

**WORLD TRADE CENTER HEALTH PROGRAM
SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE (STAC) MEETING
June 2, 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**

NINTH MEETING

SCIENTIFIC/TECHNICAL ADVISORY

COMMITTEE (STAC) MEETING

June 2, 2016

The verbatim transcript of the
Meeting of the Scientific/Technical Advisory
Committee Meeting held on June
2, 2016, 9:00 a.m.

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PARTICIPANTS

(alphabetically)

THOMAS ALDRICH, MD - COMMITTEE MEMBER
ROSEMARIE BOWLER, PHD - COMMITTEE MEMBER
BARBARA CAPORALE - PUBLIC COMMENT
ANTHONY FLAMMIA - COMMITTEE MEMBER
KIMBERLY FLYNN - PUBLIC COMMENT
ROBERT HARRISON, MD - COMMITTEE MEMBER
GREGORY HOMISH, PhD - COMMITTEE MEMBER
JOHN HOWARD, MD - PROGRAM ADMINISTRATOR
EMILY HOWELL – SENIOR ATTORNEY
CATHERINE McVAY HUGHES - COMMITTEE MEMBER
VAYLATEENA JONES - COMMITTEE MEMBER
RACHEL LIDOV - PUBLIC COMMENT
MICHAEL McCRAWLEY, PhD - COMMITTEE MEMBER
STEVEN MARKOWITZ, MD - COMMITTEE MEMBER
ANNYCE MAYER, PhD - COMMITTEE MEMBER
GUILLERMINA MEJIA - COMMITTEE MEMBER
JAMES MELIUS, MD - PUBLIC COMMENT
PAUL J. MIDDENDORF, PhD - DESIGNATED FEDERAL OFFICIAL
LILA NORDSTROM - COMMITTEE MEMBER
DAVID PREZANT, MD - PUBLIC COMMENT
WILLIAM ROM, MD - COMMITTEE MEMBER
MARGARET RYAN, MD - COMMITTEE MEMBER
GLENN TALASKA, PHD - COMMITTEE MEMBER
ELIZABETH WARD, PhD - COMMITTEE CHAIR-PERSON

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WELCOME AND INTRODUCTION

DR. MIDDENDORF: After that exciting entry by our chair—thank you, Liz—make sure that’s unmuted. Okay. Just quick check, Mike, can you hear us?

DR. McCRAWLEY: Yes, sure can.

DR. MIDDENDORF: Well, we might as well go ahead and start. Most of you have heard this drill before but we’re going to have to go through it anyway. Good morning. I am Paul Middendorf. I am the designated federal official for the World Trade Center Scientific/Technical Advisory Committee. I would like to extend a warm welcome to each of our committee members. I very much appreciate that you’re here and very much looking forward to your thoughts and ideas today on the topics at hand. Also want to extend a warm welcome to the members of the public who are here, either with us in person or on the phone. Also with you, we very much appreciate your interests in these proceedings. And it is important for us to remember why we’re here and set the appropriate tone for the meeting, so let’s just spend a few moments in silence to remember those who were killed in the attacks on 9/11, those responders and survivors who have since died because of those attacks, and those who have been injured or died in other terrorist attacks around the globe.

[Moment of silence.]

Okay, thank you. I have to deal with a number of administrative issues. First, I’ll let you know where the fire exits are. If we have to evacuate the building, you go out the back doors and immediately turn to your left and go out the double doors, double glass doors on the left side there, and immediately go to the left. That’s where the fire exit is. There will be stairs that will take you down and out of the building. The bathrooms, if you need to use the restroom, go out the same set of glass double doors. Just continue on down the hall; it’s about halfway down the hallway on the right. Also, I want to remind everyone here that water only is allowed in this meeting. No coffee, no soft drinks, nothing else. Fizzy water is okay, so we don’t have any problem with that, but no coffee, Coke, other food. Committee members, if you need a drink or anything like that, we have the area off here to my left where you can go and get something other than water. For those of you who have signed up to provide public comments, they are scheduled to begin at 9:20 this morning, and that’s Eastern Time. All of our public commenters are here, so please come up to the podium when I announce you. Copies of the public comments that were received by May 27 have been provided to the committee before the meeting and they will be posted in NIOSH’s docket 248-E, which is available through the committee’s website. The next thing I get to do is a roll call. So Tom Aldrich?

DR. ALDRICH: Here.

DR. MIDDENDORF: Rosemarie Bowler?

DR. BOWLER: Here.

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DR. MIDDENDORF: Anthony said he would be here a few minutes late. Bob Harrison?

DR. HARRISON: Here.

DR. MIDDENDORF: Greg Homish?

DR. HOMISH: Here.

DR. MIDDENDORF: Catherine Hughes?

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val Jones?

MS. JONES: Here.

DR. MIDDENDORF: Mickey said he would not be attending. Steve Markowitz?

DR. MARKOWITZ: Here.

DR. MIDDENDORF: Annyce Mayer?

DR. MAYER: Here.

DR. MIDDENDORF: Mike McCawley?

DR. McCAWLEY: Here. Yes.

DR. MIDDENDORF: And I just want to check, can you see the web?

DR. McCAWLEY: Yes.

DR. MIDDENDORF: Okay, great and Guille?

MS. MEJIA: Present.

DR. MIDDENDORF: Lila?

MS. NORDSTROM: Here.

DR. MIDDENDORF: Bill Rom?

DR. ROM: Here.

DR. MIDDENDORF: Megan Ryan?

DR. RYAN: Here.

DR. MIDDENDORF: Glenn Talaska?

DR. TALASKA: Here.

DR. MIDDENDORF: And Liz Ward?

DR. WARD: Here.

DR. MIDDENDORF: So we'll just make a note for the transcript when Anthony arrives so we've got that. Anything else? Okay, just to let people know, copies of our agenda for this meeting are in the back and for those of you on the phone, you can find the agenda on the committee's website. The focus for our meeting today is on the two policies and procedures used by the Program to add health conditions to the list of covered conditions, and the identification of peer reviewers when adding a health conditions. So with that, I will turn it over to Liz.

DR. WARD: I'd like to welcome everyone who is here today, both members of the panel, especially the new members, relatively new members who are meeting with us for the first time today, and the members of the public. So our first speaker today will be Dr. John Howard.

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ADDITIONAL RESPONSIBILITIES OF STAC UNDER REAUTHORIZATION AND CHARGE TO THE COMMITTEE

DR. HOWARD: Good morning, everybody.

PARTICIPANTS: Good morning.

DR. HOWARD: So thanks, as I always say, for taking time from all your busy, busy schedules and for coming from such a long distance, many of you—some of you not so far, on the subway—but thanks so much for taking your time to provide advice to the Program. We really appreciate it. Sometimes, you know, we discuss the issues internally for months and months, and we're always interested in additional advice on some of those issues, and we have plenty of opportunity as a committee to go on to provide that advice. So thanks. I also want to thank Marvin Howard, who runs the conference center here, who is always so helpful to us, extremely helpful to us. Otherwise, we wouldn't be able to enjoy this beautiful room. So I want to thank Marvin.

Second, I want to thank you for the work that you did with regard to the recommendations for the children's research. That was extremely helpful to us. And what we are trying to do, even though some of them are more long-term issues, is to provide some feedback to you. I know that when I have served on advisory committees, it's always interesting, you say a lot of things and you write a lot of recommendations, and oftentimes it's sort of a blank wall (inaudible @ 7:51). And so what we wanted to do is to give you some feedback and that's in your book and we'll continue to work on those. I think you guys did a terrific job with a very difficult issue. We are revisiting issues that are now over a decade old and trying to deal with them is awfully—you know, very difficult. So thank you very much for those recommendations and we will continue to update you guys on what we're doing with regard to that.

Next, this meeting is designed to solicit input from you all on some new responsibilities that have arisen as a result of the reauthorization of the Zadroga Act. And in your book, under that tab, is reproduced a short ten pages of legislative language with regard to that; page number within the many thousands of pages that are associated with the Omnibus bill, that the Zadroga Act Reauthorization was inserted into. So I'm going to be referring to that, so you may want to (switch @ 9:19) that tab out, at least (open @ 9:23).

So the recommendation that was provided a couple of years ago by the General Accountability Office, when they were (redoing @ 9:33), the Program's policy and procedures for adding cancer to the list of World Trade Center-related conditions, they noted some things that they would have liked the Program to have done, and that was read then by the drafters of the reauthorization. And the Congress wanted to ensure that the Administrators' action to add a health condition to the list was subject to independent peer review of the foundational science and technical evidence that (validated @ 10:16) that is the basis then for adding a

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health condition.

So in order to carry out those recommendations of the (JO @ 10:26) and which then was incorporated into legislative language, if you look at page 1899, and the reauthorization language, the first issue is the identification of individuals to conduct peer review, this independent peer review that was having to be done. So if you look at section (ii) there on page 1899, you will read that the Administrator is required to seek the recommendations from you, the committee, "...regarding the identification of individuals to conduct independent peer review." So the committee can do anything it wants. It can recommend specific individuals who may be experts in various health conditions or make a recommendation about selection procedures that we should use, where appropriate, to find those individuals, or come up with whatever you all think would be a great idea. We welcome all advice on this issue, and some of you are quite expert in this area, having been peer reviewers yourself and (inaudible @ 11:48) in peer review on others' work.

The second issue is to review and evaluate the Program's policy and procedures—things that we've written, our roadmap of how we do things that we use to determine whether there is sufficient evidence to support adding a health condition to the list. That's the second activity that (inaudible @ 12:20). So on the previous page, 1898, you will see there in section (i) under "Program Policies", the reauthorization language which sets out the second responsibility here that you have today, to review and evaluate the current policies and procedures that the Program uses to determine whether the evidence is sufficient to add a condition to the list. So this is pretty heavy stuff and I think it behooves us in the Program to be able to tell you where we're at now in this area.

So what we've done today is in the first half of the day to give you a good background and to ask questions of the presenters. We are going to do three presentations for you. The first is a general overview of independent scientific peer review as a topic that we do generally in NIOSH and is done throughout the federal government and throughout academic science. Dr. Piacentino, who is our Associate Director for Science at NIOSH, is going to do a presentation on general peer review that you will be able to ask questions about that responsibility (inaudible @ 13:52) recommendations around peer review. And then second, we're going to do two presentations on the issue of reviewing our policy and procedures relative to adding a condition. So we have two separate policy and procedures. One is adding cancer to the list and then the second policy and procedure is adding non-cancer to the list, so there's two separate ones, and we're going to have two separate presentations. So the presentation on policy and procedures for adding types of cancer to the list is going to be done by Dr. Tania Carreón-Valencia, who is a research epidemiologist in the World Trade Center Health Program. So Tania is going to do that presentation. Then lastly, we're

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going to have a presentation on the Program's policies and procedures for adding non-cancer conditions to the list and Dr. Dori Reissman, who is the Associate Administrator of the Program, is going to give you that presentation. So after those presentations, you will have a background about peer review, about the two policies and procedures that we have—one for adding cancer, one for adding non-cancer—and you will be able to query those at the end, later on, deciding how we are going to approach this task.

So I hope that you enjoy those presentations, and most of those experts are happy to answer questions (inaudible @ 15:22), and we look forward to your recommendations. There is no timeline, so don't get worried; the committee is free to set its own timeline and to look at these issues however it chooses. So again, thank you very much for being a member of the committee and for helping us out. I think this is an exciting time. We are of course, as all of us, very pleased that (inaudible @ 15:51) so to speak, and we don't have that hanging over us, and so we have an opportunity to now look back at the scientific procedures we've been using over the first five years and review them. I look forward (to your reviewing @ 16:12). So I will, I've probably exceeded my time but thank you very much and look forward to your comments.

PUBLIC COMMENTS

DR. MIDDENDORF: Okay, so I think we need to go to public comments now but first, just for the record, just to note that Anthony Flammia (inaudible @ 16:33). Welcome, Anthony. Thank you. So since we are starting the public comments portion of our agenda, each of our public commenters has signed up on a first-come, first-served basis. Each of them will have up to five—excuse me—up to five minutes to present. It's often surprising to people how fast five minutes can go by when you're talking on a subject with (latent @ 16:57) points of view, so at four minutes, I'll let the commenter know that they have one minute remaining to allow them to make their final points. Also, if I point out that you do have the option of submitting written comments to the docket for this committee. The docket number is 248-E and information on how to submit comments can be found in NIOSH's docket webpage. 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; it's also on the committee's webpage. The policy outlines what information will be kept and what information will be redacted before it's posted to the docket. So our first presenter is Jim Melius.

DR. MELIUS: Hi. Good morning, everybody. (Inaudible @ 17:58) just some overview on them and provide some more context for (inaudible @ 18:16). I am, look, as background, I work for the labor union that represents a lot of people that worked at the World Trade Center after 9/11 and many people that are in the Health Program and the Compensation Program, and I also chair the—the name of it is

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the World Trade Center Responders' Medical Program Steering Committee, which the acronym—you have the acronym STAC, we have RSC, which is the Royal Shakespeare Company also. A good company for our acronym. I want to make three points regarding the context of today's meeting. One is that it's unclear in the documents as to what will be the transparency of naming the peer reviewers and how they will be attributed in this process. There is one comment that to be effective, the peer review should be compiled without attribution (inaudible @ 19:20) docket and how that applies and what they will be named at all is not clear, at least from what I can read. I would just plead it's very important for the credibility of this program, to a number of people, that the peer review process be as transparent as possible. I see no real need for secrecy of the peer review. It's not like a federal review or a (study section @ 19:49) process. This is a peer review process that will affect public policy, important public policy. It will affect the many, the hundreds of thousands of people in this program, and I think it's important that the names of the peer reviewers and their comments be made public in a very transparent manner. And I see really no downside to that; that actually, there is much more of a downside to if one doesn't—keeps that information secret or confidential, that's something that raises people's questions about how they were chosen, what they were saying, what they really said and so forth. And I think, if I'm looking at other programs, at the docket comments, comments, comments even on other NIOSH programs, the peer reviewers are usually named and—well, (known @ 20:47), named and attributed to—their comments are attributed to (inaudible @ 20:52). So again, I would urge that process that we relook at that and certainly clarify, because it's not clear (inaudible @ 21:04).

Secondly, so I would also urge that there be some sort of public process for nominating the peer reviewers, in the sense that the people from—who are involved in the program, either as representatives of groups or from various clinical and academic institutions involved or people with other interests, be allowed to, you know, provide (inaudible @ 21:30) again on a periodic basis—it doesn't have to be every time a peer review panel is put together—but at least the process was for you to nominate peer reviewers on a sort of periodic basis to provide to the Administrator. I think that could be opened up in some way through some sort of a docket or something, and I think it could be done. And again, I don't think it would harm the process at all or the credibility of the process, but it would provide, again, an opportunity for the public to have some input into that. Finally, going through the policy, that has, as Dr. Howard (inaudible @ 22:12) review, it's difficult, and I think we have to recognize that even though it's going on 15 years after the exposures and there has been a lot of medical follow-up of the people that were exposed both (acutely @ 22:28) and then at the work sites, I think it's important that the—that you recognize that the information will never be

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complete and comprehensive to address every possible disease outcome that may result from these exposures. Lots of reasons for that, just sample size and limitations on what's known about exposure and so forth. So I think one is going to have to have a process for adding new conditions that is not based simply on an epidemiological follow-up of the various cohorts involved but we have to bring into play other types of things such as information, which has already been done for cancer. And given that, I think it's important that the two documents that you'll be commenting on today, presumably those may or may not be revised as a response to this, but be equally clear, particularly as we'll now be involving peer reviewers, outside peer reviewers, in making recommendations regarding adding new conditions in a form that these peer reviewers understand the criteria and understand what information is available, what is not available and so forth from the follow-up of the cohort as well as other scientific information and (inaudible @ 23:51) criteria to be in—what criteria has been used in the past. I found, I think the criteria on cancer are pretty clear and there's a number of decisions that the Administrator has made in terms of adding cancer as a covered condition for types of cancer. I think that for non-cancer conditions, I think though, there needs to be—those criteria need to be clarified because I think, as I point out in my comments, for cancer we have IARC, we have NTP, we have all these sort of credible outside organizations that do very intensive reviews of the available scientific information on those substances (related to @ 24:36) to the cause of cancer. We don't necessarily have the same kind of criteria available for our non-cancer conditions. There are some out there but they are not as clear-cut and they're not as consistent among the different types of conditions. And I think some time spent on clarifying that and making sure that the document, a strong document is developed for that would be useful both for STAC's review process as well as for the outside peer reviewers (inaudible @ 25:09). Thank you for your time and thank you for spending the time doing this.

DR. MIDDENDORF: Thank you very much, Jim. Just for the committee's benefit, I'll explain what is intended by the term "without attribution". Obviously, if it's not clear what is meant, it'll maybe be modified and clarified in the writings. What is intended is that the peer reviewers would be identified but their specific comments would not be attributed to them individually. They would be pulled out and all of the comments would be made public, and—sorry, got lost on the screen up there. All their comments will be pulled out, they would be addressed individually, and then the comments and the Program's response to those comments would be made available. That's the current procedure that is envisioned but that's something that you can comment on later about its appropriateness or inappropriateness. My next presenter is David Prezant. Dr. Prezant?

DR. PREZANT: Hi. I'm David Prezant, I'm with the New York City Fire Department, representing the New York City Fire Department at the World Trade Center Health Program.

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It's good to see you all here this morning. I see a lot of familiar faces; I see a lot of new faces. Thank you for all you do, and thank you for taking on this new task. We are concerned about several issues involved with the new regulation, and predominantly, they involve more transparency, a much clearer timeline, and a much clearer mandate to use the STAC. And I think that actually some of the issues here even confuse the use of the STAC, and I'll try to address those comments very briefly.

First in terms of the timeline, there is a very clear timeline detailed in both the non-cancer and cancer guideline proposals that you have in front of you on 90 days for the Administrator to call the—to decide whether to call the STAC into motion; 90 days for you to review something, with the ability to extend that an additional 180 days—and I certainly don't want to curtail the scientific review of these issues, and I defer to NIOSH on whether 90 days or 60 days or 180 days is adequate. What I have identified, however, is that that has never been the problem. The problem in the past has not been the 90, the 90, the 180; it's been after the decision has been made, and it goes to rule-making. And there, there is no timeline at all in these guidelines or (inaudible @ 28:24) or whatever they're referred to, quite possibly because NIOSH has no control over that so I do understand that, or they have little control over it, and I understand and certainly acknowledge the fact that everybody is trying to get these rules out as fast as possible. But the rule-making on two issues right now—the issue on COPD and the issue on musculoskeletal—has been going on forever. I have heard that something is imminent, and I appreciate that, but after public comment, for which I also think there is a timeline of 60 days, there should be some reasonable timeline for rule-making.

Next, echoing Dr. Melius, I feel there needs to be a lot more transparency about the peer review group, how it's selected. My understanding from reading this, or at least my interpretation, is you are asked for info in the selection of the peer review panel. That means you have input; it doesn't mean you are determining the selection. It is unclear who is determining the selection, actually. One is presuming that it would be the Administrator but I don't see that clearly identified. And since there is nothing in the legislation, at least upon my reading, that details this process, it seems to me quite reasonable for there to be public nominations, for there to be public comment, for there to be a mandate that certain types of peer reviewers are on the peer review panel, just as there was for the STAC. That is not to say certain types of opinions; that's to say certain types of expertise and certain types of representation of the issues that are out there. Especially, again echoing Dr. Melius, that the issues for deciding whether a new condition is related to the World Trade Center are quite complex, and for us to think that those issues are purely scientific would be incredibly naïve. The fact of the matter is that the most expert scientific matters of peer review are handcuffed by certain issues that have nothing to do with the World Trade Center, and that has to do with the

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difficulty in finding comparisons. For cancer, it was difficult enough but at least you had SEAR 13 and other types of SEARs and New York State and New York City rates. This is not true for the new conditions that are coming for the Administrator in the future. For example, the autoimmune disease that was recently brought to the Administrator—he reviewed one, and now there are two publications from FDNY on this subject, but you know, the use of a comparison group is very difficult. There is no registry of autoimmune diseases like there is a registry of tumor diseases. So there needs to be a great deal of maturity as well as expertise on the part of the peer review.

Finally, and perhaps most importantly, is the concept that the Administrator mentioned that we are now functioning relatively in perpetuity, and that means that there will be new conditions in the distant future, there will be new Program Directors, there will be new STAC Committees and there will be a new Administrator. And as much as I would hate to ever see that happen, that is the reality. And therefore, I wonder if we should be concentrating as much power in the Administrator's position. The STAC Committee can only be convened if the Administrator chooses to do so, and it seems that that would only happen if the Administrator feels that there is a high likelihood that a new condition is likely to be related causally. In these documents, there's essentially three categories, in my view. There's the it's not related, it's modestly related and it's likely to be related. And I wonder if the STAC should be required to be convened for the modestly related. And the confusion that occurs is that if the Administrator feels that it is related and doesn't even need the STAC Committee, which I ask you to comment on, you're still going to be asked to figure out the peer—to have input on the peer review. So that also creates a sort of complexity in that you weren't involved in the original decision but are involved in the input of peer.

And just to finally state, to get back to the timeline, which I forgot, there is actually no timeline for the peer review. So that's another thing that desperately needs to be put in here and that you do have control over—at least, the Administrator has control over. Maybe not the timeline for rule-making, which I would love to see, but certainly the timeline for peer review. I thank you very, very much for listening and for everything you've done.

DR. MIDDENDORF: Thank you very much. Our next public commenter is Rachel Lidov. Is Rachel here?

KIMBERLY FLYNN: No, she is on the phone. She is on the phone. Rachel?

DR. MIDDENDORF: No, she's not on the phone because she doesn't have the speaker number. It wasn't made clear that she was going to be on the phone and not here.

PARTICIPANT: (Inaudible @ 34:16).

DR. MIDDENDORF: Okay. What I can try to do, Sue?

OPERATOR: Yes?

DR. MIDDENDORF: There are two people who are on the phone that we will need to be able to have

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OPERATOR: access, or they need to have access to be able to speak. One—
Okay. Okay, let me just give the announcement because I don't see their name—I can't see their names right now. But if you do need to be a speaker, just press * followed by 0 and we can open your line. And one moment to see if they will press that here, one moment.

DR. MIDDENDORF: Okay.
[Break.]

DR. MIDDENDORF: the other person be?

PARTICIPANT: (Inaudible @ 0:01).

OPERATOR: Rachel is on now.

DR. MIDDENDORF: Okay.

MS. LIDOV: Hello, can you hear me now?

DR. MIDDENDORF: Can everybody hear her?

PARTICIPANT: Yes.

DR. MIDDENDORF: Okay. Yes, we can hear you, so please go ahead.

MS. LIDOV: Okay, I will. I'm Rachel Lidov. I'm speaking to you today on behalf of parents as a—I'm speaking to you on behalf of the Concerned Stuyvesant Community, on behalf of parents and children who were exposed to the WTC disaster at Stuyvesant High School on 9/11/2001. For the past 15 years, we have been advocating for an assessment of how all children in Lower Manhattan have been affected, physically as well as emotionally, by the disaster. While some of us have our children at home for a few more years, many of us have already become grandparents. We all know already that all levels of government worked together to get Lower Manhattan back to work, in total denial of the dangers of the dust and smoke, even for children. In those early months, they refused to protect our children from preventable exposures, but especially indoor exposures. And to our reports that many of our children were suffering from rashes, eye problems, coughing themselves to sleep at night—to provide just a few examples of what (were dismissed @ 1:25)—they demonstrated a complete lack of concern. So our early demands for a screening program for our kids fell on deaf ears. A few studies were completed but until the passage of the Zadroga Act in 2010, there was no commitment expressed that there would be ongoing scientific research on kids. It was crucial that a pediatric environmental health specialist be appointed to this committee, the Scientific and Technical Advisory Committee for the World Trade Center Health Program, and it was a priority for a research agenda to serve people who were exposed to the contamination from the fall of the WTC, and children, to be developed by this committee. So we were, as parents, grandparents (inaudible @ 2:17) over the Memorial Day weekend that when Dr. Trasande had resigned from that position in order to pursue research he had advocated for, he was replaced not by the pediatrician and an environmental health (specialist @ 2:32) who we recommended, as had others, but by two

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professionals who appear not to have the expertise to address the research into children.

Going forward, who on the staff will be able to help other members understand the implications of research now underway and the need for longitudinal studies? Speaking of research, what has happened to the publication of the STAC's final recommendations on 9/11 children's research? Did we not have an understanding that a fully transparent and accountable peer review process for adding new conditions was published by the WTC Health Program was in place? Who can we count on in the fight against further reductions in the operating budget that affects future research funding? How is it possible that we can't even make a nomination for this all-important position and be heard? We have had no response to our nomination. What happened to the process of meaningful community (inaudible @ 3:33) research? We have spent such time as we could spare from the holiday weekend trying to figure out what happened. The NIOSH docket (appears to have been @ 3:45) constructed to make it nearly impossible for us to discover the process by which this happened. The lack of transparency in this day and age is (inaudible @ 3:55). The absence of scientific review in meetings and in dealing with the most vulnerable members of the affected community is astounding and frightening. We are nearly 15 years out and the next generation of a loyal, committed group of citizens is on its way. Is our government here for them? It is essential that the STAC now lay a foundation for longitudinal studies of mental and physical health effects including comorbidity. The betrayal of the affected community, especially those that have children, is essentially not an option (inaudible @ 4:37). Thank you for the time to speak today.

DR. MIDDENDORF: Thank you very much, Rachel. I just do want to address one thing. The process for selecting members to the STAC is a very long process. The letter to which Ms. Lidov referenced was actually sent in March of 2016. The two environmental medicine/environmental health specialists were added based on the 2015 selection announcement and they were selected in December of 2015 based on the individuals who were, nominees who were made available to us at that point in time. So the 2016 selection of new members is currently in process, and that should be announced this year. So I just wanted to clarify that. Our next speaker is Mariama James.

PARTICIPANT: So Mariama is not going to be here today.

DR. MIDDENDORF: Okay, she's not going to make it. Okay. So then I guess we go to Barbara Caporale. Barbara, are you on the phone?

MS. CAPORALE: Yes, I am, can you hear me?

DR. MIDDENDORF: Yes, we can hear you.

MS. CAPORALE: Okay, great. This is Barbara Caporale. I'm a Lower East Side resident and parent, and have long advocated for proper clean-ups of World Trade Center contamination from our homes, schools and workplaces, and for healthcare for all

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those whose health has been harmed by the toxic smoke and dust. First I want to comment on the procedure for adding non-cancer conditions. Peer reviewers need to be completely ignorant of the unprecedented nature of the World Trade Center disaster. The conditions downtown, the lack of proper cleanup and the fact that people in the community, as well as responders, were exposed simultaneously to many toxins including lead, asbestos, PAHs, dioxins, benzene, fiberglass and alkaline dust with a pH (inaudible @ 6:33) and the list goes on. NIOSH needs to give these reviewers as complete as a list of possible. And just as for the deliberations on adding cancer, where the studies (in fact @ 6:43) were not limited to those who were (inaudible @ 6:45) responders and survivors, peer reviewers must be expected to consider a full range of studies that link environmental exposures to chemicals that were in the World Trade Center dust and smoke—a complete list. Peer reviewers must be instructed that our exposures were synergistic, so it's not just an exposure to lead but an exposure to lead with PCBs, with alkaline dust (inaudible @ 7:08). There are no such studies other than a limited number of studies of World Trade Center populations of the synergistic effects of all the scrap that we breathed, swallowed, absorbed through our skin, eyes and over the duration of time. And I must remind that residents who could not afford to leave the impacted neighborhoods experienced longer durations of exposure in addition to workers and residents who returned to buildings that did not have proper cleanup. We must add the fact that the fires burned for months and the nonstop and continuing construction and demolition in the area re-suspended many of the particulates of concern. Reviewers need to be informed that the regulations setting so-called safe thresholds for exposures to chemicals are often more (scientific @ 7:50) and not very accurate, and some of these even don't have established safe thresholds. And I must impress that our children were greatly exposed in many, many ways, including (primitive @ 8:01) behaviors like hand-to-mouth actions and movement through areas of what the EPA categorized as unfrequented areas, not a priority for cleanup, such as under beds; and most buildings never had a cleanup at all. The fact that we no longer have a pediatric environmental medicine specialist on the STAC is a slap in the face to parents and the health and futures of our children, some who are now young adults. It ignores lessons learned and sets a very bad precedent for response of governmental agencies and public health authorities for future disasters. From the beginning, (inaudible @ 8:35) had been unacknowledged, affected, neglected collateral damage from 9/11. All who have been involved who are on this phone call know how we all fought as a community—workers, residents, students, medical providers—to have a more equitable public health response. We have fought and continue to fight for our children to be given more prominent attention. What happened to the STAC well-deliberated 12 pediatric research recommendations? Since immediately after the event, we were told

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(inaudible @ 9:05) symptoms that were not from World Trade Center exposures but was a result of (GSTB @ 9:10), was in her head. So I object to the continued imbalance where mental health becomes the sole focus of research and there is no research on physical health impacts. It's so frustrating. It's (inaudible @ 9:20) and so replacing (inaudible @ 9:22) pediatric environmental medicine doctor, Trasande, with a non-ped and even a mental health person is giving me a further mental health condition, which is a typical by-product of persons with World Trade Center health impacts since 2001 whose needs and requests are ignored and we have to fight yet again. (Time @ 9:44) the information gathered at the Centers of Excellence and medical advocacy has proven differently and has validated a range of health impacts linked to the World Trade Center event—Trade Center event—and this will continue. Replacing Dr. Trasande with, although distinguished, medical personnel—I'm sorry, I've just lost my place—with a non-ped and even a mental health person is... I'm sorry. I hope that such an expert would be held in queue for when a mental health spot opens up and that an expert in pediatric environmental medicine be immediately found for the vacated position instead. We as parents demand that our children are given equal consideration in studies, funding and representation of pediatric medical expertise on this stuff, as represented in the impacted populations. This body is accountable to us and all affected populations and we insist that we are heard. We insist that our children get their research needs met and that the peer review process is transparent, with public input. So thank you for the opportunity to express my concerns as we seek proper treatment and diagnosis (linking the types @ 10:56) of conditions being seen in our Centers of Excellence, and this is connected to the future lives of our children and setting precedent for future public health response to any disaster. I hope for adequate response to the points that I've raised. Thank you.

DR. MIDDENDORF:
MS. FLYNN:

Okay, thank you, Ms. Caporale. Our next public commenter is Kimberly Flynn. Good morning. I make these comments on behalf of the World Trade Center Health Program Survivors' Steering Committee which I chair, and I guess I'm going to start by saying that we echo the comments that were made by Dr. Jim Melius, chair of the Responders' Steering Committee, and also by Dr. Prezant, and I'm going to finish—I'm going to deal with the peer review, obviously, but I'm going to finish by reiterating the call for a pediatric environmental medicine specialist to be added to this body ASAP.

The new procedures, including the requirement for an independent peer review process, can either strengthen the process of adding new conditions or create further obstacles. It is not acceptable for those who are suffering with World Trade Center impacts, many of which are serious and even catastrophic, many of which are now chronic, to wait for care because, in effect, they have fallen through the research gap. Pages 3 and 4 of the policy and procedures for adding non-cancer

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conditions refers to a process of assessing scientific and medical information that is focused on, quote, “peer-reviewed public epidemiologic studies of 9/11-exposed populations”, close quote. We are opposed to restricting the evidence that will be assessed to studies of 9/11-exposed populations only, and obviously we are opposed to only considering epidemiological studies which, as the community now fully understands, you know, epidemiology is the “too-late” science. As with the assessment of cancers, it is appropriate that studies of health impacts of other populations exposed to the same toxic substances as were present in the WTC smoke and dust also count as evidence, because it is evidence. It is crucial that mechanistic studies elucidating the underlying development of diseases be considered. Moreover, we would advocate, as with the decision on adding WTC cancers, the principle of biological plausibility should be applied where appropriate. You know, as has been stated several times, a lot is at stake in this process and I’m just, you know, going to reiterate, that process can be very, very tricky and you know, I now realize that my comments are actually inadequate to address the possible wrong turns in a process and, you know, we look forward to the opportunity to present written comments. But you know, it’s—we just, as a caution to the committee, please think this through very, very carefully.

To reiterate, it is essential to create a fully transparent process. It is therefore important that the public, as well as the STAC, have an opportunity to nominate experts with the appropriate subject matter expertise for the peer review panel. It is critical for a full accountability and credibility of the peer review process that the peer reviewers’ comments as well as their identities always be made public. It appears that the current policy and procedures documents do not require this measure of transparency. Our position is that there is no real accountability when undisclosed reviewers issue opinions to which the public and the affected communities have no access. And you know, we want to know who is ultimately the decider for who sits on the peer review panel, another thing not addressed in the policy/procedure document. Another issue is that some peer reviewers—maybe even all—who are appointed to assess whether a condition should be added will not be familiar with the key facts about the WTC disaster, principally, the unprecedented nature of the environmental disaster, and thus of the toxic exposures to which 9/11 responders and survivors were subjected. We believe it’s essential that NIOSH produce a briefing document to provide an orientation to researchers who have no idea what actually went down here, and of course I’m also referring to the character and duration of responder and community exposures resulting from the failed and utterly inadequate disaster response by the EPA, OSHA and others.

So now, actually, I’d like to address some calls for greater transparency from the STAC. First of all, we really need NIOSH to understand that the community and

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the broader public are not versed in the federal government's preferred style of communication. Part of our call for transparency is about your need to be accessible—NIOSH's need to be accessible. So first of all, we want to actually, we want to thank Paul Middendorf and Jessica Bilics for responding immediately to a request for a few paragraphs stating in plain language what these two policy and procedure documents are, what the STAC's charge is and what's at stake. And it went up on the website, and we are very appreciative. But the STAC really needs to do more. On nominations—the Survivors' Steering Committee spends a great deal of time and energy discussing, researching and reaching out to experts we'd like to nominate to STAC. We don't understand why more of our nominees are not appointed, particularly a nominee for responder stakeholder who is universally endorsed and is exceptionally competent. We'd also like you all to do a better job of introducing new members. There are new members here; we don't know who you are. We'd like to know, and to you all we'd also like to say, you know, welcome but please realize that you are entering an ongoing story in the middle. Finally, with respect to the STAC's deliberation on children's research needs which, you know, we participated in fully and we have high hopes of, you know, these are some follow-up issues here. We have never seen the STAC move to a new topic for deliberation without releasing final recommendations on the last topic. So what's the status of those recommendations? And with all due respect, Paul, the NIOSH docket is where public comments go to die, or at least become irretrievable to people like us. So they have to be in the docket, we get it, we know it's a legal requirement but frankly, you know, a lot of people at NIOSH, including Laurie Breyer and Amy Filko, have worked very hard to make the World Trade Center Health Program website an effective interface with the public. So why aren't recommendations, why aren't comments up on the World Trade Center Health Program's website? And you know, it actually would help NIOSH; it would help the program. It would show that you all are interested in the truth, however inconvenient it may be. It shows that you are engaged with the affected community. It means that you are capable of being self-critical. It gives your part of the federal government the credibility that was destroyed by the EPA and other agencies, and it may even convince survivors and responders that you might be a good place that they can get the World Trade Center healthcare they need. Finally, we want NIOSH's assurances, immediately or in the very near future, that a pediatric environmental health medicine expert—environmental medicine expert, sorry—will be appointed to the STAC with a term starting in September of 2016. Other speakers have spoken about how important that is for us, and if we don't have assurances, we may need to make our voice louder by explaining the situation to Manhattan Community Boards 1, 2 and 3 and Brooklyn Board 2. Catherine Hughes, who ably chaired Community Board 1 for many years, and Val Jones, who leads Board 3's health committee, can further explain what the

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Community Boards are and why they're important. Shorthand is they are the most grassroots level of New York City government. So again, you know, children who were exposed on 9/11 and in the environmentally toxic aftermath of 9/11 have been waiting a very, very long time for a consistent, intensive approach to research on the harm that resulted. And you know, it's long, long overdue. We don't know at this point, you know, what NIOSH envisions. We have sent a letter to Dr. Howard asking some very pertinent questions but you know, we need—the conversation has to continue with a pediatric environmental medicine specialist at the table on this body. There are research funding issues that I won't address right now and...and NIOSH has to move forward. Thank you for the opportunity to speak.

DR. MIDDENDORF: Thank you very much, Kimberly. We had everybody.

DR. WARD: Okay. So one thing we didn't do at the beginning that I believe would be useful is to have all of the members of the committee introduce themselves and say a little bit about your background and research interests if you are a researcher. So we will start with Dr. Mayer.

DR. MAYER: Hi, I'm Annyce Mayer. I'm an occupational and environmental medicine physician at National Jewish Health in Denver, Colorado, and as an occupational medicine specialist at a respiratory hospital, we see and evaluate patients with occupational lung diseases. And we have had a number of people who were responders who we had seen initially through the AOEC Red Cross Program, so have had some experience with evaluating, all adults, who have suffered World Trade Center-related conditions and have worked with our industrial hygienist to put together information to provide to students at the University of Colorado in regard to the World Trade Center exposures.

DR. WARD: Anthony.

MR. FLAMMIA: Good morning, everyone. My name is Anthony Flammia. I'm a retired disabled police officer from NYPD, variously affected by 9/11. I've been part of the FealGood Foundation, part of the Responder Remembrance Park, getting all this, the remembrance of the responders' needs. I've also participated in, for about eight years, down in Washington D.C. lobbying for this health bill. It's an honor to sit on the STAC Committee and hopefully we can get things moving forward.

MS. NORDSTROM: Hi, my name is Lila Nordstrom, I am the director of StuyHealth, which is an outreach and advocacy group that focuses specifically on young adult populations that were exposed to the—exposed to the disaster on 9/11 but also the cleanup, and we work very closely with 9/11 Environmental Action to make sure that our members, who are heavily dispersed nationally, have access to resources that help them, you know, know what their health—what their healthcare options are and how they can more effectively advocate for themselves.

DR. WARD: Megan.

DR. RYAN: Good morning, I'm Dr. Margaret Ryan. I'm an environmental and preventive

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medicine physician, currently professor at UCSD, also—University of California San Diego. I also work for the Department of Defense. I am a new member of the committee and very honored to be part of the committee. I spent much of my career in the US military and have done a fair amount of environmental and infectious disease research in the military, including a number of studies of reproductive health and birth defects and exposures that the military had, as well as firefighters and other kinds of first responders.

DR. ALDRICH: I'm Tom Aldrich, I'm a professor of medicine at Albert Einstein College of Medicine.

DR. MIDDENDORF: Can you turn on?

DR. ALDRICH: All right, I'll repeat. Tom Aldrich, I'm a professor of medicine at Albert Einstein College of Medicine and Montefiore Medical Center in the Bronx and I've been, since soon after 9/11, I have been involved in research regarding exposures and pulmonary function and other consequences of World Trade Center exposure through the Fire Department.

MS. McVAY-HUGHES: Good morning. My name is Catherine McVay-Hughes. I am currently chair of Manhattan Community Board 1, which includes the 1.5 square [kilometers], roughly, south of Canal Street, which includes the World Trade Center site. Our family of four was living, and we still live, one block east from the World Trade Center site. In terms of my background, Senator Clinton appointed me to the EPA World Trade Center Expert Technical Panel as the community liaison, where we discussed vigorously, for several years, the fingerprint and footprint of the World Trade Center dust. I've been on the STAC since it started. I've been working with everybody since September 11 on air quality issues and environmental cleanup. And also in terms of publications, before 9/11 I even senior authored a guide called "Get the lead out", which was actually used by New York City and New York State at different agencies.

DR. MIDDENDORF: I'm Paul Middendorf and I'm the designated federal official for the Scientific/Technical Advisory Committee. I have been since the beginning of the STAC. I also serve as the Deputy Associate Director of Science for NIOSH. I was part of the NIOSH team that responded to 9/11. We were a group that did a lot of the exposure assessment at 9/11 right after it occurred.

DR. WARD: Hi, I'm Liz Ward. I am chair of the STAC Committee and was for 21 years, I worked at NIOSH in the Industry-wide Studies Branch and was primarily doing research on occupational cancer but developed a pretty broad background in exposure assessment and other diseases related to occupation. I am currently at the American Cancer Society where I am Senior Vice President for Intramural Research in a program that is primarily research on the causes and prevention of cancer.

DR. ROM: I am Bill Rom at Bellevue Hospital in New York University School of Medicine. I was involved right after 9/11 in care of some of the individuals exposed to World

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Trade Center dust, and studying the particles from their lung. And then in, subsequent to that, I was on sabbatical with Senator Clinton, negotiating with EPA to develop World Trade Center dust programs; and more recently, over the past year, I have been with the NYU College of Global Public Health, teaching environmental health, including the World Trade Center dust health outcomes.

DR. HOMISH:

Morning, I'm Greg Homish.

DR. MIDDENDORF:

It's hot.

DR. HOMISH:

Morning, I'm Greg Homish. I'm a new member of the committee. I'm honored to be here. I'm associate department chair in the Department of Community Health at the University of Buffalo School of Public Health. My areas of research expertise are social and environmental factors related to mental health and substance use. I work a lot with special populations including US Army Reserve, firefighters and police departments.

MS. JONES:

Hi, I'm Vaylateena Jones. I am chair of the Health Committee of Community Board 3. I'm a resident of the Lower East Side. I got involved because I have a niece who during—who lived in the Smith Houses on the Lower East Side and subsequent, a few days I think, after 9/11, her children all had difficulty breathing and had to walk across the Brooklyn Bridge so that my brother could meet them and take them to his house out in Queens, and I've seen the effects on her children as they have grown, because she had three: one in a carriage, one walking and another one walking across the Brooklyn Bridge. And myself, I walked to work, I could smell the benzene in the air and just assumed that I was going to be okay as I walked to work every day after that. I think I was off the day of, and I walked to work every day after. So for me, this is very much about trying to get, to make sure that whatever can be done to assist the parents, the children and the residents of the Lower East Side will be done.

DR. MARKOWITZ:

I am Steven Markowitz, I am an occupational medicine physician and epidemiologist, and Director of the Queens Center actually for our World Trade Center Program for almost a decade, and I'm currently involved with World Trade Center research.

MS. MEJIA:

Good morning, my name is Guillermina Mejia. I am the Director of the Safety and Health Department for District Council 37 of the American Federation of State, County and Municipal Employees. DC37 represents 121,000 members that work for both the City government and State of New York. We had hundreds, probably thousands, of members who responded to 9/11 during the rescue, recovery and clean-up phases and as such, my expertise is worker protection. This is my second term on the STAC but I am also a member of the World Trade Center Steering Committees.

DR. HARRISON:

I'm Bob Harrison, occupational and environmental medicine physician at UC San Francisco. I've been on the STAC I think from the beginning and this may be—I don't know how the terms go—it may be my last meeting depending on how the

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cycling goes. I diagnose and treat work-related diseases and injuries as part of the many things that I do at UC San Francisco. So in terms of the particular issue facing us today, I am probably going to be thinking mostly about the weekly experience I have in determining the cause of occupational and environmental diseases in my patients and how I dive daily into the literature—you mention autoimmune disorders, and a patient that I am treating now with renal disease who was exposed to hard metal dust about 15 years ago in the San Francisco Mint who now has severe renal disease, and whether or not that disease is related to immunological toxicity. And how to go from the literature to the individual diagnosis, determining criteria, is something that my residents and I do every week, so it's—and I appreciate the challenge that faces the scientists at NIOSH and the STAC and whoever these peer reviewers are going to be, to figure that out.

DR. TALASKA: Hello, I'm Glenn Talaska, I'm Professor and Associate Director of the Department of Environmental Health at the University of Cincinnati. I've been on the STAC since its beginning and my research as a genetic toxicologist has been in the area of exposure to polycyclic aromatic compounds, aromatic amines and other carcinogens by and large, but I also have expertise in respiratory diseases in general.

DR. BOWLER: Hi, I'm Rosemarie Bowler. I've been on the STAC since last year and I am a neuropsychologist, one of the few neuropsychologists working in the area of chemicals, and have a long history of chemical disasters, several decades in California, and emerita from San Francisco State. Sorry, I have a bit of a cold. I served on the ATSDR board for a few years and also was part of a committee at the National Academy of Sciences on bioterrorism 10-15 years ago where we predicted some of the things that ended up happening, and discussed them at that time. So when the 9/11 happened, I was invited to participate and to learn about problems of the police, New York City Police who were involved in 9/11 response. This was followed by the Registry, very generously, granting us access to the police data on the three waves in fact, and we have publications, six of them, on the police. So was very committed to the police. Then on the last year's meeting, or in the publications on PTSD, PTSD and comorbidity, and social integration and social support and the relationship to mental health—last, the last summer's meeting, I was urged by the Registry individuals who were here and were talking to us that I really should look into the tower survivors because they have not been studied very much at all, and that is so. There really are only two or three papers on the WTC tower survivors. And I have, since this last summer, spent like eight months to finally be given the data on the tower survivors, and it's very, very interesting, I'm in the middle of writing the first paper on tower survivors, that of course have some of the highest PTS—rates of PTSD. And we're finding—a sneak preview—women have a lot worse problems than men, so we are

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stratifying that entirely on sex. And I even submitted a proposal on the tower survivors to NIOSH because one area of interest, as a neuropsychologist, last meeting again when it was proposed that so many of these people have come with different impairment, and have said you can't say somebody has cognitive impairment because we have three items on the wave three questionnaire about that, that really has to be investigated. So this is one of the proposals that went in to the tower survivors. And still, I was interested in the police as well, and it's a real conflict, and—but the tower survivors are of great need. So I have been very pleased to be able to contribute, and I think that my work probably has contributed some in terms of being out in the literature and now with the tower survivors being so relatively unknown and unstudied, it's quite fascinating and I hope that I can make a contribution to that group as well. So thank you very much. I've enjoyed being on the STAC so far.

DR. WARD:

Thank you, and Mike McCawley on the phone?

DR. McCAWLEY:

Hi, this is Mike McCawley. I am chair of the Department of Occupational and Environmental Health at the School of Public Health at West Virginia University. I also spent 27 years as an industrial hygienist at NIOSH before starting into this job after 2002. My background at NIOSH was mostly occupational respiratory diseases but for the last 10 or 12 years, I've been looking at unconventional natural gas development, otherwise known as fracking, and looking at the effects on communities and the people in the communities for... what their exposure is and what the health effects are that are associated with that. Along with that, I have done research on mountaintop removal mining and on the communities in those areas. Currently, I am studying the perinatal effects of exposure to hydraulic—hydraulic fracturing activities.

DR. WARD:

Thanks, Mike. So now we'll—

CATHERINE HUGHES: I have one comment.

DR. WARD:

Yes.

PARTICIPANT:

I want to say, Dr. Bowler, before I forget, on your study for survivors, I think you also have to do—because I understand from the last 15 years of psychological studies, that you should have cut on income and also education.

DR. BOWLER:

Yes. Yes.

CATHERINE HUGHES: Because if you're comparing men to women, you might find that—a difference in that as well. So I just wanted to be on the record for that.

DR. BOWLER:

Thank you very much. That's also what we're seeing, that the income is quite different by sex as well and that those...

CATHERINE HUGHES: And the education probably at that time.

DR. BOWLER:

Although the tower survivors probably are the most similar group to us all. They, most of them, except obviously the support personnel, on the lower end of the education, they are most of them college graduates, and so it's very fascinating. Thank you for that pointer.

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OVERVIEW OF PEER REVIEW AND APPROACH TO POLICY AND PROCEDURE DEVELOPMENT

DR. WARD: So we'll turn to our next speaker, John Piacentino, who will talk to us about the requirements in the legislation for the peer review, and also, I think, will try to get as many of our questions about the intent of the language on the table after John speaks, so that we're really clear on, you know, what the language says and what the intent is. Yes.

DR. PIACENTINO: Okay. Well, good morning and thank you. My name is John Piacentino. I'm the Associate Director for Science at NIOSH. Thank you very much for this opportunity to discuss peer review with members of the committee. I recognize that many members of the committee or some members of the committee may actually have experience either serving as peer reviewers or perhaps even directing peer reviews, and there may be others that have no such experience. And so what I've tried to do is just pull out what I would think are some key concepts or basic concepts regarding peer review, regardless of your experience, to help facilitate the discussion and help with the STAC and its new responsibilities to identify peer reviewers. If you have any questions during this presentation, please don't hesitate to stop me if I'm not clear. And I also would point out that, in your books, the slides are available to you if you prefer to follow along in the book under the tab marked "peer review". So how about if we go ahead and, if we're okay, let's just go ahead and get started.

I specifically titled my presentation "Independent Peer Review" and the subtitle "For meeting the standards of the scientific and technical community". And I just wanted to highlight that because I find it helpful to remind myself why we conduct peer review, and I think that it's helpful just to remember that, when conducting peer review, what you're trying to do is determine whether or not whatever is being peer reviewed—in this case, it would be a notice of proposed rule-making—is meeting the standards of the scientific and technical... Oh, I'm sorry it's not...maybe if we could just advance the slides.

DR. MIDDENDORF: Maybe. I think the problem is with Adobe Connect.

DR. PIACENTINO: Okay.

DR. MIDDENDORF: I'm going to bring it up.

DR. PIACENTINO: And while we're doing that, I'm just going to continue on. I'll invite you all to just follow along on the slides, and you don't have to necessarily follow the slides, per se. So it's just a short set of slides. I think what we'll do is just remind ourselves of the requirement in the Zadroga Act Reauthorization. I'll go through some basics in terms of purpose and methods of peer review, and then we'll get right to it in terms of identification of peer reviewers, and certainly leave time for questions. So next slide please.

And so, as Dr. Howard pointed out earlier today with regard to the addition of health conditions, the list of World Trade Center-related health conditions, section F states that, prior to issuing a final rule to add a health condition to the list in

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paragraph 3, the World Trade Center Program Administrator shall provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such a final rule. And next slide please. And so what comes to the Advisory Committee, then, is that not later than one year after December 18, 2015, and not less than every two years thereafter, the World Trade Center Program Administrator shall seek recommendations from the Advisory Committee regarding the identification of individuals to conduct individual peer reviews under sub-paragraph F. And so this is what we'll be focusing on this morning in terms of identifying individuals to conduct individual peer review. So let's move forward. So I tried to answer what I thought was an easy question, that is, what is peer review? And I've offered up maybe a few different ways that you can think about peer review. And so we sort of started off in terms of, well, we conduct peer review to ensure the quality of the public information meets the standards of the scientific and technical community, but there are other ways to think about peer review. And so, if you'd like, you could think about it as a process, right? Peer review, it's a form of deliberation. It's an exchange of judgments between the people who produced the draft versus others that are reviewing the draft, and the exchange of judgments is about the appropriateness of methods and strength of the author's inferences. And then the third bullet is just to remind ourselves that peer review of a draft product is not—it's for quality by specialists in the field, so there is this idea of specialty or expertise, but the folks who were not involved in producing the initial draft. And so there are at least three different ways, I think, that we can think or try to remember what peer review is. Let's have the next slide please.

So what do peer reviewers evaluate? In this case, so very specifically speaking, peer reviewers would be evaluating a notice of proposed rule-making. Peer reviewers are given a charge. So what that means is, when you hand over a notice of proposed rule-making or some document, you would ask peer reviewers how to—we're going to ask you specific questions, and so embedded within the policy and procedures—so, remember, later on this morning, you'll hear from Dr. Reissman and Dr. Carreón-Valencia the different procedures in terms of how to add conditions or for adding conditions to the list of covered conditions. Embedded within those documents is the charge to peer reviewers, and so, if you read through, the questions would be: Are you aware of any other studies which should be considered? Have the requirements of this policy and procedures been fulfilled? And is the interpretation of the available evidence appropriate? Does it support the conclusions to add the health condition, as described in the regulatory text, to the list? So you can see that this is what's shaping the peer review that would happen within this particular context. Let's move forward please. So we have a—so this idea of selection of peer reviewers, it's based on consideration, I would say, of five points. And so the first consideration is

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expertise necessary to evaluate the science relied on. The second would be any potential conflict of interest; independence from the sponsoring agency; balance with regard to a diverse representation of respected scientific perspectives; and the last one would be rotation. And what I'll do is I'll take all of these in order. We'll go through them one by one, because this would be the common language, I think, that will assist members of this committee as you try to think about how you would go about identifying peer reviewers and whether it's identification of peer reviewers directly or making some other recommendation with regard to a process. So let's work through each of these criteria, if you will.

So let's start out with expertise, and so expertise, how do you know what appropriate expertise might be useful or valuable? And I find it helpful to think about expertise in terms of qualifications, knowledge, and experience. I selected clinical expertise. I think that that would be something that this committee might look at with regard to adding health conditions to a list of covered conditions. This list of clinical specialties, if you will, is by no way meant to be exhaustive. It's just simply meant to be illustrative, that you might think about what necessary clinical expertise would be desirable when reviewing a notice of proposed rule-making. So let's go to next please.

Take a moment just to discuss conflict of interest. Conflict of interest means any financial or other interest which conflicts with the service of the individual because it could significantly impair the individual's objectivity or could create an unfair competitive advantage for any person or organization. Let's take a minute to just reflect on this in terms of conflict of interest. And, here, the principle that's being exercised is that you may have someone with the appropriate expertise, when you're evaluating for conflict of interest, because the general interest here is to make sure that expertise is delivered in a way that does not impair the individual's objectivity, so the interest here is to make sure that you're having some sort of objective opinion. Because, remember, the goal of peer review is to establish whether or not the evidence relied on meets the technical standards of the scientific community, and so there is an interest in looking at whether or not reviewers may have a conflict of interest. Can we go to next?

And I purposely put this slide next because this, here in, I think helps distinguish the value of and difference between peer review and stakeholder review and public comment. And what I mean by this is that peer review, in terms of selecting scientific expertise to help you establish merit, is one scenario. That's not to mean that you would not find merit or value in having review from stakeholders in the public. This is a different process. In fact, stakeholders and members of the public may have valuable input for rule-making, however, there is a distinction between having an interest in the notice of proposed rule-making and the input that you would get, versus having an impartial—or being free from conflict of interest. In fact, stakeholders and members of the public may even have expert knowledge

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that would be beneficial for evaluation or for review. Move on please.

And so, lastly, remember, we said there were five principles. We did one and two already. Here's three, four, and five all in a row. Specialists in a field who were not involved in producing the notice of proposed rule-making, independence from the sponsoring agency. And let's talk about this. So the first one is independence. Narrowly speaking, independence would mean that you would want to have a review by individuals who were not involved directly in producing the notice of proposed rule-making. Independence would be extended, though, beyond that to be that you would select individuals who would not be part of the sponsoring agency. And so there's an array or a spectrum of independence that might be beneficial for review of a notice of proposed rule-making.

Let's take a moment and talk about balance, and here we're discussing breadth and diversity within the scientific and technical community, and here the principle is that you would like to identify peer reviewers that represent a diversity of scientific and technical opinions you try to balance. There may be no single individual that would be capable of providing you the full array of expertise necessary to adequately review the scientific basis. And so what you would try to do then is to identify several experts, if you will, in order to balance the review, in order to create some breadth and diversity. Recognize, of course, that many folks, and folks on this committee themselves, have multiple expertise within the same individual. So, for example, during introductions, folks would mention whether or not they had an expertise in, say, occupational medicine or pulmonary medicine, but go on to say that they also had research experience. And so there you can see an example of somebody who would have multiple areas of expertise within the same individual and, therefore, be able to provide you the benefit of multiple perspectives while still being just a single individual. And so the idea of breadth and balance is something that you may want to consider as you try to think through identification of peer reviewers or a process for that. And, lastly, the last principle is rotation, the idea of rotating peer reviewers so as not to ask or maintain a stable—not to get an opinion from the same individuals consistently, if you will, over a period of time. Next slide please.

So I tried to create a little bit of a summary that would sort of help launch you all into a discussion, and this is my last slide, "Tips for Identification of Peer Reviewers". I would say that what you would like to do is match the peer review expertise to the health condition being proposed for addition, and that may not be possible to know that in advance, that may not be something that you would know with a lot of time, that may be something that just comes up rather quickly. You would certainly want to identify individuals with sufficient expertise and independence and freedom from conflict of interest, identify a balance of individuals representing a diverse set of scientific perspectives. And, to my first point in terms of the challenge of identifying peer reviewers, it may not be possible

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to know which expertise might be beneficial at any given moment, and so, perhaps, you may all want to consider whether or not you'd like to describe a process for identifying your reviewers. And I think that that takes me to the end of the presentation. I'm happy to answer any questions or give you plenty of time to get through your questions.

DR. WARD: So I had one question based on—related to one of your slides. So your slide that the individuals who would be selected as peer reviewers would not be involved in the proposed rule-making, but that made me realize that I don't really—I'm confused about the time sequence. So does that imply that there would be a whole process where the STAC might be consulted and then NIOSH would make a decision that they're going to propose a new condition, and then there would be a peer review? Because that was implied by the statement that the individuals couldn't be involved in drafting the proposed rule-making, but is...

DR. PIACENTINO: So I'm not sure I quite tracked your question, but let me try to reframe what I was saying. When I said that you would want to select individuals that weren't involved in the notice of proposed rule-making, it would be those individuals that are drafting the notice of proposed rule-making. That's a smaller team.

DR. WARD: But wouldn't the notice of proposed rule-making be drafted after NIOSH had already made a determination?

DR. PIACENTINO: Oh, procedural. I hadn't thought about that. I don't know the timing on that. I don't know (inaudible @ 16:22).

DR. WARD: Okay, I guess—so I think that some clarification on that would be useful to the committee and also some clarification just to the whole time sequence of how these new conditions might be proposed.

DR. PIACENTINO: Right. Paul please, yes.

DR. MIDDENDORF: Typically, the time sequence is that, when a petition comes in and is determined to be valid or when the administrator makes a determination that he wants to go through the process of adding a condition, the science team will get together—and all this is in the policy and procedures—the science team gets together, they review the evidence, they make a recommendation to the administrator. Then the administrator decides, yes, we're going to go forward with this, if he decides that we are going to move forward and develop a notice of proposed rule-making, then the initial determination is published in the notice of proposed rule-making. That is what, under the current policy, is sent off to the peer reviewers to review. At the same time, we put out the notice of proposed rule-making, asking for stakeholder input.

DR. WARD: Other questions?

DR. MARKOWITZ: Yes, it's Steve Markowitz. So why—I mean, again, there's more on these policy and procedures later, but why is this independent peer review envisioned after essentially the administrator has made a decision about whether to add a condition or not? Clearly, the administrator has made that decision by the time of

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the notice of proposed rule-making in consultation—after a science team review, with or without the participation of the STAC, but that decision has been made. And now that the external peer review occurs, I'm just wondering—I don't have an opinion about this, I'm just wondering why it was placed there as opposed to earlier in the process where it may have influenced more the administrator's decision.

DR. PIACENTINO: Sure. Paul, do you want to speak to that?

DR. MIDDENDORF: Sure. Typically, when you have a petition, you only have 60 days from the time of the petition until you can publish the notice of proposed rule-making. So there's only 60 days in there for the full science team to do its thing, in addition to all the administrative things that have to happen. And there are a lot of administrative things that happen including writing the notice of proposed rule-making and having it reviewed by CDC, sometimes it goes up to HHS or even potentially OMB. So that 60 day—initially, what was 60 days, which is now 90 days, still about half of that time period is taken up by administrative actions. So, in looking at it, the best time to do it seemed to be during the time when the notice of proposed rule-making is published. It seemed to be the best time to be able to actually accomplish a peer review.

DR. MARKOWITZ: It sounds like essentially it's the only time because 90 days is too short to do that independent peer review.

DR. MIDDENDORF: That—

PARTICIPANT: We can't hear you.

DR. MARKOWITZ: No, I was just making the point that 90 days is too short to do an external peer review, so essentially it's the—the only time, given these time frames, to do that external peer review seems to be during the notice of proposed rule-making.

DR. WARD: Other questions and comments?

MR. FLAMMIA: I have a question. Doctor, thank you for your presentation. I wanted to address—and actually how do you address the—and I see independent peer review and I see it throughout all of the slides that are here, and you made a great representation as to the difference between peer review and stakeholders, but how is the peer review going to address the transparency and accountability as what the public said on public comment? How are you going to streamline the process? I mean, I see it just as another bureaucratic level of bureaucratic stuff. So can you address that?

DR. PIACENTINO: So, I'm sorry, when you say the bureaucratic level, which part? I don't understand what you're saying is the bureaucratic—

MR. FLAMMIA: The bureaucracy, you're adding another layer of bureaucracy. You're actually adding time to the process, and that's what you're doing. It's a layer of things to get through. How are you going to address that?

DR. PIACENTINO: So built in—so in the reauthorization, there is a requirement for the peer review.

MR. FLAMMIA: So a specific (complication @ 20:53) of the law, I'm aware of that, but how are

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- you going to address the transparency, the accountability, and streamlining the process, and not adding any more time to it?
- DR. PIACENTINO: Okay, yes. So this is—so, Paul, I'll take a crack at it. If you have something else you want to—please. So that's a—so I think the question is about timing, if you don't mind, the question is about timing. How is it that you can get peer review put into an event that's already unfolding according to timelines? And so the peer review can happen concurrent with something like public comments, so it's not as though you have to run peer review, necessarily, in series, if you will. You can actually run it in parallel to try to accommodate the time frames, but also to make sure that you're achieving the peer review as well. Anything else, the colleagues present think?
- DR. MIDDENDORF: Yes, thank you.
- MS. MEJIA: So, in looking at your presentation, I notice—we have this document also added to our packet, which is this Bulletin for Peer Review, and it seems—and I read this last night. It was really a long read, I must say, but it seems that your presentation only picked and choosed certain elements of this bulletin, because it seems like chapter two applies to certain reviews and chapter three applies to other reviews. Can you elaborate a little bit further on why you picked and choose certain elements of this and how it applies to maybe the work that the STAC is doing?
- DR. PIACENTINO: Sure, thank you, thank you for the question, and thank you for bringing up the bulletin. So the bulletin—and what I think—sorry, I'm missing your...
- MS. MEJIA: Guille.
- DR. PIACENTINO: Guille, I think what Guille is referring to is the OMB Bulletin for Peer Review. This is a bulletin that guides agencies in terms of practices and—basically, general practices for how to—or best practices for peer review. And so, you're right, I could not, in fact, portray any and all of the information that came out of the OMB Peer Review Bulletin. I tried to select information for my presentation that would drive most closely with the time. So this part of the presentation, which is identification of peer reviewers—and so there is certainly information that's in that bulletin that's not represented in this presentation. I tried to very quickly get you oriented to what criteria, if you will—or how one goes about identifying peer reviewers and then selecting peer reviewers. There is other information in the bulletin that includes procedures. This gets to, Mr. Flammia, your question about timelines, how do you manage timelines for peer reviews? Those types of—that area in terms of procedures is something that I suspect will come up later as you guys hear the policy and procedure presentations regarding adding cancer and non-cancer conditions. But certainly they're intertwined. I just tried to grab a little bit of focus for this part.
- MS. MEJIA: No, I appreciate that, but it seems like, again, you carved out certain areas, and I think it was important to maybe highlight what's in this in your presentation, so that it's very clear that we're not just limited to, you know, what you're saying, but there

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- are other factors that need to be considered.
- DR. PIACENTINO: Yes, thank you.
- DR. TALASKA: Thank you. And the earlier questions cleared up several of the things that I had some concerns about, but, in your opinion, though—oftentimes in peer review when we are reviewing a paper or suggest reviewers for a journal, we'll look at the references of the material that was provided to look for who are experts in that field. Would you consider that, for this committee's purposes, the people—we could include reviewers who were people who we cited in a proposed rule when we did the evaluation and our recommendation, or would we have to go to the authors of the papers that those authors cited?
- DR. PIACENTINO: And why would you see that?
- DR. TALASKA: Because would there be any conflict in doing something like that, from your point of view, at this point, in using the—?
- DR. PIACENTINO: I think it might—I don't know that I could speak to that. I don't know that I could speak to that in general, give you good advice generally. I think that, as the context arose, that would be something that would be considered. So, remember, you're trying to get the benefit of the best expertise possible, at the same time, you're trying to manage conflict of interest. I'm not sure that I can advise in terms of whether or not there's a hard line or contour regarding this generic presentation. But I think that, at the time of reviewing a set of reviewers, that would certainly be something that would be taken into consideration.
- DR. HARRISON: It also strikes me that there are at least two models for peer review that you mentioned. One is the scientific journal peer review model where the reviewers are anonymous and unknown to the person that's submitting the research paper, and I've been on both sides of the equation, both submitting the research paper and being a peer reviewer. And then the other model is in the—a peer review where the reviewers are identified or identifiable, but their comments are anonymous to the person submitting the proposal for review. And an example of that would, I think, probably be NIH, the NIH peer review where, correct me if I'm wrong, the panel is identified, but the comments, when they're given, are not identified to the individual. And there may be other models, but those are the two that I'm most familiar with. It strikes me in this case that model B, which is the NIH peer review model, is more appropriate to this overall process of the World Trade Center which, I think—correct me if I'm wrong, Paul—reflected your comment earlier that it was the intent of the NIOSH proposal for peer review to have the reviewers identified, but when they are giving their comments, not—
- DR. MIDDENDORF: Attributed.
- DR. HARRISON: Attributable. Now, that being said, and I agree with that, it seems that model is more appropriate to this. It'd be kind of hard, just as a practical matter, if there's only three reviewers, but, that being said, I don't think there's any way around it because the congressional—it's clear in the act that there's only three peer

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reviewers. It's kind of hard to be anonymous as a peer reviewer if there's only three. But, that being said, I think that plan seems more appropriate.

DR. MEJIA:

Yes.

DR. ROM:

Yes, two very quick questions. First of all, usually I get an email asking me to be a reviewer from one of the staff at NIH, so who's going to identify all these reviewers? Is Paul or the administrator going to be identifying a stable of reviewers? And is this a stable or is this a specific event, say somebody petitions coronary artery disease, which is going to be a huge area, and there's a 60-day or 90-day period, and the administrator says, "Yes, this may be a disease of concern," and then who's going to choose that panel of reviewers, the administrator or the STAC, Paul? And the second question is we do have a panel of reviewers that the GAO chose and there's a list of ten of them and they look very well-chosen. Who did that? Who chose those people? Did GAO do that and NIOSH have no input, or how did that happen? So those are the two questions.

DR. PIACENTINO:

Sure. So let me start out with the second one because it's a bit easier for me, and that is I'm not sure how the GAO identified their peer reviewers. However, back to your first question in terms of selection of peer reviewers, because there is a difference between identification versus selection of peer reviewers. Identification is you're thinking about a potential pool or a potential candidate, versus selection which is actually the invitation to the individual to perform the peer review. And I think, Dr. Rom, you have rightly pointed out that there is some timing and difficulty in terms of making sure that there is an appropriate candidate available for peer review. And I think the timing is related to, as a petition is brought into the program, there's certain milestones that must be met. And so identification in terms of peer reviewers, at that point, is something that has to happen either extremely expeditiously, if you will, or something that may have had to happen prior to that time period. And I think that's something that the STAC should probably take a little bit of time and think about in terms of the practicalities of what it means to identify peer reviewers, and perhaps one approach will be to spend some time identifying a pool of candidates and, therefore, you've already pre-identified candidates. As you think about what conditions perhaps might be likely to be coming to the program for a request, it might be helpful to try to identify a pool that then could be selected from at some point, when the time is right, if you will. And you also may want to think about a procedure—what would it mean or how might you think through the issue of the time—but now is the time, you know, now the petition has been declared and we had pre-planning up to this point, but at this point now, we really need to make sure that we have the right selection of candidates. I would encourage you to think about this and how would you navigate or recommend that the program navigate that situation? I don't think this is particularly easy, by the way. I think this will require a certain amount of thinking. And I look forward to the recommendation.

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- MS. McVAY-HUGHES: Catherine Hughes here. I just wanted to point out, in the timeline, the potential conflict between the real world and the academic and scientific world. I just want to point this out as we approach the 15-year anniversary. It has been an issue for someone who is suffering from a disease or dying from a disease, in terms of getting the data out and even getting, you know, the first wave of peer review items. So I just wanted to mention that issue and how that disconnect can be incorporated into the real world.
- DR. PIACENTINO: Thank you for that comment. If I may, I think that, again, thinking through that and having a recommendation in terms of how you think it would be best to manage that, I think that would be helpful. I think it's an important issue.
- DR. MARKOWITZ: Steven Markowitz. I wanted to just follow up, I'm still a little stuck on the timing of the peer review. If it occurs—it's envisioned to occur during the notice of proposed rule-making.
- DR. WARD: Mic please.
- DR. MARKOWITZ: Yes, so the mic is on, but—
- DR. WARD: We're just not hearing everything.
- DR. MARKOWITZ: Okay, okay, I'll swallow the mic. So I don't know the timeframes of the notice of proposed rule-making and how they accommodate the peer review. I assume they're more generous than the legislated time constraints that NIOSH has, but is it that the external peer review might occur simultaneously with the public comment period? Because, if that's true, then that means the public won't have the ability to comment on the product of the external peer review. I realize you may not have gotten to that level of detail, but I'm still kind of stuck on whether it's going to even work during the notice of proposed rule-making period.
- DR. PIACENTINO: I'm trying to think through that process in my head, in terms of when the peer review actually occurs and what opportunity there is for exchange between the public and—
- PARTICIPANT: And the peer review.
- DR. PIACENTINO: And the peer reviewers. I'm not sure I can answer that right now. However, Paul, if you want to chime in. Sorry.
- DR. MIDDENDORF: Yes, I was just going to say, as currently envisioned, there isn't enough time in that timeframe to allow the peer review comments to come out before the stakeholder comment. There are regulatory requirements as well as statute—the statute only gives us a certain amount of time. The best time to do the peer review is the same time as the public comment period. And, yes, it does eliminate the public from being able to comment on the peer review comments, but we couldn't figure out another way to do it. If you can figure out another way to do it, give us good advice on how to accomplish that, we'd very much appreciate it.
- DR. WARD: Yes, Annyce?
- DR. MAYER: One thing that might help me is a, like, a flow diagram that would outline the specific steps that need to occur and sort of the estimate timeframe for those, to

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try to see how maybe these different pieces could fit together.

DR. PIACENTINO: Thank you.

MR. FLAMMIA: If I may, Doc, just to add onto that flow diagram, it actually would improve the transparency and the streamlining process for the public and for everyone else, to visually see it.

DR. PIACENTINO: Sure, thank you. (Inaudible @ 35:25).

MS. JONES: I guess I somewhat feel the same way. I don't quite get this total process here or the timeline or what it is that we can comment on, because as somebody who very often comments from somewhat a public place, the more information I have before I comment, the better I think my comments are going to be. So I don't quite understand where we are or what we can do or what our input can be about this timeline.

DR. PIACENTINO: Okay.

MS. JONES: You know, in terms of—you know, I don't quite understand what constraints are in place that we can, in some kind of way, determine that public comments are after a peer review report comes out or whatever. You know, what are the constraints that makes that impossible to comment on this timeline?

DR. PIACENTINO: Okay, so thank you for that. So how about—I'll offer a suggestion. Now, I don't have a flow diagram or I'm not aware that, in any of our presentations, we have a flow diagram for you today, okay? So I don't think that that's going to come up. Now, that being said, I think, Ms. Jones, you offer a very important point and that is—but it's hard then, for me, to understand how can I assist or help with identifying peer reviewers if I don't quite understand the flow or the process? And so here's my suggestion in terms of how you may want to come out of this. One is you could think very quickly that right now what you'd like to do is focus on identification of peer reviewers. This is something that's directly in the reauthorization of the Zadroga Act. There is an idea there that the STAC would assist in terms of—or provide recommendation on how to identify peer reviewers. Regardless of where it shows up in the process, you could try to isolate that and think through, how would we go through identifying peer reviewers? Now, another option or some other way to think about this is, just generically speaking, what happens is—so think about the scenario where there is a notice of proposed rule-making and this is what is going to receive peer review, also, embedded within that process, would be this idea that the public will also have an opportunity to comment on the notice of proposed rule-making. And, Dr. Markowitz, this gets back to your comment in terms of, well, I have a question regarding timing. There are some scenarios where you could, in fact, have a panel of peer reviewers so that they could have an exchange with the public, and this is how you could start out, if you will, a public comment period. Another opportunity would be to try to somehow time the two events, one versus the other. Now, for today's purposes, there is no flow diagram to actually refer to. I'm simply trying to give you some

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tools to think about what you think is important. What do you think is important in terms of establishing the scientific and technical merit of the underlying scientific evidence used for this notice of proposed rule-making? And, to the extent that the procedures are important to that, you would think through that. And, remember too, embedded within this, of course, is the idea that you'll have to—not have to, but make recommendations for identification of peer reviewers. I don't know if that helps you or not.

DR. WARD: I would suggest that maybe we move on to the presentations on the policies and procedures for adding cancer and non-cancer conditions, because I think those presentations may make us a little more clear on the processes and in what sequence they'll occur, and also in the interest of time. But thank you. I think this is a—that was a very helpful introduction.

DR. PIACENTINO: Great. Thank you very much for your time.

OVERVIEW OF POLICY AND PROCEDURES TO ADD CANCER CONDITIONS

DR. WARD: Our next speaker will be Tania Carreón-Valencia, talking about policies and procedures for adding cancer...

DR. CARREÓN-VALENCIA: Good morning and thank you for the opportunity to discuss with you today and present an overview of the policy and procedures to add cancer conditions to the World Trade Center list of related conditions. My name is Tania Carreón-Valencia and I am a researcher, epidemiologist with the World Trade Center Health Program. Under the Zadroga Act, there are two pathways to add a cancer condition to the list. The first one is the administrator of the World Trade Center Health Program initiates the process at his own discretion, or the administration initiates the process after receiving a petition by an interested party. In both cases, a health condition may only be added to the list by rule-making. Once the process has been started, the science team of the World Trade Center Health Program reviews the scientific literature to determine if there is a sufficient basis to potentially add the condition to the list. They do that by conducting a systematic literature search, and this includes studies that regard the type of cancer among 9/11-exposed populations, studies that evaluate potential causal associations that cancer and a condition is already on the list, or the most recent classifications by the World Trade Center Health Organization's International Agency for Research on Cancer, and the National Toxicology Program's Report on Carcinogens. All this evidence is reviewed, and the scientific team then determines if this information is relevant, and it is presented to the administrator. This information must be presented in peer-reviewed, published epidemiologic studies of the cancer in 9/11-exposed populations. The Program also evaluates the quality and quantity of relevant studies that are reviewed for their potential to provide a basis for deciding whether to propose adding this cancer to the list. The scientific team also evaluate the findings of the information about IARC classifications and the NTP Report on Carcinogens. All of these are summarized and discussed with the

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administrator.

The administrator then receives this information and decides if there is relevant information and if it's adequate to proceed with—propose adding a condition to the list. If the evidence does not provide a sufficient basis for that decision, then the evaluation is documented and archived. And if it's initiated by a petition, then the determination is published in the Federal Register and the petitioner is notified in writing. If this evidence, however, has the potential to provide a basis for that decision, then the administrator directs the science team to assess the scientific and medical evidence, and he may request advice from the STAC.

Then, once this process—it continues, the science team conducts an assessment of the available evidence. To do that, we follow four methods, and at least one of these methods must be fulfilled to propose adding the condition to the list. Method one is reviews epidemiologic studies of September 11, 2001-exposed populations. Under method two, established causal associations with a health condition already on the list are reviewed. Under method three, we review evaluations of carcinogenicity in humans by IARC and NTP. And under method four, we conduct a review of information provided by the STAC upon request of the administrator. I'm going to discuss these methods in detail in the following slides. This information is gathered, reviewed, and presented to the administrator and discussed with him.

Under method one, the published studies peer reviewed epidemiologic evidence in 9/11-exposed populations are assessed and added to the list if they meet the following Bradford Hill criteria. We look at strength of the association between a 9/11 exposure and a health condition, and we also look at the precision of the risk estimate. We look at consistency of findings across multiple studies, and if there are only one studies, we cannot look at consistency, so we place more strength in the strength in the association and the precision of the risk estimate. We also look at biological gradients and those response relationships between the 9/11 exposures and the health condition. And, finally, we evaluate the plausibility and coherence of known facts about the biology of the health condition. Under method one, currently no cancers have been added to the list, however, there are several studies that have been published and that provide some evidence that cancers are related between 9/11 exposures and these conditions.

Under method two, a cancer may be added to the list of World Trade Center-related health conditions if there is a well-established scientific support of multiple studies that provide a causal association between a cancer and a condition that is already on the list. One example of that is adenocarcinoma of the esophagus that progresses to gastroesophageal reflux disease or GERD. This condition is already on the list and we know there is good evidence that supports that association.

To add a cancer to the list under method three, there are two criteria that must be

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satisfied. First, 9/11 agents have been reported in published, peer-reviewed exposure assessment studies of responders, of survivors, in the New York City disaster area or the Pentagon and Shanksville. And, two, either the National Toxicology Program has determined that these agents are known to be human carcinogens or reasonably anticipated to be human carcinogens, or IARC has determined that there is sufficient or limited evidence of this association. Examples of the cancers added under these methods are mesothelioma and ovarian cancer.

Finally, under method four, a type of cancer may be added to the list of World Trade Center-related health conditions if the STAC has provided a reasonable basis for adding it. And one example, of course, is childhood cancers.

Once these methods are reviewed, the science team provides the information to the administrator, who then decided to continue and develop a notice of proposed rule-making in the Federal Register, if at least one of the four methods is fulfilled. If none of these methods is fulfilled, then the administrator decides not to propose a rule and publishes such determination in the Federal Register. Finally, the administrator may publish a determination in the Federal Register when there is insufficient evidence and decides to take any of these actions. The same applies whether the request was in response to a petition or it was initiated by the administrator.

Now finally, to propose the rule-making to add the cancer condition, the administrator publishes a notice of proposed rule-making in the Federal Register which requests public comments. Also, at this point, peer reviewers are identified, with consideration from STAC's input, to conduct an independent peer review. Dr. Piacentino has already discussed what this peer review entails and what questions are asked. These peer reviewers are three subject matter experts and they are asked to provide a short, written review of the available proposed rule. Finally, if there is sufficient support to add the condition to the list, first, the administrator considers and responds to comments from peer reviewers and the public, and then determines whether this evidence continues to support the addition of the cancer, and publishes the final rule in the Federal Register. This is all I have for you today. I'd be happy to answer any questions you may have.

DR. WARD: Questions or comments?

DR. MARKOWITZ: Steven Markowitz. So I just wonder why the nature of the evidence that the science team will look at seems to be restricted to the epidemiology that exists for the WTC-exposed populations, and why you're not looking more broadly at relevant epidemiology, but also at potentially relevant animal studies or mechanistic studies.

DR. CARREÓN-VALENCIA: Well, under method three, we look at all of the other relevant information and see if it fulfills the criteria, and also it supports an evaluation of carcinogenicity under IARC or NTP evaluations. These evaluations, by the way, also consider

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- mechanistic evidence as well as animal studies.
- DR. MARKOWITZ: So let me clarify because, you know, sometimes NTP and IARC periodically review or re-review agents, and it's timely or not, depending on their schedules. So I agree, obviously, with relying on their assessments, but sometimes they're not available at the time that you need it or it may not be updated. So let me just clarify then, when the science teams review, they will be looking at more than just WTC-related published studies, epidemiological studies, is that right?
- DR. CARREÓN-VALENCIA: Only under method three and only if both conditions are met. So if the IARC evaluation is out of date or hasn't been updated, and it hasn't been supported, we would not be considering adding to the list. Is that an adequate assessment, Paul?
- DR. TALASKA: Thank you. Thank you, Tania. This clarifies some of the issues that I think we've had about how the whole program works, because the STAC is evaluated in a relatively limited sense in, oftentimes in this. I guess—so to follow up on what Steve said, if there is literature suggesting that there is an agent that is, say, genotoxic, but in an animal study or in whatever, that data would not be included unless it was included in a review by IARC or NTP?
- DR. CARREÓN-VALENCIA: That's correct.
- DR. TALASKA: So any mechanistic studies that we propose, similarly, just would not be included even though they—okay, that's an important thing.
- DR. WARD: Yes, Annyce?
- DR. MAYER: So I'm not sure how this—sorry—if this would be feasible or how this fits within the framework, but, you know, one of the things that, in addition to looking at the disease and what's in the literature, is the concept of looking for sentinel health events, either new diseases that are seen with an exposure or unusual clustering of cases of a disease within an exposed group. And I don't know if this would be feasible, but is there the possibility that there could be, like, a registry for—if physicians are diagnosing disease in these people who the conditions are not an accepted condition, could present the information on the disease and limited information about, you know, what type of work they did, where they were located. That may help to identify earlier unusual diseases that may not be picked up by one individual provider or in epidemiologic studies, but could be captured and assessed periodically, that if you're seeing an excess representation, that that would provide a mechanism for that to be evaluated.
- DR. REISSMAN: Hi, I'm Dori Reissman. I'm the Associate Administrator for the World Trade Center Health Program. And I came up here really to try and help answer that particular question. In our program, we actually do health monitoring of the people who are in a response category and on the survivor category for those who have certified illnesses. What that means is that there's regular annual medical exams that are done where a lot of questions are asked, not only on symptoms, but on other physician-reported diagnoses, and that information is supposed to be looked at on

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- a regular basis like a surveillance type study. And when there's signals, like you mentioned, whether it's sentinel or a surveillance signal, then the question starts to be, when do we actually go after active surveillance, get case records, really look for the abstracted information?
- DR. MAYER: Okay, thank you.
- DR. WARD: Other questions or comments?
- DR. HARRISON: Yes. I just want to come back to the—I guess this criteria number three which, as I understand from what you said, requires that IARC or NTP have done a review. It's just to continue to—as I recall, the STAC went through this pretty good, elaborate process of coming up with some criteria. I think when Julia Quint was on the committee, she had just done a terrific job leading some of this effort and writing a document, as I remember, on what criteria... And I think—we definitely believed in IARC and NTP. I just want to make sure that we periodically loop back and just reconsider, and I would encourage NIOSH to reconsider whether there are any other authoritative agencies that do perform reviews of the chemicals and cancer in the workplace or the environment. I'm thinking of the US EPA or the California Environmental Protection Agency or even federal OSHA, as they're going through some process that we would have confidence are authoritative, that may be more timely than IARC or NTP. I don't know what those would be, but I think it's always worth thinking about and re-looking at that question periodically.
- DR. MIDDENDORF: Just to give a brief response to that, we did look at a number of different agencies and tried to figure out which of those might be able to provide information. And we stuck with IARC and NTP, which was one of the STAC's recommendations, in large part because the other evaluations don't necessarily identify what cancers are being caused, and we have to add specific cancers, so that's one of the conditions that we need to have to be able to use evaluations.
- DR. HARRISON: So, like, a US EPA review doesn't identify with that level of specificity?
- DR. MIDDENDORF: I don't believe it does.
- DR. HARRISON: Okay.
- DR. MIDDENDORF: But I—it's been a number of years since we looked at it. If somebody else has some information, I'd be more than happy to consider it.
- DR. BOWLER: I think they do. In at least the area I've worked in and still work in, manganese, they have some very good modelers going on and collect, you know, the data from the air monitors for years. So I know, in manganese, they do. I don't know about the other substances.
- DR. WARD: Yes, and, you know, my impression is that EPA and some of the other organizations don't have as regular a process of searching the literature and getting nominations for what substances should be reviewed. So I'm not sure what triggers an EPA review.
- DR. HARRISON: Yes, I don't know.
- DR. WARD: It might be the need for an environmental regulation. But, in the case of both IARC

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- and NTP, you know, there's a regular nomination process of new things to be reviewed. So I think that they're desirable in that respect, but I certainly think that, if a review is out of date, then, you know, it would be reasonable to consider new evidence that wasn't considered at the time of the last review.
- DR. TALASKA: Yes, I agree. And I also think in—and I can cite one example of events that could be considered, in the case of cancer, that would be indicators that we might expect this thing. For example, for some reason I think of this study that was done in rubber workers where some biomarkers were identified in exposure that was related to exposure to ortho-toluidine in hemoglobin adducts, and then later, subsequently, it was shown that there was an increase in bladder cancer in that same group of people, as the data were then turned out. So sometimes those indicators are very useful just of and by themselves.
- DR. WARD: Yes. And, most often, we're looking at the NTP and the IARC reviews for specific exposures that occurred at the World Trade Center, so that's kind of... So, basically, we're not even talking about new agents. We're talking about new agent target organ associations, so that even complicates things further. But, as Dr., as Bill has pointed out to me, you know, many—we really are looking at an increasingly small number of cancers that are not already covered.
- DR. MIDDENDORF: Covered.
- DR. WARD: John says one.
- DR. HOWARD: One cancer. Only one.
- DR. ROM: This is what cancer?
- DR. WARD: So...
- DR. ROM: What's that one?
- PARTICIPANT: One left.
- DR. WARD: Maybe on your point—yes.
- PARTICIPANT: Respiratory? (Inaudible @ 21:06).
- DR. HOWARD: One of the ones here.
- DR. MARKOWITZ: Steve Markowitz. So on one of your slides, Tania, in method one, I mean, you used plausibility and coherence with known facts about the biology of a health condition, one of the recognized criteria, but you also restrict your examination to 9/11-related epidemiologic studies. So how do you examine plausibility and coherence, looking at biology, if you're only looking at 9/11 epidemiologic studies? I'm just trying to understand the process.
- DR. CARREÓN-VALENCIA: Well, there have been three cancer studies of 9/11 populations, and so we have looked at all three of them for consistency and coherence.
- PARTICIPANT: We try to—
- DR. BOWLER: Which conditions?
- DR. CARREÓN-VALENCIA: (Inaudible @ 22:04).
- DR. MIDDENDORF: (Inaudible @ 22:05).
- PARTICIPANT: Three.

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- DR. CARREÓN-VALENCIA: Fortunately, there are more than one at this point, and there are continuing follow-up of...
- DR. WARD: Dr. Howard would like to make a comment.
- DR. HOWARD: Yes, thank you, Tania. And I just wanted to clarify with the committee, we may be mixing apples and oranges. I would suggest that the intensity of review concentrate on the non-cancer additions. You have all done marvelous work for the program in your review of cancer, and there is only one cancer left. I can assure you if—that will come to the STAC so you can finish your work. So the issue, I think, for the program is non-cancer conditions being added. That's where the methodology that we're using, we would really like your intensive review of. Cancer is pretty much done.
- DR. WARD: Great. Thank you. Can someone tell us what the one cancer—
- PARTICIPANT: Yes, what is the one cancer left?
- DR. MIDDENDORF: I think it's uterine.
- PARTICIPANT 7: Uterine.
- DR. WARD: Uterine cancer. Thank you.
- DR. MIDDENDORF: Oh, and mesothelioma with...
- DR. WARD: So it's now 11:34. Paul, do you think we should proceed with the next presentation before lunch or break for lunch?
- DR. MIDDENDORF: I'd rather keep the presentation and the discussion together.
- DR. WARD: Okay.
- DR. MIDDENDORF: If we're going to get into those intensely, as Dr. Howard has asked, then we should probably go ahead and have a break for lunch now, and then come back and really delve into them.
- DR. WARD: Okay, so we'll take a break for lunch. In the interest of—let's see... It's 11:35. Shall we reconvene at 12:15? I don't know if we need a full hour, and then we can continue—so we'll continue at 12:15. Thank you.

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- DR. REISSMAN: Welcome back from lunch. It's always the struggle for that first hour. So I don't know how interesting I'm going to be, but I'll try. Anyway, I am the Associate Administrator for the World Trade Center Health Program, as I mentioned earlier. And I really want to encourage you, especially based on the questions that I heard for the previous policy. I want to encourage you to truly think about this opportunity as a way to provide us feedback on the strengths and weaknesses of what we've done from a policy perspective. And the whole purpose of this meeting is to learn from your collective wisdom. If there's areas that we need to improve on. So on our first slide this entire policy is pathways to add a non-cancer health condition to the list, and we've outlined all the steps that are actually in the policy which are also in your packet. So it starts with the administrator of the health care program initiating the process at his own discretion just like in the cancer policy. And they can initiate that

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process either by receiving a petition or based on his own review or his scientific team telling him that it's appropriate to do so. When he's doing it by partition he's following another policy that we have online that's not today's discussion, but that policy is referenced for your convenience here and that's how do we respond to petitions and what makes a valid petition, those kinds of things. The only way you can add the health condition is to add it by rule-making with is something that was discussed earlier, and that's according to our legal requirement.

On the literature review side, the program science team leads a review of scientific literature which involves a scientific or a systematic literature search, and in that we're looking for the evidence review from the peer reviewed published epidemiological studies of 9/11 exposed populations. So here it is only the 9/11 exposed populations, and they are epidemiologic studies. I know that came up earlier so I wanted to highlight that for you. The quantity and the quality of that evidence is looked at, and then if it was... the whole process was initiated by a petition, we're also looking at medical basis that is provided in that petition which goes back to the policy on what makes a valid petition? It has to have a medical basis. The findings of the reviewer documented are discussed with the administrator.

If the evidence does not provide a sufficient basis for a decision, we document that, we archive it. If it's initiated by a petition then the determination or our findings are published in the Federal Register which is the Federal newspaper, and the petitioner is notified in writing. If the evidence is found to have a potential to provide a basis for a decision then the administrator may come to you and ask for advice or he may direct the science team to assess the scientific and medical evidence directly, or both.

When the science team is engaged they conduct an assessment of this peer reviewed published epidemiologic studies of the 9/11 exposed populations and use the Bradford Hill criteria from epidemiology which is basically the strength of association between exposure and health effect. And we're looking at how precise the risk estimate of those studies are. The consistency of the finding across different studies often it... we look at it from different cohorts as part of the different studies, the biological gradient or a dose response relationship when we're dealing with exposure in the health condition, and the plausibility and coherence with known biological facts around that health condition.

Again, if this looks somewhat repetitive from an earlier slide, because it is. We do the same thing here. If you don't have a sufficient basis for a decision, then you'd archive it. If it's a petitioner we publish it and we notify the petitioner. And if it does have the ability to provide a basis for the decision—actually, I think we went backwards on this—we would go to the STAC.

That looks better. Okay. The evidence provides substantial support. So let me retract what I just said a moment ago in going through an old slide. So if we're

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finding that evidence is providing a substantial support for a causal association between the 9/11 exposures and the health conditions that are under consideration, we will publish that in the Federal Register and a notice of proposed rule-making to add that health condition to the list of World Trade Center related health conditions is done. If the evidence is substantial against a causal relationship we'll also publish that in the Register and the basis for that determination, why it was found to be substantially non-supportive.

Then the last one is if the evidence is insufficient to provide substantial support for or against a causal association then we publish that finding in a Federal Register notice, and we indicate that there is insufficient evidence to add the condition. And that whole area like that, the substantial support is really similar to method 1 that you heard about in the policy and procedure for cancer.

So if the support level is only modest support then we request additional assessment of whether the causal association is supported by other peer reviewed epidemiological studies between 9/11 agents and the health condition. Other studies can include the assessment of the similarity of the exposure conditions to 9/11 terrorists attacks cleanup. This really gets into the magnitude route of exposure, the physical form, the duration, the timing, all the things that you would normally use to look at exposure characterization to see if you can get at a characterization that has enough similarity to 9/11 that you can look at that information.

For outcomes from sub-chronic exposures the consistency of the presence of the 9/11 agent during the response and recovery should also be assessed. And that's to try and, again, get at evidence that something's really there. So this is somewhat similar to method 3 of the policy and procedure for cancer where we used IARC and NTP.

If the additional assessment enables substantial support for a causal association we publish that in the Federal Register, the notice of proposed rule-making is done to add the condition. If this assessment cannot substantially support a causal association that finding is published in the Federal Register, but the term we use there is evidence is insufficient to take action. It's not a door-closer, that's just we're not there yet.

So a couple notes on all of this. The World Trade Center Health Program may provide treatment for a requested health condition found to be causally associated with a health condition on the list. If the request condition meets our definition of a medically associated health condition. And the things that do meet medically associated definition is in our regulations and that has to do with progression of the underlying certified disease or an adverse effect, a primary adverse effect of the treatment of that World Trade Center related disease.

Note number 2, the administrator's assessment of information for non-cancer health conditions may involve review of recommendations provided by you all,

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where the administrator has requested such.

And a little bit on timing. So if the administrator decides to request your recommendation for a petition, the administrator has to make this request within 90 days of that petition to add a new condition. If the administrator requests your recommendation from either because of their own discretion or a petition that we received, a letter is sent to the STAC chair and the advice is requested and it establishes a time period of 90 days which can be extended to 180 days for the committee to provide recommendations and the scientific medical basis for those recommendations. So it's not just that you think something, but why you think something.

After receiving that recommendation from the STAC the administrator then evaluates and takes the appropriate action no later than 90 days after receipt of the recommendation. So all this timing is to make sure the administrative process is following a standardized format and is transparent in that fashion. So the rule-making components, the NPRM stands for Notice of Proposed Rule-making, and that's when you propose to add something and it's done in the Federal Register, public comments are asked for, peer reviewers are identified with consideration of your input around this independent peer review. After that final rule can then be published and the program is required to respond to the comments by peer reviewers and the public in that final rule. The administrator determines whether evidence continues to support the addition of health conditions to the list and it's part of all that final rule text.

So those are the formal slides. Thank you for your attention to that and I can take some questions from you.

DR. HARRISON: Can you remind us what are the non-cancer conditions that are currently accepted? What ones have been petitioned or are in the pipeline for review or have gone under review? And then, finally, are there any non-cancer conditions that you think are likely to be of interest coming up? Like what are some examples of conditions that might be seen that we need to think about as we move forward? So maybe any comments on those three aspects?

DR. REISSMAN: Sure, and if I forget one remind me what I forgot. In terms of what we're currently covering I may not be exhaustive, but it'll be exemplary I think. From an upper airway perspective, we have chronic rhinosinusitis, anything involving the nose to the sinuses. We have World Trade Center cough, which is not what I have, and all kinds of upper respiratory diseases that are obstructive in their basis. So asthma, chronic obstructive, pulmonary disease that was exacerbated after 9/11. We have interstitial lung disease. We have gastroesophageal reflux disease. There are a certain musculoskeletal conditions like carpal tunnel syndrome and low back pain that have other requirements attached to them, but we do cover them. Psychiatrically, we have a variety of conditions from PTSD, depression, anxiety, substance abuse. That's kind of the gamut offhand.

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- DR. HARRISON: And then the pipeline? Anything...
- DR. REISSMAN: The pipeline, I can tell you a little bit and it's on our website as well, all the petitions we received and all the findings for that, but off the top of my head I can remember one for cardiovascular disease in general and for peripheral neuropathy, I believe and autoimmune disease. There are about four different petitions for autoimmune disease. That's what I can recall offhand. And I don't think that any of those led to additions to the list. I think most of those were found for insufficient evidence or there was no... It was insufficient evidence in my memory. It's not in front of me.
- DR. HARRISON: And then the final question was a crystal ball question.
- DR. REISSMAN: Crystal ball question, you know, I think autoimmune disease is still on people's radar. There have been a number of discussions where concerns have been expressed by our program membership around certain neurological diseases that are not well characterized as well, as yet. Of course, there's the traumatic injury and new onset chronic obstructive pulmonary disease which is in a rule-making process. Other questions?
- DR. MAYER: This gets back to the point I was making before about reporting of diseases, that certainly when people are referred through the program, you're going to be getting that information. But, for example, about two or three years ago I saw somebody who participated in rescue and recovery work who was sent to me for World Trade Center exposure evaluation, was not part of the World Trade Center program. And, interestingly, we diagnosed her with connective tissue disease related interstitial lung disease. I gave her all of the information about filing and made that recommendation, but I don't know whether or not she did. And so it's possible that there may be cases like this that you guys are never getting word of. And again, if there was some kind of possibility of a physician being able to provide that information for somebody who isn't a part of the formal program as a way of capturing additional cases.
- DR. REISSMAN: Thank you for the comment.
- MS. JONES: Dori, my question really is on process, not so much the methodology that's going to be used to determine whether something's going to be added or not. But just for my own information, can you define what substantial support means as opposed to minor support? And is that based on the judgment of the science review team or is that based on facts that they have discovered? So how does that work?
- DR. REISSMAN: That's a great question. Substantial support really refers to the gestalt when you look at Bradford Hill criteria. So if all the criteria are met you're going to be substantial. So that is fact, but it's also judgment of the science team. It's a combination aspect of that. When it's not substantial it's less than meeting all four of those criteria and you are dealing with the judgment of the science team at that point. So modest versus not even modest becomes qualitative.

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- MS. NORDSTROM: Back on the literature review slide. It sort of reads to me, at least—and maybe I’m misunderstanding—as if you sort of... one of the requirements before you’ll consider a condition is that there already be epidemiologic studies of that condition in 9/11 exposed populations. I’m wondering if there’s any sort of criteria that allows for conditions that have not been studied at this level or newer onset. I mean, I guess this is sort of the case of autoimmune diseases at the point. But that feels like a very late way of identifying diseases that are already in process that people are already suffering from. So I’m wondering if there’s any sort of route that you guys take around that or if that’s something that is sort of in—that should be discussed.
- DR. REISSMAN: It is a great question and I can appreciate it. Early on in the program the way around that was observation. That was before there was a **Zadroga** act. The legislation in and of itself placed a whole different paradigm on this. And so the paradigm in the policies that we’ve developed are an attempt to respond to the legislative mandates. So at this point even though we’ve been reauthorized from a funding perspective till 2090 we can be called to the Hill at any point to respond to “Why did you do that?” We have to have a sound scientific and administrative platform from which to add things to the list. So we can’t start to cover things without that weight of evidence, so to speak. And I can appreciate that, yes, that seems a little late, but it’s something we have to do. We’re open to suggestion to hear what you have to say.
- DR. WARD: Well, in addition, I think, and that’s kind of part of the role of the STAC is to make recommendations on research. So if there is a condition that has emerged in some studies or that we think is of particular interest, when we’re called upon to make recommendations on research we can certainly recommend that.
- DR. REISSMAN: Absolutely. Thank you.
- DR. MARKOWITZ: You know what, Dori, I’m going to ask similar questions of what I asked this morning which is, why is the nature of the evidence that is described here, that is listed here to look at, it seems to be so limited. In the case of cancer you’ve got NTP and IARC to fall back on where non-cancer conditions don’t. So I would think you’d even have more motivation rational to look at a broader set of scientific data. Because take rheumatoid arthritis, autoimmune, whatever, there are a couple of studies published within WTC groups. Those studies aren’t definitive by any means. If I were to look at the question of autoimmune disease in relation to toxicity, I’d look at more than just WTC exposures studies. I’d look at other studies that have addressed those diseases, what evidence there is that they’re caused by toxins. I’d even look at other risk factors because I want to know how that impacts the WTC. It might be biased or confound the WTC studies. So I’m wondering why you don’t, why this description doesn’t...it seems so restrictive in terms of the nature of the evidence that you’re going to look at.
- DR. REISSMAN: Well, thank you for that comment. I think that’s one of the things I believe you’ll be

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discussing this afternoon and providing us feedback on. So I do recognize that there may be other approaches that we either did not code into our policies, but we were looking for things where we could move the conditions forward and not have a whole lot of pushback on what we were attempting to do methodologically. So we took a very conservative road.

DR. MARKOWITZ: So if I could ask a second question. Actually, if you could turn to the slide, the modest support slide. There's just a couple of issues of language that I don't quite... the first dash is "Other studies must include an assessment of the similarity of exposure conditions to 9/11." So what does that mean "similarity of exposure conditions to 9/11?"

DR. REISSMAN: By getting at the characteristics of exposures whether it's both the type of exposure and how things led to that exposure, so the scenarios. You're trying to see what it is that's comparable. Obviously, the 9/11 event was what is usually said unprecedented. So it's difficult to find comparisons. But if there's a specific example of chemicals that were identified and the scenario is confined space you may have things in other confined space studies that could be helpful to provide evidence toward something.

DR. MARKOWITZ: Thank you. And then on the next dashed item for "Outcomes from sub-chronic exposures, the consistency of the presence of the 9/11 agent." So "consistency of the presence", do you mean simply how long that agent was likely to have been there during the nine months of cleanup?

DR. REISSMAN: I think when your—sub-chronic is sort of like it's not an acute short-term exposure. It's something that is under the radar and ongoing. So there is an attempt here to get at the persistence. So a longer duration. Does it have to be the whole time? No.

DR. MARKOWITZ: Okay. Thank you.

DR. TALASKA: So, hi, Dori. Thank you. So it sounds like the group... you would be open to expanding the expert advice that you would take into consideration for a non-cancer outcome to groups that maybe not identical but similar to IARC or NTP, like expert peer groups which provide advice to their membership about exposures and, in fact, either for autoimmune disease or for other health effects. So if there was pulmonary group that provided expert advice to say that this condition is related to an exposure like this, that could be taken into account. Do you think that would be valid?

DR. REISSMAN: I think I can answer the first part of that which is would we be open to it? Absolutely.

DR. TALASKA: Yes. That's the key thing. Would it be valid? We'd have to look at it. But that would be taken into... could be taken into consideration if we make that recommendation and that other groups be looked at for non-cancer outcomes.

DR. REISSMAN: That's the purpose for bringing the policy before you.

DR. TALASKA: Thank you.

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DR. WARD: Other comments or questions? Thank you.

DR. REISSMAN: Thank you very much.

DR. WARD: Paul, would you like to show the flowchart now?

DISCUSSION OF POLICY AND PROCEDURES TO ADD NON-CANCER CONDITIONS

DR. MIDDENDORF: [I have a] rough draft that I hope is reasonably representative of the time flow and that the time frame in which things happen within the policies and procedures. I've got a number of days listed here. This is just my best guestimate. So basically when you receive a petition and review its validity that actually does take some time which isn't accounted for here, but that usually is several days to a week depending on availability of people. Yes?

MR. FLAMMIA: That's on page 106 of the book, also so we could see it? Is that correct?

DR. MIDDENDORF: No, I don't think this is anywhere.

MR. FLAMMIA: No? Okay. Okay, thank you.

DR. MIDDENDORF: I made this up at lunch.

MR. FLAMMIA: Got you.

DR. MIDDENDORF: That's why it's so rough and such a draft. I mean, I can make it a little bit bigger. That might help.

PARTICIPANT: (Inaudible @ 0:50).

MR. FLAMMIA: Thank you.

DR. MIDDENDORF: Yes?

PARTICIPANT: Maybe put on top, intake. That's the begin point, when maybe we want to adopt—

DR. MIDDENDORF: Yes, we received the petition. But when the petition is received and then its validity is reviewed that usually takes a day or two depending on availability of the reviewers. Once they do that and they determine it's valid, then the science team does a literature review. They work with the librarian, set up a systematic review of the literature and that can take up to about seven days. And these are calendar days. (Because sadly @ 1:28), we work from calendar days in Zadroga, not work days. So once the literature review is completed, the abstracts are all looked at, the science team reviews those and identifies anything that may be relevant, and that may take about four or five days, roughly, once they get that. Then the science team evaluates whether the literature has a potential to provide a basis for a decision. That can take up to 14 days depending on how much literature there is. If there's only one two articles it would probably take less. If it's a lot of literature it would take more.

Once they have a chance to look at it and decide whether or not there's a basis for a decision they'll advise the administrator what they found and then the administrator will make a decision. That's roughly three days depending on the administrator's availability. The science team, if he decides to move forward with it, and then that's make that assumption, he can move forward in two ways. It should be aligned here where he can over to the STAC and ask the STAC to review or it can be done internally. Let's just follow the internal process at this

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point. The science team will then assess the literature a lot more fully looking at it in great detail going through all the detailed steps. And that's typically, again, about 14 days. And after they complete that review they advise the administrator what they found and what they recommend, and the administrator makes his decision as to what he wants to do with it. Assuming he makes the decision to go forward with adding the condition the notice of proposed rule-making will be written and published, and that usually takes about 45 days, recognizing that there are numerous internal reviews. These things have to go up through channels. First off was in the program, then up to CDC and HHS, and potentially OMB. So a lot of potential internal reviews that have to take place. So allotting 45 days for that. So that takes you up to about your 90 days right there. So that's how quickly things would have to take place.

I encourage Liz and some of the other folks to comment at some point about how long it might take EPA to do a review or... and I can tell you how long it takes NIOSH to do a full detailed review of a particular agent, and compare and contrast the time frames in which these things are being done. But then once the notice of proposed rule-making is written and published it would be sent out for peer review and public comments simultaneously, and that's at least a 30-day period. It can be longer if the administrator chooses. But once the peer reviews are received and public comments are received those are all reviewed, responded to, and then the administrator decides whether or not he wants to move forward or if he wants to move in another direction or just what he wants to do. So that's a very rough outline of what happens. Is that helpful? Is that what people were looking for? Okay.

DR. MAYER: Yes, that's very helpful. Thank you. And thank you for missing lunch to put that together.

DR. MIDDENDORF: I didn't miss lunch; I just cut it short.

DR. MAYER: Yes.

MS. MEJIA: So based on this, there seems to be a little disconnect towards the end of this where you have the peer review and the public comment happening concurrently, I would think, but the public has no ability to comment on what the peer review findings are. So the only one that's really looking at the peer review findings is going to be the administrator. Am I correct? So is there something that...

DR. MIDDENDORF: Yes, the science team and the administrator.

MS. MEJIA: We can look at, Elizabeth, to see how we might be able to make this a little bit more transparent to address some of the concerns that were raised by some of the public comments that were made about transparency?

So yes, I mean, if the STAC has some thoughts and ideas on how to accomplish this within this kind of a time frame, I'm more than happy to listen. We certainly have people who have been on both sides of the peer review asking for peer review to be done and doing the peer review, and they can comment as to

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- whether or not there are other ways to accommodate, both the peer review and the public comment within the 30-, 45-day time frame.
- DR. WARD: Can I just ask a clarification question?
- DR. MIDDENDORF: Sure.
- DR. WARD: I thought someone said earlier that once the... so you're saying that once the rule-making is published there's 45 days? I thought that was flexible?
- DR. MIDDENDORF: It's usually 30 or 45 days.
- DR. WARD: For public comment.
- DR. MIDDENDORF: Yes. I mean, it usually doesn't go much beyond that, it may go 60 days, but usually not beyond that.
- DR. WARD: And you're also saying that the peer review prior to the publication of the rule-making is not possible because if there's the 90-day rule after receiving a petition?
- DR. MIDDENDORF: Right. Yes. There's that very limited time to develop a basis for a decision. The science team takes about 45 days, and then you're going to have all the administrative things that have to happen as well. So we, roughly, give them half the amount of time that's available.
- DR. WARD: Right. Yes, I think for most of us it's a little... I mean, ideally from a scientific point of view for someone who's been involved in peer review processes you'd like to see the peer review before the publication of the rule-making because that's... I mean, once you've taken a position there's a tendency not to want to change the position. Plus, it might be that the peer review is going to say, well, NIOSH staff felt that the evidence wasn't very strong, but in our opinion it is strong. And in that case it might actually influence whether the rule-making gets published. So it seems like that scientific review is really, I mean, logically would proceed the publication of the rule-making if there wasn't this constraint imposed by the 90-day time period.
- DR. MIDDENDORF: Yes, but that's only a proposed rule. I mean, yes, there is an initial determination, what the administrator wants to do, but it's not a final determination.
- DR. WARD: But the proposed rule only occurs if the administrator deems the evidence sufficiently strong to go with the proposed rule, but that might be exactly where the peer review committee should have the opportunity to weigh-in before that decision is made because, otherwise, it never gets to the peer review committee. Lila, you had your hand up.
- MS. NORDSTROM: I was going to echo that point. I also though, wanted to ask since I am not a doctor, how long peer review panels are normally given to review material or from people who maybe participated who are on the panel to give those of us who aren't doctors a sense of how much time you would normally take to weigh-in on something like this and what that would entail?
- DR. TALASKA: Three to six weeks.
- MS. NORDSTROM: Okay.
- DR. TALASKA: John Howard thinks that it is 15 days (inaudible @ 9:27).

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- DR. ALDRICH: The administrator stated that it was 15 days for the peer review to turnaround their comments.
- DR. WARD: Margaret.
- DR. RYAN: I just wanted to echo that. I mean, just from listening to the public comments I agree with you. I don't think that peer review at that stage is likely to differ from... it's already been notice of rule-making after rigorous NIOSH review. I just doubt peer review would ever change anything. So the public's concerns about we want to be able to see this peer review, who they are, be transparent. I believe the public's impression was that's happening before because at that point that's really just very likely to just endorse the proposed rule-making. It's already been through that rigor and peer review, I doubt, is going to change anything. I think that the contentious part is before that. I don't know if there's any possibility of changing that flow, but I believe that was the public's concerns.
- DR. WARD: Tom.
- DR. ALDRICH: This committee does peer review and we're not NIOSH employees. We don't have that conflict of interest. So it seems that the peer review after us is a little bit duplicative and, yet, I guess it's mandated by Congress.
- DR. WARD: Well, I think the clarification is that John Howard is not... We're not an inherent part of the process. So John Howard decides whether he wants us to ask the **STAC** to address a particular nomination and it's really completely at his discretion. So I don't think, aside from the cancer petition, I don't think we've addressed the addition of any World Trade Center condition and, you know, John has received the petitions, but he has not chosen to involve the STAC.
- DR. ALDRICH: So if the recommendation goes by the route of the in-house science team then it probably does require peer review. If it has gone through the STAC how is a second peer review going to differ from that?
- DR. MIDDENDORF: Well, it would go to the STAC before a determination is made and ask them for their advice. And the STAC then would come back with their recommendation. The administrator would still have to make a decision to move forward and depending on what he decides that would... and the scientific basis for that decision would then go to peer reviewers.
- DR. RYAN: Would it be possible for the STAC to consider concurrently with that peer review so then you really have two independent groups who are providing that information?
- DR. MIDDENDORF: Yes, I'm not sure that you would want two independent peer review processes going on at the same time.
- DR. WARD: Yes, just for clarification, and then we've got five tents so I think we'll take them counter clockwise. But I think if the administrator decides to involve the STAC then that changes the timeline a great deal because you have the 90-day period for the STAC to respond and then you can extend that up 180 days. So you're no longer constrained by the timeline and you could—that would give you a little bit

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- more flexibility in terms of the peer review process. But I don't think you want to set up the process to be contingent on STAC review because it may not always take place. Go ahead, Anthony.
- MR. FLAMMIA: Just to echo what Ms. Mejia said about the transparency and the sharing of information. Easily said you can... and I've said it before, is to share the information online and basically with the website itself to make it a transparent process. Be fluid in the reporting. And there are other government agencies out there that have this model already in there. I mean, you could do it.
- DR. WARD: Val.
- MS. JONES: As I look at this and I see at the bottom 30 days, by that point you have like a timeline and you know the timeline way before that, because I'm like wondering is some of this issue notification. Because I don't quite see why the public can't comment that the peer review could be 21 days and the public comment the last 7 because this is all timed out. You kind of know where you're going very early in the process. You know dates very early in the process. If notification is an issue you know this very early in the process that it's probably not going to change much. I don't quite get why this can't be more.
- DR. MIDDENDORF: Yes. We do want to allow public comment for a greater period of time than just seven days. I think a minimum of 30 days would be necessary. You're running a peer review process for three to six weeks using Glenn's estimate, and then running another 30 days puts you pretty far out.
- MS. JONES: I guess so those 30 days for the peer review can't be after—the 30 days for the public comment can't be after those 30 days.
- DR. MIDDENDORF: That would give you a 60-day window. I guess you could try to do it that way.
- MS. JONES: Oh, okay. I thought maybe there was some reason why that was impossible that the peer review couldn't be 30 days and then the public comment for the 30 days after that. I mean, I think that would be...
- DR. MIDDENDORF: I guess what you may want to do then is if you're going to do it 30 days you would still have to have your written... Well, I'm just trying to think it through. If you have the notice of proposed rule-making, once you have that and the administrator has made an initial determination do you want to run your peer review behind the scenes and then just let people know what the peer reviewers said or do you want to run the stakeholder comments and the peer review concurrently; allow the stakeholders 60 days and peer reviewers only 30 days. I'm just trying to think it through what it would look like.
- DR. MARKOWITZ: I think in series. Not parallel, series.
- DR. MIDDENDORF: Well, the stakeholder would be...
- MS. JONES: Right, series. Right. Because I think that's what people were basically saying, is that to make the process more transparent they wanted to be able to hear what the peer review had to say. And so looking at this I'm like is there some stipulation that one can't follow the other for the 30 days because we know that it's coming.

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- DR. WARD: It's not like it's something here; it's like this looks very thought out and very, very practical so that it looks like it would be amenable to notification because I know sometimes that becomes the issue. So I mean, I just think that's a consideration. Steve.
- DR. MARKOWITZ: Yes. It is odd to have peer review and the public comment simultaneously. But this only comes up when the administrator is proposing the addition of a new condition to the World Trade Center list. The NPRM describes this condition that he or she wants to add. The peer reviewers are likely to agree, they may not. They may argue against it. But the public commenters probably not going to have a lot of specific comments about the peer review itself because those are scientific issues. Public comments are likely to address a broader set of issues. So in fact, the public is likely to support the inclusion of the condition. So in reality I'm not sure that it matters all that much that they run in parallel. And the advantage of them running in parallels it shortens the time and the sooner the condition is added to the list the sooner people are helped. So in reality I'm not sure... I mean, it'd be better to have a sequential process, but in reality I'm not sure it really matters.
- MS. JONES: I think the issue for a lot of people is the whole concept of transparency. The concept that if they're running parallel and I'm somebody, say, from the community and I actually want to hear this I can't go to both sessions. So that doesn't look very transparent. There's some kind of way you knew this all this along and you set up the meeting so that I have to make a choice between one or the other. I can either get to go the peer review meeting or I get to go to the public comment which makes the perception is that that's very not transparent and the perception might even be that this is a way to make sure that I only get to go to one. If I'm somebody from the community that has children or have issues and I'm concerned because my kids didn't have asthma before 9/11, now they all got asthma. So I just think that that perception, why would you just intentionally schedule two meetings about the same issue on the same day?
- DR. WARD: Yes, just for clarification, I think in most cases these will not be meetings, they'll people submitting comments to the record. But the principle applies in that the public will not have access to the peer review comments which might conceivably bring up issues that they otherwise would not be able to bring up. Bob.
- DR. HARRISON: NIOSH could consider a faster triage on the left-hand side. But as a public health official myself I have a great deal of sympathy for the left-hand side of triage slide and NIOSH is only taking 26 days there, if I've got the numbers correctly, about a month which is really fast, actually, to evaluate and decide whether a petition even has merit. So I'm not suggesting that NIOSH necessarily back away and say, yes, you guys can do it faster. Otherwise, if you can't I don't see any obvious solution here. I like what you put up here. I can't find an answer. I don't know what the answer is.

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- DR. WARD: Glenn.
- DR. TALASKA: Yes. I think part of it what our thinking is, is that usually the customer of a peer review gets to respond to the peer review. If you submit a grant you see the reviews or the critiques that are given or if you see a paper you see the critiques, and then you're able to respond to the editor, and the editor makes—in education. In this case, the person who's responding is the administrator and the administrator is the one who would be able to evaluate what the peer review comments are, and then proceed or not proceed based upon what the overall decision that he's made. Now they've already committed to publishing this, so they were already thinking there's sufficient evidence. So chances are the only time there would be conflict is if the peer reviewers found something that would be a fatal flaw in the argument to include the material—or that's what I mean, to disagree and to not include the condition into the program. So but it's still the administrator's education. They have to decide. They're the one who makes that decision usually without us, as you indicated, at almost every condition except for cancer is not going through this particular process. So I guess I would be in favor of adding at least letting everybody see what the peer reviewers' comments are, but I'm not sure it would make much of a difference, that's the other side of it in terms of process.
- MS. MEJIA: Well, my question is this, again, not knowing really the process too well, is it possible given the time constraints that, obviously, Paul, you put up there, is it possible that in the NPRM that the charge for the peer reviewers can be added into that notice or the questions that they're being asked to answer can be put into that notice at least as public disclosure as to what the peer reviewers are really being asked to do. Is that something that is possible to include in that notice?
- DR. MIDDENDORF: Yes, I don't see a reason why it can't be. I mean, they're already laid out in the policy and procedures, and that's public information. But they can be repeated there.
- MS. MEJIA: No, I understand that, but in a note at the bottom, they'll say that the questions may change depending on the condition that's being addressed. So I think that, again, this goes to the whole transparency issue of at least let people know what is it that you're asking these independent peer reviewers to do.
- DR. MIDDENDORF: Yes, I don't see any reason why it couldn't be.
- MS. MEJIA: It's an option.
- DR. WARD: Yes. I guess coming back to the point I was making earlier because I still think it's important, I mean, I think the issue we've been discussing about the sequence of the peer review and the public comment is important too, but I still think that... and especially under the scenario that David Prezant mentioned in his public comments that there is concern about how readily new conditions will be added by a future administrator or a future, a scientific program. It does seem to me that the lack of peer review especially for the close calls like when there's modest

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evidence and there's really a judgment call being made, it seems to me that from a scientific point of view the lack of peer review at the stage is a little bit of a fatal flaw because it may be that you would bring in experts. Let's say if it's a renal disease issue or, you know, that you really would want the expertise that could only be provided by a peer review panel to make that call. That's really the most important decision you're making, is whether to do the proposed rule-making or not. So from a scientific point of view I think that really is an important question looking at the future. Again, it's really the science versus the inflexibility of the time frame. But I think in this case the science should prevail, if at all possible. So in terms of comments we'll go counter clockwise again, because I can't keep track of whose hand goes up first.

MS. NORDSTROM: Just a suggestion, I don't know if it's possible, but, again, thinking about what are we seeing clinically, would there be a way that as this is being initially reviewed to query the database as to how many cases of this particular condition are being seen? And, again, not to be repetitive, but having the ability for physicians outside of the system to be able to report suspected diseases is another place to gather information on cases.

DR. WARD: Yes, and maybe, I don't know who—well, I guess we don't... I mean, it does seem to me that the issue of surveillance using the World Trade Center Health Program and the Registry might be a separate discussion that the staff could present on what existing surveillance mechanisms there are and we could talk about potential augmentation, but I think for the purpose of this discussion I think the sense is that the primary evidence for these new health conditions to be proposed will be from published studies rather than case reports or reports from the program or the Registry.

MS. NORDSTROM: I'm sorry. I wasn't meaning to suggest that that in and of itself would be sufficient evidence, but at least a way to, again, with a sentinel health event to think about, well, wait a minute, we wouldn't expect this from the literature, but there are a number of reported cases, that would then be looked at for what was the diagnosis, what was the exposure and if we're seeing a cluster then, again, consider that in addition to the fact that this really is a novel exposure.

DR. WARD: So we can put that on the table as a suggestion for future discussion and certainly the program people are here and they're hearing the comment, and I'm sure they'll take that into consideration. Anthony.

MR. FLAMMIA: Yes. Being involved in the 9/11 community for many, many years and being down in Washington, D.C., there is still an enormous amount of distrust from the 9/11 community. As we all know, Congress kept on moving the goal posts farther away as we tried to get the legislation passed. And they kept on moving it, but we kept on going ahead, and we were always seeking the transparency and the collaboration, and we never got it, and they kept on doing it to us. With that said, I'm going to echo what Val says. We have an unprecedented event of this

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disaster on 9/11. We need to make an unprecedented model as to create in a STAC and peer review session. We need to come up with something different. We need to think outside of the box on this one.

MS. NORDSTROM: I wanted to just express a point that's related to this discussion, but sort of outside the frame in which we've been talking about it, which is that I think one of the reasons that it's so important for those of us in the community to feel like we have the ability to comment post the peer review, is that I think we have the disadvantage of always being on the defensive when we discuss these issues and when we sort of express for support for something like this, you know, the administrator knows that the community is going to deliver comments in favor of whatever condition or for inclusion because we're initially usually the people that lobbied for that inclusion in the first place. But often times the community is given far less credence when they raise their arguments because they are not often rigorously scientific because they are about things that we are seeing and hearing from our community, and we're not doctors and we're not providing study results or study evidence-based on science often times. And so I think that one of the ways in which we can sort of counterbalance this sort of differing power of the voices that come through this process is by giving the community a chance to at least make their comments after they've seen what all of the medical professionals who are commenting on it have to say. I think that's one way in which the community is able to offer those sort of most useful arguments for why we should move forward with some of these rules. And I think that that is something that isn't really addressed if we are doing them concurrently, which is at least I think from my perspective why it's so important that we have the ability to comment after we see what the sort of medical community has to say about a lot of these things.

DR. WARD: Yes. Let's take further comments, but I'm beginning to get a sense of consensus around some issues. So once we're done with this round of comments and, Glenn, we'll maybe stop and say, do we really have consensus on some points? Margaret.

DR. RYAN: So again, I think I'm just agreeing with the chair here, but respectfully pointing out that there's a big part of the diagram that's not there, which is all the determinations of insufficient evidence. They go into the Federal Register, but that's not on the tree there because only notice of rule-making. So sufficient evidence is there. That means insufficient evidence didn't go to peer review, didn't go to public comment, and those are the ones that the public's concerned about. So I think maybe if the process would say, you know, at the point of publication in the Federal Register, whatever that determination was at the NIOSH level that's the point where I don't know if that's too onerous for all that peer review, but that's the point where peer review, and then I would agree after peer review public comment would happen because those are the ones that are contentious where it

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- was insufficient evidence in the initial review.
- DR. WARD: Tom.
- DR. ALDRICH: I heard a couple of members of the committee note that the peer review is unlikely to change the initial determination, and if it's that case then there's no point in doing peer review, but I don't think that's necessarily the case and, besides, we're required to do the peer review. So I think it has to come before public comment, and it seems to me there's room for it. Why is there 45 days required to write the rules? Wouldn't the rules be written in 30 days? And the administrator mentioned to a couple of us during the break that 15 days was what would be needed for a peer review. So are about 15 days out of those 45 days for your peer review and then you're okay as far as this timeline goes?
- DR. WARD: Catherine.
- MS. McVAY-HUGHES: Hi. I have two questions. The first question is, I guess, for the medical experts here. Since we have roughly 50 cancers that have been added and typically cancers are the endpoint of a particular disease, are there diseases along the way that have not been included that are non-cancerous that can be by default included as covered diseases? So that's a question for your technical wizards. My second question is going back, again, from this theory framework into reality. So if something were—I'm just looking at cardiovascular, and I was reminded that with... there's usually correlation of air quality, toxic exposure with cardiovascular disease. So say, we were going to look at that. If we wanted to, say, to go through this entire process before the end of 2016, we're saying it would be a three-month process or a four-month process to get it included? Can you just clarify?
- DR. MIDDENDORF: You mean to change the actual policies?
- MS. McVAY-HUGHES: Yes.
- DR. MIDDENDORF: Probably a few months.
- MS. McVAY-HUGHES: So if we were to put cardiovascular disease, because it's already in the pipeline, say, it started running tomorrow, June 3rd, it would be June, July, August, we would back for a meeting in September, and then it's another one month, two months? I'm just giving it as an example if it were to go through process. Say, everything was yes, yes, yes, the shortest amount of time to go through this framework would be? I don't know. That's my question.
- DR. MIDDENDORF: Yes, I don't think I'm quite following what you're asking.
- MR. FLAMMIA: Add the numbers up.
- MS. McVAY-HUGHES: So I'm just saying, so if we were...
- MR. FLAMMIA: Yes, it's right there. It's right there.
- MS. McVAY-HUGHES: I'm just saying, so if we were—if, I'm just saying disease A that's non-cancerous, say we wanted to start on June 3 to start going through that tunnel process, the soonest it could get through would be September 1, if every fork... So it's a three-month timeframe. So June, July, August, September is a really a four-month timeframe. So in a three-month timeframe. So if a condition were to be... So

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- there's still an opportunity for conditions to be added in 2016, I guess. And the last date for disease to be considered in 2016 would then be September 1? Because that's a three...
- DR. WARD: Well, the administrator has 90 days. Let's assume it's a petition. Right? So let's say he gets a petition. He has 90 days to act on the petition; is that correct?
- DR. MIDDENDORF: Yes. Ninety days to make a determination and publish either a notice of proposed rule-making, a Federal Register notice denying the petition.
- DR. WARD: Right. And from that point on there would be 30 days.
- MS. McVAY-HUGHES: Another 90 days.
- DR. WARD: Well, there would be a 30- to 45-day public comment period that NIOSH is proposing would be combined with the peer review period. If the determination is to propose—if the administrator determined he wants to add the condition there would be a rule-making published in the Federal Register and there would be a 45-day period. And what they're currently recommending is that the peer review would be accomplished simultaneously with the public comment which we've heard a lot of comments that that's not acceptable or that's not agreeable to many members of the STAC. So yes, so I guess it's 90 plus 45 would be the very shortest.
- MS. McVAY-HUGHES: So roughly four to five months for a possible disease to make it in at one end and out the other end. And then I guess if a disease were to be added in 2016 we have to start putting it through that pipeline now. Okay. So my next question is, for the medical experts here, if the endpoint is cancer, but there are often diseases along the way before you get the cancer in that particular body part by de facto then are those other diseases could they be included as a non-cancer disease? Because you've already proved that the endpoint has been included.
- DR. ROM: I'll try to answer your question. It depends on whether you're a lumpner or a splitter. Cardiovascular disease Dori said was in there and if you're a splitter then you want to know about ischemic heart disease, myocardial infarctions, stroke, peripheral vascular disease, and so on and so on. I think it might be best to **leave** it as cardiovascular disease in the first place. In the pipeline she said "new onset COPD" was in there and that they apparently done a notice of rule-making, but it was being reviewed at higher levels. Exacerbation of COPD is already approved. And then in the crystal ball she said that there was autoimmune disease and what in the heck is autoimmune disease? I mean, we have interstitial lung disease already approved. We have carpal tunnel syndrome already approved, and that covers a lot of autoimmune disease. So we're kind of getting like cancer, there's almost nothing left.
- DR. MARKOWITZ: I don't think intermediate conditions, as I understand it, would be covered. Conditions that occur before cancer develops. So to give an example, scarring of the lungs would be a risk factor for lung cancer. Lung cancer would be covered. Assuming for the moment that scarring of the lungs is not covered, which I think it

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is, but if it weren't then it would be hard to interpret it as being coverable because it later led to lung cancer. So if I understand the question correctly, I don't see how you could justify—the current approach would include intermediate conditions before the cancer develops

DR. WARD: Yes, I mean, for certain cancers where there are known intermediate conditions like for cervical cancer, and there's like dysplasia or for colorectal cancer there is adenomatous polyps and where the screening is already done and those precancerous conditions are treated, and I assume that that is covered.

DR. RYAN: Is it covered? Can someone verify that?

PARTICIPANT: Yes.

DR. RYAN: It is definitely covered?

DR. MIDDENDORF: Yes.

DR. RYAN: Okay.

DR. WARD: Yes, but for other cancers we don't really know what the premalignant state is or we can't detect it. So at this point it wouldn't, I think, be a reasonable way to go. Glenn.

DR. TALASKA: Okay. All I wanted to say was that I had been thinking about this more and thinking about what Tom said and also that I agree with Val and Lila about having these things done in series. I think it's a good idea mostly because if the administrator has already decided to publish the peer review, that would be a problem that would come back as being negative and then that would also give not only the community but also the other scientific community a chance to respond to those reviewers, and that's in the scientific sense. Because reviewers make mistakes, too, as all of us who have submitted grants and papers know sometimes they don't read all the literature, sometimes they just don't do everything, especially if they're going to have a 15-day time period to turnaround, that they may make a mistake and that will allow the scientist to be able to respond to the peer reviews as well as the community.

DR. WARD: Yes. So let me restate the two points I think many people are saying. So one point is if due to various constraints NIOSH has to have both a peer review and the public comment period after the proposed rule-making is published. Then we'd like to see them done sequentially so that the peer review comments can be made available to the public during the public comment period. So I think that's something I think many people have spoken in favor of.

The other point is that if the constraints allow we think it would be desirable to conduct the peer review before the rule-making because that way the peer reviewers get to weigh-in on the decision to go forward with the rule-making or not, and that's really the most critical decision for which scientific expertise is required because in many cases that's going to be a bit of technical and scientific judgment call. So in terms of procedure we could take those as two separate issues and maybe we could go to votes because I think for the first one there's

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almost unanimous; everyone agrees, I think. And for the second one only a few people have specifically spoken on the point, but we could discuss that further and then go to a vote on that. Lila.

MS. NORDSTROM: My only concern would be that we... and we've sort of touched on this briefly, that with peer review panel I think those of us who deal from the community and would want to insure that they had some background in, you know, they were given some context for what they were looking at because a lot of what they're going to be deciding on doesn't have complete medical evidence and isn't always the— doesn't have the most sort of ideal scientific basis that you would look for if you were just sort of casually peer reviewing something that, you know, in like sort of the non-policy science world. So that before we would vote on that I feel like I would want to discuss whether or not we can make recommendations in terms of how we can provide context to them or what we can do to make sure that they are familiar with this sort of unprecedented nature of this issue.

DR. WARD: Paul, do you want to respond?

DR. MIDDENDORF: Well, I think what I want to do, or I was trying to do and it may not be addressing your point directly, Lila, is make sure that the committee comes back to what it's being asked to do today, and that is, one, identify a process for peer review... for identifying peer reviewers. That part has to get done or work reform or whatever, the committee needs to focus in on that. And then it can also focus in on the policies and procedures, which includes the peer review process. So if you want to make recommendations on that that's fine, but I just want to make sure that we don't lose that first part because that's a critical part of what the STAC is being asked to do.

DR. WARD: Yes. And so I think since a lot of the discussion has been around the timing of these processes, it might be good to—I mean, we can defer those, but it might make some sense to put those behind us. I do think that the topic that you're raising would make sense to address in the discussion of how does one choose peer reviewers because, I mean, there's two ways to address it. One is to make sure that—recommend that at least one of peer reviewers have some direct knowledge and experience of World Trade Center exposures and World Trade Center related diseases, epidemiology. The other would be to make recommendations on how if that's not the case how the reviewers can be brought up to speed and what types of information would be available to them. And I would say that certainly if the peer—I mean, if the peer review is done before the publication of the rule-making it would be after the program has developed all of the materials and information for them to review. It would basically be when the draft rule-making had been compiled and was ready for review. I mean, you know, so I would suggest that at least we entertain a motion for making the recommendation that if the peer review is to be done after the publication of the rule-making that the peer review and the public comment period been sequential

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so that the public can have access to the peer review comments at the time they comment.

DR. TALASKA: So moved.

MS. MEJIA: I second.

DR. WARD: So I think we're ready for a vote on that.

DR. MIDDENDORF: So I need to write it out so we know exactly what we're voting on.

DR. WARD: If the peer review is to be conducted after publication of the proposed rule-making that the peer review and the public comment period be sequential so that the public can have access to the peer review comments when they... Tom.

DR. ALDRICH: Isn't that a little narrow? Shouldn't we suggest that the peer review ought to be after the draft rather than the publication of...?

DR. WARD: Well, that's a second—I was thinking that's a second point. We could do that as a separate point.

MS. NORDSTROM: It could be after the draft and after the publications. Wait a minute. No.

DR. WARD: Well, because I think that the—I mean, the proposal that NIOSH came in with which presumably was something they thought about a lot was that there would be the proposed rule-making published in the Federal Register and then there would be the peer review and the public comment. So my sense was it would be good to separate that from the recommendation that they reconsider the timing of the peer review such that it would take place before the rule-making because that would allow the peer reviewers to consider whether the decision to go forth with the rule-making or not was the right decision.

DR. ALDRICH: So in terms of making a motion now should we just say the last part, that the two things should be sequential and not limited to—has to be—after publication?

DR. WARD: Well, I guess...

DR. ALDRICH: (Inaudible @ 48:22)?

DR. WARD: Maybe. But I think if it's after the rule-making then, in fact, NIOSH has a... I mean, you don't get to the rule-making unless the administrator decides that he's going to propose to add it as a covered condition. So that's why we're saying that we have concerns about doing it after the rule-making. So what we're saying is do the peer review before the rule-making so that NIOSH has input on whether these expert peer reviewers agree with NIOSH's assessment of the level of evidence for that being a covered condition. So this one is somewhat conditional because we know that NIOSH is operating under constraints that this committee does not have to, you know, that we're not fully aware of. And so this is an if. It may make more sense to make the other recommendation first. The second one would be that STAC recommends that NIOSH consider conducting the peer review before the decision is made on the proposed rule-making so that the peer reviewers can comment on the scientific basis for proceeding or not proceeding with the rule-making.

PARTICIPANT: There's a common element missing.

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- PARTICIPANT: There's literally (inaudible @ 49:59).
- DR. WARD: Yes. And before the decision. Because the problem is if they decide not to proceed all that gets published, I think, is the decision not to proceed. Right? There's not a full scientific justification and public comment period. The issue is dead for that time period, and the only way you bring it back is by submitting another petition or the administrator could bring it back based on new evidence. But that decision not to move forward is not made available for public comment. It's there.
- DR. MIDDENDORF: Yes. I'll just point out that what the STAC would be doing then is recommending that the program go beyond what Congress has stated. There's not a problem with that. I'm just saying that that's what's happening.
- DR. WARD: Well, I mean, it did occur to me that one—I mean, the case that I'm most concerned about from a scientific point of view is a situation where NIOSH determines that there's modest evidence, but not sufficient evidence because that's really where the major judgment calls are likely to take place. And we certainly don't want to make a recommendation that's going to bog the committee down. But I do think especially in the case where it really is a judgment call between modest and sufficient. But that's where you need the scientific peer review.
- DR. MIDDENDORF: Yes. I'll also point out that that's the point at which you have a lot more time and effort that has to go into developing the information so that you're really squishing the timeline even more because the science team will have to go out and find additional literature and look at it and evaluate it beyond just the 9/11. So it's really getting...
- DR. WARD: In terms of modest. If you're in the modest.
- DR. MIDDENDORF: Yes, if you're in the modest category. Moderate category, whatever it is.
- DR. TALASKA: But the administrator wouldn't propose that to go to rule-making unless they had some thoughts that they were intending to rule-make, and then the reviewers might change their mind. Right? There's a chance of that. The reviewer may cause the... the review might cause the administrator to pull back on a condition where they had thought to do it before going public, and so the public wouldn't get a chance to comment then. I'm just thinking what might happen in some cases when you think about the process is that the administrator usually will go forward without a peer review using the NIOSH scientists as their guide and using the information that was provided and in every case the administrator will propose a new rule adding something. You send it out for review before it goes for public comment and the peer reviewers might change their administrator's mind. Correct? And the administrator will then withdraw it and you won't get the even... there will be no comments. It won't go out at that point. And so the only thing that will ever be public... so actually reduce the transparency in that case.
- DR. WARD: Lila.

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- MS. NORDSTROM: I think I agree with that assessment of what's going on. I think it sounds like what this would do would be... have the entire sort of scientific discussion happen inside of a bubble and a lot of policy would never make it to the public comment section and without really any sort of justification as to why.
- DR. WARD: Tom.
- DR. ALDRICH: Yes, I agree. I think we should strike that whole first paragraph.
- DR. WARD: Okay. I mean, just so you know you all recognize that that means that there really will be no public comment on situations where NIOSH determines that the evidence is modest and they're not going to move forward with a proposed rule-making. No one will look at that science. No one besides the NIOSH staff will look at that evidence. So the failsafe would be that the peer review takes place before the publication of the rule-making.
- DR. ALDRICH: But didn't we just hear that if that's the case, it would never appear in—on the website or anywhere else?
- DR. MIDDENDORF: No. If a valid petition comes in the—there is a determination that's made. There is a review of the science, and that is published in a Federal Register notice if it's—which if the administrator decides not to go forward with adding a condition, there is a Federal Register notice that goes out that describes the rationale for that decision not to add the condition. So it's not done in secret or in private. The information is put out there for people to read.
- DR. ALDRICH: So even if we unstruck that paragraph that information would be public? If the peer review occurred after the draft but before the final rule. And the administrator, as a result of the peer review, changed his mind and does not add the relevant condition to the list then the rationale would be publically apparent?
- DR. MIDDENDORF: Yes, the rationale is laid out in the Federal Register notice, why the petition is being denied.
- DR. ALDRICH: Then I think we should put that back.
- MS. NORDSTROM: Yes. I think there was a misunderstanding.
- MS. MEJIA: Liz, I'm sorry. But I think we have a motion on the table. So that seems to be an amendment to the original motion. I'm a little confused. So what exactly is the motion that...
- DR. WARD: Well, yes, I mean, I think the reason that I proposed the second one first is that I think it's the one that everybody agrees on even though it's a contingent recommendation, it's the one everybody agrees on. And the other one I think there's a little bit less clarity around...
- MS. MEJIA: Right. But that's not a motion yet. So can we deal with the first motion? And, if not, maybe add as a friendly amendment to that motion of, you know, or A, B?
- DR. WARD: Or a second motion.
- MS. MEJIA: Yes. Otherwise we'd be going back and forth between the two things and I, you know...
- MS. HUGHES: So you want to do the two together?

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MS. MEJIA: No, I think the motion is only the—is the second one. That’s the only motion. I would like to add a friendly amendment to the first motion, to that motion which is what I had said earlier that as part of the publishing the notice that the charge to the peer reviewers be included in that as well as the questions that they’re being asked to answer. So that, again, it goes to that transparency issue.

MS. JONES: (Inaudible @ 57:13) the motion that was motioned and (inaudible @ 57:18).

MS. MEJIA: Right. But I can add a friendly amendment to the motion so we have to vote on my—whether you accept my friendly amendment, and then we could go back, adjust the motion and then you vote on the motion. I think that’s the way Robert’s rules works. Right?

PARTICIPANT: That’s right.

DR. WARD: I’m good with that. Can we proceed that way?

MR. FLAMMIA: Just a question. With these peer reviewers, are they named publically on who they are, what they do?

PARTICIPANT: It’s the intent—

MR. FLAMMIA: I think we were trying to decipher that.

DR. MIDDENDORF: Yes, the intent of the program is to make those known and lay them out. The issue was whether or not the term that’s used in the policy and procedures is that we would publish the comments without attribution. That was being interpreted that we would not identify who the peer reviewers were, and that’s not the intent. The program just needs to make it clear we’ll identify the peer reviewers, we will lay out what their comments are, but we won’t say who said specifically what.

MR. FLAMMIA: So just a matter of clarification, so either good or bad we’ll know who the peer reviewers are?

DR. MIDDENDORF: Yes.

MR. FLAMMIA: Okay. Thank you for the clarification.

DR. WARD: Tom.

DR. ALDRICH: Isn’t it the sense of this committee that peer review and public comments ought to be sequential regardless when it’s done? So why do we have this “if” clause in this?

DR. WARD: Okay. That’s fine.

DR. ALDRICH: I would just say peer review and public comment should be sequential.

DR. WARD: Yes.

PARTICIPANT: Okay. I accept that one.

MR. FLAMMIA: That’s good.

DR. MIDDENDORF: Okay. So motion 1 is, excuse me, the peer review and public comment should be sequential so the public commenters have access to the peer review comments. Maybe we should ask Mike if he has anything?

DR. WARD: Oh, good. Thank you. Mike, are you still on with us?

DR. McCRAWLEY: Yes, I still am. I’m listening.

DR. WARD: Do you have any comments on this...

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DR. McCAWLEY: I like the way you're proceeding your right now.
DR. WARD: Okay, great. Thank you.
DR. MIDDENDORF: Yes, and I apologize that you can't see because we're not using Adobe Acrobat, but we kept losing the connection and it was causing problems.
DR. McCAWLEY: That's okay. I pretty much, I think, followed. Thank you.
PARTICIPANT: So you need to get the friendly amendment on the board so we can consider that.
DR. MIDDENDORF: Do you want to make it a friendly amendment or do you just want to make a separate motion?
PARTICIPANT: No, no, Guille—this is Guille's...
DR. MIDDENDORF: You want to just make it a separate motion? They're not contingent on each other.
MS. MEJIA: No. I thought it would go along with the motion. If you want I will withdrawal my friendly amendment so we could just deal with the motion, and then we can...
DR. WARD: Yes, I mean, I think presumably the charge to the peer reviewers would be made available.
MS. JONES: (Inaudible @ 1:00:25)
DR. WARD: Yes, the question is do we need to say that because it's almost understood.
MS. MEJIA: So I will withdrawal my friendly amendment.
MS. JONES: So we can vote on the motion.
DR. MIDDENDORF: Okay. So the motion on the table... there it is. The peer review and public comment should be sequential so the public commenters have access to the peer review comments. Make this easy on myself. Tom Aldridge.
DR. ALDRIDGE: Yes.
DR. MIDDENDORF: Rosemarie.
DR. BOWLER: Yes.
DR. MIDDENDORF: Anthony.
MR. FLAMMIA: Yes.
DR. MIDDENDORF: Bob.
DR. HARRISON: Yes.
DR. MIDDENDORF: Greg.
DR. HOMISH: Yes.
DR. MIDDENDORF: Catherine.
MS. McVAY-HUGHES: Yes.
DR. MIDDENDORF: Val.
MS. JONES: Yes.
DR. MIDDENDORF: Mickey's not here. Steven.
DR. MARKOWITZ: Yes.
DR. MIDDENDORF: Annyce.
DR. MAYER: Yes.
DR. MIDDENDORF: 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: Glenn.

DR. TALASKA: Yes.

DR. MIDDENDORF: And Liz.

DR. WARD: Yes.

DR. MIDDENDORF: That would be 16 yeses and zero nos.

DR. WARD: You got Mike?

DR. MIDDENDORF: Yes, I asked Mike. So motion passed.

DR. WARD: Good. So then the next question is do we want to make a recommendation regarding doing the peer review prior to the administrator's determination of whether to move forward with a notice of proposed rule-making which means that the administrator and the scientific program folks believe, which will really only happen if the administrator determines to propose to add the condition to the World Trade Center list of the conditions. If not, it's my understanding that a Federal Register notice will be published, but that Federal Register notice will just say that it was considered and the decision was made that the evidence was insufficient.

DR. MIDDENDORF: But it will explain what evidence was considered and why the decision was made.

DR. WARD: But there will be no...

DR. MIDDENDORF: There's no opportunity for public comment.

DR. WARD: There's no opportunity for public comment if it's a negative.

DR. HARRISON: Would you clarify that? I'm confused.

DR. MIDDENDORF: What are you confused about?

DR. HARRISON: Motion 2. Your explanation of motion 2, really what we're voting on there.

DR. WARD: Okay. So as it currently stands if... let's take an example, autoimmune diseases, for better or worse. So autoimmune diseases is proposed. NIOSH receives a petition that autoimmune diseases be added. So the administrator goes through this process of asking his scientific program staff to conduct a review and make a recommendation as to whether that autoimmune diseases should be proposed or not. If the answer is yes, there's a Federal Register notice of proposed rule-making with both a peer review and a public comment period. If the answer is no there's no peer review, there's a notice published in the Federal Register that that was the decision and why that decision was made, but there's neither a peer review nor a public comment.

So the point I was raising is that the intent—the most important role of the peer

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review, I think, is to help NIOSH make the judgment call when there's some evidence, but less than complete and convincing evidence of whether to move forward or not in proposing something as a covered condition. So to put the peer review after that decision is made essentially you're—the peer reviewers are only going to look at the instances where the administrator decides to move forward. So the question is in a situation where the administrator is averse in a hypothetical situation in the future where the administrator might not be completely unbiased or where the, you know, or where the scientific program staff is not as fully cognizant of all the scientific issues as the peer reviewers might be. You're really losing the whole purpose of peer review if the peer review only takes place for things that the administrator judges to be kind of worthy of the consideration as covered conditions. So there's a risk there. It may be that the risk is justifiable because it's more streamlined and the people who made this were obviously more concerned about the administrator proposing something as a covered condition that should be than concerned about the administrator not proposing something as a covered condition that should be. So they're only dealing with one type of scientific error. Bob and Guille.

DR. HARRISON: Oh, I sort of got that. It's really... I thank you, Liz, for trying to explain that. I think it's very... it's still not... maybe at some point you can add it, Paul, to the list of the flowchart. I did not grasp until, Liz, you just explained this, that the peer review is only if the administrator decides to add a condition, that they're only reviewing things in one direction. So thank you. I was sitting here for a while thinking, oh, because peer review when I send things out for peer review, whether it's positive or negative I send it out, if I decide if we're not ruling on something or we are. But in this case it's only if the administrator puts something in, not if he takes something out.

DR. WARD: Right. Not if he doesn't not still want to add.

PARTICIPANT: Doesn't want to add it.

DR. HARRISON: If he doesn't want to add, the peer reviewers don't look at it.

DR. WARD: Right.

DR. HARRISON: But if he was, and he has to add, then you have to get the peer reviewers.

MS. JONES: It's one-dimensional.

DR. HARRISON: Yes, it's one-way, it's a one-way street.

MS. MEJIA: So I think looking at motion number 2 means that technically we could probably have two peer reviews. One before and one after. Because otherwise you're going to have to change motion 2 to show that a peer review should take place when the administrator doesn't feel like there's sufficient evidence to publish because that's the time where you're going to be able to change his or her mind or am I confused here?

DR. WARD: Tom.

DR. ALDRICH: Well, I was kind of thinking the opposite situation if a frivolous petition is

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presented to cover hangnails for a covered condition, would that have to go out for a peer review? There has to be some kind of threshold of potential scientific acceptability, and I don't know how to create such a threshold.

DR. WARD: Yes, I mean, what the program has put together kind of does that a little bit. I mean, there's three categories. There's just insufficient and then there's a category of modest evidence, and then there's sufficient evidence. So we could recommend that in instances where there's the judgment... the program determines that there's modest evidence, then there is going to be a fuller evaluation of all the evidence including some additional related studies, and at that point you could invoke having peer review before the final determination which I think would, again, if our goal is to really make sure that the best scientific judgment is applied to these decisions I think that would be a reasonable thing to do. Anthony.

MR. FLAMMIA: Yes. Actually, this is one of the things that Dr. Melius had echoed in his presentation about the transparency and this not being clear. And the peer review is going to influence public policy. So there's a lot of weight there so we got to be careful.

DR. WARD: Well, I guess the other question is that I assume that if the decision was made that the peer review could be conducted before the Federal Register notice, then the peer review comments could be made public. They wouldn't necessarily be then subject to public comment if the decision was not to move forward with the Federal Register notice, but at least they would be made public such that if a petitioner wanted to come back with that same petition subsequently, at least the petitioner would know what the peer review comments were that resulted in a negative determination so those comments could be addressed.

DR. TALASKA: I think that would be a good solution. But the Zadroga Bill gives the administrator a lot of leeway. And one of the places where the administrator is supposed to go for scientific opinion when he needs some guidance is this group. And so when he or she is uncertain, that the administrator could come to this group or the guidance that they needed, for example, for cancer which worked out, I think, pretty well. Instead of going to a small peer review panel, could either make or break their decision, particularly in the case where the administrator has decided to move forward, and then the peer review group may suggest that there are certain weaknesses in the data and that causes the administrator to withdraw the condition. That's one that I worry about more because it's made by a very small group and based solely upon perhaps the science without the understanding that it's been expressed here from the community.

DR. WARD: Yes, and I guess it's really... I keep getting back to you on statistics, you know, the type 1 error and the type 2 error. I mean, I guess I am more concerned about the possibility in the future that the administrator would decide not to move forward with a condition that has modest evidence without having an additional

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level of review than I am that the peer review of—that the opposite would take place, that the peer reviewers would negatively influence the administrator. In reality either one could happen, but I think as long as the results are transparent and as long as... I mean, as long as there's a provision for the peer review comments... when there's a peer review panel assembled that the peer review comments are published as part of the public record then at least it's a transparent process. And, again, there is always the opportunity for a petitioner to come back and raise an issue again.

DR. MARKOWITZ: I think we're confusing the timing of the peer review with the fact of peer review... why don't we just recommend that external peer review occur whenever NIOSH concludes there's modest or substantial, or an addition of a covered condition as a simple recommendation and deal with the issue of the timing when that external peer review occurs separately?

DR. WARD: I think that's fine, although I think it is kind of not consistent with the process as NIOSH has outlined it today. I mean, I think we can make the recommendation that way, but it is inconsistent with the flow that NIOSH is proposing. And I think that... is the flow that NIOSH is proposing really inherent in the wording of the Zadroga Act? No. So we can propose that and that might be a good solution. So could you restate that, Steve?

DR. MARKOWITZ: I realize it leaves some details to be settled later that maybe NIOSH can figure out. Our proposal would be that for any condition for which NIOSH concludes there is modest or substantial support for that condition to be a WTC covered condition, that NIOSH would secure external peer review for their determination.

DR. MIDDENDORF: Can you do the last part of that? Hang on, Steve.

DR. MARKOWITZ: NIOSH would secure external peer review of their determination.

DR. WARD: Or to inform their determination or "of their," either one?

DR. MARKOWITZ: Whatever, whatever.

PARTICIPANT: (Inaudible @ 1:14:27)

DR. MAYER: So then where would the STAC fit in?

DR. WARD: It might not fit in at all. So the way the STAC is, I mean, the way the STAC works is that it's really totally at the administrator's discretion whether he involves the STAC in a decision or not.

DR. MAYER: But I'm wondering for transparency and as you allude that in the future there may be an administrator who is bent on not having any new conditions added. And I don't know how many of these conditions are petitioned for each year, but if it's six conditions a year would it not be appropriate to not only have the administrator consider it, but the STAC consider it and potentially even a peer review, and to the extent where if I was asked to do a peer review for a hangnail that would, you know, be a pretty straightforward thing to do, but it would at least be another independent voice who was weighing in on the question and, again, in the context of making that transparent, then that decision of those three bodies I think would

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- be helpful.
- DR. WARD: Yes. I see where you're coming from, but I think that the role of the STAC vis-à-vis the administrator is written in the Zadroga Act and we can't... it's not something that we can modify. So it really is... and, you know, and I see some downsides too. I mean, if somebody said, you know, if the STAC had to debate every single petition then we would have to meet a lot more frequently, that takes resources. So I think the STAC really, and Dr. Howard has really explained this to us numerous times over the history of the committee that we really serve at his pleasure, and I think from time to time we've proposed, well, the STAC really wants to get together and talk about this and John says, "No, that's my job." His role as the administrator is to determine what issues he wants to consult with the STAC on, and that is based on the way the Zadroga Act is written.
- PARTICIPANT: (Inaudible @ 1:17:05) peer review too.
- DR. WARD: So we have motion 2 drafted. Yes.
- MR. FLAMMIA: Hold on a second. Page 25. Stakeholder review and public comment. Stakeholder and members of the public may have valuable input for rule-making. I'm just thinking about it. They spoke about peer review, stakeholders, members of the public, valuable input for rule-making.
- DR. WARD: Catherine.
- MS. McVAY-HUGHES: Yes. I just have a question, how precise we want to be in all of this because whenever our presidential candidates might want to do away with NIOSH altogether, so what would happen in a situation like that?
- DR. MIDDENDORF: NIOSH could go away with the World Trade Center Health or not.
- PARTICIPANT: You would go away?
- DR. MIDDENDORF: It'd BE attached somewhere else.
- DR. WARD: Yes. Yes, there will always be an administrator. I mean, I personally feel okay with saying NIOSH because, you know, it's essentially the World Trade Center Program staff. Would that be better?
- DR. MIDDENDORF: It's really the administrator's decision. It all goes back to him or her.
- DR. WARD: Right. And so the second NIOSH should be replaced by the administrator too. Yes, Tom.
- DR. ALDRICH: Is it going in this motion or a separate motion that a peer review should be public regardless whether it results in rule-making?
- DR. WARD: I think that should be in this. I would say it's great if we put it in this motion, but if anyone else has a strong preference to separate it.
- DR. MARKOWITZ: I, personally, think it's a point that deserves emphasis and, therefore, a separate motion.
- DR. WARD: Okay. So let's get that motion down.
- DR. MIDDENDORF: What is it?
- DR. MARKOWITZ: Any peer reviews performed blah blah blah should be public regardless whether they result in rule-making.

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DR. WARD: Great.

DR. MIDDENDORF: So we're going to go back to two?

DR. WARD: Yes. So we'll need a second on motion 2.

DR. MAYER: Just a point of clarification. What's the definition of modest?

DR. ALDRICH: One of those things you know when you see it.

DR. MARKOWITZ: No, that's on page 140. It's Dori's word, modest support.

PARTICIPANT: She did explain it.

DR. HARRISON: Motion to the word "their" determination. Probably "this" determination. Should secure external peer review of this determination.

DR. TALASKA: Yes. Or should've been possessive.

DR. HARRISON: Yes.

DR. TALASKA: One or the other. That "their" should be either "their" or "this."

DR. HARRISON: No. Yes. Right. That's "this." It should be "this." Right there.

DR. TALASKA: There is modest. That's right.

DR. HARRISON: Okay. Yes, that's good.

DR. WARD: Okay. So I guess we're ready for a vote on motion 2.

DR. MIDDENDORF: Okay. Motion 2 is, for any condition for which the administrator concludes there is modest or substantial support for... should that be for "adding a WTC covered **condition.**"

PARTICIPANTS: Yes.

DR. MIDDENDORF: So starting from the beginning. For any condition for which the administrator concludes there is modest or substantial support for adding a... sorry?

PARTICIPANT: For adding it as a WTC...

DR. HARRISON: It as a... yes.

PARTICIPANT: It as.

PARTICIPANT: Right.

DR. WARD: Lila.

MS. NORDSTROM: I'm just trying to figure out how this as it's currently worded differs from the charge listed in the Zadroga Act in the first place? Like are we saying that they should secure external peer review before the rule-making process? Like are we not commenting on the timing of that? Because otherwise isn't that what they have to do? Isn't that why we're including peer review process in the first place in this timeline? I'm a little confused.

DR. MARKOWITZ: If you look on page 18, the language towards the top, independent peer reviews. All it says is that the program administrator will provide independent peer review as the basis for issuing a final rule. So right now that's interpreted as only during the notice of proposed rule-making process. We're trying to help... I think this motion...

MS. NORDSTROM: To do it before the rule-making process.

DR. MARKOWITZ: Is consistent with the legislative language, but it's trying to add some conditions under which the external peer review will occur.

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PARTICIPANT: That's my understanding.

MS. NORDSTROM: But this is not stating that it should occur before or after the rule-making... or the notice of...

DR. MARKOWITZ: Right. This is separating the timing from the fact.

MS. NORDSTROM: This is distinguished from the timing. Okay. Sorry.

DR. HARRISON: Paul, it might take for any condition for which the administrator determines because that way the word "determines" at the end alludes back to determines.

DR. MIDDENDORF: I think that's consistent with the way the policy and procedures are written.

DR. WARD: Good. I think we're ready for...

DR. MIDDENDORF: Okay. Well, let me read it since I haven't gotten through it all yet. 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.

DR. WARD: Good. So we can vote.

DR. MIDDENDORF: Ready? Tom Aldridge.

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Rosemarie.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine.

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val.

MS. JONES: Yes.

DR. MIDDENDORF: Steven.

DR. MARKOWITZ: Yes.

DR. MIDDENDORF: Annyce.

DR. MAYER: I abstain.

DR. MIDDENDORF: Mike.

DR. McCRAWLEY: Yes.

DR. MIDDENDORF: Guille.

MS. MEJIA: Yes.

DR. MIDDENDORF: Lila.

MS. NORDSTROM: Yes.

DR. MIDDENDORF: Bill.

DR. ROM: Yes.

DR. MIDDENDORF: Megan.

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DR. RYAN: Yes.

DR. MIDDENDORF: Glenn.

DR. TALASKA: Yes.

DR. MIDDENDORF: And, Liz.

DR. WARD: Yes.

DR. MIDDENDORF: So 15 yes, 1 abstention, zero nos. Motion passes.

DR. WARD: Good. And I think we're actually probably ready to vote on motion 3 unless there's any further discussion of it.

DR. ALDRICH: The word "regardless" should be in there. Regardless whether they result in rule-making.

DR. WARD: So regardless of whether?

PARTICIPANT: Or whether or not.

DR. WARD: Whether or not. Good. Good.

DR. MIDDENDORF: Any further discussion? Okay. So motion 3 is any...

DR. MARKOWITZ: I'm sorry. So the peer review doesn't result in rule-making. But more important this doesn't really specify what aspect of the peer review. There was some discussion this morning about names of the peer reviewers, their comments, their conclusions, the written product of the peer review. Should the peer review process itself, the meeting itself, should that be open? So I don't know how much detail you want to include in this, but generic language like this doesn't get at some of those issues.

DR. WARD: Yes. And I guess my sense is we don't necessarily have to. I mean, I think there may be a meeting, there may be written comments. NIOSH probably does have to compile the comments and response to the comments in a written form and that's I would assume what would be made public. So do you think we need to specify? I mean, there was some discussion about lack of clarity about how we were... whether we were going to specify names, but not attribute specific remarks to specific people. Do you think that needs to be in here? But I don't think we need to dictate whether the meeting... I mean, I don't think—at least my opinion is that we would not necessarily require or suggest that NIOSH should have a public meeting when the process could be done by written comment.

DR. MARKOWITZ: Well, you know, I'm looking at Dr. Melius's written comments. The first one is about transparency of the peer review process, and I'm not sure where his concerns came from, but at the end of the first paragraph he says that both the peer reviews will be compiled without attribution imposed to the rule-making docket, and just before that he says it's not clear whether the peer reviewers will be personally identified. And I think, Paul, you clarified that this morning. I'm okay with leaving it general like this, but that does allow NIOSH to determine details of how much of the peer review process will be public.

DR. WARD: Yes, and I think we want to strike a balance between making the general recommendation and not making the process so burdensome for NIOSH that it

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bogs them down or makes it impossible for them to do a job at a reasonable way in the time frame that's specified in the Act would be pretty free. So I don't want to add so much burden to NIOSH that it can't do its job well by over-specifying our recommendations.

DR. MARKOWITZ: I yield to... this is judgment here. I agree.

DR. HARRISON: I was just saying is the intent here that the written peer review... so just put the word "written" and if that's the overall intent that would make it better.

MS. NORDSTROM: I agree.

DR. MIDDENDORF: We added some language down at the bottom so I want to make sure this is what the committee intends. Just read it carefully.

DR. WARD: Paul, when you say "at the bottom" do you mean under motion 3?

DR. TALASKA: What do you mean "at the bottom?"

DR. MIDDENDORF: Motion 3. I'm sorry. Yes.

DR. WARD: It's just the two...

DR. TALASKA: That's separate. That's completely separate.

DR. WARD: Okay. "Bottom" confused me.

DR. MIDDENDORF: Sorry. The latest motion.

DR. WARD: I think that captures it.

PARTICIPANT: Let's call the vote.

DR. WARD: Ready for a vote.

PARTICIPANT: Second.

DR. MIDDENDORF: Okay. I heard a first and a second.

DR. MAYER: Can I just ask a question?

DR. MIDDENDORF: Yes.

DR. MAYER: So my understanding of the way the peer review would work is that the peer reviewers would be asked to each provide their written reports, and then that information abstracted and compiled. So does that any written peer review mean that it would be the compiled report or that it would be each individual written report? It's a little vague as it's written.

DR. MARKOWITZ: I don't think NIOSH wants it attributed to individuals.

DR. MAYER: Agreed.

DR. MIDDENDORF: Yes, typically what we have done is ask a series of questions of each of the peer reviewers. They put in their responses. All the responses from the first question are put together in an order as they are received, and then they're responded to individually each of those comments. We don't identify who said which thing. So that's...

MS. JONES: Do we need to add that or that's just understood? I mean, looking at this motion do we need to add that, you know, the peer reviews, you know, any written... that it will not be... the person who wrote it will not be identified?

DR. MIDDENDORF: No, I don't think we need to.

MS. JONES: No?

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PARTICIPANT: (Inaudible @ 1:31:21).
DR. MIDDENDORF: That's...I don't want to speak for the committee.
DR. WARD: Lila.
MS. NORDSTROM: This motion presumes that we are doing peer review before the rule-making process which we took out the motion 2. So I'm just sort of wondering if there's some sort of...
DR. WARD: I think it presumes that it's based on the previous recommendation that the peer review... a peer review will be done whether it's... when it's modest or substantial, and it doesn't specifically say before or after.
MS. NORDSTROM: Okay. So this is just if the peer review is done, it will be public not when the peer review will be—okay.
DR. WARD: Even, yes, it occurs before or after.
MS. BOWLER: Didn't we say sequential at one point?
DR. WARD: We just said sequential...
DR. MIDDENDORF: (In a @ 1:32:03) different...
DR. WARD: The public comment period would be after the peer review comments are available. Okay. I think we're ready for a vote on motion 3.
DR. MIDDENDORF: Okay. Tom.
DR. ALDRIDGE: Yes.
DR. MIDDENDORF: Oh, that's it, you're ahead of me. Let me read the motion. Motion 3 is any written peer reviews should be made public whether or not the administrator determines to propose rule-making. Tom.
DR. ALDRIDGE: Yes.
DR. MIDDENDORF: Rosemarie.
DR. BOWLER: Yes.
DR. MIDDENDORF: Anthony.
MR. FLAMMIA: Yes.
DR. MIDDENDORF: Bob.
DR. HARRISON: Yes.
DR. MIDDENDORF: Greg.
DR. HOMISH: Yes.
DR. MIDDENDORF: Catherine.
MS. McVAY-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: Glenn.
DR. TALASKA: Aye.
DR. MIDDENDORF: I'd have to put down a Y and now I have to put down an I?
MS. JONES: There's got to be evidence.
DR. MIDDENDORF: Liz.
DR. WARD: Yes.
PARTICIPANT: My favorite.
DR. MIDDENDORF: Okay. So 16 yes, zero nos. Motion carries.
DR. TALASKA: May I make a motion related to the one earlier about modest? It's not identical, so I thought I would do it separately. It's in regard to a question that came up when Dora was talking where they have no—for the non-cancer outcomes there's no provision for the scientific committee to use any other group like NTP and IARC that available for cancer outcomes. I would propose that for modest actions that the scientific committee could use any specialist advisory organization, say, for example, in pulmonology or in renal disease that makes recommendations relating exposure to a condition, and that would include things like the WEEL committee or toxicology advisory committees, that they could use those resources to make that determination instead of having to only rely upon... or not being able to rely upon anything else.
PARTICIPANT: If you'd add expert to the (inaudible @ 1:34:30)
DR. TALASKA: Oh, expert. Yes. Specialist expert advisory committees. So the motion would be to add specialist, expert, advisory, organizations could be used to in determining administrator actions for modest outcomes.
DR. WARD: Okay. So does anybody want to speak... anyone else want to speak in favor of that motion or opposed to it?
DR. MARKOWITZ: Sure. So in the cancer world IARC and NTP are considered very authoritative and have a very transparent, thorough consensus process. I don't know whether that really applies to these other consensus statements by unnamed organizations and I don't think it would be wise to suggest that NIOSH would in any sense defer to them for decision-making about these non-cancer conditions. I don't see any reason why they shouldn't consider these consensus statements, but I can't quite think of a comparable process or authority that would provide something similar to NTP or as highly respected as NTP and IARC.

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DR. TALASKA: I'm an industrial hygienist, so a couple of industrial hygiene organizations come to mind. One being the WEEL committee of the American Association for Industrial Hygienists. The other being the ACGIH, TLV, BEI committees which provide that sort of information. But then I assume that are... I assume and assume always gets you in trouble, that renal groups or pulmonary physicians also have bodies that advise them on conditions and related exposure in relationship to conditions for silica, I don't know what.

MS. MEJIA: (Inaudible @ 1:36:52) family.

PARTICIPANT: Pulmonologists and mean that...

DR. TALASKA: No. We say specifically that they publish these things, that published information by... and, again, the word "consider" was in there because they could use published information that's provided by those groups.

DR. BOWLER: Oh, (inside the @ 1:37:12) groups.

DR. WARD: Yes, I guess I'm ambivalent to that because I'm just not aware that that is something that's commonly done. I mean, certainly, you know, the one example that keeps coming to mind is silica in relation to autoimmune disease because I know there have been some studies associating silica with autoimmune disease and that would be something that I would think that should be considered if one is looking at autoimmune diseases and the World Trade Center exposures. But I think cancer's kind of a very unique disease in terms of how much effort has been put into categorizing agents in relation to cancer. I mean, the only thing I could think of would be, let's say, well-regarded occupational medicine textbooks. You might go to a source like that to look at, okay, what are the agents that have been associated with renal disease or other types of diseases. But I honestly don't think that there's an analogy for most of these other diseases.

PARTICIPANT: (Inaudible @ 1:38:29).

DR. TALASKA: Isn't the issue here that NIOSH and the administrator should, need not be limited to using 9/11 epidemiologic studies to make their decision?

DR. WARD: Yes, and no. I mean, I do think that that is opening—I mean, my premise is that the reality is that they will not be looking at these conditions unless they've seen it in a 9/11 study.

DR. ALDRICH: Quite right. But...

DR. WARD: But you're saying that... So basically we're saying there's levels of insufficient, modest, or substantial. Right? If we take those three categories. Kind of the way it's structured now if it's modest they broaden... if they think the EPI literature is modest they broaden that and look at other literature, but they don't use other literature to go from insufficient to modest. That's how they've laid it out today.

DR. ALDRICH: Doesn't it seem—and on page 138, the top slide, that the only studies that can be considered are 9/11 epidemiology studies. I'm just saying that the science need not be limited to that. I mean, it can be limited to that, but it need not be limited.

DR. TALASKA: And that's the point. If an organization like the American Association of

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Occupational Physicians says that there's a relationship between... I'm making this up. And I'll use ridiculous examples. But there's a relationship between an exposure that was known to occur during 9/11 and an autoimmune disease. If a professional organization makes that recommendation without it... according to this, it can't be use as any evidence at all other than by the individual studies that are being provided.

DR. HARRISON: When I see a patient with an occupational disease, I review the medical and scientific literature and when I do so I include information from a wide variety of sources. For example, I'll look at the California EPA Chronic Reference Exposure Limit documentation because they have excellent reviews of the mechanistic and the toxicology literature. I'll look at individual case reports. I look at the totality and I look at the epidemiological literature, of course. So it's not clear to me from reading the NIOSH policy and procedures whether in reviewing the evidence they're limited to within the confines of the 9/11 health studies or not. So I would concur with the recommendation from this committee that they not be limited. That NIOSH is not limited in just looking at within the confines of the 9/11 published studies and we make that explicit. I can't see why the NIOSH scientists would not look at the totality of the published literature particularly in biological plausibility alone. I mean, we know what the range of chemicals are. It's a finite list. It's a large, but it's a finite list.

DR. WARD: Yes, and I think maybe the problem is we don't want this to be overly restrictive, but we also don't want our recommendations to be introverted such that every... that NIOSH has to do an unreasonably wide search. I mean, there should be room for scientific judgment as to what additional information is relevant to a particular determination. I guess the question is how do we say that.

DR. HARRISON: Well, I'm still looking at the NIOSH policies here and to the degree that I think I understand them. On page 147 of our handout book. If you look at what NIOSH should be doing for modest support for a causal association, it pretty specifically says that the NIOSH science team should look at the 9/11 data and other studies to the extent that they parallel the exposure from 9/11. It doesn't say that they're supposed to look at toxicology or mechanistic data on non-cancer conditions. And I'm not sure why not. I'm not sure I completely grasp why for non-cancer it doesn't say that as it does for cancer.

DR. WARD: Well, I think one reason...

DR. HARRISON: By analogy that is other these other—that other lines of evidence can be considered we aren't necessary.

DR. WARD: Yes. I mean, I think one reason cancer is unusual is that we recognize that there's long latency and we recognize that the existing epidemiologic study, in addition to latency the existing studies are limited in size. So you have power issues and you have latency issues. I think the other conditions that are likely to arise in 9/11 populations are conditions that are recognized as a result of excesses being

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observed in studies. And so there you're starting off with some evidence from studies that's triggering the review. Whereas in cancer, I mean, we recognize from the get-go that we would have to rely a lot on indirect evidence because it would be a very long time before the epidemiological evidence would be definitive, if ever.

DR. HARRISON: So there's some thought that if non-chronic conditions become evident in the 9/11 cohort they're going to be seen early, that we don't expect them to be diseases of long latency, that if we know about them we'd know about them by now.

DR. WARD: Well, not necessarily, but I guess at this point if there isn't evidence of a condition in... a specific condition in the studies do we really think it's reasonable that there will be a mechanistic... there'll be a proposal to designate something as World Trade Center related based on mechanistic evidence alone.

DR. HARRISON: Well, that's a good question. But I think that's an important question because if the answer to that, yes, I agree with you then I would agree that the guidelines are correct, but if I'm not sure of that I wouldn't necessarily want to preclude the NIOSH scientists from looking at these other lines of evidence and just a priori concluding that that's not going to be the case so don't even bother to look at it.

MS. JONES: I guess, I'm not sure I'm following this totally, but on page 24 where they write about selection of peer reviewers, I figured we would go to that next at some point and I'll comment then. But based on expertise necessary to evaluate the science relied on seems rather broad to me and seems somewhat like where I think we might be trying to go to go that it'd be broader. I'm just using the fact that they have... this is what's part of their presentation this morning and I assumed we would go to that next. But just that it's rather broad, but it's stated expertise necessary. So whatever that might be that's relevant, it's relevant to...

DR. MARKOWITZ: So if I had seven days to produce a literature review I would restrict to it 9/11 epidemiologic studies in order to get it done. That, to me, is the most likely explanation for the relatively narrow approach they're taking. So I think if we could say something like to the extent feasible we encourage NIOSH to examine the broader literature beyond 9/11 epidemiologic studies including other epidemiologic studies, animal studies, mechanistic studies that are of reasonable relevance to the question.

PARTICIPANT: Yes, that's fine.

DR. MARKOWITZ: In other words, so give them language that to the extent feasible and that is directly relevant. Give them language, but at the same... that narrows it, but at the same time encourage a broader look. And I don't know if that's doable in seven days, but maybe it's doable in some small multiple of seven days.

DR. WARD: Yes, and I think it's important that we say that because you don't want someone in the future to interpret this as we're, you know, if the NIOSH policies specifically exclude consideration of that type of evidence even if it's not relevant. So I think it's important that we make that comment.

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MS. McVAY-HUGHES: I totally agree we need it to the extent feasible, but I also want to put in the record that there were so few studies on children for so long that there just isn't the data to go with. And as a mom of two kids and representing the people who live and work in the neighborhood, children specifically. At this point I just want to make sure that this is a particular concern.

DR. WARD: Lila.

MS. NORDSTROM: I also wanted to echo that there were gaps in who was studied and specifically with among the populations that will live with these conditions the longest. So it is important that the guidelines here not be so narrowly focused that they don't feel that they can look outside of 9/11 epidemiological studies to look for evidence for connections that will make sense specifically in the pediatric population, but also just like in any gap population because there are plenty in the survivor communities specifically, but in the broader community as well.

DR. WARD: Yes. And I think I would just make it a little softer and say relevant rather than directly relevant. I think that captures it because I think ultimately we have... I mean, ultimately this process is going to rely on the scientific judgment of the people doing the review.

PARTICIPANT: So I would replace lines of evidence with scientific evidence. And then I would say... after evidence I would say including epidemiology, toxicology, and mechanistic studies. So there's some specificity.

DR. BOWLER: Yes, they've said for here, PTSD would be, how important it is to have all of the relevant risk factors that we certainly know about whether there'd be other severe life events, serious life events and how many and with the police, how many visits they had to community people who had... guns were involved and the lives were threatened and not just misinterpret that, that all these other considerations are made, that it's like any good research studies.

PARTICIPANT: So are you suggesting adding another word?

DR. BOWLER: I'm wondering if somehow that we would, could add...

DR. WARD: Well, again, I think maybe, Rosemarie, what you're getting more at is the kinds of things that would be looked at in the peer reviews, is do the studies that do show an association, have they looked at all the possible confounding factors. So I would think that would be addressed in the scientific reviews of the studies that provide the evidence for the associations.

DR. BOWLER: Risk factors.

PARTICIPANT: So do you want to make this the administrator and any peer reviewers?

PARTICIPANT: Yes.

DR. BOWLER: Yes. It's very important, I think.

PARTICIPANT: Just to be more readable I would recommend moving beyond 9/11 studies up the previous line before including.

DR. WARD: Yes.

DR. BOWLER: Good. Excellent.

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PARTICIPANT: And just to make it a little clearer instead of saying “when feasible” I would actually take that out and put it at the beginning of the entire sentence “to the extent feasible” the administrator...

DR. BOWLER: And just to make sure I guess it’s presumed that prior conditions in the same area would also be excluded. I mean, or at least to be looked at.

DR. WARD: Well, we’re not talking about an individual determination, we’re talking about the aggregate...

DR. BOWLER: Yes, but in the studies that this is considered...

DR. WARD: Right. But that’s more, again, evaluation of the methodology of the studies. Yes. Okay. I think we’re ready to vote on this motion.

PARTICIPANT: The case—this is a mild quibble—“to case report”. When we say “epidemiology studies” does that include case report?

PARTICIPANT: Yes.

DR. BOWLER: Really? Individual one only?

PARTICIPANT: I don’t know. I’m just...

DR. BOWLER: I don’t think so.

PARTICIPANT: I’m never quite sure.

DR. WARD: Well, I will say that we probably don’t want to get into too much of defining; and, secondly, we still haven’t addressed the main question that NIOSH put to us which is how should the peer reviewers be selected. So we probably should vote on this and move on to that.

DR. MIDDENDORF: Yes, we need to vote on this and we do need to address identification of peer reviewers. This does fall under the heading of reviewing policies and procedures, so that this is fine. We just need to make sure we get to that.

DR. WARD: Right.

DR. MIDDENDORF: Okay. So motion 4. To the extent feasible the administrator and peer reviewers should consider scientific evidence beyond 9/11 studies including epidemiologic, toxicologic, and mechanistic studies. I’ll make those changes. Okay. So are you ready, Tom?

DR. ALDRIDGE: Yes.

DR. MIDDENDORF: Was that a yes, you’re ready or yes, you vote for it? Rosemarie.

DR. BOWLER: Yes.

DR. MIDDENDORF: Anthony.

MR. FLAMMIA: Yes.

DR. MIDDENDORF: Bob.

DR. HARRISON: Yes.

DR. MIDDENDORF: Greg.

DR. HOMISH: Yes.

DR. MIDDENDORF: Catherine.

MS. McVAY-HUGHES: Yes.

DR. MIDDENDORF: Val.

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- MS. JONES: Yes.
- DR. MIDDENDORF: Steven.
- DR. MARKOWITZ: Yes.
- DR. MIDDENDORF: Annyce.
- DR. MAYER: Yes.
- DR. MIDDENDORF: 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: Glenn.
- DR. TALASKA: Yes.
- DR. MIDDENDORF: And, Liz.
- DR. WARD: Yes.
- DR. MIDDENDORF: Sixteen, yes. Zero nos. Motion carries.
- MS. JONES: I guess now I have two questions, page 24 and 25; 24, are we going to talk about selection of peer reviewers? And on 25, I think Anthony brought up stakeholders and members of the public may have valuable input for rule-making. Have we addressed that or discussed that or are we going to discuss that? I guess, because that to me is very important that we respect the people and the first responders that came out. And to me that's one way that you respect the people that came out.
- DR. MIDDENDORF: That's part of the process. Yes. And it's required. I mean, it's in the regulations we have to do that.
- MS. JONES: So this is done already?
- DR. MIDDENDORF: The public comment is already a requirement. It's required for new rule-making.
- MS. JONES: As part of the input for rule-making.
- DR. MIDDENDORF: Yes.
- PARTICIPANT: And, furthermore, the STAC has members who are stakeholders.
- MS. JONES: And so what about 24, the selection of peer reviewers? Is that done already?
- DR. WARD: No, that's what we're going to talk about next. We should probably take a short break. I would really ask that it be a short break, though. I know a few of us have planes to catch, so if we could close a little bit before five that probably would help us get to our planes before they leave.
- DR. MIDDENDORF: Be back here by 3:20.

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DR. WARD: So, in the next part of our discussion, we'll be talking about our recommendations for the selection of the peer reviewers. And I understand that the idea is that there will be three peer reviewers involved in the peer review, so we should bear that in mind. You know, the program hasn't determined yet whether there would be a unique set of peer reviewers identified for each proposed condition or set of conditions, or whether there might be a stable group, or a combination of the two. One thing I think is pretty straightforward or that we might want to talk about, it's pretty straightforward, is that I would assume that if someone is an author of one of the primary 9/11 studies that are being used, you know, to consider the determination, that that person would not be an appropriate peer reviewer because that person might already have a very strong viewpoint on the interpretation of their study and possibly conflicting evidence. And somebody brought that up earlier as a question, and I think we probably would all agree on that. I don't know if we need a specific motion, but just that that kind of person would probably not be suitable.

DR. BOWLER: Or you could exclude the person when it comes to voting.

DR. WARD: Well, but there's only three peer reviewers so—

DR. MIDDENDORF: And they don't vote.

DR. WARD: And they're primarily giving their opinion and advice.

DR. BOWLER: On the STAC.

DR. WARD: Yes.

DR. MIDDENDORF: Not on the STAC.

MR. FLAMMIA: Look, Liz?

DR. BOWLER: Not on the STAC?

DR. WARD: Yes, Anthony?

MR. FLAMMIA: Are these paid reviewers? Are they paid for through the program—

DR. BOWLER: Never.

MR. FLAMMIA: Or they're just independent volunteers?

DR. WARD: I would assume no, but Paul can comment.

DR. MIDDENDORF: Yes. We have considered that, and what we've considered is that we can pay them, but we haven't determined that we will or won't yet.

MR. FLAMMIA: I'm sorry?

DR. MIDDENDORF: We have not determined whether we will or will not offer payment.

MR. FLAMMIA: I guess that'll be determined at a later date?

DR. MIDDENDORF: Yes.

MR. FLAMMIA: Thank you.

DR. WARD: Lila.

MS. NORDSTROM: Diving in. Do we have—so one of the things that we're supposed to sort of consult on at this point is how we're finding these names or where these names are coming from. Is there any protocol so far as to where these names will be coming from and who will be suggesting them?

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- DR. WARD: I think the STAC is charged with making recommendations for, you know, what are the qualifications of the peer reviewers? You know, we could make recommendations on a process.
- MS. NORDSTROM: Okay.
- DR. WARD: I have been assuming that we would recommend a process and that the program staff would primarily be responsible for carrying out that process.
- MS. NORDSTROM: Okay.
- DR. WARD: And I do think, you know—for that, I think we do have a framework, the framework through which scientific peer reviewers are often selected. And, you know, Steve is a journal editor, and I think maybe if—Steve, would it be possible for you to review some of the criteria that you use to select peer reviewers for your journal articles?
- DR. MARKOWITZ: Well, so very briefly. WTC in particular is difficult because there are only a few groups around town who are doing this work, and only a few groups around who are at all interested in this work. So, you know, and even if you blind the process, meaning you don't tell the reviewers who the authors are and vice versa, you know, when an article comes on cancer among firefighters who were at World Trade, you know, everybody knows who did that manuscript. So the blinding is illusory. So, you know, do I send the manuscript that comes in from FDNY, do I send that over to the World Trade Center Registry who are, in a sense, comrades, in a sense, competitors, because they have a cancer manuscript as well pending? So it gets complicated. When I've tried to reach out outside of New York City to get reviewers, I get very little interest in World Trade Center issues, except for Bob Harrison, of course. So it's a bit of a challenge. I'm not sure that's helpful, but, you know, we pick peer reviewers who are knowledgeable about that topic. They may or may not be the person who published something, you know, in the past year, but they need to be knowledgeable about that topic. And that's important here, particularly in the non-cancer outcomes because, if you're going to look at autoimmune illnesses, if that's the question, then you need people who have that particular expertise. And they're findable, NIOSH can find them, but this is an argument for a kind of ad hoc peer reviewers, meaning an assembled panel for each particular question, and not for a standing committee or a standing pool from which you draw, you know, as questions arise.
- DR. TALASKA: I would agree with the last point specifically, that there shouldn't be a standing pool because the conditions that are going to be considered are so diverse and the expertise just isn't there. I mean, Liz, you made a great suggestion this morning. I don't know if you remember it, but that we recommend that the editorial boards of the specialty journals or specialty—specialists be considered to be the first line of reviewers, so that we have—for the specialty groups within a discipline.
- DR. WARD: Yes, and I think that's a good point. And I think, when I was talking to Dori at the break, you know, I had been thinking that we need clinical experts in particular

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diseases, but, after talking with her, I think what we need are, you know, people who are—at least the most essential group are people who are doing studies of associations between environmental or occupational exposures and those diseases.

DR. TALASKA:

Yes.

DR. WARD:

Presumably, those people will also have some clinical expertise in those diseases, as well. Yes?

PARTICIPANT:

I have—

MS. JONES:

I don't remember who the speaker was this morning, but one of the gentlemen, I think, who was, like, first brought up the issue of a public process for nominating peer reviewers. So I just wanted us to consider that because that was—I don't know his name.

DR. MIDDENDORF:

Dr. Melius.

MS. JONES:

Yes, I guess it was Dr. Melius that brought up the concept of public process for nominating peer reviewers. So could we just somewhat, I guess, consider that in this? But it sounds kind of like, with three people, that might be difficult, but I just kind of think—oh, no? Oh, okay.

DR. WARD:

Yes, I'd like to hear comments on that from the panel. Lila?

MS. NORDSTROM:

I also echo that I think that's a great way to provide some of the transparency that the community commenters were talking about, and I think also gives a sort of—you know, provides an opportunity to maybe seek some outside opinions in terms of what kinds of expertise we're looking for, depending on what kind of problem we're considering, because some of these problems, there's not a huge amount of, you know, evidence in these epidemiological 9/11-based studies with, you know, these very specific cohorts, but there might be—in the sort of wider medical world, there might be more sort of, like, of an understanding of an association or something that we can grasp onto. But that is something that I think—you know, I don't think it harms us to get advice from—to have many cooks in terms of, like, naming potential people to serve and peer review studies, because, obviously, the final discretion will still lie with NIOSH, but I think it's something that would be beneficial to the process.

DR. WARD:

Catherine?

MS. McVAY-HUGHES:

Yes. In terms of possible people outside the World Trade Center arena, what about, like, the Veterans Administration for people who have been at war, like, those in the oil fields, because there might be some overlap?

DR. WARD:

Yes, I don't know if government employees would be precluded from serving in that role?

DR. MIDDENDORF:

No.

DR. WARD:

No? Okay.

MS. MEJIA:

So I agree. I mean, I think it is important to have public input into who the peer reviewers are, obviously, with the understanding that, because you recommend

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someone, doesn't necessarily mean they're going to pick that individual. So yes, there has to be an opportunity to at least put those names forward or the organizations forward. And it's also consistent with this bulletin with respect to making sure that there is transparency there. And, you know, a lot of people don't trust government, I mean—and so this is another way to, you know, squash that and to give people the opportunity to just, you know, comment.

DR. WARD:

Steve?

DR. MARKOWITZ:

I have a question for Paul about the process if the public were invited to submit nominations, because of the importance of timeliness, and so would this necessarily involve notice in the Federal Register and all that that involves? Because if that were necessary, maybe you could tell us how much time it takes to submit a notice in the Federal Register and how much time you have to give for nominations and the like?

DR. MIDDENDORF:

Typically, when I submit a Federal Register notice for a meeting or to solicit nominees, I have to turn that in six weeks before it's due, before the time. So, if you're talking six weeks, that's 42 days, that's half the time period. That might be doable because once you turn it over, we're writing the notice of proposed rule-making, yes, that would be about the same time. So it might be doable to put out a Federal Register notice soliciting for comments on the peer review package.

DR. MARKOWITZ:

But then you have to give a few weeks for the nominations to come in—

DR. MIDDENDORF:

Yes.

DR. MARKOWITZ:

And then you have to look over those nominations, so I'm just—

DR. MIDDENDORF:

Yes, it—there might be...

DR. MARKOWITZ:

Is there an alternative to a Federal Register notice process?

DR. MIDDENDORF:

I'm going to look toward Emily, any thoughts on that? Emily Howell is an attorney with OGC and does a lot of advising on the World Trade Center Health Program.

MS. HOWELL:

Hi, I'm Emily Howell. I'm with the Department of Health and Human Services—

DR. MIDDENDORF:

Emily, is that on?

MS. HOWELL:

Office of the General Counsel.

DR. MIDDENDORF:

It's on the other side.

MS. HOWELL:

All right. Hi, I'm Emily Howell. I'm with the Department of Health and Human Services, Office of the General Counsel. With regards to selecting peer reviewers and getting public comment, certainly we would like to use Federal Register notices. There are some other mechanisms for receiving that input, but I think one thing you may want to clarify is whether you're asking for general public input on who effective peer reviewers might be overall, versus specialized peer reviewers for specific subject matter that's under consideration. So, certainly, for timeliness purposes, having more generalized public input about who might be good peer reviewers for a broad array of conditions might be something that could be accomplished, similar to how the program gets STAC committee member recommendations on a more annual basis.

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- DR. WARD: Yes, I think we are leaning towards the idea of selecting particular reviewers for particular health conditions, but it does seem like it might be feasible—I mean, if the program decided to accept this recommendation—that, at the time you get the petition or the administrator decides to move forward with review on a topic, that you post a notice saying that you are, you know, in a pre—you are looking at this topic and it may go—the determination may require a peer review, and allow nominations to be taken, and then those nominations would be in by the time you would need to consider the peer review panel. So it could be done.
- DR. MIDDENDORF: Yes, I'm not—there's just so many things to think about and consider.
- DR. WARD: Right, right.
- DR. MIDDENDORF: There are possibilities here, but...
- DR. WARD: Right.
- DR. MIDDENDORF: We really have to think that through.
- DR. WARD: Anthony and then Annyce?
- MR. FLAMMIA: Thinking outside of the box, I'm just thinking they do this in law school and they do it with case studies in law school, and I'm thinking about our younger doctors coming out of med school that are hitting the ground as full MDs, taking the best and the brightest, and taking them in to do these case studies. I'm just, you know, throwing it out there, thinking outside of the box, you know, the best and the brightest.
- DR. WARD: Annyce?
- DR. MAYER: This isn't what I was going to say, but, you know, just thinking of myself coming out of med school, I don't think I would have had the background or the expertise to be able to do that. In regard to—you know, it was mentioned this morning that it's critically important that people who participate in the peer review really understand World Trade Center exposures that are quite unique, and people are going to be coming in with this with different degrees of background, and just wondering if it could be feasible that there be some kind of orientation program that would provide people with information about the potential spectrum, information about the different intensities, duration, depending on where people were. That, I think, would be helpful.
- I think the other thing is it's not typical, when one performs a review, that the review be available for public review. And I think it would be very helpful, as part of that orientation, for people to understand the background and, you know, initial EPA and other denials of things going on, and to understand why that public transparency is such an important part of this process.
- MR. FLAMMIA: To add to what you said—and we're all older here. I mean, are we going to be around at the end of the Zadroga bill? I don't think so. I mean, so the younger generation, getting them into—
- DR. BOWLER: 2090.
- MR. FLAMMIA: Tune with this.

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- DR. WARD: Lila has a shot.
- DR. HARRISON: I would propose some kind of a hybrid motion along the lines of that NIOSH or the administrator should develop and implement a process for soliciting public nominations, nominations for peer reviewers. Maybe say something about the range of different disciplines of those reviewers, and then say something like, in addition, the administrator should supplement or can decide specific subject matter experts where necessary. So there's some process for developing a stable, if you will, of scientific reviewers who would be willing to serve. That would allow the administrator to have a group that they could pick from, but that wouldn't be hamstrung—just you wouldn't have to limit yourself to that group, because I think NIOSH needs the flexibility to be able to rapidly move ahead if there's a petition and there's not the right person that they can find—it's tough within a 90-day period to actually, you know, figure out who is going to be able to do this, who has the time, to get them the materials, and get it done. So something like that where it—I think that would be in the spirit of the discussion.
- DR. WARD: Catherine Hughes?
- MS. McVAY-HUGHES: Yes, I also, in terms of—I like the idea of the stable and I actually think we should start... Something should go out for a federal notice in case there is something we want to do in 2016, because it takes so long for that to go through the cycle. But two possible pots to consider are former World Trade Center STAC members, because some people had to rotate off, but maybe they could—you know, depending on their background, might be a possibility. And also some of the EPA World Trade Center Expert Technical Panel members who are not at the table. So just depending on those particular individuals, yes.
- DR. WARD: Glenn and then Rosemarie.
- DR. TALASKA: Related to both of those, I think, is perhaps we could have a group of—say, if we have three reviewers, two of them could be reviewers with specific expertise in the particular field who could be chosen ad hoc, but then one of the reviewers, to deal with the fact that they would understand World Trade Center situations, would be someone with World Trade Center experience. Those people could be recruited ahead of time and then, because there would always be one of those people on the review panel, they could be recruited and then just be pulled as they're needed, and, relative to conflicts and things like that, to be excluded individuals.
- DR. WARD: Rosemarie?
- DR. BOWLER: I am a little bit concerned about paying reviewers. I mean, for journals, at least, I mean, I've never, ever gotten paid, and it wouldn't seem right to get paid. So, if that becomes an issue—I mean, if there were some other ways of honoring the people who do the reviews—it would be a concern for me to pay them. So I wouldn't mind getting paid, but I think it's better not.
- DR. WARD: Okay, Val and then Lila.
- MS. JONES: I think that this might echo what some other people said. We have people around

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the table that are here from various organizations that, I think if the process were open, those particular organizations—like, I'm here on behalf of the World Trade Center Steering Committee, the Survivors Steering Committee, and I think there are people in terms of that group that would be able to identify people that would be good to be peer reviewers. So I think that that would be, in some ways, an open process, and I think that people in the community would be somewhat comfortable with that. Because I think, as someone said, I think—you know, and I hate to say this, but I think it's just the reality. What I heard listening to people, especially from Community Board 1, was they do have a real distrust of the government, because they were told they could walk out their houses back and forth with nothing on, you know, with no mask or anything. So I think that there are some groups around the table, you know, the survivor group, the responder group, et cetera, that would probably have that information, and I think that that would—to me, would seem rather respectful to make that part of the public process, that those groups could possibly submit people for consideration to be peer reviewers.

- DR. WARD: Okay, Lila, then Anthony.
- MS. NORDSTROM: I agree with that. I think all of us that are here as community reps come from groups that would be well, you know, able to provide adequate recommendations, and not just, like, a random guy in Cincinnati recommendations for this process.
- DR. MIDDENDORF: He's a random guy from Cincinnati.
- MS. NORDSTROM: You're not random. You have a name tag. Yes.
- PARTICIPANT: He's rapidly aging.
- MS. NORDSTROM: Exactly.
- PARTICIPANT: I like that side of the table.
- MS. NORDSTROM: Who knew? Cincinnati. I thought I was really going random. In any case, I echo that that is, I think, something that—when we say public, you know, recommendations, we're generally talking about sort of stakeholders and people that are sort of adequately versed in what we're looking for in this sort of circumstance, so if that's—and then, also, one quick question for the medical professionals at the table. What are the circumstances in which people normally get paid or not paid for peer review work? Just since that came up, I'm curious, because I don't know.
- DR. ROM: So NIH does compensate reviewers for their review time so—
- DR. BOWLER: Yes, that's true.
- PARTICIPANT: So (inaudible @ 21:54).
- DR. BOWLER: But that's not for publications. That's more going to committees, right?
- PARTICIPANT: For grants.
- PARTICIPANT: Yes.
- DR. BOWLER: That's different.
- PARTICIPANT: True.

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DR. BOWLER: That's not what we're talking about. Totally different.

MS. MEJIA: This is policies—

DR. TALASKA: The level of commitment would be much more significant. It's like ours.

DR. BOWLER: Like this.

DR. TALASKA: We get compensation.

DR. BOWLER: Well, not—but yes.

MS. JONES: Yes, that's what I was thinking, we all get—

MS. NORDSTROM: Yes, we get paid to be here.

MS. JONES: You know, compensated.

DR. BOWLER: It's different, yes.

DR. WARD: It's an honorarium.

MS. JONES: It actually—huh?

DR. WARD: It's an honorarium, it's not getting paid.

DR. TALASKA: Honorarium, yes.

MS. JONES: Right, yes.

DR. BOWLER: Yes.

MS. JONES: Oh, no, let me tell you, I—it's linked with my Social Security benefits.

MR. FLAMMIA: We pay taxes on it. That's right.

MS. JONES: We...

MS. JONES: Him.

DR. ROM: You don't do reviews for the money.

MS. NORDSTROM: Yes, right.

MS. JONES: Yes, no. Right.

DR. ROM: It's for your professional experience.

MS. NORDSTROM: Okay, yes. My main question is whether—like, just in terms of being able to get people in, obviously there's a very small pool of people with expertise in this area, and so I just want to make sure that, if we sort of state that we—if we as the STAC decide that we're, like, against paying peer reviewers, but, you know, then have an impossible time finding experts who are willing to work with us, because this is such a specialized area, that we don't sort of eliminate that possibility. But I don't know the politics within the medical community of it, so that's why I'm raising it.

DR. ROM: The good reviewers are always too busy to do it—

PARTICIPANT: Right.

DR. ROM: So you need someone like Dr. Markowitz to ask you and when he asks you, you can't say no.

PARTICIPANT: Right.

MS. NORDSTROM: Right.

DR. ROM: The other thing is that...

DR. MARKOWITZ: I've got that down, Bill.

DR. ROM: I know.

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PARTICIPANT: Bill gets paid.

DR. ROM: The other thing is that you can—well, reviewers are like every other person, they have political points of view, and some may feel very strongly that there shouldn't be any more conditions approved for World Trade Center dust lists, and others may feel the opposite way. And when you look at a number of reviewers, like there's 15 reviewers for the GAO's review of NIOSH's program, I can tell you which ones are very pro-industry and which ones are very pro-labor and which ones are neutral. We all know that. And I looked at this list and I found some of all types on that list, so it was pretty good balance, and I don't know if that was on purpose. I don't think it was. I think it was by just total randomness, but they did a good job.

DR. MIDDENDORF: Even If they're from Cincinnati.

DR. WARD: Megan.

DR. ROM: Oh, so the turnaround time of 15 days for reviewers is actually kind of—is a relatively short window. Reviewers are given usually more time to review papers or even grants. And so to push it—I would hate to exclude payment if it caused somebody—they had to take extra time, but—

DR. MIDDENDORF: And I was just going to say, the only times I know of that NIOSH has paid peer reviewers is when they have difficulty getting reviews. In a situation where, if you're asking somebody to turn around a peer review in 15 days, you need to have some great incentives.

DR. WARD: So let's go to Megan who has been waiting patiently.

DR. RYAN: So I think I definitely agree. You know, when I accept peer review is when somebody prestigious asks me to, because, you know, the compensation would never be enough for the time that you put into these things. This is federal government compensation. This is never—it's not going to be enough, but it might be enough to make somebody feel like at least they were appreciated. So I don't think paying or not paying really changes it for the kind of prestigious peer reviewers we want, because we're talking about a—it's really whether they feel honored to be asked to do it, they will agree to it or not.

But I think it's an important point about the issue that you brought up, sir, about NIH reviews. Are we envisioning this peer review to be three people who get a document, and take it home, and take 15 days, and give back their opinion? Or are we picturing it to be three people who get together in some way and talk about it, which is harder to do and sometimes requires compensation, because you've got to coordinate that? It's more expensive, it's harder to do, it's harder to get the people to do it, but I think it's an important point, because it changes everything, whether or not you're saying, "Oh, it's like a journal, like, three people, you take yours home, I'll take mine home, and we'll give it back to Dr. Markowitz, and he'll figure it out." Or three people get together and try to—like an NIH review.

DR. WARD: Paul, do you have a comment on that or Dori?

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- DR. MIDDENDORF: Yes, the current vision is not to have a panel where you pull everybody together. It's to send out the information, ask them to do the review, provide them with whatever information they need, and ask them to come back with their individual peer review, rather than trying to get the people together, getting them together, getting all the travel done, you're talking weeks—finding time in their schedule that they can get away. It's a very difficult process.
- DR. WARD: Yes. So my suggestion, hearing the comments, is that we maybe put to the side the issue of paying them, because I think that's something with can leave to NIOSH's judgment. I think we all feel somewhat ambivalent about it, but I don't think it's something—so I don't think we're going to come to consensus, yes or no, or that that would necessarily be valuable advice. So Rosemarie?
- DR. BOWLER: I would caution you a little on the 15 days. Most people who are really good have a lot of other things going on, pressure, deadlines, and I simply—I would not do reviews in two weeks.
- DR. WARD: Yes. And that would be my second suggestion, is that we not focus on the 15 days, because, really, the timeframe is going to depend on how NIOSH decides to do it, when they decide to do it. I think we just don't—we kind of, again, I mean, I think we all recognize that 15 days is extremely short, so let's not use that as a criterion. I did like this—I mean, I think the one—I think the suggestion that we were talking about for a while of whether you at least want to have a pool of reviewers that could serve for a number of different health conditions or could be available, and either those people be people who are already familiar with the 9/11 scenario and literature, or that we develop an opportunity to educate them, you know, bring them all up to a certain level of knowledge, whether that might be, like, a one-day meeting where everyone is given background and training and some orientation. I mean, I actually think that would not be a bad idea at all, because one of the things that we struggled with when John first asked us whether to, you know, list cancer as a World Trade Center-related condition is that NIOSH doesn't really have a very defined set of criteria for what is a World Trade Center condition and what is not. So we had to really come up, to a large extent, with our own definition and criteria. But I think, if we are going to rely on these people for, you know, their peer review of these determinations, giving them a basic orientation to the exposure scenarios and the limitations of existing—you know, the existence and limitations of existing study populations, and at how other health conditions have been reviewed and determined to be World Trade Center or not might be really valuable. And then, again, I think we all—I think there probably is a consensus that, for specific topics, you may need one or two reviewers that are experts in that topic, but that we need at least one person on each committee who is knowledgeable about the exposures and about the criteria for how these determinations are being made. Tom?
- DR. ALDRICH: For internal reviews by NIOSH that do not go to the STAC, would it be out of the

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- question for one or more of the reviewers to be STAC members?
- DR. WARD: I thought about that too and it's something—you know, I don't know if anyone from the program wants to comment on—I mean, on the one hand, I think, you know, the people who've served on the STAC certainly have accumulated a great deal of knowledge that would be useful. On the other hand, it's kind of giving that person double weight, because they—even if they're not—even if the STAC isn't considering that particular nomination, that person's point of view is being expressed on the STAC and it's also being expressed in the peer review. So I can see it both ways. Anybody else want to comment on that?
- DR. BOWLER: I also think this could be a very big difference depending on the specialty area that you want. For some, you will have many and, like, cardiac or, well, others, you won't have many who are experts in that area, so you have to consider that too.
- DR. WARD: Yes, although there's not—I mean, I think the pool of experts who study cardiac disease and toxic exposures or cardiac disease and psychological exposures, those will be more—the pool is more limited than those who are specifically experts in treatment and diagnosis. Does anyone have any other comments, either on what we've talked about or other ideas for what to suggest to NIOSH and how they approach the selection of peer reviewers?
- MS. McVAY-HUGHES: Hi. Catherine here. I have one comment. It seems like, because we don't have a pediatric specialist right now on the panel, you might want to get a pediatrician in your peer review immediately on board. You know, if you're looking at that list on page 24, it's like, it just said—it listed some examples of qualification, knowledge, and experience. It has, like, pediatrics, who we might want to review, like, are there any gaps around this room, and those are some of the people that we might want in that area.
- PARTICIPANT: What page is that, Catherine?
- MS. McVAY-HUGHES: That's page 24 under the peer review.
- DR. BOWLER: I would say that, really, if there's neurology and psychiatry, you should have either—you should have psychology too.
- DR. WARD: But, again, these are just examples. This isn't the real—
- MS. McVAY-HUGHES: Those are just examples—
- DR. BOWLER: Oh, oh, (controls @ 33:10).
- MS. McVAY-HUGHES: But we have psychiatrists around the room—
- DR. BOWLER: It's not all—
- MS. McVAY-HUGHES: At this table already, but at the current moment, we don't have a pediatrician at the table.
- DR. BOWLER: Yes, yes.
- MS. McVAY-HUGHES: So maybe what you want in your stable of peer review experts is a pediatrician, so when you're—
- DR. BOWLER: Of course, of course, that's—
- MS. McVAY-HUGHES: NIOSH is going to go out, however they going to do it, with the Federal Register or

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searching for that stable of peer review experts. At least one of them would be a pediatric expert.

DR. MAYER: But I'd suggest that, you know, pediatricians are just as specialized as physicians who treat adults. So, if you're considering a lung disease, you'd really want a pediatric pulmonologist, as opposed to a general pediatrician or someone with expertise in another area.

DR. WARD: Yes. I guess my inclination is to think that, for these kind of clinical specialties, you wouldn't necessarily assemble a panel of clinical experts that would be on call. You would probably do those on a condition-specific basis. But you might want to look at, you know, chronic dis—let's say epidemiologists who study the relationships between environmental and occupational exposures and chronic diseases. Or, you know, I think the composition of this panel is actually pretty indicative of what you would want to see in a stable peer review group, maybe heavily weighted towards occupational, environmental and occupational experts, people who do clinical work, but they also do research to determine the relationship between occupational and environmental exposures and diseases. Guille.

MS. MEJIA: What I was going to say was, well, I certainly can't speak to the qualifications of each reviewer that may be required to address some of the petitions or anything that comes before the administrator, but, however, I do believe that NIOSH is bound by this document in terms of—from OMB with respect to the peer review. And, if you look on page 18—16—it talks about the selection of reviewers. And, you know, something, a motion that could be written in general terms based on the language here—or page 18, I'm sorry, at the bottom, it says, "Respect for the independence of reviewers may be enhanced if an agency collects names of potential reviewers (based on considerations of expertise and reputation for objectivity) from the public, including scientific or professional societies." So this kind of, like, does allow NIOSH to have sort of, like, a pool, not always an expert on everything, but—

PARTICIPANT: What page is that? I'm sorry.

MS. MEJIA: That's on page 18 and 19.

PARTICIPANT: Of the book?

MS. MEJIA: Of the bulletin.

PARTICIPANT: Oh, the bulletin, okay.

PARTICIPANT: It's separate?

MS. MEJIA: It's in the book.

DR. MAYER: Yes, it's 18-19.

DR. BOWLER: What page is this?

DR. WARD: What section is the OMB bulletin under, Paul?

DR. MIDDENDORF: It's in—

MS. MEJIA: I'm sorry. Let me see.

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DR. MIDDENDORF: Peer review, behind the—
PARTICIPANT: It's the December 16, 2004.
PARTICIPANT: Peer review. Page 44.
DR. MIDDENDORF: Thank you.
DR. WARD: Oh, thank you.
DR. MIDDENDORF: Page 44 on that. New page numbers.
PARTICIPANT: Sorry about that.
DR. WARD: There we go.
MR. FLAMMIA: Can you restate that again?
MS. MEJIA: Sure. So it says here—it starts off on page 44, bottom, the last paragraph. It says, "Respect for the independence of reviewers may be enhanced if an agency collects the names of potential reviewers (based on consideration of expertise and reputation of objectivity) from the public and scientific and professional societies."
DR. WARD: Okay. So we could think about some kind of a mechanism where there's a request for public nomination, but there's also specific outreach to organizations like the Society for Occupational and Environmental Medicine. I'm sure the NIOSH staff is more aware of all the—American College of Industrial Hygienists, the governmental—whatever you call yourselves nowadays.
DR. TALASKA: We're from Cincinnati.
DR. WARD: Yes. So I think that actually resonates pretty well with me, but the intent, I guess, would be to come up with a list of people who potentially could be considered for these individual committees. But I think that—you know, so maybe that would be one recommendation. It doesn't get around the issue of making sure that there's representation on the committee or that the experts selected are sufficiently knowledgeable about World Trade Center exposures and the unique characteristics of those exposures, to, you know, have sufficient orientation to really do an adequate peer review. But it does, at least—it's at least one strong recommendation coming from the committee, that there be some component of that process which takes nominations from the public, and also takes recommendations or solicits recommendations or self-nominations from professional organizations that have relevant expertise to this topic.
DR. TALASKA: Well, I think that's why I made the motion of separating—having a more stable group of people who have general expertise in 9/11 exposures and effects and outcomes, and then the ad hoc pair who are selected from the scientific organizations or from the advisory panels.
DR. WARD: Yes. We may even—I mean, I would suggest that maybe we could initially ask certain professional organizations that would heavily be rep—you know, would have heavy interest in these topics for people to self-nominate. For example, you know, the kind of people who would self-nominate for the STAC, you know, similar people might—you might reach out to similar people for a different role in

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the peer review process.

DR. HARRISON: I have a motion.

DR. WARD: Okay.

DR. HARRISON: I'll put it in the form of a motion. The administrator should develop and implement a process for soliciting public recommendations for the designation process for soliciting public recommendations for the designation of suitable scientific experts for performance of peer review.

MR. FLAMMIA: Put "from the public".

DR. HARRISON: From the public, yes.

DR. WARD: So, now—

DR. HARRISON: Suitable recommendations from the public, so that—

DR. WARD: The way that's phrased, I'm not 100% clear what the intent is. So are you asking for the public to recommend—or the process or are you asking for them to recommend individual—

DR. HARRISON: Individuals, yes.

DR. WARD: Individual—

PARTICIPANT: So it's not phrased correctly.

MS. JONES: What is the problem?

PARTICIPANT: For peer review.

DR. HARRISON: A public process, so the intent of the motion is that there be a public mechanism for the administrator to solicit, from the public, recommendations for scientific peer reviewers. Maybe this is not artfully said, but that was the intent here. Yes, something like that. Yes. Yes, that's cleaner.

DR. BOWLER: I wonder about the World Trade Center Health Registry, just as much as I wonder about us providing the reviews, being willing to provide reviews.

DR. WARD: Well, I think, you know... I think the World Trade Center Health Registry lead investigators—

PARTICIPANT: Previous (inaudible @ 42:15).

DR. WARD: May also—you know, may be the authors of some of the studies that are being considered.

DR. BOWLER: So, right...

DR. WARD: But I don't think they necessarily play a unique role, yes.

DR. BOWLER: Right.

DR. REISSMAN: Sorry that I—I just need to mention that, when I look at the motion 5 that), that's kind of—it appears to me like a ball bouncing back to the administrator when what we're trying to do is ask the committee for specific criteria and help to actually figure this out.

DR. HARRISON: Oh, okay.

DR. REISSMAN: If you bring it back to us, you've missed your opportunity.

DR. BOWLER: Yes.

DR. HARRISON: Oh.

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DR. REISSMAN: So I really hope that something else is thought about—

DR. HARRISON: You want more specific advice, all right.

DR. REISSMAN: Yes.

DR. WARD: Well, but I think the piece of specific advice that the group is trying to give you here is that there be a public nomination process—

DR. HARRISON: Yes.

DR. WARD: That, rather than what one would typically do—for example, when you review grants, it's not a public nomination process. You look in the literature and you see who's publishing in the field. So rather than just doing it as a group of scientists or program officials doing what we typically do, the idea is that you solicit open nominations from the public, as well as maybe, you know, contact—but that it be an open, public process.

DR. HARRISON: Process, yes.

DR. WARD: I think that's really the intent of this one, the specific recommendation.

PARTICIPANT: Do you want more than that? Do you need more than—do you want more detail?

DR. REISSMAN: Probably. Yes, yes.

PARTICIPANT: Okay, all right.

PARTICIPANT: (Inaudible @ 43:49).

PARTICIPANT: Yes, all right. Expand.

MS. McVAY-HUGHES: So I have a question, so I think we're concerned about how the information gets out there so people will know that there is the opportunity to apply to be on the peer review panel, and so you want the public input, but you also want to do the outreach to the professional organizations, but you also want to make sure that the right people who—of the people who apply, that the right people get put in that stable on the peer review.

PARTICIPANT: Right.

MS. McVAY-HUGHES: So it's, again, a flowchart, but I think you want to spread the net wide rather than not. You know, I would never have heard about the STAC if I wasn't intimately involved in World Trade Center issues for the last 15 years. But, you know, there might be other people, you know, who are experts in fields that—there are experts in fields that I don't know who they are.

MR. FLAMMIA: In response to Catherine, I just don't want the good old boy network out there trying to grab their friends in here and doing it. And I want to do it with that cast-wide net and, you know, preserve the integrity.

DR. BOWLER: Okay, I would like to ask—I mean, we have Dr. Markowitz here. Are there a lot of people who apply to be peer reviewers? That's what they're talking about.

DR. MARKOWITZ: No, (inaudible @ 45:15).

DR. BOWLER: People who want to do all that work.

PARTICIPANT: You've got to drag them kicking and screaming.

DR. MARKOWITZ: There are a lot of people who, if you put peer review in the header of your email, you know, won't open it, more likely.

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- DR. WARD: No, but I do think, on the opposite side, I think many, many people who were affected by 9/11 directly or indirectly, and have a feeling that they want to serve the public interest or the public good, which is why we're all here on this committee, you know, could be motivated to volunteer themselves as potential reviewers for this. I think it's a little bit of a different thing than reviewing a paper for a journal or even reviewing a grant proposal. I think this—people will really see this as a service, an important service to the public health.
- DR. BOWLER: So it's a reviewing of what, then? If it's not a grant proposal, it's not a journal, what do they need to review?
- DR. WARD: Well, they're reviewing proposals to add certain conditions to the list of World Trade Center-related conditions.
- DR. BOWLER: Grant proposals.
- DR. WARD: Well, yes, they're reviewing the evidence—no, they're reviewing the evidence for adding certain conditions to World Trade Center-related conditions, which, in turn, will determine whether people are eligible for treatment through the World Trade Center Health Program. So it's of direct benefit to survivors.
- DR. BOWLER: I don't know how many people you would get for that.
- DR. WARD: Well, I think the point that people are making is maybe you won't, and maybe you'll have to fall back on—
- DR. BOWLER: The editor.
- DR. WARD: I mean, I think the fallback position is that you identify peer reviewers using the same types of algorithms that you use to identify grant reviewers. You know, you look in the published literature, you exclude people with direct conflicts of interest, you invite people, and they come. I think the idea here is to, A, allow an opportunity for the public to nominate people who might not be caught by that net and, secondly, to do outreach to—you know, the suggestion to do outreach to professional organizations that might be able to help identify people who are interested enough to want to do this. But I think, you know, you're still, as we heard earlier, you're still using the basic principles of who is qualified to conduct scientific peer review on complex scientific, medical, and technical issues, so you're still going to probably experienced professionals who are publishing in a related field and have that expertise. Guille?
- MS. MEJIA: No, I was going to agree with you. I mean, I think the whole point of this motion is really to provide transparency, I mean, and I think that's what's key here. No one—certainly, if someone doesn't want to be a reviewer, certainly you can't force them to be a reviewer, but it does give the administrator an opportunity to solicit from the public. And the administrator can determine that, based on the solicitation, he or she doesn't have enough reviewers there, that there's going to be another step there where they're going to have to then figure out how do you fill that void? So, you know, I think, Dori, I think this is just mostly just to ensure that there's transparency out there, and then the administrator can do whatever he or

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DR. BOWLER: she needs to do if that public process doesn't generate a good pool of reviewers. Still, I don't see it that much different from a review article on a particular illness, and then I would look at journal article reviewers, that qualification. The other gets really confusing and, I don't know, you still need to have expertise—

MS. MEJIA: But I think—

DR. BOWLER: To know the literature, to be able to read the literature, to make judgments.

MS. MEJIA: Well, but I think the work of the reviewer is really going to be the charge that the administrator, you know, dictates. And what is that charge? What are the questions that are being asked? And then that will, you know—it's not necessarily really one article, I think, that's already been peer reviewed. I think they're looking at the whole process in terms of, you know, did the scientific—maybe you could correct me if I'm wrong—did the science team really look at everything? Is it comprehensive? Did they miss something there? Is the methodology that they used wrong? I mean, and I think that's why you need, you know, a diverse group of reviewers, not necessarily someone who's very familiar with 9/11, but, rather, maybe with the—I don't—the methodology or, you know...

DR. WARD: So let me make a suggestion. I think it's late in the day, and we have limited time left, and I'm not getting a sense that we're coming to a consensus around anything but the motion five that's on the table. So my suggestion would be two-fold. One is we consider voting on that motion and, secondly, that we consider forming a workgroup that will come back to the committee with some recommendations that they'll probably hash out over a number—you know, a period of time. Because I don't feel that anything else is really emerging as a clear recommendation that we can act on today so...

DR. HARRISON: Yes, I would agree with that. I was starting—because I heard from our NIOSH colleague that NIOSH would appreciate more specificity, I was starting to add some specific guidance to NIOSH, but for the sake of time—

PARTICIPANT: (Inaudible @ 51:36).

DR. HARRISON: Sorry?

PARTICIPANT: (Inaudible @ 51:38).

DR. BOWLER: Let us know.

DR. HARRISON: Oh, well, okay, I mean, I was going to add things, but there might be more—and this is maybe a small committee. I was going to add things like, the scientific experts should have—and I started a list. No financial conflict of interest in the determination for adding health conditions. Two, suitable expertise in the disciplines including epidemiology, pediatrics, clinical medicine, toxicology, and I would just keep on adding. And then there might be threes or fours added to that bulleted list, depending how much, you know, guidance NIOSH would like to seek from us directly in terms of fleshing out the details. This motion I left very general because I thought, well, you know, frankly, NIOSH can figure out the details of how to develop and implement this public process, but we just heard from NIOSH

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they'd like more detail. So, unless we want to spend more time discussing each of these, I agree with a subcommittee.

DR. WARD: Yes. I honestly don't think we have time.

DR. HARRISON: Yes.

DR. WARD: And I think that's a great start and I hope you just volunteered yourself for the subcommittee

DR. HARRISON: I'm taking notes. Yes. I'm taking notes and I'll volunteer to be on a committee.

DR. WARD: That's great.

DR. TALASKA: One other thing to add would be solicit from the public and relevant professional organizations.

PARTICIPANT: Yes, representation, okay, got it.

DR. WARD: Megan?

DR. RYAN: So just echoing your thought, again, about maybe the committee point, because— and trying again to help NIOSH say they want something more specific and picturing what we give to the peer reviewers, I don't think that we've settled that in terms of, like, do you want them to just go thumbs up, thumbs down? Do you want them to say weight of evidence—think about the way we talk about weight of evidence, category A, B, C, and, you know, not whether it was based on cohort studies or so on, and then degree of confidence, probable, possible, so on. There's so much more that you could ask of the peer reviewers than just thumbs up, thumbs down, and it probably isn't that simple. And so I do think that there is more guidance we might give on what peer review should look like, including that orientation, which I think is very important. Because I think peer reviewers, it's not the same as reviewing a journal article, and the peer reviewers need to know what you want back from them.

DR. WARD: Yes, yes. I would think, in the end, it's going to be like, at least for a main group, there's going to have to be a commitment and a training, so people really understand what they're doing. So I would still suggest, if the committee would like, we can vote on this motion. I think several people have spoken very strongly in favor of it. And then we can take names for the workgroup and we'll—

MS. JONES: Well, wait a minute.

DR. MIDDENDORF: Or do you want the workgroup to fill this out more fully?

MS. JONES: Solicit from the public and relevant scientific organizations. I'm just going to say this is how I feel, that, me and Steve here, I don't think we're from a scientific organization, so I think that you also need to include, like, the group that Anthony's from, the group that I'm from, the Survivors' Steering Committee—

PARTICIPANT: Sure.

MS. JONES: And I don't think those are considered scientific organizations.

DR. WARD: No, I think your groups were considered public, but I think we—

MR. FLAMMIA: Public.

MS. JONES: Public, oh, public.

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DR. WARD: Can certainly add—

MS. JONES: We're public, okay.

MR. FLAMMIA: Yes.

MS. JONES: So public and—we're not considered a group? Oh, okay.

PARTICIPANT: No, no, just public.

PARTICIPANT: Yes.

MS. JONES: Okay, public, all right.

PARTICIPANT: The public and scientific—

DR. HARRISON: I can add something to make it clear, it's fine.

DR. MARKOWITZ: I think it weakens it to add "and scientific organizations". I think the main point is that the public—we want the public involved.

PARTICIPANT: Yes.

DR. MARKOWITZ: And because, once you start the list, the list can go on, and then the point about the public gets lost. Plus, we don't have such—in occupational medicine, we don't really have such strong organizations, so I would advocate removing that term.

MS. JONES: Make it public, okay.

DR. WARD: I think that's fine. I mean, if NIOSH chooses to contact professional organizations, they can—it's not saying they can't do so. It's our strongest recommendation is to open it to the public, so...

PARTICIPANT: And the working group can decide or make recommendations based upon specific (inaudible @ 55:58).

DR. WARD: Right, right, right.

DR. BOWLER: Yes, or specific text.

DR. ROM: Do we need the word "the" in front of "public"?

DR. BOWLER: Or how about solicit input from the public, direct—yes.

PARTICIPANT: Public recommendations...

DR. BOWLER: Direct—yes.

MS. NORDSTROM: (Inaudible @ 56:17).

PARTICIPANT.: You're right. Bill's right.

MS. NORDSTROM: I think it's—no, no.

PARTICIPANT: (Inaudible @ 56:21).

PARTICIPANT: I think—

DR. WARD: I think it has the same meaning either way, "from the public" or "public recommendations".

PARTICIPANT: Public recommendations. From public recommendation.

MS. NORDSTROM: Well, is he saying "solicit from the public recommendations" (inaudible @ 56:31).

DR. TALASKA: Solicit public recommendations from scientific experts...

PARTICIPANT: It doesn't sound right.

DR. WARD: I think the meaning is the same.

PARTICIPANT: I agree with Bill.

MS. NORDSTROM: The meaning is the same.

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DR. MAYER: Yes, I agree.
PARTICIPANT: Oh, it's right here.
PARTICIPANT: It's grammatically correct.
DR. MAYER: You'd want to get rid of the "of" before peer review.
PARTICIPANT: Yes.
PARTICIPANT: Public recommendation.
DR. WARD: Well, I think we're ready to read the motion.
DR. MIDDENDORF: Okay, motion number 5. The administrator should develop and implement a process to solicit, from the public, recommendations of scientific experts to perform peer review. Okay, Tom?

DR. ALDRICH: Yes.
DR. MIDDENDORF: Rosemarie?
DR. BOWLER: I guess I have to abstain because I feel like I don't know enough about it. Maybe once we have that fleshed out with Bob Harrison putting in this additional text or the workgroup, I will definitely vote on that, but right now I...

DR. MIDDENDORF: Okay, Anthony?
MR. FLAMMIA: Abstain.
DR. MIDDENDORF: Bob?
DR. HARRISON: Yes.
DR. MIDDENDORF: Greg?
DR. HOMISH: Yes.
DR. MIDDENDORF: Catherine?
MS. McVAY-HUGHES: Yes.
DR. MIDDENDORF: Val?
MS. JONES: Yes.
DR. MIDDENDORF: Steven?
DR. MARKOWITZ: Yes.
DR. MIDDENDORF: Annyce?
DR. MAYER: Yes.
DR. MIDDENDORF: Michael?
DR. McCAWLEY: Yes.
DR. MIDDENDORF: Guille?
MS. MEJIA: Yes.
DR. MIDDENDORF: Lila?
MS. NORDSTROM: Yes.
DR. MIDDENDORF: Bill?
DR. ROM: Okay. That's slightly less than, yes...
DR. BOWLER: Slightly yes.
PARTICIPANT: Slightly less.
PARTICIPANT: Slightly less than yes.
PARTICIPANT: (Inaudible @ 58:09).

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DR. BOWLER: Well, I'll take slightly yes.

DR. MIDDENDORF: And Megan?

DR. RYAN: Yes.

DR. MIDDENDORF: Glenn?

DR. TALASKA: Yes.

DR. MIDDENDORF: Okay. And Liz?

DR. WARD: Yes.

PARTICIPANT: That's what my kid says, Bill.

DR. MIDDENDORF: 14 yes, 2 abstentions.

PARTICIPANT: Bill, that's what my kids say.

PARTICIPANT: Yes.

DR. ROM: Okay.

PARTICIPANT: When you force them into a corner.

DR. WARD: So, for those who haven't been members of workgroups before—we've only had one—what I would think we would try to do with the workgroup, just so you know what you would be committing to, is setup a series of telephone conferences calls and see how much progress we can make in drafting recommendations. The recommendations would then be brought back to the full committee, either during a telephone meeting or during an in-person meeting, depending on the timing, and then the full committee would actually have to vote on the final recommendations. So, with that, who would like to volunteer to be a member of the workgroup?

DR. HARRISON: You've got me down already.

DR. WARD: Okay, Bob, Rosemarie, any...?

MS. MEJIA: Can you please explain actually what we're going to be doing in the workgroup?

PARTICIPANT: Workgroup.

DR. WARD: Well, we're going to be discussing—we're going to be formulating more extensive and definitive recommendations to NIOSH about the selection of peer reviewers for this process.

DR. MIDDENDORF: Let me also add that whatever the workgroup does has to come back to the full committee for the full committee to deliberate on and vote on before it goes to the administrator.

PARTICIPANT: Paul, but that could be a brief phone call, of a public call with the full committee?

DR. MIDDENDORF: It would be a full meeting.

PARTICIPANT: Yes.

PARTICIPANT: It would be a full.

DR. HARRISON: A full—

DR. WARD: But the workgroup meetings are not public, they're not announced to the public, so we have a little bit more flexibility about having them, but then the recommendations—

PARTICIPANT: Then we discuss the recommendations.

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DR. WARD: It's a way of getting work done in between meetings, essentially.

DR. MIDDENDORF: One thing I do want to do is I want to make sure that we have good representation from the various categories of members, so that we don't have just scientists. I want to make sure that we have survivor and responder representatives, as well as some of our scientists.

MS. McVAY-HUGHES: I'll volunteer—oh.

DR. MIDDENDORF: Catherine. Are you rescinding yours?

MS. McVAY-HUGHES: No, I'll vote, I'll volunteer.

MR. FLAMMIA: I'm good also.

DR. TALASKA: How many do you have? Do you need...?

DR. WARD: Glenn?

DR. TALASKA: I don't know if you need more.

DR. MIDDENDORF: I'd like more.

DR. TALASKA: Okay.

PARTICIPANT: (You have to pick Steve. I mean, he's the one who (inaudible @ 1:00:44).

DR. HARRISON: No. Steve's too damn busy. He's going to—

DR. BOWLER: He's too busy. Yours—

DR. HARRISON: Steve recruited me. He already did his job.

DR. MARKOWITZ: I'm holding out for the next committee.

MR. FLAMMIA: Steve, we need you for the motions.

DR. HARRISON: Dr. Markowitz already recruited me, that was the—

PARTICIPANT: He does draft good motions.

DR. WARD: Dr. Markowitz was drafted for the last committee.

PARTICIPANT: He was.

DR. WARD: And Bob volunteered for this one.

MR. FLAMMIA: He's the motion guy.

DR. HARRISON: I'll volunteer to chair this one.

DR. WARD: Did you volunteer to chair?

DR. HARRISON: I did, I volunteered to coordinate.

MR. FLAMMIA: Yes, you did.

PARTICIPANT: That's the chair.

DR. MIDDENDORF: No, the coordination is my job.

DR. BOWLER: The workgroup he coordinates.

PARTICIPANT: Facilitate?

MR. FLAMMIA: Bob, maybe you're—you're the co-motion guy.

PARTICIPANT: Facilitate.

PARTICIPANT: Loco-motion.

PARTICIPANT: Loco-motion.

DR. WARD: I will volunteer to be a member.

MR. FLAMMIA: Just go like this.

DR. HARRISON: It's not a big deal, I've just got to draft some questions for NIOSH for the review.

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DR. MIDDENDORF: (Inaudible @ 1:01:36) what to do about the policy and procedures.

PARTICIPANT: Keep it a little more focused so they get it done.

DR. HARRISON: Yes, just really...

DR. WARD: Well, I guess I'm imagining that, if this—

DR. HARRISON: (Inaudible @ 1:01:44).

DR. WARD: We've made a number of recommendations on the policy and procedures, and I guess, as we go through our recommendations about selection of peer reviews, if there are additional recommendations, this workgroup could make them. I don't think we need a separate workgroup. At least, my opinion would be we don't need a separate workgroup for policy and procedures.

PARTICIPANT: Oh, she's just expanded the charge.

DR. WARD: Unless there's—

DR. MIDDENDORF: Because the policy and procedures is more than just the peer review, so I want to make sure that you have the opportunity to fully address the full policy and procedures. Are there issues there that the committee wants to pursue beyond the peer review part?

DR. WARD: Well, I think the one issue that we talked about is more clearly articulating the definition of what level of evidence that the program thinks—I mean, what are the criteria for becoming a World Trade Center-related condition? I don't think that's been articulated clearly in the past. I think that, when the GAO did their report, it talked about ways that—when they did their report on the cancer determination, they did cite instances where other federal programs were using similar reasoning, and maybe it wouldn't hurt at this point in time if the program could come back and propose criteria. It might even be proposing criteria based on the decisions that have been made to date, kind of articulating the basis of decisions post facto. I think it would be helpful for the program to propose that rather than for us to propose it to the program. Does that make sense to anyone? I mean, all I can say is that, when we were asking for guidance on what criteria to use for whether cancer should be designated as a World Trade Center-related condition, the program said, basically, well, we'll leave that up to your judgment. But I don't think that's going to work with these individual peer review committees, and I would think, at this point in time, that NIOSH would be able to articulate a little more clearly how they're going to make those determinations.

DR. MIDDENDORF: Yes, so beyond the three categories, substantial—

DR. WARD: Well, if they can, if they can. I mean, I don't know.

DR. TALASKA: Four categories that were used—

PARTICIPANT: We add to list of conditions.

DR. TALASKA: For determining cancer. There were four levels of—that the, four levels that the administrator chose.

PARTICIPANT: But this is conditions

DR. TALASKA: But there are examples for, like, for beryllium disease, for example, where there's

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- a federal program to compensate people in DoE for exposure and for berylliosis and beryllium disease. People in our lab received compensation for the year—work they did in the 1950s, for example—not my lab, but in Kettering.
- DR. WARD: Well, I guess, I mean, the most extreme example would be if you look at the IARC determinations of carcinogenicity, they very clearly talk about what, you know, levels of evidence is needed for different levels. Now, it may not be possible to do that for World Trade Center conditions.
- PARTICIPANT: Right.
- DR. WARD: I think, you know, the initial list of conditions were ones that no one would argue with. They had already been well established clinically. They were big excess risks. You know, we had to come up with different criteria for cancer. You know, again, it may not be worth—possible to do, but that's the one thing that I think might make the work of the—if the different determinations aren't well enough defined for peer review committees, then they won't really know what they're being—you know, the criteria they're supposed to use to determine whether the decision of the administrator to go forward with a rule-making is correct or not.
- DR. MIDDENDORF: So I guess what I'm hearing is that the committee, at this point, does not have specific recommendations. There's just a general thought from some of the committee members that the criteria need to be better—at least, if possible, the criteria should be better developed. And, at some point, if those criteria are developed and it results in a change in the policy and procedure, then that would need to come back to the STAC because of the way the Zadroga Reauthorization is...
- DR. WARD: Right. And I guess what I'm saying is I don't think—I don't believe that, at this point, a workgroup to review the policy and procedures further would be that useful. I think we've discussed the big issues that we had concerns about at this meeting. So, unless—Dori?
- DR. REISSMAN: If I could just get a clarification because I'm not sure I understand what's being said. Are you saying the motion would be more along these lines or are you saying—it sounded to me like you were saying the way the policy is written lacks the clarity that you would like in order to train a peer reviewer according to the standards we might use. I think that's what I heard you say, so is that correct?
- DR. WARD: Yes.
- DR. REISSMAN: Okay. In order to sharpen those criteria more, that is in part what we were hoping to hear from you. We can't sharpen them more than we have yet, even with the experience we have. That's where we are in our evolution, in our process. I think if there was, you know, more and more time, and more and more opportunities to test ways of thinking on things, perhaps you could. But for us to do that, it means that all these things are going to take years. That's the best I can say today.
- PARTICIPANT: Yes.
- DR. REISSMAN: And I don't know that that makes—I don't know that you have solutions either, but

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- what we're doing is sharing the problem.
- DR. WARD: Yes, and I get it. I wasn't even proposing that as a motion. I was just saying that, you know, that concern has crossed my mind, that it will be difficult for peer reviewers to respond complete without further clarification. And maybe what we could do, you know, any of us could do, is look at examples where such criteria have been laid out more clearly.
- DR. REISSMAN: That's fair, and I think in the interchange of... I guess the richness of scientific exchange, when you're looking at some of the technical matters of these things, it gets clearer because of the dialogue, because of the (back @ 1:09:08)...
- DR. WARD: Right.
- DR. REISSMAN: You know, when people are poking holes in various arguments, you get clearer on where you've been and where you're going than just where you are today.
- DR. WARD: Yes.
- DR. REISSMAN: So even though it doesn't provide the most beautiful clarity to start off with, it's the painful process that we go through—
- DR. WARD: Yes.
- DR. REISSMAN: In order to try and make a sound judgment.
- DR. WARD: Right, right. And I would say, you know, one way, if you want to get more input from the STAC on it, that one way to do that might be to come—you know, to have another meeting and really talk about some examples of petitions that have worked, determinations that have been brought forward for consideration and, you know, what the level of evidence was, and how those determinations were made. Because I think you—this is one of those things where I think you learn most by experience and, you know, maybe working collaboratively with the program, we could help to develop maybe a little bit more clear criteria, looking retrospectively. But I do think—I like the idea of this being an exchange between the program and the STAC, rather than us going off and coming back to you with recommendations. Because I think what we struggle with is how to be helpful to you without necessarily having the in-depth experience that you're having in trying to make these decisions.
- DR. REISSMAN: Thank you.
- DR. WARD: So let's think about, you know, how we might move that process forward.
- DR. MARKOWITZ: Liz, I actually don't think that we've systematically gone through the policies and procedures and necessarily looked at all the issues that need to be looked at, and I can—I mean, we've done one or more, but I don't think it's—and I can't pinpoint any particular issue, but I don't think we've fully discharged our responsibility to evaluate them and provide input. And so I don't think that we should leave it as it is till the next STAC meeting, whenever that is—right? With the idea that we've made whatever motions pertain to that piece of the charge and that we're done with it.
- DR. WARD: So are you proposing to—

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DR. MARKOWITZ: Yes, yes.

DR. WARD: Good, Steve. So I guess—I think what Steve is proposing—that we do have a second workgroup that’s going to look more systemically at the policies and procedures, and come back to the full committee with recommendations or concerns or questions. And I think Paul was leaning towards that as well, so is there anyone else who would like to volunteer for that committee?

MS. NORDSTROM: I'd volunteer.

MS. McVAY-HUGHES: I will. Catherine.

DR. TALASKA: Anybody else? Do you want to help?

MR. FLAMMIA: Anthony.

DR. MAYER: I'll help.

DR. MARKOWITZ: Okay, so Paul's getting the names, right?

DR. MIDDENDORF: Yes. I'm taking names. Lila, Catherine...

DR. TALASKA: Steve, do you want help?

DR. MARKOWITZ: Okay.

PARTICIPANT: Anthony.

DR. MIDDENDORF: Yes, I've got Anthony.

DR. WARD: And I'm taking it that you're volunteering to chair, Steve.

DR. MARKOWITZ: Yes.

DR. WARD: Paul will volunteer to coordinate.

DR. MARKOWITZ: Paul isn't volunteering. He has to.

DR. MIDDENDORF: Yes. Liz, would you want this one or?

DR. WARD: Yes, I'm happy to be on it.

DR. MIDDENDORF: Okay.

DR. MAYER: Am I on the list?

DR. MIDDENDORF: I've got you, Annyce.

DR. MAYER: Okay.

DR. MIDDENDORF: Yes. Annyce, Anthony, Lila, Catherine, Steven as chair, Glenn, and Liz. Anybody else? Did I miss anybody? I'm usually pretty good at taking down names.

ADMINISTRATIVE ISSUES AND ADJOURN

DR. WARD: So great, so, Paul, is there anything else from the administrative point of view that we need to cover before we adjourn?

DR. MIDDENDORF: Nothing that comes to mind.

DR. WARD: Okay, well, thanks everyone. I think we had a lively discussion. I think, by the end of the day, we're all tired and we get less and less clear as we go on, but I think it was a productive day and we came up with some very solid recommendations to NIOSH. Thank you.

DR. MIDDENDORF: And just let me add my thanks to everybody as well. Thank you very much.

PARTICIPANT: Thank you. Thank you Paul and Liz.

DR. MIDDENDORF: I've got it.

MS. NORDSTROM: Thank you.

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PARTICIPANT: Thank you.

[END MEETING]

I hereby certify that, to the best of my knowledge, the transcript of the June 2, 2016 meeting of the Scientific/Technical Advisory Committee is accurate and complete.

6/22/2016
Date

Elizabeth Ward
Elizabeth Ward, PhD
Chair, Scientific/Technical Advisory Committee

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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