR. BOWLER: Yes.

DR. MIDDENDORF: Mridu?

DR. GULATI: Yes.

DR. MIDDENDORF: Catherine?

MS. HUGHES: Yes.

DR. MIDDENDORF: Val?

MS. JONES: Yes.

DR. MIDDENDORF: Steven?

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce?

DR. MAYER: Yes.

DR. MIDDENDORF: That was a yes. Mike?

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille?

MS. MEJIA: Yes.

DR. MIDDENDORF: Lila?

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill?

DR. ROM: Yes.

DR. MIDDENDORF: Megan?

DR. RYAN: Yes.

DR. MIDDENDORF: That's a yes. Micki?

MS. SIEGEL DE HERNÁNDEZ: Yes.

DR. MIDDENDORF: Glenn?

DR. TALASKA: Yes.

DR. MIDDENDORF: Liz?

DR. WARD: Yes.

DR. MIDDENDORF: Marc?

DR. WILKENFELD: Yes.

DR. MIDDENDORF: Fifteen yeses, zero noes, no abstentions.

DR. WARD: Great. So the next recommendation is the recommendation that Bill made earlier which reads, "The NIOSH science team is recommended to seek input of expert consultants in definition of condition including symptoms, clinical findings, imaging, and laboratory findings that may define a condition. Conditions and/or diseases are complicated and expert consultation can provide insights into whether a condition is present prior to determining whether WTC dust exposure was related to development or exacerbation of a condition." So is there a

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discussion on that recommendation?

PARTICIPANT: I would just drop the word “dust.”

PARTICIPANT: Yes, first thing.

DR. MIDDENDORF: Where is it?

PARTICIPANT: Second line from the bottom, far right; WTC, because there’s a variety of other exposures. So just leave “WTC exposure.”

PARTICIPANT: Generally in the process I assume there’s been expertise in defining the presence or absence of condition. Do you want to specify for when expertise is not present or when it’s a rare condition or when it’s a more complex condition? Because, I mean, sort of differentiating why you actually brought it up now.

DR. WARD: Bill, do you want to respond to that?

DR. ROM: I thought it would be important to define a condition.

PARTICIPANT: But isn’t that—no, no, I know that, but I assume that’s been—the presumption is it’s been happening all along, right? So in terms of why we’re adding this particular thing now, are we talking about experts—you talked about getting expertise with a—specialized expertise that doesn’t already exist within...

DR. ROM: I think the challenge here is as a research scientist to define asthma is not so simple, and we’ve already put asthma in the original Zadroga Bill and the new conditions are diseases we’re going to be asking the administrator to look at or by petition are going to be more complicated, and they need a definition of exactly what everyone’s talking about to make a reasonable ascertainment as to what the condition is.

DR. WARD: Well, I think there’s another piece to it which I kind of understood when Bill was talking, but I don’t think it’s really—it’s not exactly the same as what’s written down. In a lot of cases the petitioner might be saying autoimmune diseases, for example.

PARTICIPANT: No, I understand that.

DR. WARD: Or a specific—no, but I think, to me, that’s the other aspect of this recommendation is that to make it—for the administrator to—there has to be some guidance to the administrator when they define what—how do they take a petition and interpret it. So if somebody’s just asking for rheumatoid arthritis are they specifically looking at—you know, the question is, is do you capture a number of related conditions under a larger subcategory or do you look at specific conditions. And it seems to me that you kind of need expertise in that clinical area to know should this be considered a group of conditions or should we be looking at an individual condition.

PARTICIPANT: I’m not disagreeing with that. I just—

DR. WARD: No, I know...

PARTICIPANT: My assumption was that this was sort of happening and, obviously, happening all along because that should happen for all diseases and so—

DR. WARD: Yes, well, it makes—right.

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PARTICIPANT: Right? I guess I was making that assumption.

DR. WARD: Yes. We're assuming that is changing. Yes.

PARTICIPANT: And the second pieces because you bring it up now, do you want to specify that this is given the nature of the fact that many diseases we're going to be dealing with are complicated. Does that make sense?

DR. WARD: Right. Yes. And I think...

PARTICIPANT: Sort of show the burden a little bit more.

DR. WARD: Yes, yes. Good. Micki?

MS. SIEGEL DE HERNANDEZ: There's some overlap with that paragraph and the one underneath, and so I think that's part of it because I had a similar kind of question. So there might be a way to combine those and to use some of the wording from the paragraph that Bill was suggesting. In the paragraph that we have, number one, that talks about NIOSH should consider creating an ad hoc team or seek outside consultation, and it can list a variety of reasons why including further definition of a condition, or something like that.

DR. WARD: Val?

MS. JONES: Where it says "Conditions and/or diseases are complicated and expert consultation can provide insights into whether a condition is present prior to determining..." I like "insights into the possibility the World Trade Center exposure was related to development or exacerbation." I don't like this—

PARTICIPANT: Well, I think there's a piece to some of these conditions. It's hard to make a diagnosis if a condition exists or not even before you're getting to the exposure, particularly on the autoimmune diseases because they kind of evolve over time. So I do think it's important to kind of define whether or not there is some kind of autoimmune—you know, in particular autoimmune diseases, that there is autoimmune disease.

MS. JONES: I'm going to say I personally I don't like that. I'm just saying me, personally, in terms of—I don't like that in terms of if somebody has a condition I just—this is just me personally, I don't like the wording "is present" as if somebody can definitively say that it was or wasn't for someone. I like the idea, that's just me personally; "insights into whether the World Trade Center exposure is possibly related," that's just me. I just think that's—I think that's fairer to the individual who now is sick and was down at the World Trade Center working or living, whatever. I just think that that's a fairer expression than "is present" because I think that's a lot of times the whole issue, 'was it or wasn't it present prior to the World Trade Center?' And the bottom line is somebody could've had asthma before the World Trade Center and then they work down there and their asthma is a lot worse than it had ever been prior to their exposure down there, maybe before that they used the pump once in, I don't know, once in six months or a year. I've heard patients say that, that have asthma and they use a pump, you know, every six months or, you know, you ask "When's the last time?" "Six months ago." So I'm just saying I

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just think that—I don't like that in terms of consideration for the individual that's sick.

DR. WARD: Guille, Marc, and Steven.

MS. MEJIA: I agree with Val. I think that word "present" I have a problem with. So, but—I just lost my train of thought. But I do have a concern about just using that word "present." Oh, here it is, the other thing is, is that moving forward. I mean, I think one of the things that the clinics have been grappling with is the fact that the population is getting older, and so with age there comes also breakdowns in the body that may not have anything to do the World Trade Center exposure. So I'm wondering whether this doesn't capture that.

DR. WARD: Marc?

DR. WILKENFELD: Yes. I understand what you're saying and I understand what you were saying. I think maybe—yes. I think what Bill was trying to get to—if I understand it clinically—is you want to make sure that the diagnosis is accurate. So it's not a matter of a condition being present, it's a matter of that everyone is agreeing as to what that condition is. So no one's saying they're not sick or no one's saying that they're not sicker. The question is to whether you're dealing with the correct diagnosis and that's why you need expertise. The example of autoimmune disease, what is an autoimmune disease? So if you want to change the wording to "accurate diagnosis" instead of "condition is present."

PARTICIPANT: Yes. I'm sorry, that's actually what I meant as well. Nobody's denying a symptom, it's just you could be short of breath and that could be your heart or your lung. We're just talking about making sure that the diagnosis is accurate.

DR. WARD: Lila?

MS. NORDSTROM: Oh, I feel like—I think that the sentiment that maybe everyone's responding to is the sense that the wording sort of felt like it was creating new criteria. I think that the "accurate diagnosis" thing addresses that, but that's something I think we should be mindful of as we continue to edit this, that it not seem like it's creating new criteria and new obstacles to people who are sort of seeking inclusions and their conditions are getting care to accessing that. So...

PARTICIPANT: So then you could say, "consistent with existing criteria," "existing standard criteria."

MS. NORDSTROM: Yes, something like that would be...

PARTICIPANT: I would agree with that as well. Going back up to the top, I think if we—the NIOSH science team recommend to seek out, the NIOSH science team should seek out. So replace "recommended to" with "should seek out." And then I think in definition of "conditions including..." ...I think I would replace the word "conditions." Insert the word "potentially ambiguous conditions" instead of the wording that we have here. That would ameliorate some of the problems people are having with defining conditions.

DR. WARD: Well, I'm wondering if we would just instead say "proposed WTC related health

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condition,” because it seems to me you need a clear definition. It’s a continuum of ambiguous to clear, and whatever the condition is you need a clear definition. And, again, it should be “NIOSH science team should seek input of experts consulted when needed in definition of a condition as appropriate,” or “when needed” is fine, “in definition of”...

PARTICIPANT: “To define conditions including symptoms,” okay. “To define conditions.”

DR. WARD: Yes, I think I was proposing to add the “a proposed WTC related health condition” in the first part of the sentence rather than later; “in definition of a proposed WTC,” so right after the “of” in the first line. Yes. And then we don’t need the last phrase in the sentence.

DR. BOWLER: Take out the second “condition.”

DR. WARD: Yes, period after “findings.” I’m not sure if the second sentence...

DR. BOWLER: You have to take out one of those “conditions.” There are two now in the second line.

DR. WARD: I think we took it out.

DR. MIDDENDORF: I just did.

DR. BOWLER: Now it’s out.

DR. WARD: Yes, so I’m not sure that—the second sentence I think is a little confusing to me. What is the main point that we’re trying to make?

DR. BOWLER: I would take out the “complicated”; all conditions of. I mean...

DR. WARD: I mean, do we need to elaborate on the first sentence? Okay. So we can just this sentence.

DR. BOWLER: Yes, that’s better.

DR. WARD: And we could add in a comment like “Such clarity will be essential in implementing decisions regarding newly designated conditions.”

PARTICIPANT: You’re going back to oversight now.

DR. WARD: Okay. Well, okay. We don’t have to explain ourselves. Hopefully, it’s obvious.

MS. SIEGEL DE HERNÁNDEZ: Liz?

DR. WARD: Yes?

MS. SIEGEL DE HERNÁNDEZ: Just one comment. I mean, I think the phrase “when needed” is important because this is something that goes on continuously in the Program. It had to be done and by the clinical centers, it had to be done, for example, with sarcoidosis. There wasn’t a clear definition and those parameters had to be figured out and agreed upon across clinical centers. So I think leaving it with that one sentence and that’s when it’s needed for a certain disease that’s fine, but I don’t even think you can say “consistent with current recommendations” because there may be a variety of definitions that are out there.

DR. WARD: Val?

MS. JONES: I’m just curious, when we say “when needed” what does that mean?

DR. WARD: I can give you an example from my field and let others—like within the cancer field there’s some cancer conditions where the classifications are continually changing

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like lymphomas and leukemias. So if you were trying to make a ruling that a certain type of leukemia or lymphoma was related to World Trade Center you'd really need to bring experts in to make sure, okay, you want this whole big subclass of lymphomas? Do you want a subset of those? How do define them? I imagine in all the other fields it's the same way too. And just the concerns of, again, you know, for the Program I think there will often be questions of how broad the disease definition should be or how narrow. And I think that those kinds of questions an expert could help as well. Any other examples or thoughts?

MS. JONES: That sounds reasonable. Is that captured there?

DR. WARD: Marc?

DR. WILKENFELD: Yes?

DR. WARD: Your tent is up. Did you want to speak?

DR. WILKENFELD: Oh, no, no. Sorry. It was up from before.

DR. WARD: Yes. Anyone want to comment on this any further? You want to vote on this as separate point.

PARTICIPANT: Yes. Yes.

DR. WARD: Okay. Good.

DR. MIDDENDORF: Okay. I just want to point out that we have moved into the policy and procedures as opposed to strictly the peer review part of this. So just a point of clarification and make sure everybody's aware of that. So the recommendation is, "The NIOSH science team should seek input of expert consultants when needed in definition of a proposed WTC related health condition including symptoms, clinical findings, imaging, and laboratory findings."

PARTICIPANT: (Inaudible @ 00:50:08)

PARTICIPANT: Second.

DR. WARD: We'll go ahead and vote.

DR. MIDDENDORF: Okay, Rosemarie.

DR. BOWLER: Yes.

DR. MIDDENDORF: Mridu?

DR. GULATI: Yes.

DR. MIDDENDORF: Catherine?

MS. HUGHES: Yes.

DR. MIDDENDORF: Val?

MS. JONES: Yes.

DR. MIDDENDORF: Steven?

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce?

DR. MAYER: Yes.

DR. MIDDENDORF: That was a yes. Mike?

DR. MCCAWLEY: Yes.

DR. MIDDENDORF: Guille?

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MS. MEJIA: Yes.

DR. MIDDENDORF: Lila?

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill?

DR. ROM: Yes.

DR. MIDDENDORF: Megan?

DR. RYAN: Yes.

DR. MIDDENDORF: Micki?

MS. SIEGEL DE HERNÁNDEZ: Yes

DR. MIDDENDORF: Glenn?

DR. TALASKA: Yes.

DR. MIDDENDORF: Liz?

DR. WARD: Yes.

DR. MIDDENDORF: Marc?

DR. WILKENFELD: Yes.

DR. MIDDENDORF: Fifteen and zero; 15 yeses, 0—the motion passes.

DR. WARD: Great. Okay. We'll move on to the next recommendation. "The NIOSH science team should include experts with a range of relevant expertise including at a minimum clinical medicine, epidemiology, exposure assessment, and industrial hygiene. These are the core disciplines that are needed to address elements of a specified policy and procedures for adding conditions to the list of World Trade Center related conditions including biological gradient, plausibility, coherence, and exposure qualifications. If possible NIOSH should also consider creating an ad hoc team of discipline-specific experts, external or internal to NIOSH, that can readily assist the NIOSH science team in the review of additional proposed conditions including psychiatry, cardiology, rheumatology, and others, if needed." Any discussion on that?

DR. MARKOWITZ: So I think Micki made a suggestion that in the second line after "exposure assessment" that we include a parentheses that would say "including World Trade Center exposures" in the parentheses. Is that right, Micki?

MS. SIEGEL DE HERNÁNDEZ: That's correct, Steven

DR. MARKOWITZ: Micki says that's right.

DR. WARD: Great. Any other comments? This is Guille speaking.

MS. MEJIA: This is Guille. The last sentence "If possible NIOSH," blah blah blah, isn't that the same as what we just did on number 9 that we just voted on? It's pretty much consistent with recommendation number 9.

DR. MARKOWITZ: So can I just respond to that? So number 9 was about the disease and this really focuses more on the issue of causation, on whether that condition is related to World Trade Center or not.

PARTICIPANT: I have a question, too. From my understanding this is going to be of the NIOSH science team itself that are going to be doing the—preparing the documents and

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pulling those things together. The NIOSH science team and not necessarily the peer reviewers. So I wonder if we limit it to just people with World Trade Center experience whether there's going to be a big enough pool if people within NIOSH who've done that sort of work. That's my concern.

DR. MARKOWITZ: It wasn't intended to limit it to World—people with World—scientists with World—WTC experience. So the added language “including WTC exposures,” if that's interpreted as restricted to those people and no other exposures, that would be wrong.

PARTICIPANT: Okay. That's clear.

DR. WARD: Mike?

DR. MCCAWLEY: Actually, it doesn't say what you said it should say which was looking at causation. It doesn't say that anywhere. It was kind of ambiguous to me when I was reading it what we're trying to do with this. So if you could include a phrase “NIOSH science team should include experts to help determine causation,” or something like that. I mean, it doesn't say why you're forming this team. It just says you should have a team.

DR. WARD: Or could we just say “The NIOSH science team evaluating the petition?”

DR. MCCAWLEY: Yes.

PARTICIPANT: I like the idea of having a definition piece of the disease and then also a definition of the exposure relationship and causality. I think they're separate. And then just back to the “including World Trade Center exposure,” maybe you could say “preferably including but not limited to those who have expertise in World Trade Center exposure,” so it leaves it open.

DR. WARD: Did you catch that, Paul?

DR. MIDDENDORF: No.

PARTICIPANT: “Preferably including...”

DR. MIDDENDORF: Where are we?

PARTICIPANT: (Inaudible @ 00:55:30). “Preferably including but not limited to those with World Trade Center exposure experience.”

DR. WARD: Okay. Any other comments, additions, or questions? Do we have a motion to vote on this recommendation?

PARTICIPANT: (Inaudible @ 00:56:01).

DR. WARD: Do we have a second?

PARTICIPANT: Yes.

DR. WARD: Excellent. We're ready for a vote.

DR. MIDDENDORF: Do you want to read it?

DR. WARD: “The NIOSH science team when evaluating a petition should include experts with a range of relevant expertise including at a minimum clinical medicine, epidemiology, exposure assessment, (preferably including but not limited to WTC exposures), and industrial hygiene. These are the core disciplines that are needed to address elements of a specified policy and procedures for adding conditions to

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the list of WTC related health conditions including biological gradient, plausibility, coherence, and exposure qualifications. If possible NIOSH should also consider creating an ad hoc team of discipline-specific experts, external or internal to NIOSH, that can readily assist the NIOSH science team in the review of additional proposed conditions including psychiatry, cardiology, rheumatology, and others, if needed.”

DR. MIDDENDORF: Okay. So Rosemarie?
DR. BOWLER: Yes.
DR. MIDDENDORF: Mridu?
DR. GULATI: Yes.
DR. MIDDENDORF: Catherine?
MS. HUGHES: Yes.
DR. MIDDENDORF: Val?
MS. JONES: Yes.
DR. MIDDENDORF: Steven?
DR. MARKOWITZ: Yes.
DR. MIDDENDORF: Annyce?
DR. MAYER: Yes.
DR. MIDDENDORF: That was a yes. Mike?
DR. MCCAWLEY: Yes.
DR. MIDDENDORF: Guille?
MS. MEJIA: Yes.
DR. MIDDENDORF: Lila?
MS. NORDSTROM: Yes.
DR. MIDDENDORF: Bill?
DR. ROM: Yes.
DR. MIDDENDORF: Megan?
DR. RYAN: Yes.
DR. MIDDENDORF: Micki?
MS. SIEGEL DE HERNÁNDEZ: Yes.
DR. MIDDENDORF: Glenn?
DR. TALASKA: Yes.
DR. MIDDENDORF: Liz?
DR. WARD: Yes.
DR. MIDDENDORF: Marc?
DR. WILKENFELD: Yes.
DR. MIDDENDORF: Fifteen yes, zero noes. The motion passes.
DR. WARD: Okay. We'll move on to the next recommendation. “The Program should consider whether the mechanism of a STAC teleconference or other mechanism could be used to solicit external comments when a petition is likely to advance to the World Trade Center Health Program science team assessment phase. We see this as

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distinct from a formal request by the administrator for the STAC to make recommendations on a petition but rather as a mechanism to allow opportunity for public comment and benefit from the scientific expertise and knowledge base of the STAC.” Any discussion? Someone make a motion?

MS. SIEGEL DE HERNÁNDEZ: Discussion. In just thinking about this and time frame, which now we’re in the 90-day time frame from the receipt of a petition. And I think this is a great idea, to get some input from the STAC. Would that require putting that in the Federal Register and all of those kinds of things which may—we might want to reword this. Maybe the STAC can be also part of that ad—no, I guess that can’t be part of the ad hoc committee. No.

DR. MIDDENDORF: If the administrator goes to the STAC officially then it has to be—it comes under FACA, you have to put notice in the Federal Register, you have to convene a quorum of the committee. So all of this would have to go under FACA rules and regulations.

DR. WARD: So I think we recognize that, but we put it in there, I guess, with the idea that if the—you know, we’re just making a suggestion and if it’s clear early on that this is going to be a more complex review, you know, it’s possible that that would be recognized in time to do a—the Federal Register notice has a six-week period and then still have the STAC meeting in time. And it really is one of the few mechanisms that NIOSH has available to it, that can bring this group together and hear external comments and get commentary from the public. So it is a venue. It is a very desirable venue from the point of view of getting external input. So we’re putting it in as a suggestion, but we recognize that it may not always be feasible.

MS. SIEGEL DE HERNÁNDEZ: I’m totally in favor of input from the STAC. Would that preclude in terms of the rules of the STAC, would that preclude the administrator from, then, taking the petition and asking the STAC for specific recommendations? This is apart from that; correct?

DR. WARD: That’s part, I think, the legal stuff that would have to be resolved. If the administrator wanted to use this type of a mechanism I’m sure there would be some internal discussion of whether or not it would preclude the other route of going to the administrator—I mean, the administrator coming to the STAC and asking for a recommendation which would, then, kind of delay the decision on the rule, but give a longer time frame for the deliberation. I would think that in most cases he would do one or the other.

MS. SIEGEL DE HERNÁNDEZ: I mean, I think the difference is that this proposal is input earlier, when you’re trying to figure out whether to advance it, at the point that he would decide that it’s likely to—that he would propose this as an added condition that that might be the time where the STAC would, then, have it’s 90 to 180 days.

DR. WARD: Well, he could say—I don’t know—I mean, again, it really is all according to what he wants to do. But my guess is that if he wants to involve the STAC it’s very likely to decide that fairly early on, and that would be a different route than the route that

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we've been discussing. But I'm sure he and his team of lawyers and experts would have to figure out what scenarios are possible under the legal things and which are not. I'm thinking this would be one mechanism that would make sense in situations where it's a difficult decision and the administrator wants more input before—he thinks he will have enough information to decide whether he wants to propose a rule or not propose a rule, but that it would be desirable to have additional input before that decision. Does that make sense?

MS. MEJIA: I think—this is Micki. I mean, I think it's a good recommendation, however I see it as a conflict with what's already in the legislation. And so we're changing pretty much we're trying to recommend that there be changes in this legislation and not—that's a hell of a—in terms of how the STAC works. So I would just ask for a legal opinion in terms of whether this is something that is doable because now you're changing the role of the STAC and how the STAC participates as different from what the...

DR. WARD: Yes. And I think that's why we phrased it as "the Program should consider whether the mechanism of the STAC teleconference would be—or other mechanisms," so we left the option open for other mechanisms as well. We're not saying they have to do this. What we're really communicating is we would like NIOSH to explore all possible options that would allow greater visibility into the process where the determination is made whether to proceed with the Federal Register Notice or not. That's basically what we're saying. We're offering this one specific example. But I think the phrasing does recognize that NIOSH may consider it and they may decide it's inappropriate given the rules of the—you know, given the Zadroga Act and their policies and procedures, and that's fine. We're just making the suggestion.

MS. MEJIA: So those are hard to ask.

DR. WARD: Right, right. Okay. So any other comments before we have a motion?

DR. MCCAWLEY: The phrasing, "but rather usually" stands in opposition. You could just simply put "and."

DR. MIDDENDORF: What are you talking about Mike?

DR. MCCAWLEY: Okay. The sentence that begins, "We see this as distinct from a formal request by the administrator to the STAC to make a recommendation on a petition and," it's not "but rather." It's not in opposition to the first part of the—what follows is not in opposition with the first part of the sentence.

DR. WARD: Thank you.

PARTICIPANT: "Recommendation on a petition and as a mechanism to allow the opportunity..."

DR. MCCAWLEY: Take the "rather" out.

DR. WARD: Thank you. Any other comments? Ready for a motion.

PARTICIPANT: I'll motion at this time.

DR. WARD: Thank you. Do we have a second?

PARTICIPANT: I'll second.

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DR. WARD: Thank you. Okay, Paul we're ready for a vote.
DR. MIDDENDORF: Okay. (Inaudible @ 01:05:48). Rosemarie?
DR. BOWLER: Yes.
DR. MIDDENDORF: Mridu?
DR. GULATI: Yes.
DR. MIDDENDORF: Catherine?
MS. HUGHES: Yes.
DR. MIDDENDORF: Val?
MS. JONES: Yes.
DR. MIDDENDORF: Steven?
DR. MARKOWITZ: Yes.
DR. MIDDENDORF: Annyce?
DR. MAYER: Yes.
DR. MIDDENDORF: That was a yes. Mike?
DR. MCCAWLEY: Yes.
DR. MIDDENDORF: Guille?
MS. MEJIA: Yes.
DR. MIDDENDORF: Lila?
MS. NORDSTROM: Yes.
DR. MIDDENDORF: Bill?
DR. ROM: Yes.
DR. MIDDENDORF: Megan?
DR. RYAN: Yes.
DR. MIDDENDORF: Micki?
MS SIEGEL DE HERNÁNDEZ: Yes.
DR. MIDDENDORF: Glenn?
DR. TALASKA: Abstain.
DR. MIDDENDORF: Liz?
DR. WARD: Yes.
DR. MIDDENDORF: Marc?
DR. WILKENFELD: Yes.
DR. MIDDENDORF: Fourteen yes, zero noes, one abstention. The motion passes.
DR. WARD: So I'll read the next recommendation, Recommendation 12. "The Policy and Procedures for Non-Cancer Conditions describes three potential phases of the NIOSH Science team review of scientific evidence: 1) initial review (p. 2); 2) a fuller assessment (p. 3-4); and 3) if "modest support" is found, a supplemental assessment of additional scientific literature (p. 5). This supplemental assessment is limited to epidemiologic studies of 9/11 agents with special emphasis on the relevance of exposure conditions. It would be important to give the NIOSH Science team some flexibility in the range of scientific studies they review by adding at the end of Section IV.B.1.d. (p. 5, line 9) the phrase "and additional

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knowledge based on peer-reviewed scientific studies that they deem highly relevant.” Any discussion on that recommendation? Mike?

DR. MCCAWLEY: Why only epidemiologic, in this case; “limited to epidemiologic studies.”

PARTICIPANT: That’s what’s in the procedures now.

DR. MCCAWLEY: Is that what’s in there, okay.

DR. WARD: Any further discussion?

MS. JONES: What was your response to his question?

PARTICIPANT: That’s what in the procedures. I just noted that the word “epidemiological” is in the procedures and that’s why we had to use it.

DR. WARD: Any other discussion? Okay. Well...

PARTICIPANT: I’ll move to accept.

DR. WARD: All right.

PARTICIPANT: Second

PARTICIPANT: Second.

DR. WARD: Ready for vote, Paul.

DR. MAYER: I’m sorry, this is Annyce. One question. On the last sentence if we wanted to say something—add in a measure of quality.

DR. MIDDENDORF: Okay. Annyce, can you start over?

DR. MAYER: In the last sentence would we want to also mention something about quality?

DR. WARD: Steve, would you like to respond to that?

DR. MARKOWITZ: Yes. Well, I don’t really see that is necessary. But if specific language is proposed—peer review takes care of part of that, but I kind of assumed that the science team is going to judge quality as part of what they normally do. So...

DR. MIDDENDORF: I would point out that the policy and procedures already does say that the papers will be reviewed for relevance, quality, and quantity.

DR. MAYER: Oh, okay.

DR. WARD: Okay. Ready to vote.

DR. MIDDENDORF: Okay. Recommendation 12. Rosemarie?

DR. BOWLER: Yes.

DR. MIDDENDORF: Mridu?

DR. GULATI: Yes.

DR. MIDDENDORF: Catherine?

MS. HUGHES: Yes.

DR. MIDDENDORF: Val?

MS. JONES: Yes.

DR. MIDDENDORF: Steven?

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce?

DR. MAYER: Yes.

DR. MIDDENDORF: Mike?

DR. MCCAWLEY: Yes.

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DR. MIDDENDORF: Guille?
MS. MEJIA: Yes.
DR. MIDDENDORF: Lila?
MS. NORDSTROM: Yes.
DR. MIDDENDORF: Bill?
DR. ROM: Yes.
DR. MIDDENDORF: Megan?
DR. RYAN: Yes.
DR. MIDDENDORF: Micki?
MS SIEGEL DE HERNÁNDEZ: Yes.
DR. MIDDENDORF: Glenn?
DR. TALASKA: Yes.
DR. MIDDENDORF: Liz?
DR. WARD: Yes.
DR. MIDDENDORF: Marc?
DR. WILKENFELD: Yes.
DR. MIDDENDORF: Fifteen yeses, zero noes, zero abstention. The motion passes.
DR. WARD: Great. Well, I think that concludes our deliberations on the questions that NIOSH has asked us.

ADMINISTRATIVE ISSUES AND ADJOURN

DR. WARD: Paul, I think we still have a few minutes on the agenda for administrative issues, if any.
DR. MIDDENDORF: Yes, I don't think I have anything other than to remind folks who are traveling, get your travel vouchers in as quickly as possible.
DR. WARD: And as far as I know there's no specific plans for when the next meeting will take place, but Paul will be in communication about that.
DR. MIDDENDORF: Just as soon as the administrator decides he wants to have another meeting, you will all be informed. Actually, you will be canvassed; find out when your availability is; find the best available date for the administrator, the staff, and STAC members, make sure we have a quorum.
DR. WARD: Thank you all for hanging in there, and especially to those on the phone. I really am impressed with your ability to stay connected to this meeting on the phone. I know how difficult it is and I'm sure that at many times you were straining to hear what was being said. Thanks to everyone in the room including our public members. We'll go ahead and adjourn. Thank you all.

[END MEETING]

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G L O S S A R Y

ATSDR	Agency for Toxic Substances and Disease Registry
CCE	Clinical Center of Excellence
CDC	United States Centers for Disease Control and Prevention
CDC-INFO	Centers for Disease Control and Prevention National Contact Center (1-800-CDC-INFO)
CME	Continuing Medical Education
CUNY	City University of New York
DOE	Department of Energy
DOL	Department of Labor
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
EPA	Environmental Protection Agency
ERHMS	Emergency Responder Health Management System
FDNY	Fire Department, City of New York
FEMA	Federal Emergency Management Agency
GERD	Gastroesophageal Reflux Disease
HHC	New York City Health and Hospitals Corporation
IRB	Institutional Review Board
LHI	Logistics Health Incorporated
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIMS	National Incident Management Systems
NIOSH	National Institute for Occupational Safety and Health
NPN	Nationwide Provider Network
NYPD	New York Police Department
ODAR	Office of Disability Adjudication and Review
PTSD	Post-Traumatic Stress Disorder
STAC	Scientific/Technical Advisory Committee
SUNY	State University of New York
VCF	Victim Compensation Fund
WTC	World Trade Center
WTCHP	World Trade Center Health Program

I hereby certify that, to the best of my knowledge, the transcript of the March 22, 2016 meeting of the Scientific/Technical Advisory Committee is accurate and complete.

12/9/2016
Date

SIGNATURE ON FILE
Chair, Scientific/Technical Advisory Committee