**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**

ELEVENTH MEETING

# SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE (STAC) MEETING

September 18, 2019

The verbatim transcript of the

Meeting of the Scientific/Technical Advisory

Committee Meeting held on September

18, 2019, 9:00 a.m.

## C O N T E N T S

September 18, 2019

## P A R T I C I P A N T S

(alphabetically)

JESSICA BILICS - POLICY COORDINATOR
TANIA CARREÓN-VALENCIA, PhD – DESIGNATED FEDERAL OFFICER
THOMAS DYDEK, PhD - COMMITTEE MEMBER
ANTHONY FLAMMIA - COMMITTEE MEMBER
KIMBERLY FLYNN - PUBLIC COMMENT
MRIDU GULATI, MD - COMMITTEE MEMBER
GREGORY HOMISH, PhD - COMMITTEE MEMBER
JOHN HOWARD, MD - PROGRAM ADMINISTRATOR
TRAVIS KUBALE, PhD – ASSOCIATE DIRECTOR FOR RESEARCH INTEGRATION
JOHN MARTELL - COMMITTEE MEMBER
CATHERINE McVAY HUGHES - COMMITTEE MEMBER
VAYLATEENA JONES - COMMITTEE MEMBER
STEVEN MARKOWITZ, MD - COMMITTEE MEMBER
DAVID NEWMAN - COMMITTEE MEMBER
NICHOLAS NEWMAN, DO - COMMITTEE MEMBER
LILA NORDSTROM - COMMITTEE MEMBER
DORI REISSMAN, MD, MPH - ASSOCIATE PROGRAM ADMINISTRATOR
ROBIN SASSMAN, MD - COMMITTEE MEMBER
MICKI SIEGEL DE HERNÁNDEZ - COMMITTEE MEMBER
ELIZABETH WARD, PhD - COMMITTEE CHAIRPERSON
MARC WILKENFELD, MD - COMMITTEE MEMBER
LEIGH WILSON, DO - COMMITTEE MEMBER

**WELCOME AND INTRODUCTION**

DR. CARREÓN-VALENCIA: Well, good morning, everybody. My name is Tania Carreón-Valencia, and I'm the Designated Federal Officer for the Scientific and Technical Advisory team. I'd like to welcome all of you today.

Sitting next to me is Dr. Elizabeth Ward, who is the chair of this committee. And before I turning the mic to her, I have a few administrative announcements that I need to make. First of all, if there is an emergency you should go through those doors at the end of the room, and then through the glass doors and immediately to the left, the hallway. There's a stairwell there that will take you right out of the building. Restrooms are on the left side of where I am sitting, on the hallway at the end. As you know, and I hope you please remember, food and beverages are not allowed in this room, only water. However, there is a break room on the left, right next to me, where you could have them. There's also a cafeteria on this floor. Again, go through the glass doors and continue through the hallway, and then to the left.

Finally, we are having this meeting transcribed today, so I will ask you that when you comment, please state your name, and then do your comment.

Well, as you know last week was September 11, and for us, for this committee, it has always been a tradition to start with a moment of silence. We do that to remember those killed in the September 11 attacks. We also remember those responders and survivors who have died since and, also, remember others who have died or suffered from terrorist attacks around the world.

[Moment of silence.]

Thank you. I would like to give a warm welcome to all of you and, of course, our new committee members. I, also, want to welcome the members of the public. I know some of you are going to make public comments. That will begin at 10:45 a.m. I will ask you to come to the podium, and then do so when I announce you. So right now I would like to start with a roll call for all of our members. If you are here please let me know and, also, if there have been any changes, you have a new conflict of interest, or there have been any changes on your conflict of interest since you signed your forms, please indicate so. Thomas Dydek.

DR. DYDEK: Present.
DR. CARREÓN-VALENCIA: Any changes in your conflicts of interest?
DR. DYDEK: No, ma'am.
DR. CARREÓN-VALENCIA: Anthony Flammia?
MR. FLAMMIA: Present.
DR. CARREÓN-VALENCIA: Changes?
MR. FLAMMIA: No, ma'am.
DR. CARREÓN-VALENCIA: Mridu Gulati.

DR. GULATI: Nice pronunciation. Yes, I'm here. No changes.
DR. CARREÓN-VALENCIA: Greg Homish.
DR. HOMISH: Present. No changes.
DR. CARREÓN-VALENCIA: Catherine McVay Hughes.
MS. MCVAY: Present. No changes.
DR. CARREÓN-VALENCIA: Val Jones.
MS. JONES: Present. No changes.
DR. CARREÓN-VALENCIA: Steven Markowitz.
DR. MARKOWITZ: Present. No changes.
DR. CARREÓN-VALENCIA: John Martell.
MR. MARTELL: Present. No changes.
DR. CARREÓN-VALENCIA: David Newman.
MR. NEWMAN: Present. No changes.
DR. CARREÓN-VALENCIA: Nicholas Newman.
MR. NEWMAN: Present. No changes.
DR. CARREÓN-VALENCIA: Lila Nordstrom.
MS. NORDSTROM: Present. No changes.
DR. CARREÓN-VALENCIA: Robin Sassman.
MS. SASSMAN: Present. No changes.
DR. CARREÓN-VALENCIA: Micki Siegel de Hernández.
MS. SIEGEL DE HERNÁNDEZ: Present. No changes.
DR. CARREÓN-VALENCIA: Liz Ward.
DR. WARD: Present. No changes.
DR. CARREÓN-VALENCIA: Marc Wilkenfeld.
DR. WILKENFELD: Present. No changes.
DR. CARREÓN-VALENCIA: Leigh Wilson.
DR. WILSON: Here. No changes.
DR. CARREÓN-VALENCIA: Okay. Also, we have here some NIOSH staff. So I will like to ask you to please introduce yourself.
DR. REISSMAN: Dori Reissman. I'm the associate administrator (inaudible @ 00:08:21).
MS. SPRING: Christina Spring, associate director for Communication and Research to Practice.
MS. BILICS: Jessica Bilics, policy coordinator and governmental affairs liaison.
DR. CARREÓN-VALENCIA: Do we have Dr. Kubale back there?
We have two people that have been very helpful today, Nancy Wilson who is around helping us with the setup and, of course, Mia Wallace which if you don't know her, she is one of the most important persons. She works tiredly behind the scenes to make sure that the committees and all the activities that take place, so we can have the committee occur in a timely manner. So if you haven't met her, please do so.
So with that, and before I turn on the mic to Liz, I would just want to go over

briefly on the agenda for today. You have agenda on your books that are sitting here in the first page after the cover of the book. We will start with Dr. John Howard who is the administrator of the World Trade Center Health Program and director of NIOSH who will give us our charge. Then we will go through public comments. This morning we will also have Travis Kubale who will provide an overview of the World Trade Center Health Program research. In the afternoon I will talk about the Development of the Inventory of 9/11 Agents. We'll have Jessica Bilics who will update on policies and procedures to add non-cancer conditions and having public updates. Then I will lead you on a discussion on peer review.

So with that, I'm turning the mic to Liz.

DR. WARD: Thank you. And I would like to add my warm welcome to Tania's, who spoke to the new and returning staff members, the members of the public who are here. For those of you who are new what we usually do when we get to the question period after presentation, everyone indicates that they'd like to speak by turning a name card up. I usually try to go in order, but if I lose track and there's a lot of people who want to speak, I'll sometimes just go around the table to make sure I get everyone. We want to make sure we hear from everyone who wants to speak. And with that, I'll turn it over to our first speaker who is Dr. John Howard.

**CHARGE**

DR. HOWARD: Thank you very much, Liz. And welcome everybody. This is the 11th meeting of the Scientific Technical Advisory Committee for the World Trade Center Health Program. I want to, certainly, thank everybody who is new to the program. Dr. Thomas Dydek. Am I pronouncing that correctly?

DR. DYDEK: Yes, sir.

DR. HOWARD: Okay. Thank you. Mr. John Martell. Thank you, sir; Dr. Nicholas Newman. Thank you; and, Dr. Robin Sussman. Thank you very much; and, Dr. Leigh Wilson. Thank you. And I want to welcome Greg and Anthony back after a short sabbatical they took off the committee. We're happy to have them back for continuity purposes. And I, also, want to say a warm goodbye to Lila who will be enjoying a new chapter in her life, and I want thank her for representing an extremely important segment of our membership so well. So thank you very much, Lila.

So today, briefly, we're going to dispense with a long drawn-out program update. I just want to tell you that we have 99,111 members as of yesterday. So we're nearing the 100,000 mark which is really remarkable for all of us who started out many years ago, 18 years ago. Of those 99,111, 76,632 are responders, both in the category of those that were grandfathered in when the program came in 2011, and those that have been added new. And we have 22,479 survivor members. People often ask well, what's the

denominator here? Well, we're never really sure about that, and all we have are some estimates which are probably as good as we're ever going to get. That estimate for responders is somewhere around 90,000, who knows, give or take. We're certainly nearing a substantial amount of those, and the survivor community number is estimated to be much, much larger, somewhere in the three to four hundred thousand range. Since the end of August, in terms of responders, the total number of responders who have come in the program as of 2011 when the program was fully authorized that number is 19,932 as at the end of August, and it may indeed be closer to the 20,000 today as we speak. The Zadroga Act itself, the James Zadroga 9/11 Health and Compensation Act of 2010, requires that the Secretary of the Department of Health and Human Services notify Congress when the program has enrolled 80 percent of the statutory maximum enrollment limit of 25,000. So as you can see we have probably reached that and we're pretty close to the 20,000 or the 80 percent. That then triggered the secretarial notification to the Congress which we did, the Secretary wrote a letter to various committees of Congress on the 4th of September. Okay? And I think you have a copy of the Secretary's letter in your materials. Happy to take any questions that you all have on that.

For the meeting today, as Tania's pointed out, first, Dr. Kubale will present an overview of the research activities of the program and provide a summary of the key research findings as well as the current research activities and available resources. And, certainly, this is the major issue for our for a committee meeting today. We really need guidance and your advice about the research program. Are we investing in the right things? How are we maximizing the output of our research that is being published and all the things that go with the complex research environment that we have? We, of course, are very blessed to have a statute that allows us to fund research, and this is being done competitively as you know. So Travis is going to give you an update on that, and we really welcome your ideas about that.

Second, Dr. Carreón, Tania, will present the inventory of 9/11 agents. This is a project that took us, perhaps, way too long to do, but it's done and we've used that term '9/11 agents' for years without a lot of specificity, and it's extremely helpful for us to be able to have an inventory of what those agents are. And, certainly, if you have comments about the scope or organization of the inventory, those comments are welcome. We think it looks pretty good, but then you looking at it could certainly help. It's on the website. And one of the reasons that we put things on the website as opposed to wasting paper and ink is that they can be more easily adapted and changed through time.

The third issue, Jessica Bilics is going to update the committee on some minor revisions to the policy and procedures for adding non-cancer

conditions. The committee, as some of you will remember who were on the committee at that time, in 2016 did a thorough review of that policy, and in 2018 the committee, again, reviewed some of the previous revisions. So today I welcome your views about the few minor, basically, non-substantive revisions to this just to keep you all up-to-date on that.

So, again, I thank you very much for taking time from your very, very busy schedules and lives to be able to participate in our meeting. And happy to answer any questions that you all may have at this time. Liz, is that appropriate? If not, I'll be here all day. It's an amazing thing, I'll actually be here all day. So have a great meeting, and we'll talk to you as we go on.

[Applause.]

DR. WARD: So thank you. I think we're now at time for public comments. It's 10:45.

**PUBLIC COMMENTS**

DR. CARREÓN-VALENCIA: So we have two people that have requested to come and provide public comments. So when I announce your name, please go to the podium. You will have five minutes to provide comments. I, also, want to make you aware, I hope you received a copy of the redaction policy for public comments, but if you need them, please ask me for photocopies. So our first speaker, public speaker is Anthony Flammia.

MR. FLAMMIA: Good morning, everyone. My name is Anthony Flammia, and at the time of 9/11 was a police officer and NYPD Highway Patrol. Unfortunately, permanently disabled to many World Trade Center conditions because of my exposure at Ground Zero. If not for the well traits in a program, I would not know where I would have been. In 2010 I was appointed to the Board of Directors of the Fealgood Foundation, participated in education and outreach to various levels of government at both the federal, state, and local levels. Our foundation passed 13 9/11 health bills, and most recently, in the reauthorization, the Victim's Compensation Fund this past July. We provided outreach and support to many in the responder community. The foundation also built a memorial wall for responders who have died after 9/11. Tragically, we just added 204 names to the wall this past Saturday.

This is my second term of being appointed to the World Trade Center STAC committee as I thank Dr. Howard and the powers to be for this wonderful opportunity to serve the 9/11 community. However, I'm speaking personally what I'm going to speak about. I have numerous requests for the STAC committee and program administrator to act on the following conditions as we have numerous studies which support these conditions of many responders, volunteers, and downtown residents.

For many they are still suffering 18 years later. These are both uniform and non-uniform responders. I request neuropathy, autoimmune, heart disease which recent medical journal JAMA, 44 percent more likely to develop

cardiovascular disease, various neurological conditions including post-traumatic stress which I feel should be compensatable. The children of responders, secondary exposure, passed onto spouse and their children. I already requested this a couple years ago. I'm requesting it now. We have numerous responders reporting significant disabilities related to secondary exposure as to when responders and volunteers came home from Ground Zero. I'm clocking at several hundred people that we have found to have these conditions. Conditions range from epilepsy, global delays, autism, and all the other types of disabilities. It's personally affected me and my daughter who was in utero at the time of 9/11. My wife was three months pregnant with her. She has significant disabilities as a result. Doctors from both NYU and Stony Brook pointed my exposure to 9/11, connecting my daughter's illnesses to my exposure and bringing home the dust to both our home and family cars.

The VCF was passed; 10.2 billion for the next 10 years. Additional funding in 2019. This covers the 9/11 first responders for their entire lives. There shouldn't be an issue of how we're going to pay for it. Fact: 241 NYPD officers have died in 18 years since the attack. That is 10 times the number killed in 9/11 when 23 lost their lives; 204 FDNY members as of July, in addition to the 343 who died on that fateful day of 9/11.

We also need an explanation for the 22 petitions and why they are not given to the STAC committee for review and recommendation. And I'm referring to the 22 petitions that are currently on the website that were up for review. Why were they not given to the STAC committee? we need further transparency as to the decision-making process of the World Trade Center Health Program. I ask why, why? We are both health care and compensation for responders for many years to come, so the issue should not be a fear of losing fund and worrying about how you're going to pay for it, I say it again.

I respectfully request that the World Trade Center Program Administrator, Dr. Howard, to schedule more STAC committee meetings instead of having a get-together once a year. There are many conditions that need to be addressed. The charter states that the frequency of meetings shall be determined by the World Trade Center program administrator.

Thank you to both Dr. Howard and my fellow STAC committee members for your time and consideration.

DR. CARREÓN-VALENCIA: Thank you. Our next speaker is Kimberly Flynn. You have five minutes.

MS. FLYNN: Thank you. I'm Kimberly Flynn, and I chair the Survivor Steering Committee. I make these comments on behalf of the Survivor Steering Committee, and I will start by stating the obvious. So I missed the charge, but I was told that part of the meeting addresses research integration. So I'm going to state the obvious which is that you cannot integrate research that does not exist. I'm

referring to the disparities between the amount of NIOSH support for research on the largely male population of responders and research on the much more diverse population of survivors. We actually think it's fair to say that for many years NIOSH's approach to research has, in effect, been women and children last. We are not arguing that this is deliberate. We understand that, in general, responders got sickest fastest, and we are, of course, committed to research on health conditions affecting responders. We honor their service. We're permanently in their debt. We understand that the responder population includes a large number of people whose health the program has been monitoring over time. We understand that there is baseline data for the 9/11 infected FDNY cohort, and we deeply appreciate the leadership, the research leadership of Dr. David Prezant from which the entire 9/11 community benefits.

Nonetheless, research gaps have persisted over many years that undermine the program's ability to meet the 9/11 health needs of its female and young adult population. This is both unjust and bad science. Through the years key research proposals are passed over. I will cite a study of breast cancers in the survivor program clinical population. I will note the fact that there is no survivor blood bank. And I will, once again, remind the World Trade Center Health Program about the urgent need for research on those who experienced 9/11 as children.

By reading from comments I made to the STAC in 2015, although children are especially susceptible to harm from environmental exposures, 18 years—I changed that number—18 years after 9/11 we still know very little about the physical health and effects of the WTC disaster on the more than 35,000 children living or attending school or daycare in the New York City disaster area. SSC has urged NIOSH to move quickly to fill these major knowledge gaps by supporting a portfolio of studies that would investigate a range of biologically plausible health effects, especially cardio, metabolic, endocrine, developmental, reproductive, autoimmune, and cancer impacts.

In addition, over many years the SSC has been calling on the World Trade Center Health program to fund a critical effort; to create a sufficiently large and representative research cohort of the WTC-exposed child population. The cohort would be drawn for more than 19,000 New York City public school children attending disaster area schools in the 2001/2002 academic year. This is a high-stakes effort. Why? Because creating this cohort is key to meeting what the program and the STAC have called children's 9/11 research needs. This cohort, in fact, is the necessary foundation for the World Trade Center Health Program to define and meet young adults 9/11 health needs into the future.

Currently, this critical project, which is called the 9/11 Millennial Study, would

create and follow a large cohort longitudinally. It is now in a feasibility phase to work out the logistics of reaching out to former students. Unfortunately, this project is a risk. The World Trade Center Health Registry, which is leading the project, has moved too slowly.

The Registry gained the agreement of the New York City Department of Education in 2017 to transfer contact information for 19,000 WTC-exposed students along with a group of less exposed students. The Registry has now accepted 1,000 contacts for a feasibility phase and worked with the SSC and others to develop a mailer. It has taken more than two years for that mailer to go out to a small sample of students. It was sent out, I think, on Friday.

In addition, the Registry has not been appropriately transparent with the SSC. One example: we have requested the protocols for the feasibility phase, most recently, in a September 5th SSC letter. We have yet to receive those. The SSC believes that this uniquely valuable effort should be a priority. It needs a full commitment from the World Trade Center Health Program to the study. It needs a faster timetable, and for the next steps to prepare for the study to be funded and taken now.

Furthermore, everything needed should be done to protect the 9/11 Millennial Study and ensure it's moving forward. So we, actually, are proposing a resolution where the STAC would actually state their support for the 9/11 Millennial Study, ensuring that it moves forward and protecting it, essentially, from any problems, interference, etc.

I'm happy to provide everyone with language for this resolution, and I'm also going to call for a few more additional steps by NIOSH. One is that the World Trade Center Health Program must organize a disaster science conference similar to the cancer conference called by Dr. Prezant on some years ago. The conference should bring together outside experts with WTCHP experts to discuss key research challenges for study of disaster populations. Pediatric environmental medicine experts must be at the table. One outcome of the conference should be a new set of instructions to study panels for evaluating World Trade Center Health Program research proposals. Another set should be guidelines for research on the 9/11 Millennial Study group. In addition, the program has hired RAND…

DR. CARREÓN-VALENCIA: Did you hear me? Sorry, but your time is up.

MS. FLYNN: Okay. Thank you. And I am happy at the appropriate time to provide that resolution language. The resolution is very important. And we thank you all for your consideration.

DR. WARD: Thank you for your comments. The next topic on the agenda is a presentation by Dr. Travis Kubale on World Trade Center Research Evaluation and Strategic Planning.

**WTC RESEARCH PROGRAM OVERVIEW**

DR. KUBALE: Well, thank you, everybody. I am Travis Kubale. And I want to start and welcome all the new members. We're delighted to have your involvement and input. You're coming at a very exciting time for our research. And I also want to offer my congratulations to my good friend, Tania. I am here today because, again, I was here last year. Some of you have heard parts of this, and I will apologize ahead of time for that, but Tania wanted me to come back. So when Tania speaks, I come.

So the first thing that I want to do is a little bit of homework for new members. I'm going to pass out—I didn't give everybody this because I didn't want you to have to carry it home. This document and some other research material is on an FTP site for you all as you are looking at research and helping us determine what we're doing and where we need to go. So it's important, we'll be talking this morning about how you interpret these two documents.

So, again, for this morning what I wanted to do is there are a couple of things. These are meant to be sort of for you all, reference slides. There are some of them that I'm going to sort of skip over or certainly not go and read all of these, but there are important pieces of information that I want you to keep in mind as you proceed, and as you look at what it is we're doing and where we are trying to go.

The important thing on this slide is that, really, what we're in the business to do, as far as research is concerned, is to help optimize the treatment for the responder and survivors. So that is a key component and issue for us, and it is going to mean some major shifts in our program initiatives, away from sort of just monitoring what we have been doing and what we are producing, to looking at and synthesizing the information and determining where, as you all have talked about, the first two speakers, where are our key gaps, what does the research mean for us, and then what kinds of things do we need to be doing to help people in the clinics.

So I hope I can speed this up or you'll be here all day with the clicker. just a couple of things that I want you to remember that our key as we're moving forward here. Our grant cycle in the funding is on a five-year cycle, and the second five-year cycle is coming to an end. And what we are getting ready for is as a program, writing the scope for both our Registry and our research beginning in 2020. And so, we have about a year to do that. And we are currently in an all court press. We need everybody on deck looking at what we have compiled and put together to make it easy for people to look through what the results are, what we've studied, what the areas are, and help us determine and provide input on what that structure is going to look like going forward. Now, this is not something that we'll just stop doing when we initiate a five-year cycle. We have a review every year. And so, we want to make sure that in the future we're positioned to make incremental changes in the

research depending on, particularly, what the needs, the treatment needs in the clinic are and how we inform that. Now, what we're looking at and sort of our scope here is to date there have been 77 research projects. The Registry is a major component because out of the Registry there are another probably 80 projects that are producing information as well as surveys. And the Registry is also a primary source for our survivor population. So it's an important component of the research.

Now, we're also looking—and all of this is in your packet. I think that you have the 2018 version. We will be updating it this year and sending that out in the few months for the 2019 because there are additional publications that will go in. But, basically, what we're looking at in our sphere is that we're looking at research that's produced from the data centers, we're looking at research that's produced from the Registry, and we're looking from research that's produced from those 77 research grants and contracts that started in 2011. So that's our immediate sort of scope.

Now, a couple of things that I want you to just remember about the Registry that are important, is that there are several things that they do for us that are critical and are very important. One of the things that we do is that when we have, for instance, we want to look at various types of specific conditions, poorly controlled asthma is one of them, they will do and provide some of the initial surveillance and research for us that is really important as we design studies and intervention studies moving forward. There are also looking at cancer incidence and mortality, they're working with responders on one of the large cancer studies that we have, and help us understand the unmet healthcare needs, but there are a variety of things that they do that I want to just make sure that you're aware of, and there is information in your packet about that information that they are collecting for us, and I wanted, again, for you to be aware of that and aware of their contribution.

Now, another thing that we are starting to move into and aggressively do is that we are also looking at what kinds of surveillance information the data centers have for us. Every year the data centers produce an annual report, and one of the things that we do, and that we're starting to make sure that we're doing, is that we're making sure that what they see, in particularly this 18-month period, is matching and tracking with the kinds of research that we're doing. If we see something that's emerging here that we need to know more about, then we want to make sure that we're watching and that we're aware of it, and that we're taking appropriate and immediate action.

Now, the other thing that we do is we have to have some way of organizing all of the information that's in that book, and the way that we do this tracks with outcomes that the program has been seeing since the beginning, and outcomes that have been emerging. We track not only the studies, but we

track our cost. One of the things, for instance, that we look at just as an example, is that in our cancer research we have to be very careful that we don't get stuck doing research or doing projects that are either repeating what we already know or maybe, perhaps, can be done better with another mechanism.

Now, what I will tell you here that we're looking at very seriously is that 20 percent of our cancer budget, which the program is concerned, about is going to biobanking. And it's not the biobanking is not important; it's not that biobanking does not have a place here. It absolutely does. But what we have to be careful about is making sure that we're not only aware of an expenditure like that, but are we spending money from the program for this particular effort wisely? Is there another way that we can do it? And we're talking to researchers at Mount Sinai right now to see if there is maybe another way that we can leverage involvement so that we are not overspending in an area and underspending in others. So that's an example of what we do here.

Now, I want to talk just a little bit about how we're beginning to approach what it is we're learning. Now, it's early in this process and so you're getting me at a moment where we're putting some things together, but we're not finished. But here is how we're starting. We divide areas, as you see here on the left, we're looking at do we know, what do we know, and I've given you some examples that you can look at in the database that we'll talk about in just a few minutes that you'll have access to. But are we learning and do we know enough about what the burden is? Do we know about comorbidity and how important that is? What I would say is that, at least right now, the indications for respiratory disease on the left side of the page is that we do pretty well there, you know, fairly well.

Now, where we have some worries, and that I want to talk to you a little bit, is over on the right column. Now, one of the things that we have started doing with our research is that we watch very closely and we have reports every day about who is reading the research. And this is important to us for two reasons—several reasons, actually, but two primary reasons, it's not just research that everybody is reading, while that is important and that's a particular interest to us, we also watch what people aren't seeing and aren't reading. And in the second bullet under "Poor control" is an example of a study where we are working with our clinic physicians and synthesizing the research and talking to them about here is what we're learning in respiratory disease, what kind of impact is this research have in your experience with the clinic? One of the things that they picked out in this particular study is asthma control or the lack of asthma control, and the lack of education is really important. That's a message that we need to be providing for people. Well,

guess what, nobody except probably the five or six authors has read that. That's a problem for us, and we're not going to—we're going to not only know about it, but we're going to be very aggressive in our efforts to do a couple of things. One is to get a message out to the enrollees about the importance and about what we're learning. The other thing that we're going to do is that we're going to be talking to these researchers about what else do we need to know, are there other questions in the clinic that are coming up that are related to this that we need to be paying attention to, and when we're talking about the next round of research, that we're going to be putting some money in that area. And, if it is, what is it? Help us understand that. The critical thing here is that we're going to have a presence in the clinics, and the presence in the clinics comes through the people in our group, the physicians in our group that work there regularly, and we're trying to get, desperately and quickly, the research synthesized so that they can easily talk about it and they easily understand what it is we're learning, when we're learning it, and what impact it's having in the clinic, and what our unmet needs are there. Another example of what we want to do here, eventually, is in the last bullet. And this is a progression with the fire department, with the FDNY. And this is a something that we use and we will be talking to other researchers as we go along about an example of what it is we want to do. Basically, this particular progression that you can read about talks about a very important condition that everybody is concerned about, and one it's FEV1 sudden decline, chronic decline. Now, they've been looking at this. They have described it, and they have developed what is, basically, an intervention study looking at, potentially, developing phenotypic characteristics, so that we can identify individuals within the cohort with this particular issue that respond best to medication and those that don't, so that we can begin to look at are there other biologics that may come into play here that we can use, and what specific pieces of information do we need to know about that.

So, quickly, a snapshot of the mental health research they I want to talk about. Basically, we're doing several things that I think are right, and then there are a couple places where we really need some work. We certainly understand that it is a burden and we certainly are understanding that it complicates, particularly, certain physical health outcomes because of the comorbidity. There's no doubt about that. We, also, are understanding, particularly, with PTSD that there are particular symptom trajectories that are either beneficial or less beneficial as far as people getting better. Where we are falling down, I would say, where we are concerned is that there are, like with respiratory disease, there are a sizable number of people that are not only not getting better, but they seem to be getting worse. Now, that's really a concern for us. We have been, again, aggressively talking to our clinic

physicians and our researchers, and we are working toward looking at areas where, in the next announcement, we need to get some characteristics and information about our population about why these people don't seem to be responding. Is that that they're not coming to their appointments? Is it that they have some other issues that we're not aware of that we need to be paying attention to, and that we need to be looking at? One of the things that researchers have been telling us is to please look at telemedicine. And so, there are some things that we're going to potentially look at there that may make it easier for us to do effective treatment, but effective treatment in a way that would fit lifestyle and issues that people have that are preventing access to the care now that they need.

A couple of things that I would just say about the cancer, members of the STAC have been tremendously helpful over the years with this. There is in the packet or the slide, a later slide that I'll show you here, there is a very nice training that was done by Dr. Ward and others about World Trade Center cancer that you need to see. These are some of the primary studies. These are the outcomes that we're seeing elevations and their across the different cohorts of the World Trade Center. And, as you can see, there's certainly similarities.

Now, cancer is a particular outcome that we will probably, in the next research meeting, not November, but the next June research meeting, we'll have some exciting, I think, results on a couple of three studies that we'll be talking about at that meeting. One is a large incidence study that updates cancer incidence and risk using 14 different state cancer registries, and they have been successful in getting data from all of those but one, obviously. This particular group is also just given an update on World Trade Center cancer research to 198 cancer registrars from around the country. So we are talking to them about the importance of this population, of this follow-up, and the challenges that we're facing with getting Registry data, and in a timely manner. So I wanted you to be updated on that. The other thing, another study that is coming that is very exciting for us, it involves an FDNY study of first responders of firefighters. And they are using, as a comparison population, the three city NIOSH cancer study that was completed a few years ago of about 30,000 firefighters from three municipal fire departments. Now, one of the things, and one of the components, that's really exciting about this is that they are completing, and they are probably a quarter to a third of the way through with, surveys in these departments looking at the prevalence of certain key outcomes. Respiratory disease, for example. So going forward one of the things that we will have for future disasters will be some idea in responders in that group, what are some baseline characteristics and rates for some of the outcomes that we're really

concerned about. So some exciting information there with more to come. We're, also, looking at a couple of emerging potential conditions, and one of them is cognitive aging and impairment, where there have been some initial research from primarily Stony Brook, although, the fire department has a new study almost completed and the Registry is, also—look at this as well. We have some real questions about this. We have some issues about the stability of the risk estimates based on the kind of population, comparison population that has been used traditionally and has been used in some of these studies. So we have some questions, and what we're going to do for the first time is that we're learning how to bring together on a certain topic an expert group of researchers from around the country to meet with the researchers from the World Trade Center and, most importantly, the research leadership, so that we can begin to get an understanding of how do we tell if we have a problem with mild cognitive impairment in this population, what kinds of research do we need to do, what do we need, are there other comparison populations that we need to put our heads together and determine where they are and who they are, and make arrangements to take part in that? But we are aggressively going to look at learning and bringing people together that can help us and help our researchers understand how we might approach this, so that we learn and we can communicate exactly what is appropriate for our population.

Autoimmune disorders, you all have mentioned, I think, previously here. We have a couple of studies, one from the Registry and, also, an interesting analysis from the general responder cohort that we're anticipating soon. Individuals have also talked about the feasibility study that we are doing. I will just say a couple of things about this effort. Several of you, and certainly Catherine is one of them, have helped me over the years understand the difficulty as a survivor that you face as far as looking at a very different exposure scenario than the responders. And what that means going forward as far as your fear of what could happen to you. I will say two things about this. It is my responsibility to see that we are communicating to all parties and, particularly, the survivors, appropriately, about our efforts and thoroughly about our efforts. And, as you can see, I haven't done very well with that, and we apologize. I apologize, and we're certainly going to do some things, I think, to make that better immediately. I will say with this effort that we are—it is working, we are on target, and I'm excited about the progress that we're making. I will, also, say that right now we have in-house at the Registry seven million records from the Department of Education where we're able to look pre-9/11 all the way to 2014, we know where they live, we can look at and create some exposure metric, and we can also look at things like education (and tech @ 00:55:29), and we can learn some things that are

very important to us about this cohort. And I want you to know that we hear what you're saying and we appreciate what you're saying.

So now I need to switch gears just a little bit and tell you where we're going to be going and what we have to do, and we have to do this and we have to accomplish it quickly. Yesterday would have been good, but we certainly have to have our ducks in a row by this time next year. Now, the fairly easy part is to give you the information that you've seen in the book. We also have the comprehensive database that you'll have access to that has all the full-text research articles for World Trade Center. And it's organized and segregated, and you can go and look at it and see what you think, and give us your thoughts.

Now, that's great, but it doesn't tell us what the research means. It does not tell us, really, where the gaps are. It does not tell us where we need to go and what kinds of things we need to design. Now, that's what we have to put together and that's what I want to spend the last few slides telling you about what we're going to be doing. Now, again, the fairly easy part that we've done, and is a big effort and it's a lot to sort of put in place, and those kinds of things, but we have to know before we can make and talk intelligently to anybody about our research, we have to know what we've done and we have to have it in a way where we can look through it and search through it and it's organized, and we can have a conversation with pulmonologists or we can have a conversation with a cardiologist or a psychiatrist about what it is we've done. And, more importantly, if there are areas that we need them to look at, we can give them the information so that they can quickly look at things and give us a take on the kinds of questions that we have that we need to bet answered. So we have to be e in the position where we can quickly and efficiently conduct a variety and a different kind—a variety of reviews, of systematic reviews. And that's what we're doing right now. Now, that also means that internally we have to have—identify the key people that are doing benefits, the key people that are involved with pharmacy, our leadership. We have to have the research summarized so that in their very busy day they can get a very quick, good, solid understanding of what it is we're doing so that they can then start to tell us well, it's fine that you've done A, but our questions really relate to C, D and E. So if you're going to write a scope this is the kind of question that I need to have answered. So we have to bring, not only our researchers, we have to bring our clinic physicians and we have to bring our, in-house, our division physicians. We have to get them on board and we have to get the information in front of them in a way that they can digest and they can help us understand how we need to write, going forward, scopes for our research.

So another thing that I would just say is that this also means that there are

changes that we're making in the biannual research meeting. Now, these meetings started in 2012 and they were very good and practical from sort of a grant management, are-you-doing-everything-that-you're-supposed-to-be-doing-for-your-grant, kind of thing, and that's wonderful, but that's woefully inadequate at this point for us. So we are redesigning those and we're taking a very active approach, again, with the key players that I just talked about, to have people come in and to talk to us as the research is being done and, particularly, as it's being published, what is the significance and what are the unanswered questions, and what are things that we need to be thinking about that make a difference for the people that we're trying to provide the care for.

The other thing that we do, that I'll just mention, is that we make time in every single one of those meetings to make sure that we're getting an update on survivor research and survivor questions. So the SSC, for instance, has a standing invitation to come and to talk to us about what they would like to—us to hear. We, also, have Dr. Reibman used them, there's certainly people from her staff that come in and talk to us about not only what their research questions and issues are, but what they would like to see, certainly, is as an agenda.

Again, we're doing specialty workshops I sort of talked to you about that, but I give you this slide to sort of give you an idea of where we're going with these and the kinds of things that we want to accomplish and why are we doing it. Again, this is just sort of what the research calendar looks like for us, it's busy. What we really have to do and what we're looking forward to—positioning ourselves for is the last bullet, and that we have got to be making sure that we've talked to everybody that we possibly can talk to and we have gotten input from everywhere and everybody about what the next solicitation needs—the scope needs to look like. So be warned, you have your assignment.

The other thing that I'll just end with is that they are just some resources that I think are helpful that I just want you to have. The particular slides here give you nice pieces of information on the web about the various parts of the program that I think are helpful. The other slide here talks about where you can get the Registry. We also have if you want to use this particular site to access it, where we have funding announcements, also where we have the compendium online that's searchable, and that sort of thing. It also gives you—the next to the last bullet was the training, that Dr. Ward and others provided on World Trade Center cancer that I would encourage you to look at.

The last thing is that we will have, and Tania will talk with you all about this, everything that I've talked about today will be on an FTP site and you can go

to it, and you can look at it. So all of the publications, everything, again, we've talked about and we have put together as far as research is concerned, you have it. Now, if you need any help as far as that's concerned, certainly let Tania know, and we help you with that.

DR. CARREÓN-VALENCIA: It's on page 7 of the book, the link, the password, and how you connect.

DR. KUBALE: We also have our recent publications that some of which haven't, because of the addition, haven't made it into the book, and we also, so you have an idea of what it is we're learning at the research meetings, we have the project updates and the specific presentations from the last meeting. So you can look at that information as well. Those are just abbreviations if there was anything in the slides that were of question.

And, again, I want to say just a couple things very quickly. Everything that's going right is really because of Admiral Reissman. Things that probably aren't going so well or—well, here—she has really been an incredible resource for all of us and puts the weight of the program behind these initiatives. So, as I told Steve, they'll either get done or I will be going back to the farm to sit and do livestock, probably. I don't know. So I'll either be back in a few years or I won't and you'll know where I am. But there is a tremendous staff that we have that she's helped us put in place that helped us put all this stuff together, and help us make sense of it.

The other thing that I would just like to say is that several of you, and certainly all of our researchers and our clinicians, have been outstanding sources of resource information for us, as have our survivors and the groups associated there. So with that, I'm finished. Thank you.

DR. WARD: Thank you. And we have time for questions and comments for Travis. Please remember to state your name because I may say your name, but not enough to capture it in the transcript. So we sometimes do have problems identifying the speakers in the transcripts.

DR. MARKOWITZ: So thank you, Travis. That was an excellent review and I hope that Dori and John appreciate your work. He was trying to tell me that your job keeps getting more and more difficult every year because the underlying—the people who are served are getting older, their health problems are getting more complicated, there are more research products. There's almost 500 publications. You have to understand what's being done. And the scope of the problem gets bigger. So I think your job gets a lot harder, and I just want to recognize and congratulate you for the excellent work that you do.

I do have a couple short questions. The petitions that come in, in which the scientific review and study internally by NIOSH leads to a conclusion that there's insufficient information. Does that feed into the research priorities?

DR. KUBALE: Yes. Thank you for bringing that up. Absolutely. So when I say absolutely, I will say that is an area that we were not pleased with as far as how the

research is being integrated. Now, we've done a couple of things. One is to make sure that we're looking at every possible thing we make sure that the database that is available is also something that is part of that process that we use. The other thing that we're going to start doing, and that we are starting to do, is that we're looking very closely at what are the gaps and what are the issues that could prevent something from being added. And is there something that we can find there within that documentation that we can scope as far as research is concerned? So we do look at that and we will be looking in that area to see if there are components, if there are things that we need to potentially add and to try to figure out a way to scope as far as research.

DR. MARKOWITZ: Can I ask another quick question? So, historically, bringing the research novice to the clinicians in the World Trade Center Health program has been a problem. It was a problem before Zadroga, before the establishment of the program, and it was just a screening program. And, I suppose, it continues to be a problem. One suggestion is for the salient research results in any given year, why not ask those researches to serve as a speaker, and go to the half-dozen or so clinics in the New York area, and speak to the clinical staff, and bring the results of that study, and related studies, so that they can hear it directly? It would seem to me it'd be minimally feasible. And Dr. Wilson here, Dr. Wilkenfeld from two of the clinics, and maybe they can weigh in if that's a realistic way of doing it. But that would bring it to them, and it may just work.

DR. KUBALE: Well, I think that's an excellent suggestion. Absolutely. And any ideas that any of you all have about how we can improve that, I really want to hear. It's important. But certainly we will—I think that is certainly doable, and it's not something that we've done to this point.

DR. WARD: So I'm just going to take the questions this way, and then go this way just because otherwise I'll get confused.

MS. NORDSTROM: Hi. This is Lila Nordstrom. I have a quick comment/question which is, so this is a program that does not just do research, but also is intended to sort of serve a patient population at sort of the end of that research. So I have a question sort of related to that. And kind of going off the point about the Millennial Study because that I have a lot of familiarity with, but I think this would affect a lot of research priorities for a lot of the underserved populations in the sort of larger survivor community and even responder community. Are there any considerations that you make to, in some way, expedite the process for research needs and for communities that have been really underserved in the research? so for the Millennial Study the question we always have is when does this research become meaningful to us as patients? And that's why we're hearing sort of impatience about how it's taking so long. This is a program that is ultimately meant to serve a

population that was affected by a disaster. And so, specifically when it comes to needs like women's health, reproductive health that sort of has a window ultimately closes in terms of relevance, but it's affecting a huge portion of the population. So are there any considerations that you make when you're looking both at potential research and also how the research has been conducted, and how the approvals process is being conducted, that it takes that into consideration?

DR. KUBALE: Let me take, maybe, the first part of your question. I'm not sure I understand quite the second part. But the first part is, I would say, a couple of things. We are in the process of getting better, Lila, and we have to get way better at bringing people that are experts in a particular area in when we need them to look at what it is we've done, and help us evaluate what hasn't been done. So I will tell you that we are making progress on that continuum, but are we where we want to be and where Dr. Reissman wants us to be? The answer to that is no. And I have to hurry with that.

One of the things that as you all are thinking about survivor research and that you're thinking when you're thinking about children's research, and Catherine and I talked about this yesterday, that it would be helpful for us is that sometimes on my end, which is where you have to—part of my job is, all right, how do we operationalize the needs and how do we fit that in, and how technically does that work? One of the things that would be really helpful in that effort for us is any clarity that you could give us about outcomes that you're worried about. I'll tell you one of the things when I think of children that scares me a little. I see a lot of the research that has been done it leads me to believe that there are real mental health issues in that group and in that population. And I'm worried about that because I'm not sure how well we're handling that. Now, if there are other things when we're talking about the children's cohort study, one of the things that we looked at is that we wanted to look at when we're doing feasibility, what is feasible to look at certain outcomes that we know in the research that you all have told us that you're concerned about, one of those certainly has been asthma, and the second one was cardiovascular disease. Some of the work that came out of Dr. Trasande's group. So when we're looking at feasibility and putting the platform in place, one of the things that we're really interested in is what do the numbers have to look like to look at outcomes like that. But clarity as far as what you're concerned about, for me, would be really helpful.

I'm not sure that I got the second part of your question about, is it funding? Is it that mechanism?

MS. NORDSTROM: No. I think what I'm asking is when you make considerations about the kinds of research that you're looking to find and what you're expecting to get out of that research, if you're considering that there are populations that have, for

20 years, been sort of, essentially, ignored in the research and because of that face treatment needs that are pretty immediate that—I mean, because we've been seeing a lot of petitions where there's been insufficient data and things like that, that that problem becomes more problematic for us on the patient side the longer that we're ignoring the initial research. And so, for being a feasibility study for millennials that maybe identifies research needs for the future, but if in 20 years we find out that there were terrible reproductive health consequences to this disaster, it's not really relevant to us as patients anymore, but it is something that would have been important for us to know and for the program to know quickly. So that's what I'm asking.

DR. KUBALE: Well, first of all, thank you for the comments, and, also, for what you bring to the table. I would say a couple things about that, where we need to improve and where we're working on them. To me, where I think we can have an impact as far as that is concerned, is that we have to begin to work with a little differently and talk with and understand from people like Dr. Reissman, for instance, what is it that we're not knowing right now about the population in the clinic, and who's responding to what and what it is they're seeing. It worries me, I think we have some gaps there that make it difficult for me to scope something and make recommendations on scope to the program leadership that I think address that issue, and I'm worried about that. And what I can tell you that I'm doing, and if there are other individuals that you all can recommend that I should be talking to please tell me, but we are talking to them about how is it that we learn that, and we get that information so that we can then identify and address those needs.

DR. REISSMAN: Lila, thank you and I certainly appreciate the way that you delivered that as well as the content of what you said. And you can never make up for time lost and you can't make up for things that aren't within our purview initially to have gone after. But what we are doing is trying to grease the skids based on the feasibility study at this point and understand that assuming that we are able to trace the people we're able to trace, how do we quickly move forward to the next steps to not have yet another three-year runaway before we can conduct a study. So, yes, there's expediency and there's concern about how do we get all these bureaucracies lined up because it is herding cats and it takes finesse. So we're working in that particular angle.

I think it's also important that when you're thinking about research, often people have thought about the research paradigms being only the people who are members of our health care program. And research, in and of itself, is not limited to program membership. The question is whether research is ever going to be proposed that involves recruiting people outside the program. So for all the people who might not be actively engaged in

treatment because they don't know if they have a covered condition, they don't even know if they're eligible, all those kinds of questions, there's still a way to conduct science with them. The question is who's proposing that research or not, too.

DR. WARD: Mridu.

DR. GULATI: Hi. Thank you. Thank you for sharing the research summary with us. I'm Mridu Gulati. I'm a pulmonologist. I have a question about the studying the autoimmune disorders. And I'm glad to see that it looks like there are a couples surveys and surveillance reports that are coming up later this year. I can imagine that this is a much more difficult disease-exposure disease relationship to actually establish. And so, I was curious what—even just going down to what do you mean by autoimmune disorders, how heterogeneous this population is or are you already at the outset sort of categorizing groups into buckets.

And then the second piece of that is how to go about delegating some of the diagnoses, whether you're using the bloodwork and serologies versus clinical diagnoses. I think in the background of all of this there's certainly a lot of literature establishing exposures and asthma, and other exposure settings, and I think autoimmune diseases are more difficult whatever we mean by that. So I was just curious to hear about how we're handling those challenges.

DR. KUBALE: Well, the first thing that I would say is that, yes to all of your comments, and we agree, and those are challenges. Now—Tania and, I think, if I'm not remembering something can help me here—we are looking at the physician review and diagnosis in these efforts. And it is, as you know, time-consuming and difficult, and problematic. But to answer the first question, that's how we're looking at it, and they're reviewing medical records. And I think the Sinai data center is based on that as well.

The other parts to your question, what we're seeing, at least, so far is that the majority of them we are looking at a variety of diagnostic categories within autoimmune. I would say, probably from what I remember, and I'll sort of go out on a limb here, the primary one is arthritis, I think. Rheumatoid arthritis. But there are others that their numbers are lower and I'm not sure, ultimately, what we're going to be able to do with it, but we're just going to have to cross that bridge when we get to it, I think.

DR. REISSMAN: Yes, and I'll add to that. If you have any input for ways to approach autoimmune disease research that are different than us looking at monitoring exams where people report very nonspecific symptoms, beliefs about self-reported diagnosis, where all we've been able to do is chase medical records to confirm cases, and then how many people release what they release, it really stymies the research because participation isn't as high as you'd like to

see. So if there's other ways to go about really trying to get at the question of autoimmune in this population we'd love to hear that from the expertise assembled here.

DR. KUBALE: Please. Soon.

DR. WARD: Marc.

DR. WILKENFELD: Hi. First of all, Travis, thank you so much. I know how hard you work, and thank you, Dr. Howard, and thank you, Admiral. When I first met you, after 2001, you weren't an admiral yet. So congratulations.

DR. REISSMAN: Thank you.

DR. WILKENFELD: You know, it struck me as I listened to you, and it was a very excellent presentation. As academic, it was wonderful. Everything you say makes sense, but here's the issue, and I'm trying to figure out the solution to the issue. I listened to Anthony Flammia. From Anthony's point of view he's frustrated. And we see hundreds of patients who are frustrated, and he's right. I mean, from and academic point of view, you're right. So what do we do? Because the goal is to end the suffering, and the research is to end the suffering. And the only parallel I can think of is clinical trials. It comes to a point in clinical trials where you say, okay, we have to stop the study. Now, I know it's not analogous, but I just feel very badly, and I know how hard everyone's working, and I feel badly for Anthony, and I feel badly for the hundreds of people or the thousands of people like him. And, also, I'm going to feel very badly in two years or five years, or ten years where I say, you know what, it is related. We figured it out. And some people are going to say, well, that's great, but my friends aren't here anymore to share in the news with you. So, I'm a very good consultant. I'm asking you the question, and I don't know the answer, but maybe we need a separate workgroup to discuss how we can streamline and get—because the result that you wanted is health, right? You want to improve health. And I'm trying to figure out, I've been trying to figure out how we can develop a process to get that done faster. So I'm waiting for the answer.

DR. KUBALE: Well, I would say a couple of things. I have a background before I came to NIOSH I worked on a oncology service. I was a clinical social worker. And I do think often, all of this, about what Anthony and people like him tell us, and what Catherine tells us and what Kimberly tells us, and the trauma that people have been through, and I think about it all the time. What I can tell you is that we absolutely are not where we want to be as far as marrying those two things together. I am certainly not going to come here and talk to this community and pretend that I know something that I don't. I know that we have to get all hands on deck and on board to start to figure some of this stuff out, and I will commit to that. And we will move as fast as we can, but I don't have all the answers to that right now, I just don't. And we desperately

would love to hear ideas or suggestions from any of you all about it and about what you think, and we will entertain any and all.

DR. REISSMAN: I think in addition to that, Dr. Wilkenfeld, is the—I think you're asking the question about what role does science play in public policy decision-making. I think that's really what you're getting to, what level of evidence do you need in order to say that you can change a benefit and be more inclusive. And that's very gray area, it's a very difficult area. What we've done in the program is create public policies that illustrate, as transparently as we've been able to do so far, how we evaluate the science in order to get to the point where you can make a public policy decision. It doesn't make everybody happy, and all of us share the concern that, I think, Travis really nicely put here, and the ones that were discussed by Anthony earlier. You know, there's real suffering, but how do you do attribution? An attribution ends up being scientific and public policy. There is a crossover there, but this particular presentation and what we're doing in the science realm has to be looked at separately from what you're asking. Travis is not in a position to answer that. I'm not in a position to answer that. We have to follow the kinds of procedures that we have, and I'm sorry for that.

DR. WILKENFELD: Thank you.

DR. WARD: Thomas.

DR. DYDEK: Thomas Dydek. I'm a new member of the committee, so these questions may be somewhat naïve, but that aside, as a toxicologist we always want to look at what the dose versus the response is. So my first question is, is there any decent knowledge about exposure levels over time to the dust? I see Micki disagrees. And I know that there's the issue of unraveling the mental versus physical aspects and comorbidities. Perhaps with better knowledge of exposure assessment we could disentangle the toxicological from the mental health. What are your ideas about that?

DR. REISSMAN: Well, it's clear that you're new, and I appreciate that kind of excitement. It's refreshing. We've, unfortunately, not had great exposure assessment because there wasn't a lot of actual measurement done. So anything that exists at this point is basically by proxy and by the way people described where they were, what they were doing, and for how long, and how dirty it looked. And there wasn't a lot more you could do to actually get at the real science that you know. Hopefully, what that is, is a lesson for the future and how we do response and how we measure, and how we protect. So we're hoping that that information goes forward from the materials that have been produced by this program and the stakeholder community. There were a lot of efforts that tried to get at exposure assessment through alternative means, even working with a variety of the union members trying to describe the jobs that they did, trying to come up with an exposure matrix. There was just so

much infighting about what anything meant that it really didn't get concrete answers that we could use scientifically. So the best thing that we ever came up with was, did you arrive by a certain time? Did you do a certain realm of job? Was it really dirty? What did it look like there? And that's the exposure assessment. Sad, but true.

DR. WARD: Micki.

MS. SIEGEL DE HERNÁNDEZ: Just a comment. I think it's more than there wasn't group measurements taken. There was a concerted effort to ignore the exposures that actually existed, and to not characterize completely. So, and that's why we have the problems that we have, and the health crisis that we have. I have two questions. One, everybody has been talking about, rightly so, about emerging conditions and speeding up some research that we're anxious to hear the results of. And I'm looking at Slide 19 of your presentation, Travis, about awarded projects and publications. And those areas—I mean, all of this is important, right, but the areas where we are looking at emerging conditions, things like cardiovascular disease are at the bottom of those publications and awarded projects. So, and thinking about the future, it's not necessarily speeding it up, but maybe more of a focus, so that we do have more research out there because then when petitions are put in it's a Catch-22. You know, there's in confirmatory studies, but they're also not being funded to actually confirm what the petition is being submitted for.

DR. KUBALE: Well, I think that's an excellent point, and I think that what would be, also, Micki, very helpful for us is that, as you look over that, and certainly with your experience and where the involvement that you have, I think on those emerging conditions and things, again, that we need to maybe look at that we haven't or aspects of what we've looked at that maybe we're missing, it'd be really nice to have your thoughts about that. I really appreciate that very much. Thank you.

MS. SIEGEL DE HERNÁNDEZ: And then just one other question. I just wanted to clarify something you said. I just want to make sure I understand that I wrote it down correctly. In response to, it was either Kimberly or Lila talking about the Millennial Study, I think you said that at the Registry you have seven million records, and you mentioned something about looking at an exposure matrix. And so, I wanted to know if you could clarify for the—

DR. KUBALE: Yes, I'm sorry. So it's a different analysis. So it comes from the same source, but it's not tied with the feasibility. So what was unique and nice about that is that we were able to get de-identified information from the Department of Education that allowed us, and I think there were seven million or so records that came through that would allow us, and they have it, it's being looked at and analyzed right now. And, Micki, I can't remember the exact timeline on when we're going to be reporting out on that, but the thing that was exciting

about that, and the thing that we wanted to sort of use that for to supplement some of the other efforts, is that there is quite clearly a tremendous amount about the children's cohort or children in general, survivors, that we don't know. So this was an opportunity for us to bring that the de-identified data in-house, locate where they were, and follow both pre- and post-9/11 test scores. I think those were the primary matrix that we had. Is it ideal? There are certainly limitations and those kinds of things, but it certainly was a step ahead as far as information collected for that group. So that's what I wanted to clarify.

MS. SIEGEL DE HERNÁNDEZ: Okay. I think you had said that it was an exposure matrix, and I just wanted to clarify—okay.

DR. KUBALE: I'm sorry. No. Then I misspoke, if that's what I said. Basically, we are able—it is crude, but you can look at location as a surrogate for the intensity of the exposure, and that's what it is, where they were located and where they were living, and where they were going to school.

DR. NEWMAN: Hi. I'm Nick Newman. And thanks for your presentation. It was very interesting. I was looking through, and I have been on—I was looking through this compendium, and I've also sat on the study section that reviews these proposals in the past, and I think a couple of things come out of this. One, there seems to be a need for translational research, but when I look at the current RFA, you know, that's sitting there. It doesn't really like specifically tag that as something that should be done. There was an area where it talks about health services research, but there seems to be—you know, when you look at it there's a big emphasis on, particularly, like maybe diseases or organ systems or something, and it sounds like what one of the needs that seems to be coming out, it's like how do we translate some of this research to action. And I also noticed that the funded centers are all basically within like a 20-mile radius of the World Trade Center, and it might be helpful to try to engage with other centers around the country that may have expertise, not specifically with the—directly with the 9/11 attacks, but may have a complementary knowledge about, perhaps, like improving medication adherence or community engagement, or other aspects of like airborne toxicology that had been well-studied in other types of settings, that what they know could it be, essentially, translatable here, and might speed up the process a bit. And knowing a little bit about the grant process, I understand the difficulties in trying to do any kind of like interagency type of work, but certainly the National Institute for BioHealth Sciences has a very deep bench in terms of like understanding how to do community-engaged research or some of this other—layers of translational research that, perhaps, that researchers were encouraged to work, or if there was some like program that could jointly bring these together, we might create some synergies that will

address some of these other needs.

DR. KUBALE: A couple comments about that. Thank you. I think that those are, again, excellent suggestions. I want to say a couple of things. You're exactly right about the announcement. So one of our issues is that, as you can see, with the announcement and the call that you were involved in, how these things usually work is that in the beginning it's a broad call because you're really not sure. So what the divisions and the grants offices do is that they sort of look at it like here are the general parameters, and you really want you to make sure that you're not excluding anything right out of the chute. That's fine for the first couple of calls that we've had. It's clearly, as you say, not fine moving forward, and that's what we're in the race to do because the call that's coming in 20, you know, without boring with all the details about how long it takes to get ready for these kinds of things, is coming fast, and we cannot have the same scope. So that's one thing that I would say.

The second is that I really want to stay in touch with you all about your ideas about how we expand the pool of information and talent that we have. Now, it's been a struggle for us. We do have in the Registry, we did have, that's one mechanism where we've had European and researchers from various parts of the country, but we are not, generally, where we want to be with that. Now, one thing that we can think about, and that Admiral Reissman has talked to me about making sure that we're doing, is that when we bring together people for special—so we have our structure together about what our research is and what our questions are, so that we can coherently present that to a group of people. Then we're in the position to broaden that scope and bring in identified researchers from all over the place, that not only then learn about the research, but then may be well-able to help us either in an advisory capacity or as a potentially researcher. So what would be very helpful for me to have for you all are ideas about individuals that you work with, with a specific area that you think might help us, and that'll help make sure that when we're addressing these things that we have a pool of people that you've helped with select to bring to bear.

DR. NEWMAN: That sounds great. I mean, one thing that I've seen like certain funding mechanisms, you'll get extra money to do a certain amount of things like if you do it in a specific focus area that hasn't been—being addressed, then you get a little bit of additional money, so that you can put a kind of traditional project together, and then do something a little bit more of a stretch because, ultimately, I mean, it's all money because you have to pay people to do it, which you know already, but I'm just saying.

DR. KUBALE: Well, you know, that—yes. So if I'm understand you currently, there are a couple things that we are going to look at with this call, Nick, that are important. So, traditionally, not to get, again, in the weeds about grants, but

our primary funding grant mechanism has been a cooperative agreement, and there are lots of benefits to that that I won't go into. However, if we're talking about the need to look into the clinic that we're talking about, that's a good mechanism, but it's not going to be the only mechanism. So we're looking very seriously at, say, in R21, which these are two-year grants, less money. But the focus is different, and it allows us to engage researchers just a little differently, and that sort of thing.

The other thing that I would say is that as we learn more, absolutely, your point about writing in, at some point, to the scope areas that we want to not only focus on, but there's additional money for those, absolutely. I'm not sure that will be quite there, Nick, in a year, but we're certainly going to be in a year, we're going to have to look at different types of funding mechanisms which I've already alerted the grant's office that we need to be in the position of putting through.

DR. WARD: Let me just interject the time now. So we are past the time where we had on the schedule planned to break for lunch. I do want to make sure that we hear from everyone who currently has their tent up, but we won't be adding any new tents at this point because we are going to have to come back at 1:30—1:15. Sorry. We are going to have to come back at 1:15 because we've got people on the phone or people who may be coming in to hear specific presentations. So with that, we'll go on to Val.

MS. JONES: Okay. This is Vaylateena Jones. So going back to Anthony. I was very touched by what he said, and looking at, like, the—one of the conditions he mentioned was neurological. So my question is, basically, how are you going to use this? Because looking at certified conditions that's not something that's there in terms of overview, and in terms of what Micki said in terms of emerging conditions, that's a very small amount at the bottom. And then I think one of the responses was, you know, in terms of who you have in your program, and the fact that if you don't do certain kind of research or, basically, how would you do this if these are not the people that you presently have in your program because these are not certified conditions. So what do you plan to do with the information that has come forward, say, what Anthony has said, and take it into consideration and certify conditions, and what the program has previously—the projects and publications that have previously been awarded? How are we going to take this going forward, especially, what he said?

DR. KUBALE: Okay. Thank you, Val. So if I understand correctly, help me if I don't.

MS. JONES: Okay.

DR. KUBALE: So let's talk about the neurological conditions. Now, NYU has done a series of studies that have looked at that and put that on our radar, that there is a concern in that population. And so, we're hearing it. And the research is

there. Now, one of the things that I would invite you to do going forward with this—we're going to be doing two things. One is, tell us if you have some ideas, you or Anthony, about this area, give us that information. The other thing that we're going to be doing is that we're going to be making sure that those researchers that have done, in the program, Mike (inaudible @ 01:44:49) is one of them, like I said, and have found some of these kinds of things. One of the things that we will be doing systematically is circling back to these areas and finding out what are the next steps, you know, what is their research telling us that would be a next step, something that we need to do next that we can then consider as far as a scope. So what I want to emphasize is that with these meetings and the activities, there is a different relationship with us and the researchers and everybody, but I'm using just now we're talking about the researchers. And so, I want to say the difference is we are going to find out and we will be talking with them, and we will do everything that we need to do to find out specifically from them what it is, in their view and in their experience, they think we need to be doing, so that we can consider…

MS. JONES: Would you circle back and possibly awarding more (inaudible @ 01:46:06)?

DR. KUBALE: Absolutely. Or you can, you know, as you learn things the—and I think the next point, traditionally, the announcement's been static. So you do it in five years and you maybe make a few little updates, but essentially the scope stays the same. We can't afford to do that anymore, is what I'm saying. So we have to have, in real time, the capability to understand what our research and our researchers are telling us and what that then means for a scope each year, is what I'm saying.

DR. WARD: Thanks. We'll have Catherine, then Anthony.

MS. MCVAY HUGHES: First of all, I want to thank the whole CDC team and the (inaudible @ 01:46:51) members. I just have a couple quick questions. One is for the Millennial Study, I know the study's working with the Department of Education, the public school system, but there was also a lot of daycare centers, people forget that people—I think I'm the only residential mom here on the panel, but there are people whose children did go to the local daycare centers, and people who worked in the area and also sent their kids to the local daycare centers. So I know that will be probably really hard and maybe not this round, but, for example, the World Trade Center site there was a nursery school. There was a Trinity Church right at Wall and Broadway, had its own nursery school on Church Street like two blocks south. And then there was another one in Battery Park City. So I just want to add that to your complexity for that study, not to forget about the real younger kids. Also, we know that there has been, generally, a gap on women's health, but in terms of the Millennial Study I want to make sure we don't forget about the

reproductive capabilities of boys/men now as well. And then in terms of guidelines, are you going to be doing something to take what you're learning to create more information to get out to the public in terms of guidelines?

DR. REISSMAN: Yes.

DR. KUBALE: Thank you. Yes. I was going to answer, Catherine.

DR. REISSMAN: Let me help you.

DR. KUBALE: I was going to answer.

DR. REISSMAN: We're actually in conversations about that because we recognize that some people may not—when they go to their private doctor and the private doctor may not be recognizing anything that could have a relationship. So the program is undertaking some kind of effort here to really look at a communication product and to work with our partners and the clinical centers of excellence, possibly the Department of Health to see what we can put together to facilitate that kind of conversation, because you just have to go at it in the ways that you have available, and I think that's a good avenue.

MS. MCVAY HUGHES: Yes. Because I just remember working with the Department of Health a very long time ago at the local level, and I think a lot has changed since then. So thank you very much.

DR. KUBALE: Thanks, Catherine.

DR. WARD: Anthony.

MR. FLAMMIA: Travis, I want to thank you for that presentation, and the whole team that put this together because this is really useful information that we can take back to the responder community. However, with Dr. Wilkenfeld, I'm going to piggyback off what he said. No answers. Post-traumatic stress is heightened as it is in the 9/11 responder community. If I had a responder on the phone right now listening, that's not acceptable. And I know that you can only do so much. On another note, PTSD goes on a death certificate. It's not compensatable, you know, unlike his medical conditions also, but he kills himself, PTSD goes on the death certificate. He doesn't get compensated. You know, on the police department we used a patrol guide. We used it as a guide, you know, and it offered some flexibility. You know, your guidelines, policies, procedures don't offer any flexibility. It's black or it's white. You know, you want a recommendation, you want an idea, I'll give you one. Recommendation, make it flexible. Someone has to step up to the line and call the shots, and give the flexibility of bringing other conditions in. Simple.

DR. REISSMAN: Let me just do a quick reply and completely shield Travis because he makes none of those decisions. And I think it's important that, first of all, we clarify since your comment was saying that coverage around PTSD, the health program covers PTSD. The Victims Compensation Fund has made other determinations that we don't control. So the Zadroga Act had two parts to it. One in which Dr. Howard administers the World Trade Center Health

Program. That's what this Federal Advisory Committee is about. The other one is administered by the Department of Justice. And while Dr. Howard may work with the special administrator over there to leverage federal resources as best as possible, he doesn't make the decisions over there. So that's a particular area that we cannot really respond to on our side. And I can appreciate the tenor of what you're raising and why you're raising that. If there's a specific other avenue of what you're raising in PTSD and concerns about linkage to PTSD and physical health, that's a different area that is a scientific concern, and there is a lot of scientific uncertainty, and the field is controversial. That is an area of scientific exploration, and we do have that on our radar screen.

MR. FLAMMIA: No comment on the policy and procedure part, making it flexible, having someone step up to the plate and call the shots?

DR. REISSMAN: I think the policy and procedure part is set up specifically to achieve a certain degree of rigor in scientific determination that would then deal with the resource question of how much resource do you have to work with, how do you determine who gets it. It's very complex. I don't think I could answer that fully myself standing here, but I think the next section of discussion is dealing with the policies and procedures around what things were included and the methodology that was undertaken to do so, and I think that we should reserve that discussion for that policy piece. Okay? Not this part.

MR. FLAMMIA: Thank you for your response.

DR. REISSMAN: You bet.

DR. WARD: Well, thanks especially to Travis and to Dori for their wonderful presentations and responses to questions, and thanks to the members of the committee who asked such great questions. So we'll now break for lunch, and we all need to be back by 1:15. Thank you.

[Lunch.]

DR. WARD: Okay, I have 1:14, so if everyone who can hear me can start taking their seats, and hopefully anyone who is not in the room will join us shortly.

DR. CARREÓN-VALENCIA: So I'm going to take a roll call to make sure we have a quorum to continue. Thomas Dydek? Anthony Flammia?

MR. FLAMMIA: Yes, hi.

DR. CARREÓN-VALENCIA: Mridu?

DR. GULATI: Yes.

DR. CARREÓN-VALENCIA: Gregory? Catherine?

MS. MCVAY HUGHES: Present.

DR. CARREÓN-VALENCIA: Val?

MS. JONES: Present.

DR. CARREÓN-VALENCIA: Steven?

DR. MARKOWITZ: Here.
DR. CARREÓN-VALENCIA: John?
MR. MARTELL: Yes.
DR. CARREÓN-VALENCIA: David?
MR. NEWMAN: Present. No changes in conflicts.
DR. CARREÓN-VALENCIA: Nicholas?
DR. NEWMAN: Here.
DR. CARREÓN-VALENCIA: Lila?
MS. NORDSTROM: Here.
DR. CARREÓN-VALENCIA: Robin?
Ms. Sassman: Here.
DR. CARREÓN-VALENCIA: Micki?
MS. SIEGEL DE HERNÁNDEZ: Present.
DR. CARREÓN-VALENCIA: Liz?
DR. WARD: Present.
DR. CARREÓN-VALENCIA: Marc?
DR. WILKENFELD: Here. Still no conflicts.
DR. CARREÓN-VALENCIA: And Leigh.
DR. WARD: Thank you, Tania. And Tania is wearing two hats today; not only is she the Designated Federal Officer, she is the next presenter. And she will be talking about, giving us an update on the development of the inventory of 9/11 agents.

**UPDATE ON THE DEVELOPMENT OF THE INVENTORY OF 9/11 AGENTS**

DR. CARREÓN-VALENCIA: Thank you, and thanks for the opportunity for speaking with all of you today from this side of the table.
Today I want to talk to you about how we did our inventory of 9/11 agents. You can go to the next slide, Pam.
We developed this inventory using different categories of hazard. So considering all the potential exposures that both responders and survivors could have been exposed to, and we divided them into four groups: chemical hazards, physical hazards, biological hazards, and then other hazards. And those include, and you will see many different things, but one of those is experiences that might cause psychological harm.
Now these inventories, at least all the agents, we think all of the agents, and experiences to which responders recovery workers and survivors, were possibly exposed. It does not provide doses. It does not provide information on the magnitude of the exposure; only the name of the agent. And we know and recognize that not all people would have been exposed to all the agents on this inventory, and that not all the agents present during or after the attacks might have made it into the inventory. If you can get me the next slide.

To start off with this inventory, we use the definition that the program had on 9/11 agent, which basically was a chemical, physical, biological, or other hazards that were reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area or at the Pentagon site or in Shanksville, Pennsylvania. However, we found that this definition was too limited in scope. So we changed the definition, modified it, and updated it.

So again it includes chemical, physical, biological, and other hazards. But those other hazards now include experiences that might cause psychological harm that were not considered before. It includes, of course, peer-reviewed exposure assessments of responders, recovery workers, and survivors, as the study did before. But we expanded it to add those hazards that were not identified in those published, peer-reviewed exposure assessments, but that we could reasonably assume to have been present at any of the three sites. These include environmental risk factors such as heat, cold, solar exposure. If I can have the next slide.

To start off with the inventory, there was a list of agents listed on the first periodic review of cancers. And thus, we reviewed them to make sure that they met our definition and include them on our list. Then we hired a contractor who helped us identify 9/11 agents based on what we had at the time, the original definition of 9/11 agents. So what they did is from the catalog of studies that we had from the program that Travis had put together at that time, the contractor identified any exposure assessment study or report that had agents listed there. And also, the contractor developed and conducted a literature search to fund any additional studies that may identify 9/11 agents. Then the program reviewed the methods and results and provided the contractors that were provided to us, and then we harmonized and corrected results based on the new definition.

So we have, and you are going to see that we have, the list of agents—next to my presentation in your book are those agents that have been identified to date. This inventory is not an in-depth document. It will be updated as additional information of hazards is identified and obtained.

So I'm going to cover the different categories of hazards and how we arrived to each one on the list. If I could have the next slide.

Using those agents that were identified in peer-reviewed literature, we used studies that reported air and settled dust. And for those, our methods include all the data or reports of chemical agents detected or in area dirt samples or settled dust or wipe samples. These samples must have been collected at one of the 9/11 disaster areas during the attack, response, or recovery periods. And we only took studies where the concentration or the amount identified on the sample was equal or greater than the lower limit of detection

of the sampling and analytical method.

In this group, we excluded several studies that were not independently peer-reviewed or that reported chemicals identified in other studies, so a secondary source of report. And then in those cases, we went back to the original report to get the information first-hand. And we also excluded one study that reported concentrations in water runoff. The particular reason we excluded this study was water collection locations were outside of the 9/11 disaster area, so it was very difficult to ascertain whether those chemicals pertained to the impact or not.

Now we, of course, in every issue, we always come up with uncertainties. So one of the issues is metals. When a chemical had a metal component, but is identified as such—for example, calcium sulfate—then we listed the agent as calcium sulfate. But sometimes there are methods that are destructive, and all that is reported is the metal. So there methods such as ICP plasma analyses that destroys the chemical and all you get is, like, cadmium. But you don't know if it started as a compound or it is just the metal that was found there. So we put on the inventory the information that we had on hand. Unless more information was available, we just listed the metal.

Also, if I can have the next slide, other sorts of studies that were looked at were biological monitoring studies. And for those we took studies that most reported on persons exposed during the impact, response, or recovery periods, and that have an appropriate comparison group that were not exposed during the impacts. The biomarker level in the exposed group must have been significantly higher at the 0.05 level than in the non-exposed group. And whenever possible, we considered the half-life of the chemical agent in this biomarker sample. So for example, a specimen that has a very short biological life that was obtained months after the recovery effort finished would not be considered a result of the exposure. We excluded studies that did not have sufficient information that a chemical was present at the site during the attack, response, and recovery.

Then we come to the other categories. What are those chemicals that reasonably assumed to have been present? For that, we used the best available evidence and professional judgment that was provided by the program site. As such, we included chemical hazards that are typically found at implosion and demolition sites; also those related to fires, those that are found in rescue operations, and at disaster medical assistant team stations. For example, common gases and vapors in fires.

If I can have the next slide, Mia. You will see on your document, this is the table that lists all chemical hazards. I hope you can see it. We list the chemical. We also list the chemical abstract service number, or CAS number; the source of the study where the listing or the studies where the

agent was; or if it was reasonably assumed to be present, then we say so. And then we know if there are other synonyms to the name of the agent, we put them on the table. So we identified 349 chemical agents present or expected to be present during the attack and recovery effort.

Okay, moving on to physical hazards, if I could have the next slide. So for those that were identified within the peer-review literature, we did not find any exposure assessment studies that identified physical hazards that met the criteria for indication. We then have to assume that they have been present. And we knew, based on reports and what we knew and the knowledge of the people that had been there and their professional judgment, that there were physical agents that people were exposed to. And this includes solar radiation, heat stress conditions, and cold stress conditions; also slip, trip, fall, and noise vibration; and also hazards that are typically found at implosion and demolition sites and also related to fire.

So if I can have the next slide, you can see the table that lists 14 different physical hazards, and these, as it said there, are all reasonably assumed to have been present.

Moving on to biological hazards, again, the literature searches did not produce exposure assessment studies that helped us identify biological hazards that met the criteria for inclusion. So based on the best available evidence, and professional judgment of the program, we concluded that those biological hazards include blood-borne pathogens. One the next slide, you see table three, you see blood-borne pathogens and the reason why they were included.

Moving on to the last category, if I can have the last slide, we have other hazards. So for including those other hazards, the methods we used were related to experiences that might cause psychological harm, and include traumatic and stressful exposures. And those experiences must have been significantly associated at the 0.05 level, with increased risk for a health outcome after adjustment for other mental health exposures. And they have to have been compared with an appropriate control group.

There are a number of exclusions on this category: studies that failed to achieve statistical significance; studies that reported crude, unadjusted analyses—next slide please. Metanalyses and reviews that included only exposures reported in other published papers; and also studies that did not differentiate between individuals who were unexposed to the 9/11 attacks and those exposed.

And a side thing: this is a tricky category because there have been a number of studies that report on the traumatic experiences of people that live in California, Oregon, and other areas just because they still went with something on television. So we excluded all those studies from those reports

from the inventory.

So in terms of uncertainties, you will see what hazards are listed. But there were certain social support factors, such as lack of family support, that we addressed that are not really related directly to the exposure, but can modify an individual's post-9/11 experience. However, they are not considered psychologically harmful 9/11 experience, and for that reason we excluded them from the inventory.

We only use hazards that were identified on the peer-reviewed literature. There were no other hazards reasonably assumed to have been present that the science team identified. So on the next slide, you will see Table 4, that lists some of the 26 different hazards that we identified, and the sources for that information.

If I can have the final slide—I want to acknowledge the contributors, the people that put together the inventory. Paul Middendorf was the leader on this effort, and was assisted by Geoff Calvert and I. And we also had a great group of contractors that we worked with from ATL and ORAU.

So that's the end of my presentation. I will be happy to take questions.

DR. WARD: Thank you, Tania. This time we will start on this side with Micki.

MS. SIEGEL DE HERNÁNDEZ: Thank you. I have a few questions. What were the additional hazards? I saw duration of work, but shift work is not included, and considering all the work that NIOSH has done about extended shifts and shift work, I would recommend that that be added.

Two, reasonably assume, I would also add to the biological hazards, mold hazards, and can speak specifically to the sites such as the Verizon Building, where literally it was like stalactites and stalagmites because of the water from the fire department to put out the fire that was there. And I wanted to know if you also considered, besides the hazards created by the collapse of the towers, you also have the hazards created by the work that was happening at the site. So I am wondering if you looked at any other occupational hazards, for example, with ironworking, for the ironworkers, that may or may not have been in other peer-reviewed studies.

DR. CARREÓN-VALENCIA: We will look into that. Thank you for that suggestion.

DR. WILKENFELD: Thank you for the presentation.

DR. WARD: A reminder to state your name.

DR. WILKENFELD: I'm Marc Wilkenfeld. I'm curious about the biologic hazards. How should we translate that critically in terms of the conditions that are related to the work? If someone comes in with Hepatitis B—in other words, if you have exposure, it's a broad category, and you have exposure to blood-borne pathogens, which can, theoretically, result in transmission of disease. We have never really thought about that from a clinician point of view. So how do we deal with that?

Maybe I'm asking the members of the Committee also? And if you're going to list it, right, if you list the carcinogen, then it's logical to assume that if you a see a patient with cancer, then there's a relationship. But if you're listing biological hazards, what should we do if we see someone with a disease that comes from biological hazards, which I haven't seen and also we don't look for it?

So this is my question: you're listing a hazard, but there's no monitoring for it, right?

DR. CARREÓN-VALENCIA: Right.

DR. WILKENFELD: And there's no inclusion of it. So why are you listing it? You're listing it but you're not doing anything about it.

DR. CARREÓN-VALENCIA: We're presuming that people were exposed to it through handling of cadavers.

DR. WILKENFELD: Right. So we're not screening for it, which is probably way too late. We didn't screen for it. So what do we tell a guy who contracted Hepatitis B in 2002 with no other risk factors? And he asks the examining physician whether this could be related to the work that he did after 9/11? And he sees the list of hazards, and it includes biological hazards. there's a gap, is what I'm saying.

DR. CARREÓN-VALENCIA: Right. I don't know.

DR. WILKENFELD: I think the residency director is going to answer me, I think.

DR. HOMISH: If the person has no other risk factors, not just from that time period, but since that time, and I would then ask if there was any breakage of the skin doing work at ground zero, anything that plausibly could have led to absorption of Hepatitis B, and in the absence of that, I wouldn't attribute it, because you have no positive scientific evidence that that exposure circumstance actually does lead to hepatitis B.

I'm in agreement that it's listed in this inventory, because you're better off with a broader inventory than an ostensibly narrow one. But it doesn't meant that that particular agent or any agent here necessarily led to disease at Ground Zero.

DR. WILKENFELD: And I agree with you. So if they did have a break in the skin, they were punctured in some way, there's no mechanism to deal with that in terms of getting the condition covered. I guess it's like a black hole almost. You're exposed to a hazard, but—it's like saying they were exposed to a carcinogen that we know causes a certain cancer, and therefore we're including the cancer. I'm not saying to include it as a covered condition. I'm saying to make a decision one way or the other.

DR. HOMISH: Marc, personally, what I would say is, "maybe, maybe not; let's move forward and see how we could help you."

DR. WARD: Okay, I think Steve is the next person.

DR. MARKOWITZ: Steven Markowitz. Were OSHA measurements included at all in the

chemical inventory? Some of them may have made it into peer review, but if they didn't, OSHA did a number of measurements down there. I didn't see it in the reference list, so I am just wondering how it was addressed.

DR. CARREÓN-VALENCIA: I think we excluded government reports for that reason, because they were not peer-reviewed. I know there were also other reports that I even called or contacted the main author to determine what level of peer review was there on those documents. And since he couldn't confirm, they were not added to the inventory. But I can certainly check with him on that part.

DR. MARKOWITZ: My guess is that most of the agents that OSHA measured are included in their list, because it's very comprehensive. And I understand the problem of—there were private entities that were doing measurements. And we don't have really good access to the quality assessment of those measures. So I get that.

MS. NORDSTROM: Hi, this is Lila Nordstrom. I have two questions. Well, one observation and one question. My observation about the other hazards section is that it doesn't seem to include any exposure that would have resulted from returning after the attacks to the environment. And I think that for a lot of community members, and I mean responders as well, there were stressors related to the cleanup that wouldn't have necessarily have been present on the day.

And then, I also wanted to know in the list of chemicals, does that include chemical compounds that would have, if two chemicals were present but combined to create a more dangerous chemical, like all of the combinations of chemical compounds included in that list?

DR. CARREÓN-VALENCIA: Well, you mean interactions between agents?

MS. NORDSTROM: Yes.

DR. CARREÓN-VALENCIA: First of all, no. The inventory only lists the agents individually. But I understand your point—the interaction between exposures may cause a higher response. We are just listing the agents right now, and not going beyond that.

MS. NORDSTROM: Okay, thanks.

DR. GULATI: Hi, thank you. This is actually very helpful. This is Mridu Gulati.

I have a couple of questions, probably related to much of the prior conversation. So it's helpful to have a list, although it's also helpful to have context of the list too. I suspect it's more granular than this somewhere else.

So one question I have is—are all the hazards listed here, we should presume that they were all there, or at least one person, that they were exposed at enough of a level to potentially cause disease, or were they just present?

And then my second question is do we have some sense of, or is it needed, that some of these exposures were more prevalent at a specific place and

time and occupation? Would there need to be any sort of validation? If somebody says, "I'm a survivor, and this is because I'm a first responder." That was my second question.

And then, thirdly, just a comment. I assume for some of the other disease processes, autoimmune diseases, and neurologic diseases, there is obviously a lot of literature on these individual hazards separately. So as we're going through and studying to see if there are associations to the explosion at the World Trade Center, I presume that some of these studies are, some studies external to World Trade Center exposures are also being used and weighted into evidence of figuring out if there are associations with neurologic and autoimmune diseases, if that makes sense.

DR. CARREÓN-VALENCIA: Yes. So let me go back to—actually, can you repeat question one?

DR. GULATI: My first question is are we to presume that each one of these chemical hazards were in a sufficient dosage at some point for somebody to have disease? Or were they just in presence? And if they were, were they present for everybody or only specific populations? And how are you going to determine this?

DR. CARREÓN-VALENCIA: We don't know. But we are assuming that not everybody was exposed to everything. We just know that they were present. So we don't know how much that each person was exposed to individually. We don't know, with certainty, that—well, we know that certain populations must have been exposed more than others to certain agents as opposed to others, but we cannot actually use individual exposures to that one. But we assume that all these agents were present there at some point or another. So that is probably towards your second question.

Yes. They were there in different points in time, probably. They might all have been present, but we don't know. I based them on what is reported in the scientific literature, and we assume that must have been present based on our professional judgment.

DR. WARD: I am wondering as you are trying to explore new disease exposure relationships, if you can't necessarily find it in the cohort itself. If somebody looks at a chemical hazard, one that is listed, and they know that there's an association with dementia or something down the line, how does that become a work-related, exposure-related condition? Because people can just look up a lot, and be like, "Well, I was exposed to this and I looked this up, and now I know I have this disease," even if it's not necessarily a World Trade Center-accepted condition.

DR. CARREÓN-VALENCIA: Well, one of the uses of these inventories, and Jessica is going to talk more about this on the next presentation, but once we do scientific evaluation of the evidence to determining theories on the condition that it could be added to the list of covered conditions. Dr. Howard may determine that there might

be a high but not substantial evidence. And for that, direct us, the science team to look at what has been published about all these specific agents and health outcomes.

So I believe now we have a list that we can start with, that we can use to look at that information. So that's one of the uses of these inventories.

DR. WARD: David?

MR. NEWMAN: This is David Newman. Thank you for that presentation. This is an area that I have a great and longstanding interest in, professionally and personally. I have a number of comments to make.

I think the most minor one, first; in Table 4, Other Hazards, there is a lack of precision in the terminology. It should not be listed as hazards, or other hazards, at all. It should be listed as Risk Factors for Exposure Scenarios in which you might be exposed to hazards. These are not the hazards themselves. But that's pretty minor, and it's great to see the beginnings of a list like that defined as factors.

The reliance on peer-reviewed and other studies is, of course, absolutely essential for obtaining this information, but it is also, particularly in the context of 9/11 and its aftermath, extremely limited. So I would suggest that you might want to consider to becoming more open to an examination of the data as distinguished from the studies. Not to the exclusion of one or the other, but the addition of data; there are, at a minimum, hundreds of thousands, and that's the low end of the estimate, of sampling results of 9/11 and its aftermath, the vast majority of which are reassuring or non-detect, and a small minority of which are identifying both contaminants of concern, or concentrations of concern.

This latter, smaller body of evidence is the body of evidence that is most consistent with the health outcomes that we are dealing with today. And the larger body of data, which was reassuring at the time, is obviously less relevant in many cases. So I would suggest that a renewed effort to obtain and examine these data would be likely to be at least somewhat helpful in these efforts.

To that end, the organization from which I am retired, the New York Community for Occupational Safety and Health, collected thousands, and maybe tens of thousands of pages of data for either an independent sample of results which the organization hopefully still has, and I'm sure would be glad to make available for examination. The EPA panel for which I served, as did Micki and Catherine, EPA World Trade Center expert technical review panel, had a subgroup which I chaired, called the Subgroup on Other Sources of World Trade Center Data. And our efforts might be of interest to your efforts.

Let me just quote from what we attempted to do, but did not accomplish. The

objectives were issue number one: the many thousands of results of Lower Manhattan environmental sampling efforts that were conducted by and for private organizations and individuals comprised—this is, by the way, to put it in perspective, May 2004. The many thousands of results of Lower Manhattan environmental sampling efforts that were conducted by and for private organizations and individuals comprised a potentially important part of post-9/11 environmental data, yet have not been collected for public access or scientific evaluation.

Issue number two: the additional thousands of results of environmental sampling efforts conducted in their own quarters by government agencies also comprise a potentially important part of post-9/11 environmental data that had not been collected for public access or scientific evaluation. So our efforts should be made to capture, centralize, and evaluate this data, to make it accessible. And there were reasons for that, which I don't have to go into now.

We propose that EPA, which is the operative organization in this effort, should solicit voluntary submission of the environmental sampling data from building owners, building managers, apartment owners, tenants, tenant organizations, private employers, private sector workers, unions, government agencies, and public sector works and unions.

We also propose that EPA seek the assistance of the following organizations in encouraging their members, clients, or constituencies to voluntarily submit environmental sampling data: insurance companies, AIHA, metro AIHA, ACGIH, laboratories, environmental consultants and cleanup companies, community boards and community organizations, physicians and other healthcare professionals.

And we noted that certain organizations are required by law to share environmental sampling results. These include government agencies subject to the Freedom of Information requests, public and private sector employers upon request by their employees or unions. We propose that such—I won't go into the proposals.

We identify the limitations, the likely limitations of such efforts which, again, were not undertaken. But the limitations, and you note some of them in your presentation. We noted that in most cases, submission of data would be voluntary. If there would be difficulties of outreach; that there may be insurance and liability issues; that in some cases, confidentiality would have be surrendered if data were to be of use; if the quality of data could not be assured in all cases; that the sampling methods varied and results could not always be compared, and there would be project, cost, and staffing issues. Nevertheless, we believe that these data would be relevant and I suggest we recommend and consider some of these efforts.

Also, I will share this you if you don't have it. But it lists the participants in the panel that I would suggest that you might want to talk to and add on your subgroup. This included folks from the EPA and OSHA in this document. Thank you.

DR. WARD: Thank you. Micki, did you want to speak?

MS. SIEGEL DE HERNÁNDEZ: Micki Siegel de Hernández. So I second what Dave said. There is also publicly available data on both buildings that for whom that data had to be made public, like the Deutsche Bank extensively sampled. And again, many of the contaminants may already be on the lists that you have, but I think it just adds to the body of knowledge.

I also wanted to respond to Mridu's question. One of the things that we do know from looking at lots of sampling data is that it was not homogenous. So not only wasn't every person exposed to every one of those contaminants, but it varied. It varied by location; it varied by the work that people were doing. It varied by people who were outside, inside, there were so many differences. So it is very hard, now, to make any kind of determination. That's why we're in this position.

The one part—two questions that I had: have you looked at any differences between the sites? I know we talk about the World Trade Center site; Pentagon; Shanksville, and there I don't know if there's been any…it wouldn't have been identical… if there's been any separation of data. And the second question is have you also started to talk about your potential uses of this list besides attribution in addition to contaminant attribution for a particular disease?

DR. CARREÓN-VALENCIA: To answer your second question, no. We haven't looked at it other than for petition but, as I was explaining before, in case there was relatively strong but not sufficiently, so that we might review available information, and also to assist in the evaluation of submissions. But in that respect, no, we haven't looked at other potential uses. Now, the inventory is available on our website for anybody to see and use. So we are hoping it can also serve as a resource for researchers.

And your first question?

MS. SIEGEL DE HERNÁNDEZ: I'm sorry, you want me to remember it? Oh, I asked if you had looked at data, separated it out for different sites?

DR. CARREÓN-VALENCIA: For the different sites. No, we didn't. But that is something I can look into.

MS. MCVAY HUGHES: Hi, Catherine McVay Hughes. I'm just following up on Micki and Dave. In terms of the buildings, as Micki says, it's different depending on the location. It was also different depending on what floor you were on, and how far away you were from the site. And it also depended on the size that could get through the window, whether it was closed or open. So I just wanted to emphasize the complexity of it. Thank you.

DR. DYDEK: Thomas Dydek. When there is such variability, what is sometimes done is to construct a worst-case scenario, and then to compare to worst-case exposure to known levels that would cause various disease states. And it goes back to the question I had addressed this morning about trying to separate out the physical manifestations from the mental. This is a little off the topic of your presentation, but I am wondering if anybody has looked at other very traumatic events? The Las Vegas shooting comes to mind; those people would have suffered the psychological problems without the chemical exposures. And do you know if anybody has looked at that to see what their ongoing health concerns are from Las Vegas versus what we have here?

DR. CARREÓN-VALENCIA: No, I haven't looked at it. But that is certainly something I could look into.

MS. SIEGEL DE HERNÁNDEZ: Can I just make a brief follow-up comment on that just to help out? In part, the 9/11 agent, we dealt with the psychological components of that. The traumas of exposure were not necessarily dust, chemical and others, even though they can have psychological effects themselves. A number of the psychological parameters had to do with traumatic loss; traumatic injury; witnessing horror; traumatic changes in one's business, or home, or community; things like that that went into being a 9/11 agent, as we think of agents, here.

Trying to characterize psychological agents in the way we are used to characterizing chemicals and physical and fibers and things like that, the lexicon doesn't quite work but we try to marry it in this document.

MR. FLAMMIA: Anthony Flammia. I have to support Dave Newman on this for the third one. Of the sources of the World Trade Center data, similar to a data share and fusion center type of network, or an information sharing type network, to share the conditions and everything within one type of data base or a data management system—it's just like 9/11: failure to connect the dots, and that's what was in the 9/11 report. Failure to connect the dots; you read it often in the report. If we don't connect the dots, we're going to have a more of a health crisis and more deaths.

Is there an information share mechanism within the organization?

DR. CARREÓN-VALENCIA: In terms of…

MR. FLAMMIA: Just within the program itself, the World Trade Center monitoring program. Is there an information sharing type network with the World Trade Center Program that shares information similar to what Dave is saying?

DR. WARD: Yes, there is, if I'm understanding you correctly. When it comes to the medical monitoring and claims from healthcare, claims from pharmacy, that information goes into a data center that is managed by cohort, meaning firefighter, general responder, or survivor. So that information is part of what is made available to researchers who then request information in order to refine hypotheses or proposing their funding.

What this started at, which was the 9/11 agent thing, and do we have a fusion or a centralization of that data? Our program does not, that wasn't really our centralizing function for what we were authorized to do. It doesn't mean we can't think about it, but it just wasn't there.

MR. FLAMMIA: Thank you.

DR. MARKOWITZ: Steven Markowitz. So I'm not going to argue against collecting more exposure data. But I do think some considerable thought should be given to the purpose of collecting additional data, because what we have here is literally hundreds of chemicals that, collectively, if you sort them by class, it could explain most diseases that we know to be related to environmental exposures, whether it is asthma, chronic obstructive pulmonary disease, cancer, neurotoxicity and the like. You can find in this list agents that would cause any of those, and frankly, without knowing the exposure levels, you would be very hard pressed, epidemiologically, to relate these to given outcomes.

So I'm not against collecting more data. But it is going to take considerable effort. And the question is: what's the gain, besides a more comprehensive list? In terms of predicting what might happen to people at or near Ground Zero, that visional thinking should be done before considerable effort is taken to look at private databases and all that.

DR. WARD: Yes, Nicholas.

DR. NEWMAN: I was looking at other hazards. And when you talked about social support factors, like lack of family support, I'm guessing that that is relating to the responders to the 9/11 attacks, and not necessarily the survivors. Because certainly there could be survivors who lost some family support because of the attack, and I don't know how that would be thought about, really. But I just wanted to just clarify if that's really who that was meant for?

DR. CARREÓN-VALENCIA: I don't know but I certainly can look into that. Probably, it meant both. That is possible.

DR. NEWMAN: Okay, that's fine, thanks.

DR. WARD: I just had one comment. There may be a middle ground with respect to how much effort to put into the collecting or centralizing the exposure data. I think it would certainly be good to look at the OSHA data, look at data from a couple of organizations where you have some documentation and the methods that were used. That would seem to be a minimal thing, if you're coming up with a list like this, to expand it a little bit beyond the published literature.

I agree with David to an extent. Maybe not everything that is done may not be super valuable, especially where that data might give some, there might be some quantitative data that might be useful in evaluating particular exposure, like silica for example, where I'm pretty sure OSHA had some quantitative

data that would be valuable.

DR. CARREÓN-VALENCIA: I get your point.

DR. WARD: Thank you, Tania. So we're ready to move on to our next topic, and we'll be having a presentation from Jessica Bilics, from the World Trade Center Program, on an update on policy and procedures for adding non-cancer conditions.

**UPDATE ON POLICY AND PROCEDURES FOR ADDING NON-CANCER CONDITIONS**

MS. BILICS: Good afternoon. As we've stated, I'm Jessica Bilics. I'm the policy coordinator and the governmental affairs person for the World Trade Center Health Program.

Let me look at the first slide. So the purpose of me presenting today is to talk through the non-substantive changes that we have made through the policy and procedures for adding non-cancers to the list of World Trade Center-related health conditions.

As I'm sure all of you know this, but just to go over it quickly: here are our definitions of what is a World Trade Center-related health condition. And these were given to us by Congress and then the Zadroga Act. So in essence, it's essentially health conditions, including mental health conditions, for which an individual's 9/11 exposures were substantially likely to be a significant factor in aggravating, contributing, or causing the condition.

This next slide talks about the categories that are covered under the Zadroga Act. So the Zadroga Act gave us a list of conditions to cover, and also gave the administrative authority to add conditions. So the three at the time of passing the Zadroga Act, the three top categories on your slide here, were the ones that Congress included. So the aerodigestive disorders, mental health conditions, and musculoskeletal disorders; however, the third, the musculoskeletal disorders, was only for World Trade Center responders in New York. It was not for survivors and it was not for Pentagon and Shanksville. And that was a Congressional note, that's not a program decision that was in the law.

And I won't read through all these, but this is essentially the list that we have. As we mentioned on the last slide, the administrator was given the authority to add conditions to the list, and has done so by adding cancers and acute traumatic injuries.

So there are two pathways that the administrator can add a health condition to the list of World Trade Center-related health conditions. First, he can do it at his own discretion; and second, through the petition process. And there's been a lot of discussion about that already today.

Of the lists that I showed you on the last slide, there have been two conditions that have been added via the administrator's discretion: the new-onset COPD, and acute traumatic injury. And the cancer was added through

the petition process back in 2012. Now regardless of which pathway is taken, the process of actually adding a condition has to be done through a rulemaking process.

Just going into the petition process a little bit more; we did create a petition form. It's not required, but it is out there if anybody wants to complete the form, to talk about what condition they want added, and then submit it to the program. I won't focus too much on how we decide on what is a valid petition, but I will go through a couple slides here.

This is a screenshot of our policy that talks through how the program decides what is a valid petition. There are certain things, and we've gone through rulemaking, to communicate what is required in a valid petition. There has to be a clear intent, that the intent is to petition the addition of the condition to the list. There has to the signature by the petitioner, and also they have to state the medical basis for the addition. So basically, connecting the 9/11 exposure to the requested health condition.

We see here on the slide, it gives some examples of how somebody can present that medical basis, and what we would consider valid. We look at peer-reviewed, published, epidemiological studies amongst 9/11 responders and survivors, and we also look at clinical case reports as well. We do receive a lot of submissions that state, "I didn't have this condition before 9/11, I have it now; therefore I think this condition should be added." Such firsthand accounts, anecdotally, though, we do not accept as a valid petition. We would communicate the decision of what is a valid petition to the submitter.

I won't read through all these, but here is a list of all the conditions of the petitions that we have determined are valid, to date. And we have published on all except that last one, which should be out in about a month or so. So this is 23 of, I think, 130 submissions that we have received, have been determined to be valid petitions. There's a lot of overlap in some of those others that were not determined to be valid. We have seen a lot that have reported the same medical basis for autoimmune conditions, for neurology, etc., as well as, like I said, some of the people were just stating, "I didn't have this condition pre-9/11, I have it now; and therefore…" We do not consider that a valid petition.

The next slide here is just a screenshot of our actual policy on how we go through a valid petition to make a decision on whether to add a non-cancer condition. And I believe the last time there was a presentation here, and this is impossible to see—it's even hard to see on my printout, but impossible to see on the screen here—but there is a flowchart in your books, I believe, that talks through this whole process about what can happen once we get it; what happens in the scientific review process; and then all the different functions

for how the program makes decisions: whether or not to add, whether or not to go to the STAC, etc. That is a good flowchart to refer back to as you go through slides.

So here—this talks about once we've made a decision that there is a valid petition, or the discretion of the administrator wants to go to the science team, we look for a scientific literature review from the science team. And after the scientific literature review in 9/11 populations, so it's looking at scientific studies done on survivors and responders, and then the science team does an evaluation of the science. So they are looking at the science quality evaluation—and this is one of the first changes that was made since the last time you reviewed—is that this used to be called, "Limitations" and we've reclassified it a bit to think of it more broadly as an evaluation instead of a limitation. So in essence, did the study report address the confounding issues and the exposure assessment issues, blinding, etc. And it gives a little list of those there.

The evaluation also looks at the application of the Bradford Hill criteria. And while the Bradford Hill criteria was in the policy that you saw previously, we added the citations and a little bit more explanation of what those criteria were that we look at. So the strength of the association, the precision of the risk estimate, consistency of association, biological gradient, and plausibility and coherence.

And then lastly, the evaluation considers whether or not—like, if a study was just in an FDNY population, does the evidence of that study apply to other responder populations and the survivor populations? So can it be expanded to the population as a whole, the 9/11 population?

So after the science team goes through the review and makes the recommendation to the administrator, there are basically four options. And I will go into more detail about each one.

The first option is the evidence that the science team in their lit review supports a causal association between 9/11 exposures and the requested condition. So in that case, the administrator would propose, through rulemaking, a decision to add the condition to the list. I'll go into that a little bit more here.

So here, the first thing we would do, we'd go through the rulemaking process, is to publish a notice of proposed rulemaking, an NPRM. And that's in the Federal Register, which is the government's newspaper. And once it's published, there is a comment period. And we would have a comment period of at least 45 days. And part of that is because we have, as you can see here, the independent peer-review. That was actually added after the GAO reviewed our addition of cancer, they decided there should be an independent peer review of the process. And so when Congress reauthorized

the program in late 2015, they required that there was an independent peer review added to the process of adding a health condition. So I will talk about that in a little bit more detail, and I don't know if, Tania, you are going into that more in your next conversation or not.

So the independent peer review process. We have determined that we will look and seek, solicit, recommendations for peer reviewers. While we don't necessarily know the conditions that we may consider in the future, we have an idea of some, so we would seek information from the recommendations from the STAC, from you all, as well as a solicitation in the Federal Register from the public and any other interested parties to give feedback on recommendations for specific peer reviewers.

When a condition is actually going through the rulemaking process, the administrator would have to pick three individuals to be the peer reviewer for the condition and balancing out the expertise, given the specific health condition, whether or not the person has provided peer review service, and any conflict of interest, etc. There is one more slide on this. And so in balancing, if there are any extremes in scientific views between the three reviewers, the administrator would consider that and ensure that any bias in minimized, etc.

Once the three independent peer reviewers are selected, they are given a charge and 30 days to fill the charge. They have to write a report to the administrator, with three questions addressed: is the reviewer aware of any other studies about the condition that should be considered; have the requirements of the program's policy procedures been fulfilled; and has the program's interpretation of the available evidence—is it appropriate, and does it support the conclusion to add the condition?

Those reports would have to go back to the administrator within 30 days, and the program would public those in the docket with the rulemaking docket. And they identified the reviewer, but we don't actually assign the reviewer's name with the specific comments.

So at the same time as the peer review, so the peer review is the first 30 days of the public comment. But the public comment would be at least 45 days. So there's at least 15 days after the peer review process for the public to see what the peer reviewers comments were, consider those if they want to address those in their own comments themselves. So they could address them before the public peer review comment period, or the 15 days after that. And then the program itself, once the comment period has closed, considers all the comments from the peer reviewers, as well as from the public, and considers those in whether or not to add the conditions. So based on the comments themselves, the program would decide whether or not to public a final rule adding the condition, or make a decision that there was insufficient

evidence at that time.

The second outcome of the scientific evaluation would be what Tania referred to in the last presentation as a "high likelihood." So there's not substantial evidence that the condition is causally associated with 9/11 exposures, but there's a high likelihood. So in this case, the administrator has three options in our policy:

First, they could ask the science team to go into another scientific review of non-9/11 populations. I will go into a little bit on that soon. They could also request a recommendation of the STAC. Or they could publish a Notice of Insufficient Evidence in the Federal Register. If the administrator decides to go to the science team and ask for review of the non-9/11 health studies, you can see here that we have—they look at the studies that are of 9/11 agents, which Tania just spoke about, and compared those to the health conditions. And I won't go through the definition of agents again, but that is the third revision that we made to the policy, was basically tying that definition of 9/11 agents to the newly created inventory of agents.

The body of literature the science team looks at when looking at evidence that is high likelihood but not substantial is other government sources, such as the toxicological profiles from ATSDR, the monographs from the National Toxicology Program, and the human health risk assessments from the EPA. So it is limited to those governmental sources, and I believe it will be open to other governmental sources, but those are the three we have identified at this time.

Basically, this review is searching for whether or not this information fills a gap that was in the review in the 9/11 population research, whether or not it supports or strengthens the information that was found in the 9/11 population, or counters any of the limitations that were identified in the 9/11 population. It also compares the exposures that are talked about in those 9/11 studies to the 9/11 exposures; so the route of the exposure; the intensity, duration, physical form, etc.; and then looks to see if there were any limitations such as is that information inconclusive or outdated.

As I mentioned, if there was a high likelihood, the administrator had three options. One of those other options is going to the STAC. And if the administrator decides that the expertise of the STAC would be helpful in making a decision, he could ask that the STAC consider making a recommendation on whether or not to add the list. The other options are to add the condition, or to publish a Notice of Insufficient Evidence.

I'll just go into the STAC option a little bit more here. If the administrator decides to go to the STAC, he has to make the decision within 90 days of getting a petition. And once the administrator writes, and it would be a letter to the chair, there is 90 days. And he can extend the 90 days that the STAC

has to make a recommendation up to 180 days. And the STAC has to write a written report to the administrator making a recommendation.

After receiving the recommendation from the STAC, the administrator would then have another 90 days—this is a cumulative, long process—to make a decision on the STAC's recommendation. And one thing to point out, which I don't think is thought of a lot by most people, is that the Zadroga Act, unfortunately prevents us that if we go to the STAC, it no longer gives us the option to publish a notice that there is insufficient evidence. It only gives us two options once you go to the STAC: to add the condition, or to publish an FRN that says there is no causal relationship. It does not give us the authority to publish an insufficient evidence at that time.

So the third option, after the scientific evaluation of the 9/11 population research is that there is insufficient or inadequate evidence at the time of a causal association. So at this time, the administrator would publish a federal register notice citing the reasons why we feel there is insufficient evidence, and that we would consider future research if it becomes available.

And then fourth option is that the evidence is non-causal association. Not that there is some support, but there is so support to add. We have yet to do that. Most of our FRNs have been about the insufficient evidence, if not the adding of the cancer.

So those are the four options, and with each one, there's a lot of little options. And anywhere that there is a point where you could reach the Notice to Propose a Rule linking to add a condition, it reestablishes that rulemaking process. And you can see in the flowchart, we did the stoplight theory where there is red, yellow, and green. And the reds are basically where there is no causal relationship; the yellow is where there is insufficient evidence; and the green is where there is the rulemaking process.

And that's it for today. I am happy to take questions and discussion.

DR. WARD: I just have one clarification question. If something comes to the STAC, you said there is only two options: The Federal Register Notice proposing, and the determination not to add a condition. But if that second condition is made, that would not preclude it from being nominated at a future date, or would it?

MS. BILICS: Our understanding is that that does. There would have to be new evidence, but we couldn't reopen the existing evidence.

DR. WARD: So if there's new evidence, it could be reopened. Whereas, if it were considered insufficient evidence, you could reopen it at any—without new evidence, you would look at it.

MS. BILICS: You could, yes.

DR. WARD: But you probably wouldn't. I would, eventually.

But I guess what I'm saying is it doesn't—bringing to the STAC and coming up ultimately with the conclusion that it is not going to be a covered condition

at that time does not preclude reconsideration if there is additional evidence.

MS. BILICS: Yes. It's just a higher bar to come over the next time with the evidence.

DR. WILKENFELD: It would have to be pretty substantial, because you're making a public spectacle of what is normally a scientific discussion within the program. So you would be making everything public. So it would have to be a pretty substantial study that would suddenly appear, that we would know nothing about, ahead of time.

It's certainly possible, but it's not probable. And the issue is you're making a big public record that you're going to have to reverse yourself on.

DR. WARD: And I just wanted to clarify that because I think that's the first time I have heard that particular nuance in the process.

DR. WILKENFELD: As you know, in your tour of tours in cancer, we had you as the chair to help us through that process. So in some of these other conditions, which are different than cancer, it's a little different situation.

DR. WARD: Catherine?

MS. MCVAY HUGHES: Looking at the very large flowchart here on page 133, in the best case scenario, what is the shortest amount of time for the process to go through?

MS. BILICS: So the shortest amount of time is if we get a petition that has clear medical basis, and it quickly goes to the science team. That could happen in the matter of a week or two. And then I would say, 90 days from when we got the petition, to publishing an NPRM, would be the fastest it could happen. And then the comment period, 45 days, and then the time it takes to write the final rule or the decision not to publish a final rule. So I guess that's probably about six months would be the shortest period of time.

DR. WARD: Steve?

DR. MARKOWITZ: Steven Markowitz. So getting back to this issue; it's a huge disincentive to refer an issue to the STAC because the outcomes are quite limited, right? Is that the intent by the law, or is that –

MS. BILICS: That is the Zadroga Act. So that is not a public program decision.

DR. MARKOWITZ: I just have a question about when you decide to look at non-9/11 scientific evidence, and you are restricted to the scientific evidence published by the US government. Does that mean that research that is conducted by university scientists that is published in peer-reviewed literature, that is not the government, that you don't look at that literature?

MS. BILICS: I will defer to Tania, because she is more the expert on that.

DR. CARREÓN-VALENCIA: Well, yes we do go through those documents. As you know, we only have 90 days from the receiving of the petition to coming to that. So we really have to look at all these 200-something agents and at outcomes. So these sources, authoritative sources, summarize available evidence. So it comes from universities, and public research.

DR. WARD: I will say, when this particular issue has been discussed at STAC meetings in

the past, we have raised some concerns about it only because many of these government documents may be outdated, or the government may not have chosen to review a particular substance. And frequently, if we're looking at a particular condition, you could narrow it down to maybe five or ten suspect substances and do the more traditional thing, which would be to do a PubMed search and look for the most highly relevant literature.
And you know, we've debated this at length. I just wanted, especially for new STAC members, to say this issue has been discussed before and there are some different—NIOSH has made the decision of how it will proceed, but there were some concerns. And I think some of those concerns, we could probably raise them again because from a scientific point of view, they are concerning. But we understand that the program has certain limitations.

MS. BILICS: Thank you.

DR. WARD: Anthony?

MR. FLAMMIA: Yes, hi. Anthony Flammia. Could you tell me what the gist of who puts in these petitions?

MS. BILICS: Most of the submissions that we see from are coming from members themselves; people who were exposed either as a responder or a survivor and have the condition themselves and are asking for it to be covered. We have seen—the cancer one came from the New York delegation. That was from nine members of the New York Congressmen and the two Senators from New York. The prostate cancer came from one of the NYPD union groups, and the Patrolmen's Benevolent Association. We have seen attorneys. But it is mostly from members themselves that have it.

MR. FLAMMIA: Thank you very much.

DR. WARD: Lila.

MS. NORDSTROM: Lila Nordstrom. I have two quick questions. One is—is there any way for a petition to be under serious consideration without there having been any research on a 9/11 closed population? Let's say something that's a known effect of a certain kind of exposure that we know people have experienced at the World Trade Center, but it has not been researched on World Trade Center-exposed populations? Because it looks like in order for the petition to get started, there has to be research done on the 9/11 exposed populations.

MS. BILICS: So it could be called a valid petition if the research isn't in the 9/11 population. So if one of the 9/11 agents that's in the inventory is provided as medical basis to the health condition itself, and we have seen that with manganese and Parkinson's, it was not in the 9/11 population. So it could be determined a valid petition, but the first step once it is determined a valid petition is looking in the 9/11 population. So if there isn't any evidence in the 9/11 population there would not be sufficient evidence to add it.

MS. NORDSTROM: Even if it is in a population that has not really had any research done on it

within the 9/11 population.

MS. BILICS: That is the correct policy, yes.

MS. NORDSTROM: That seems problematic. Okay, one more question. Have you received any—you said you get a lot of submission from people that are in the program that want their condition to be considered. Is there a way, if you get a lot of "illegitimate" petitions for one particular condition, does that trigger any response if there is a trend among the "illegitimate" petitions just because it's people reporting some sort of illness?

MS. BILICS: It doesn't unless there is some sort of scientific medical basis to make it a valid petition.

DR. WARD: Any other questions or comments for Jessica? Should we take an early break? Okay, so we will go ahead and take our break 15 minutes early. It's now about 2:30, so we'll come back at 2:45.

[Break.]

**PEER REVIEW UPDATE AND DISCUSSION**

DR. WARD: So our next presenter is Tania, who will be updating us on peer review.

DR. CARREÓN-VALENCIA: Thank you. So, and we have been discussing what Jessica presented before issuing a final rule, if there is evidence that support a causal association for adding a condition to the list of current conditions. Then the Program issues a Notice of Proposed Rule Making, and then we have independent peer review. So the peer review needs (inaudible @ 00:22:30) to review the evidence that is put forward by the science people.

And so one of the projects for the STAC is to develop a pool of potential peer reviewers. And so one way our program does that one, by requesting recommendations from the STAC, and also publishing a solicitation in the Federal Register.

So we published our last solicitation for peer reviewers in 2017. So I think it's probably time to publish a new solicitation for peer reviewers. This solicitation was promoted on our program's website, on NIOSH eNews, it was taken to the steering committees, both responder and survivors, and we also discussed this with you at the last meeting. So you, the STAC, didn't give us names of potential peer reviewers, but you suggested us to contact journal editors and to share the notification or the solicitation letter and ask them if they could share it with their peer reviewers, and so we did, but it has been a challenge.

I have—granted, I did this not that long ago—but I haven't received too many responses from journal editors, although a few of them have recommended peer reviewers. I talked to you before on that email in preparation for this meeting.

We, the Program, would appreciate receiving comments and suggestions for peer reviewers, so if you have any, please bring them to me or send them in

email. I will happily take those recommendations.

And so I am opening this now for discussion and see how—I'm not going to openly ask for names but if you have suggestions on how we could improve our panel of peer reviewers, we certainly can take them.

DR. WARD: Micki.

DR. SIEGEL DE HERNÁNDEZ: I'll go ahead. Oh—

DR. NEWMAN: This is brief. This is Nick Newman. One of the organizations I belong to, the Academy of Pediatrics, they have a section on epidemiology and I think effectiveness and stuff, and so I'm part of that group, and we get solicitations for peer review for like all kinds of stuff. It just goes out. It's on a listserv and people just grab whatever. It's a wide variety of people.

So I'm just wondering, there's probably other professional organizations that have similar type systems, and that might be more effective. I'm normally surprised at how quickly some people will pick up something that needs, some massive document that needs a peer review, but you know, it's something that's in their area they're really interested in. So it might—I can't think of any professional organizations off the top of my head, but that may be more fruitful.

DR. WARD: Micki.

DR. SIEGEL DE HERNÁNDEZ: Can you just remind me, are any—

[TECHNICAL ISSUE]

DR. SIEGEL DE HERNÁNDEZ: Sorry. Can you just remind me, are any, are all of the physicians or researchers associated with the World Trade Center Health Program, are they not, would they not be considered?

DR. CARREÓN-VALENCIA: Yes, they wouldn't. They wouldn't. They would not be considered because they will have a conflict of interest as well, and you as members of the STAC, you also have a conflict of interest. So it has to be independent peer review by researchers not affiliated with the Program, so that kind of gets to be anyway, yes, the information.

DR. SIEGEL DE HERNÁNDEZ: Okay. Then it seems that, with the direction things are going, it would very helpful to have expertise in particular diseases that are maybe close to having enough scientific evidence—autoimmune, cardiovascular, certainly there's always the need and it's been expressed here before for pediatric, environmental pediatric expertise.

DR. WARD: Gregory.

DR. HOMISH: Hi, just following up on what Nick had said a little bit. There's a lot of professional listservs out there that you may not have access to but many of us do. So if you rolled out something that said this is what we're looking for, and I push it out to my list, and Nick pushes it out to his list, you're more likely to get a response because those folks know us on our professional listserv. So I think that that's going to be kind of a key way in.

The other thing I think you could be doing is looking across at the university network, looking—contacting department chairs, if I'm in the room with a department chair (inaudible @ 00:27:31), I often get requests for stuff like that, and a lot of the times you'll get people who are midcareer looking for a way to kind of do some national service. So I think that that if they're prompted in the right ways and reach out to department chairs, listservs, I think that's going to be better, because I don't read the Federal Register, ever. So, putting something there for me to find it, I'm never finding it. But if you reach out and network with us, I think that may be a way of getting what you want.

DR. WARD: David.

MR. NEWMAN: Yes, I totally—Dave Newman. I totally agree with the comments that have been made, especially the last comments. I was going to say the same thing. What we need is—not the right term—but a job description, as well as a call for responders' qualifications when they're responding.

DR. CARREÓN-VALENCIA: So would it help if we put together a flyer with the requirements?

MR. NEWMAN: Yes, exactly.

DR. CARREÓN-VALENCIA: We can do that.

DR. WARD: Yes. So, then Anthony.

MR. FLAMMIA: Anthony Flammia. Looking on the 9/11 World Trade Center Health Program, the Program does a great outreach program with a lot of great outreach materials. Maybe put that out to the monitoring programs, with all the publications that they put out.

DR. WARD: It looks like we have no further comments on the peer review.

DR. CARREÓN-VALENCIA: So if you have any names or suggested peer reviewers, there's an email. Thank you.

**ADMINISTRATIVE ISSUES**

DR. WARD: So actually, the last topic we have on our agenda is administrative issues.

DR. CARREÓN-VALENCIA: So of course I want to thank you all for being here today. I really heard our charge from Dr. Howard, and we appreciate all your comments on the research part. Please reach out to Dr. Kubale if you need case contact information. I'll be happy to provide it. I appreciate all your comments you made on the inventory of 9/11 agents and all the other possible agents that we could add, as well as the addition of sources of information. So we will look into that.

And finally, I want to thank Jessica for presenting, providing you the updates on the policies and procedures for adding non-cancer conditions to the list of covered conditions.

I want to thank a few people, first Mia, who is invaluable. I also want to thank Alan Katruska and Eric Brown for putting together the book, and also Kristen Iker, who put together that flowchart that Micki suggested at the previous

meeting. I hope you find it useful to follow the procedures. And please, my contact information and Mia's contact information is at page 7 of the book. So please feel free to contact me with anything you need, or Mia. All our information is there.

As we mentioned before, there is an FTP site that is available for you, all research information. Everything that was on that book that was circulating around is available for view, as well as summaries of the research that the Program has. So there is a username and password because it's exclusively for your use. So please go ahead and use it.

One more thing. We are having a meeting in November here, the research meeting. We are exploring ways to—so those of you that are not in New York that wish to participate, could participate maybe through Adobe Connect. We are looking into that. So you will hear from us about that. And that's all I have.

DR. WARD: And Lila, you may have a comment too but I just wanted to add my thanks to you for your service on the committee.

MS. NORDSTROM: Oh, thank you.

DR. WARD: It's been absolutely delightful to work with you.

[Applause.]

DR. WARD: And I personally wanted to applaud. Thank you very much. And did you also have a comment?

MS. NORDSTROM: Yes. I wanted to move that the STAC consider the SSC's resolution about the Millennial Study before we leave for the day. I think you have the copy of the resolution but I can also read them. That the STAC or just the World Trade Center Health Registry to move with deliberate speed to assemble the 9/11 Millennial Study cohort and that everything needed should be done to protect the Millennial Study and ensure it's moving forward.

DR. WARD: As long-term staff members though, we did provide recommendations on the importance of pediatric research and we've provided some specific recommendations for pediatric research. And I think the question I have is just a procedural one.

Typically, in this committee, we basically are taking—we're answering questions that Dr. Howard has posed to us. And so this, so there's no precedent for us to address a question that we haven't been asked to address. So, Dr. Howard?

DR. HOWARD: Sure. Yes, although, it's fine with me but you need to address it to me, not to the Registry. So you can tell me to tell the Registry.

MS. NORDSTROM: Right, yes, sorry.

DR. HOWARD: I'm happy with that though, as long as you fix that.

MS. NORDSTROM: Okay.

DR. WARD: So from a procedural point of view, the Administrator is okay for the STAC to address this and to vote on a recommendation if there is an agreement. Do

members of the committee feel that they have a good enough grasp of the background for this request, or is there someone who can present more information? Nicholas?

DR. NEWMAN: I just have—I mean, other than (inaudible @ 00:34:27), other than what was said this morning and those comments were cut off, I'm not—I feel like I would just want to know a little bit more about maybe the context. And I'm not opposed to it; I just want to be well enough informed that I can feel like I should be behind it.

DR. WARD: So Dori, we'll let you speak.

DR. REISSMAN: Okay, sure.

DR. WARD: But first, we need a second to the motion.

PARTICIPANT: Second.

PARTICIPANT: Second. Third.

DR. WARD: Thank you.

DR. REISSMAN: Ready to go?

DR. WARD: Yes.

DR. REISSMAN: Okay. So to provide some context, one of the difficult things about getting the people who were children during 9/11, trying to reach them, is that there was only a very small group that was ever captured in the Registry, and there were concerns about whether or not the Registry captured a representative group that the survivor community felt really would lead to the right type of science. That's a longstanding problem, can't change what happened; it's behind us.

So the question really becomes how do you reach the population to be able to look for any further problems? If they are sick today, they can enroll in the program. They can come in and be evaluated and move forward. But from what I've heard, a lot of the questions are fear-based about we don't know if this has caused a problem. We don't know if there's issues that are related to 9/11, and there's no mechanism for us to look at that age population to put the associations together.

I have also heard that there has been a disparity between what might come through certain channels of parents and what might come from certain channels of the actual people who were the children, Lila. So it's very interesting that there are different perspectives that way, and we are trying to really get a better handle at what are the outcomes of concern as opposed to gee, don't know, let's go fishing because it's really hard to pour resources into sort of an unfocused direction.

So the only way to really go about this was to find a mechanism by which we could reach the people potentially at risk and through a lot of digging, it became, we became aware that the Department of Education in New York City had a register that they do for all public schools where, when you attend

school, you sign and you do all that, and that register is a covered privacy database that the Department maintains, and they have laws and rules and things that they have to do to protect it.

Well, it took a long time to get the departments together, the Department of Health and the Department of Education together, to enable us to do a feasibility study. And what that feasibility study means is if we looked at the public schools that were in the disaster zone in New York City and we look at the sociodemographics of the people who likely attended those schools, and we matched those sociodemographics to people in outer boroughs, could we find a sample of people who represented the likely exposed children and a sample of people who would be reasonable controls? And can we trace them and find them, because it's 20 years ago and it's not so easy?

So what we're doing is tracing them, and we're doing it through the Registry Award mechanism because that's what was available to us in all the federal arsenal we had, and we have an IRB approval through the Department of Health, and we have the Departments of the Health and the Departments of Education in New York working closely scientifically together, which was breaking new ground. This was huge, and a lot of it was due to the efforts of Ben Cheval and Dr. Jim Melius to really kind of push it over the edge, along with the United Federation of Teachers. You know, there's just a lot of politics in all of this to make it happen.

So we're at the place now where, come winter, we should know whether we're successfully able to contact a reasonable population to think that we could actually do a study. That doesn't mean that we could just go ahead and study. Then you've got to do the IRB for the study and you've got to move through other mechanisms. So there's a whole lot of logistics that we're working on, but the expediency piece that I was speaking to earlier to Lila very specifically is we're looking at that now. You know, we're saying okay, let's assume yes, then what else needs to be ready to go? And a lot of things actually have been put and made ready: data management systems, platforms, protocols. Higher-up officials have been familiarized and socialized with the concept so there's things that have been greased. So that's what that's about right now. Does that help?

DR. NEWMAN: Yes.

DR. REISSMAN: Okay.

DR. WARD: Steve.

DR. MARKOWITZ: Steven Markowitz. So I've been involved with World Trade Center issues since 2002, and from the beginning, this has always been, the issue of children has always been an area of weakness in terms of attention, in terms of clinical care and in terms of understanding what went on with them. For those of you not familiar with the city, we are talking about Stuyvesant, which

was a block to the Bronx from Ground Zero and right next to the major area where all the debris was taken to load on barges to be removed. So this is a longstanding issue, a weakness and a sore point.
And to the extent that this Millennial Study actually can begin to see if it can address 19-20 years later and understand better what this group went through and whether it had any impact, I think it deserves our strong support.

MS. NORDSTROM: I agree with you.

DR. WARD: Thank you. Micki.

DR. SIEGEL DE HERNÁNDEZ: Micki Siegel de Hernández. I'd like to speak in support of the resolution, for all the reasons Steve just outlined and in particular—I mean this, the resolution is not calling to cut any corners in the scientific integrity, but just to show the urgency with which the study should begin, and I think that the language in there about protecting the integrity of the study and ensuring that it moves forward is also very important, because there are some factors that could affect that, and I think that the STAC—well, the STAC to John Howard—to make sure that that doesn't happen, to convey that to the Registry is very important.

DR. WARD: I'll go this way again. Catherine?

MS. MCVAY-HUGHES: The Community Board 1, which surrounds and includes the World Trade Center site, has always been, you know, asking for studies, particularly on the children that are now grownups. And so I just want to add that to the record that this is something that they've supported over the years.

DR. WARD: Anthony.

MR. FLAMMIA: Anthony Flammia. I am in strong support of this. Giving the people this comfort of the specialized doctors that are in this program that have done a lot for the responders and everybody that was exposed to 9/11 is critical. It's a comfort for these people.
My direction at the federal government is find a way. This has been a common theme with government. It was a common theme when we were down in Washington D.C. educating Congress, a common thread. A question of how. We didn't question on how we would respond on that fateful day of 9/11 of '01. It's another way of government moving the goalposts further away from us to achieve what we want. Did you ever try? Why not try? 9/11 wasn't easy. I hear things that say it's not that easy. 9/11 wasn't easy. We need to give them the benefit of the doubt. If it's one person or a thousand people that we help, if you help that one person, you've saved one life. Thank you.

DR. WARD: Mridu.

DR. GULATI: Thank you. I'm also—this is Mridu Gulati. I'm also in strong support of the resolution. I wanted to go back to the feasibility piece of this because I think that seems like part of the crux of this, because it seems that if it's deemed

not feasible then there'll be concerns about going forward.
And just to go back, I mean it sounds like the question is how are we actually outreaching to the children and to—they're not children any more—in the feasibility study, because if it's only mail, I think it's going to be—and that was what I heard earlier in the conversation that this was all by mail. How else are we actually trying to reach those people because if the method is, I don't want to say flawed but if it's not the right method and then all of a sudden we deem it not feasible, are we not going to go forward with it? So that's my comment/question.

DR. WARD: David.

MR. NEWMAN: David Newman? Is this on?

DR. NEWMAN: No, just leave it on.

MR. NEWMAN: David Newman. I expect that the difficulties in moving forward in this are less technical and more political. I was a Stuy parent as well as a Stuy alumni. My daughter was discharged on 9/11 into the dust cloud at 10:30 in the morning along with several thousand other students, with no instruction. We didn't find her until like 8:30 that night. She was safe and she's not had any health repercussions that we are aware of. That's an example of the kinds of exposure or potential exposure that some of these kids had.
At the request of the parents' association, I tested for asbestos in Stuyvesant within seven days of 9/11 and the tests were positive with elevated results. I helped form and serve on an environmental health and safety committee with the parents' association in Stuyvesant (inaudible @ 00:46:11) for four years. As a result of the efforts of that committee and of the parents' association, a number of other Ground Zero schools, of which I believe there were seven but my memory might be somewhat faulty, also engaged in similar kinds of activities, had a high level of concern for potential for exposure and potential for adverse health effects for their kids.
So this is a longstanding, long-known, widespread, relatively unaddressed issue that warrants response from us.

DR. WARD: John.

MR. MARTELL: John Martell, and I am a new member. Yesterday at the orientation, I did ask this question. What are you doing for outreach? And they did explain some things but, quite frankly, for me, it was not satisfying. And I mean, I understand that you're looking at the Registry and maybe sending out mail, but if we're doing RFP for peer support and that, why can't we put an RFP out for a public relations campaign? There's all types of new things out there to reach out that we can get the people. Ads in the **New York Times, whatever it is. But it seems to me that if we're spending money getting research out for these other things, why don't we look at, in some way, getting a good PR firm on board to get it out there, and do it on a national

campaign. This is a national issue. It's a national issue and for me, it affects me. So I think we have the resources and I think we need to do it, and I do support the resolution.

DR. WARD: Any other comments? Okay, I think we're waiting on getting the text so you can all see it on the screen so we can vote.

[Technical issue.]

DR. WARD: Yes, we can read it again. It's always nice to see it too.

MS. NORDSTROM: The World Trade Center STAC urges Dr. Howard to encourage the Registry to move with deliberate speed to assemble the 9/11 Millennial Study cohort. Furthermore, everything needed should be done to protect the 9/11 Millennial Study and ensure its moving forward.

DR. WARD: Can we vote? Do you want—

[Technical issue.]

DR. WARD: Yes, I think unless there are some concerns about that specific language based on hearing it, I think we could go ahead and take a vote, and Tania will be using the roll so we will record the vote.

DR. CARREÓN-VALENCIA: Okay. So we are ready to vote on this resolution. I would like you to say "aye" when we call your name. Thomas

DR. DYDEK: Aye.

DR. CARREÓN-VALENCIA: Anthony.

MR. FLAMMIA: Aye.

DR. CARREÓN-VALENCIA: Mridu.

DR. GULATI: Aye.

DR. CARREÓN-VALENCIA: Gregory.

DR. HOMISH: Aye.

DR. CARREÓN-VALENCIA: Catherine.

MS. MCVAY HUGHES:

DR. CARREÓN-VALENCIA: Val.

MS. JONES: Aye.

DR. CARREÓN-VALENCIA: Steven.

DR. MARKOWITZ: Aye.

DR. CARREÓN-VALENCIA: John.

MR. MARTELL: Aye.

DR. CARREÓN-VALENCIA: David.

MR. NEWMAN: Aye.

DR. CARREÓN-VALENCIA: Nicholas.

DR. NEWMAN: Aye.

DR. CARREÓN-VALENCIA: Lila.

MS. NORDSTROM: Aye.

DR. CARREÓN-VALENCIA: Robin.

DR. SASSMAN: Aye.

DR. CARREÓN-VALENCIA: Micki had to leave.
MS. NORDSTROM: But she said aye.
DR. CARREÓN-VALENCIA: But she said aye, although she can't vote by proxy. Liz.
DR. WARD: Aye.
DR. CARREÓN-VALENCIA: Marc.
DR. WILKENFELD: Aye.
DR. CARREÓN-VALENCIA: And Leigh.
DR. WILSON: Aye.
DR. CARREÓN-VALENCIA: So you have 13 members in favor.
DR. WARD: So should we draft a letter to Dr. Howard to that effect.
MS. NORDSTROM: Exciting.
DR. HOWARD: Aye.
DR. WARD: That's usually how we make guidance on the issues. So we'll go ahead and draft that letter. Well, thank you, everyone. I think this has been a very good meeting. I really appreciate everybody's participation and look forward to seeing you again soon.

[Adjourn.]

## G L O S S A R Y

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|---|---|
| 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 |
| SSC | Survivor Steering Committee |
| 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 |